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The race variable presented in Table 5.1 has been expanded to include three categories instead of the original two. Frequencies (count and percentage) have been updated in Table 5.1 to reflect the expanded variable.

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# Expanding HIV Prevention Options for Women in Abusive Intimate Relationships: Exploring the Potential of Pre-Exposure Prophylaxis (PrEP)

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# Expanding HIV Prevention Options for Women in Abusive Intimate Relationships: Exploring the Potential of Pre-Exposure Prophylaxis (PrEP)

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University of Pittsburgh, 2019

#### Abstract

Intimate partner violence (IPV) and HIV are issues of public health importance that significantly impact the health and well-being of women. Extensive research highlights the cooccurrence of IPV and HIV among women, underscoring the importance of interpersonal context when addressing HIV prevention. Existing HIV prevention options for women remain underused and inadequate. Pre-exposure prophylaxis (PrEP), a valued component of HIV prevention, has the potential to expand options for women at risk of HIV, specifically those in abusive and controlling relationships. However, significant gaps remain in our understanding and increased research examining the intersection of PrEP acceptability and use and IPV is critical to improve HIV prevention within contexts of IPV. This dissertation research used the results from a systematic rapid literature review and cross-sectional survey data among a sample of women attending a family planning clinic in Southwestern Pennsylvania to provide important insights and suggestions for future research, intervention development, and practice that appropriately incorporates the risk context and needs of women with IPV experience. Findings from this dissertation highlight public health and healthcare efforts necessary to develop and implement a woman-centered PrEP intervention that recognizes the impact of violence in women's lives; values women's decisionmaking and control; and supports women's health, well-being, and safety.

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### Preface

I would like to thank several individuals for the support and guidance they have provided me throughout the dissertation process. To my committee chair and advisor, Jessie Burke, who has been my constant advocate throughout. Jessie has been an amazing mentor and friend, giving me opportunities to grow as a researcher, encouraging me to ask my own questions, and pushing me when I needed it most. To my dissertation committee: Jamie Egan, Mary Hawk, and Sarah Krier, who supported my research and provided invaluable feedback that pushed me to think more deeply about my work. I am grateful for their support, have learned so much from each of them, and value their mentorship and guidance. An enormous thank you to Planned Parenthood of Western Pennsylvania for their support of this project and instrumental assistance with recruitment for this research. I am incredibly grateful to Jenny, Nate, and Lir for warmly accepting me into the clinic and caring so much about this research. I am also very thankful to the HIV Prevention and Care Project for financially supporting this work. And to my husband, Alex Bernstein, who I am so grateful for his support and encouragement. He experienced the moments of panic, doubt, excitement, and determination with me during this process, reassured me when I felt discouraged, and celebrated the achievements. And finally, thank you to the women whose thoughts and experiences are reflected in this dissertation. Only because of their willingness to share their time and personal experiences was this research possible.

#### **1.0 Introduction**

## 1.1 Background

#### **HIV and Intimate Partner Violence among Women**

Extensive research highlights the co-occurrence on HIV and intimate partner violence among women (Centers for Disease Control and Prevention, 2014a; World Health Organization, 2004), underscoring the importance of interpersonal context when addressing HIV prevention. Despite advances in treatment and prevention, HIV continues to be a significant health issue for women worldwide. Globally, an estimated 18.2 million women are living with HIV, accounting for 52% of all adults living with HIV (UNAIDS, 2017). Women 15 years of age and older represent 48% of new HIV infections among adults globally (UNAIDS, 2017). In the United States, close to a fifth (19%) of new HIV diagnoses are among women (Centers for Disease Control and Prevention, 2017; U.S. Department of Health & Human Services, 2017). Women of color are disproportionately affected by HIV in the United States. African-American women accounted for 61% of HIV diagnoses among heterosexual women in 2016 (Centers for Disease Control and Prevention, 2017). Nineteen percent of new HIV diagnoses in 2016 were among white women and 16% were among Hispanic/Latina women (Centers for Disease Control and Prevention, 2017). The most common source of infection for women in the United States is through heterosexual contact, which represented 87% of all new infections among women in 2016 (Centers for Disease Control and Prevention, 2017). Women's risk for heterosexual HIV infection is significantly influenced by male partner's HIV risk factors (e.g., injection drug use, sex with men or other women) (Centers for Disease Control and Prevention, 2013; World Health Organization, 2004).

Often women are not aware of their HIV risk and condoms are infrequently used. For example, over 50% of women reported condomless vaginal or anal sex with a heterosexual partner of different or unknown HIV status during their most recent sex (Centers for Disease Control and Prevention, 2013), and 1 in 8 (12%) women living with HIV do not know they are infected (Centers for Disease Control and Prevention, 2017).

Substantial research has addressed the intersection of IPV and HIV among women (Campbell et al., 2008; Gielen et al., 2007; Li et al., 2014; Maman, Campbell, Sweat, & Gielen, 2000; Phillips et al., 2014). In some settings, women who experienced IPV were 1.5 times more likely to acquire HIV compared to women who have not experienced partner violence (World Health Organization, 2013). The relationship between IPV and HIV is complex and involves multiple pathways. Direct pathways, including forced or coerced sex with risky partner, and indirect pathways of limited self-efficacy to enact behaviors to reduce HIV increase risk among women who experience IPV (Coker, 2007; Dude, 2007; Dunkle & Decker, 2013; Li et al., 2014; Maman et al., 2000; Stockman, Lucea, & Campbell, 2013; Wingood, DiClemente, & Raj, 2000b). Existing research highlights that women in violent relationships have four times the risk for contracting sexually transmitted infections (STI), including HIV, than women in intimate relationships without violence (Centers for Disease Control and Prevention, 2014a; Gielen et al., 2007; Stockman et al., 2013; Wingood, DiClemente, & Raj, 2000a; Wingood et al., 2000b). Furthermore, forced sex occurs in approximately 40-45% of relationships with physical violence and has been found to increase a woman's risk for STIs by 2 to 10 times that of physical violence alone (Centers for Disease Control and Prevention, 2014a; Wingood et al., 2000a). Further, acceptability and use of existing HIV prevention methods is difficult for women who are unable to negotiate safe sex, such as those in abusive and controlling relationships. Violence or fear of violence often interferes with women's ability to negotiate condom use (Bergmann & Stockman, 2015; Decker et al., 2014; Wingood & DiClemente, 1997). For example, women with a physically abusive partner were 6.5 times more likely to fear physical abuse and 9.2 times more likely to be threatened with physical abuse as a result of negotiating condom use compared to women without an abusive partner (Wingood & DiClemente, 1997).

Violence by an intimate partner is a significant health issue for women. More than one in three women have ever experienced some form of physical and/or sexual violence by a male intimate partner globally (World Health Organization, 2013). Almost half (44%) of U.S. women have experienced sexual violence in their lifetime (e.g., rape, sexual coercion, and/or unwanted sexual contact) (Smith et al., 2015). Over 6.4 million U.S. women (or 1 in 18) experienced sexual violence, physical violence, and/or stalking by an intimate partner in 2015 (Smith et al., 2015). Intimate partner violence (IPV), defined as actual, attempted, or threatened physical, sexual, or psychological violence by a current or former intimate partner (Centers for Disease Control and Prevention, 2016), is associated with serious physical and mental health outcomes. Increased levels of depression, posttraumatic stress, and thoughts or attempts of suicide (Campbell, 2002; Chandra, Satyanarayana, & Carey, 2009; Ellsberg, Jansen, Heise, Watts, & Garcia-Moreno, 2008; Varma, Chandra, Thomas, & Carey, 2007); alcohol and drug abuse (Coker et al., 2002; Kinyanda et al., 2016); unintended pregnancy and unsafe abortions (Pallitto et al., 2013); and feelings of powerlessness, social isolation, and economic dependence (Antai, Antai, & Anthony, 2014; Matheson et al., 2015) are connected to women's experience of IPV.

### **Limitations of HIV Prevention Strategies for Women**

Current (e.g., male and female condoms) and experimental (e.g., vaginal microbicides) HIV prevention options for women often fail to consider the context of abusive intimate relationships as strategies are highly dependent on partner interest and cooperation in prevention (Choi, Wojcicki, & Valencia-Garcia, 2004; Doggett et al., 2015; Saul, Moore, Murphy, & Miller, 2004). The female condom, when approved by the Food and Drug Administration (FDA) in 1994, received substantial attention for its potential to reverse power dynamics in intimate relationships and provide dual protection against pregnancy and HIV/STIs (Gollub, 2000). However, female condom use has been lower than expected due to things such as poor acceptability and high costs (Gallo, Kilbourne-Brook, & Coffey, 2012; Weeks et al., 2015). For example, in the United States, less than a third of participants interviewed in a study of Californian women around perspectives of female condoms had ever tried using one, and those that had, reported negative experiences including discomfort, difficulty of insertion/extraction, time-intensive, unappealing appearance, messiness, and sexual dissatisfaction (Stockman et al., 2014). Insertion difficulties of the female condom have been frequently reported by women (Artz, Demand, Pulley, Posner, & Macaluso, 2002; Artz et al., 2000; Sly et al., 1997). While insertion difficulty has been found to reduce with practice - for example, from 25% to 3% among women in Alabama who practiced inserting the condom in an anatomic model and then in themselves under nurse guidance (Artz et al., 2002) limited information is known about long-term use of female condoms in studies with instruction, practice, and problem-solving guidance (Hoffman, Mantell, Exner, & Stein, 2004).

An additional challenge to female condom acceptability has been around male partners, where men's attitudes and beliefs have impacted women's acceptance and continued use of the female condom (Hoffman et al., 2004). For example, a literature review by Moore and colleagues

(2015) on female condom knowledge, attitudes, and practices found that attributes of the female condom were perceived positively and negatively within and between different country settings, and that contextual and environmental factors seem to play a greater role in determining overall acceptability and uptake. In particular, they suggest that pervasive stigma and male partner responses determined initial and continued use of female condoms, rather than product attributes (e.g., appearance, insertion/use, timing of use, dual protective properties, pleasure). Hoffman et al. (2004) highlight that the need for women to negotiate with partners for female condom use has led public health professionals to conclude that the inequality inherent in male condoms is not actually resolved with female condoms. The authors report that as a result, "the female condom is now usually referred to as 'female-initiated,' rather than 'female-controlled,' to reflect that its use is not fully in the hands of women" (Hoffman et al., 2004, p. 122).

Vaginal microbicides, a topical gel form of pre-exposure prophylaxis, is also considered a promising method that could give women increased agency over HIV prevention. While vaginal microbicides remain experimental at this point, they offer an additional potential womancontrolled HIV prevention strategy and provide important research insight. In particular, evidence of microbicide efficacy, acceptability, and adherence results have varied (Doggett et al., 2015; Domanska & Teitelman, 2012). The 2010 CAPRISA trial in South Africa demonstrated that 1% tenofovir gel is safe and can reduce the likelihood of male-to-female transmission of HIV by 39% when inserted vaginally within 12 hours before or after sex, and by 54% in women with high gel adherence (>80% adherence) (Abdool Karim et al., 2010). However, other trials (e.g., VOICE, FEM-PrEP) were unable to demonstrate efficacy, with poor adherence likely the primary issue (van der Straten, Van Damme, Haberer, & Bangsberg, 2012). Doggett et al. (2015) identified the gender-related factors potentially impacting microbicide acceptability, access, and adherence through a review of existing studies and found that influencing factors fell into categories of norms related to women's and men's sexuality and power dynamics within intimate relationships. In particular, they describe that women's sexual behavior is often less socially acceptable and more restricted than men's and may result in implications on microbicide acceptability and intentions to use. Additionally, women's limited power to negotiate the circumstances of their sex lives and intimate relationships were identified as likely impacting their ability to access and use microbicides. Other important predictors of women's acceptance and use of microbicides identified across existing studies includes male partner preferences, or perceived preferences, around product and product characteristics. For example, Domanksa & Teitelman (2012) examined articles reporting primary data around vaginal microbicide adherence by women and acceptability of their use by men and women and found that male partner preferences, especially around product characteristics (i.e., wetness), was the primary predictor of women's acceptance of microbicides.

While existing HIV prevention strategies may facilitate safer sex, uptake of such strategies among women is relatively limited (Centers for Disease Control and Prevention, 2017; Gallo et al., 2012; Weeks et al., 2015) and additional consideration to the context of prevention within abusive relationships is needed. Violence in an intimate relationship has been found to place additional constraint on the acceptability, uptake, and use of HIV prevention methods including condoms and vaginal microbicides. Violence or fear of violence has frequently been found to limit women's ability and self-efficacy to request or negotiate condom use (Bergmann & Stockman, 2015; Decker et al., 2014; Wingood & DiClemente, 1997). Decker and colleagues (2014) found that women with recent IPV (previous three months) were more likely to report involuntary

condom non-use (AOR = 1.87; 95% CI: 1.51-2.33) and fears of requesting condoms (AOR = 4.15; 95% CI: 2.73-6.30). Other studies report varied acceptability of vaginal microbicides among women with a history of partner violence. For example, Stockman et al.'s (2014) study explored perspectives on female condoms and vaginal microbicides among women in California with histories of partner violence and found that of the women currently in an abusive relationship, all were interested in vaginal microbicides over female condoms. Furthermore, women who reported current IPV all stated that they would not disclose their microbicide use to their current abusive partner in order to avoid arguments, accusations of infidelity, and more abuse. Another study, however, found that women's microbicide acceptability scores were negatively related to having experienced either physical or sexual violence (p < 0.03) (Weeks et al., 2004). Vaginal microbicides may have offered the potential for women to use covertly, however, the gel may create additional lubrication, causing concerns by women that their partner would be able to tell when they were used (Flash et al., 2014; Weeks et al., 2004).

### **PrEP: HIV Prevention Strategy for Women**

Pre-exposure prophylaxis (PrEP), a daily oral emtricitabine-tenofovir (Truvada) medication, is a promising biobehavioral HIV prevention method that is used to reduce HIV incidence among people at high risk for HIV acquisition (Centers for Disease Control and Prevention, 2014b; Fonner et al., 2016; Food and Drug Administration, 2012). A fixed-dose combination of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) has been shown to reduce the risk of HIV by more than 90% when used properly (Centers for Disease Control and Prevention, 2018; Centers for Disease Control and Prevention/US Public Health Service, 2018). Approved by the FDA in 2012, PrEP was then recommended in 2014 by the Centers for Disease

Control and Prevention (CDC) who recommended that, "clinicians evaluate their male and female patients who are sexually active or who are injecting illicit drugs and consider offering PrEP as one prevention option to those whose sexual or injection behaviors and epidemiologic context place them at substantial risk of acquiring HIV infection" (Centers for Disease Control and Prevention/US Public Health Service, 2018, p. 14). The World Health Organization (WHO) also recommended the use of PrEP in 2015 as an additional prevention option to reduce HIV incidence among people who are uninfected but at high risk for HIV acquisition (World Health Organization, 2017). Both the CDC and WHO have recommended guidelines for PrEP use (Truvada) for heterosexual women (PrEP guidelines summarized in Appendix A). Several randomized-controlled trials have published PrEP efficacy and safety findings and provide evidence of daily oral PrEP (TDF/FTC) as one HIV prevention option for sexually active heterosexual women (summarized in Appendix A). A number of ongoing or planned PrEP demonstration and implementation studies are also underway and additional information can be found online at AVAC (formerly the AIDS Vaccine Advocacy Coalition) (AVAC, 2017).

PrEP is a novel HIV prevention strategy and presents a new opportunity for a womancontrolled prevention strategy (Chen, Meyer, & Springer, 2011; Koechlin et al., 2017; Rubtsova, Wingood, Dunkle, Camp, & DiClemente, 2013; D. Seidman & Weber, 2016), though use among women remains low. For example, women represent 19% of all new HIV diagnoses in the United States, yet only 7% of PrEP users are women (AIDSVu, 2018). Outside of clinical trials, a majority of standalone PrEP studies has focused on men who have sex with men (MSM) (Young & McDaid, 2014). However, a recent review addressing the values and preferences among other populations that might benefit from PrEP (e.g., women, heterosexual men, female sex workers, people who inject drugs) found a strong interest and support for PrEP across the 104 studies identified (Koechlin et al., 2017). The authors report that while awareness of PrEP was low, once participants were presented with information, the majority reported that they would consider using it, highlighting the need for additional efforts to raise awareness and ensure accurate HIV risk perception among those who might benefit from PrEP (Koechlin et al., 2017).

HIV continues to be an important health issue for women in the United States, where approximately a fifth of new HIV diagnosis are among women (Centers for Disease Control and Prevention, 2017; U.S. Department of Health & Human Services, 2017), and there is a growing recognition of the value of PrEP as a component of HIV prevention for women. As a result, research is increasingly exploring the relationship between women's HIV risk perception and PrEP acceptability in the United States (Auerbach, Kinsky, Brown, & Charles, 2015; Collier, Colarossi, & Sanders, 2017; Flash et al., 2014; Rubtsova et al., 2013; Wingood et al., 2013). Current evidence suggests that women in the United States are interested in using PrEP, however, have often not heard of PrEP prior to study participation. Results from a nationally representative survey of U.S. women found a high acceptability of PrEP, where 64% of women aged 20-29 years and 59% of women aged 30-45 years reported they would take a daily pill to prevent HIV (Rubtsova et al., 2013). Focus groups among clients and staff of organizations providing health and social services (e.g., HIV prevention agency, homeless shelter for adult women, domestic violence organization) in the Bronx, New York found that a majority had not heard about PrEP before participation, and that among providers who were previously aware of PrEP, there were misconceptions about PrEP as only for MSM (Collier et al., 2017). Other focus group findings among women in six U.S. cities (New York, Dallas, Atlanta, Newark, Chicago, and New Orleans) report low awareness of PrEP before study participation (less than 10%), and that participants were even frustrated that they had

not heard about PrEP prior to the study, and those who had heard of PrEP, reported that they did not know it was available for women (Auerbach et al., 2015).

PrEP acceptability research among women in the United States has also explored preference on PrEP administration and existing evidence suggests that women support a variety of delivery options. Focus groups among women in Boston recruited through community health centers and HIV testing sites found that most women preferred pills to a microbicide gel (Flash et al., 2014). Pills were perceived to be easy to use and provide increased privacy, whereas gels seemed less private, inconvenient, and might cause vaginal irritation and leakage. Auerbach et al. (2015) found in focus groups among women in six U.S. cities that many women reported preference towards the injectable and the pill; the vaginal ring, however, was found to be the least popular option due to negative perceptions around a contraceptive used similarly (i.e., NuvaRing).

Results from research on women's interest in using PrEP has also varied. Reasons for openness or interest in PrEP has been found to be related to social influence and healthcare provider recommendation (Kwakwa et al., 2016; Rubtsova et al., 2013; Wingood et al., 2013). A nationally representative survey of U.S. women found that young women (20-29 years) were 2.09 times as likely to report potential PrEP uptake if recommended by a healthcare provider (p < 0.001) and if they thought that many of their girlfriends would take PrEP (79.7% vs 70.1%; OR = 1.68; p < 0.05) compared to older women (30-45 years) (Rubtsova et al., 2013). Additionally, African-American women were 2.2 times more likely to report potential PrEP use if they perceived that their female friends would also use PrEP ( $p \le 0.001$ ), and 1.65 times as likely to report potential PrEP use if it was recommended by a healthcare provider ( $p \le 0.001$ ) compared to white women (Wingood et al., 2013). A lack of interest or openness to PrEP among women has been found to include such things as low risk perception, medicine concerns (e.g., high pill burden, side effects),

cost, mistrust of medical institutions or pharmaceutical companies, newness of drug, stigma, and lack of communication among community members and healthcare providers (Auerbach et al., 2015; Flash et al., 2014; Goparaju et al., 2017; Kwakwa et al., 2016). Among focus group participants in Washington, D.C., women expressed concerns that partners, family, and friends may have hostile reactions or suspicion towards women who take PrEP/an HIV medicine and result in accusations of infidelity and mistrust by partners (Goparaju et al., 2017). Additionally, women described difficulties discussing sexual behavior with healthcare providers. For example, women report that providers rarely ask about HIV risk behaviors, short visits hinder the opportunity to establish a trusting relationship, and a concern that disclosure of sexual behavior would result in judgmental responses and harsh treatment (Goparaju et al., 2017).

#### **Expanding HIV Prevention Options for Women in Abusive Relationships**

Existing HIV prevention strategies for women are limited and PrEP has the potential to dramatically expand options for those in abusive and controlling intimate relationships (Braksmajer, Senn, & McMahon, 2016). While research is increasingly highlighting that PrEP offers new opportunities for HIV prevention for women (Koechlin et al., 2017; D. L. Seidman et al., 2016), as a discreet, woman-controlled strategy it also has the potential to dramatically expand HIV prevention options for women at higher risk for HIV, those in abusive and controlling intimate relationships (Braksmajer et al., 2016). Compared to other woman-controlled prevention methods, PrEP has several advantages for women experiencing IPV, including autonomous or covert use and not needing to be used at time of sexual activity (Braksmajer et al., 2016). PrEP is not partner dependent, allowing women to use without their partner's involvement or knowledge. Women in abusive relationships often have limited self-efficacy to enact behaviors to reduce HIV risk, such

as request condom use due to fear or experience of violence (Bergmann & Stockman, 2015; Coker, 2007; Decker et al., 2014; Wingood & DiClemente, 1997) and PrEP could provide HIV protection independent of partner. Further, oral PrEP allows women to discreetly use. Other PrEP formulations such as topical gels may create additional lubrication, causing concerns that partners would be able to tell when they used vaginal gel (Flash et al., 2014; Weeks et al., 2004). PrEP also does not need to be taken at the time of sexual activity. This offers a critical advantage over other existing methods as women experiencing IPV may not have control over when or how a sexual encounter occurs. Finally, the CDC recommends PrEP users see a health care provider every three months for HIV testing and health status monitoring (Centers for Disease Control and Prevention, 2014b, 2018). Although women in violent and controlling relationships could face barriers to attending regular health care visits (Collier et al., 2017), PrEP care engagement could facilitate connection to IPV support services. No known research has explored PrEP use within abusive relationships among other populations, such as MSM, and additional research is needed to comprehensively explore the impact of IPV on PrEP outcomes.

# **1.2 Rationale for Research**

Consistently high rates of IPV among women and the persistent HIV incidence rates among women make understanding the HIV risk context and needs of women in abusive and controlling relationships critical (UNAIDS, 2017; World Health Organization, 2013). The co-occurring and intersecting issues of IPV and HIV reduces women's ability to enact behaviors to reduce their HIV risk (World Health Organization, 2004). Further, existing woman-controlled HIV prevention methods remain underused and inadequate (Doggett et al., 2015; Moore L et al., 2015). PrEP,

however, as a discreet, woman-controlled strategy has the potential to dramatically expand HIV prevention options for women in violent relationships. Existing research suggests that IPV may have implications on women's PrEP acceptability and is important to consider when examining women's views of PrEP and willingness to take. However, significant gaps around the complex and intersecting issues of IPV and PrEP for HIV prevention among women asserts this as an area in great need of research. This dissertation research contributes to furthering our understanding of the unique HIV prevention context and needs of women in abusive and controlling relationships. It provides needed insights into the complexities of HIV prevention and potential of PrEP within the context of IPV, including acceptability and perceived barriers to PrEP use. This knowledge contributes to PrEP intervention development that appropriately incorporates the risk context and needs of women with IPV experience.

#### **1.3 Study Aims**

This dissertation research investigates the intersection of intimate partner violence and PrEP acceptability among urban women. It also assesses the perceptions of barriers to women's PrEP acceptability by intimate partner violence history. The specific study aims are:

- (1) To identify and synthesize existing research focused on PrEP acceptability and use among women in abusive relationships.
- (2) To assess the prevalence of recent and lifetime IPV and its association with PrEP acceptability (i.e., willingness to use) among a sample of women seeking care at an urban family planning clinic.

(3) To explore perceptions about the barriers to PrEP acceptability among a sample of women seeking care at an urban family planning clinic, and examine the association of barriers to PrEP acceptability (i.e., willingness to use) and potential differences by IPV experience.

## **1.4 Dissertation Organization**

This dissertation is organized into six chapters and adopts the three-paper dissertation format.

# **Chapter One (Introduction)**

The first chapter provides an introduction to the issues of intimate partner violence and HIV prevention among women and background on PrEP as a HIV prevention strategy for women in violent relationships. This chapter also outlines the rationale and specific aims of this dissertation research.

#### **Chapter Two (Paper One)**

The second chapter includes the first paper which is a systematic rapid review of peerreviewed published articles and conference abstracts examining PrEP acceptability and use among women in violent relationships. The aim of this paper is to identify and synthesize existing research focused on PrEP acceptability and use among women in abusive intimate relationships. Results of a systematic rapid review are presented to address this aim.

### **Chapter Three (Research Methods)**

Chapter three presents the methodology used in the cross-sectional survey of this dissertation study, including a description of the study design, setting and population, data collection methods, data management and analysis strategy.

# **Chapter Four (Paper Two)**

Chapter four presents the second paper which is a quantitative analysis of cross-sectional data collected from 145 women seeking care at a family planning clinic (Planned Parenthood of Western Pennsylvania) in Pittsburgh, Pennsylvania. The aims of this paper are to assess the prevalence of recent and lifetime IPV and PrEP acceptability (i.e., willingness to use) among a sample of women seeking care at an urban family planning clinic, and evaluate the impact of IPV experience on women's PrEP acceptability. Frequencies and bivariate logistic regression analyses are presented to address these aims.

## **Chapter Five (Paper Three)**

The third paper is presented in chapter five and is a quantitative and qualitative analysis of cross-sectional data collected from 145 women seeking care at a family planning clinic (Planned Parenthood of Western Pennsylvania) in Pittsburgh, Pennsylvania. The aims of this paper are to investigate perceptions about the barriers to PrEP acceptability among a sample of women seeking care at an urban family planning clinic, evaluate the relationship between the barriers and women's reports of PrEP acceptability (i.e., willingness to use), and determine if the association of barriers and PrEP acceptability vary by women's IPV experience. Bivariate and multivariable logistic

regression analyses, and qualitative analysis of open-text survey questions, are presented to address these aims.

# **Chapter Six (Discussion)**

The sixth chapter presents a summary of findings and discusses study limitations and strengths. This chapter also outlines the research and practice implications of this dissertation research.

# 2.0 Intimate partner violence and pre-exposure prophylaxis (PrEP): Current evidence and future directions for women's HIV prevention

### 2.1 Abstract

While there is a growing recognition of the value of pre-exposure prophylaxis (PrEP) as a component of HIV prevention and increasing attention focusing on women's use of PrEP, there is a substantial gap in research explicitly examining acceptability and use among women in violent intimate relationships. Current HIV prevention options remain underused and fail to consider the context of intimate partner violence and PrEP presents an opportunity to dramatically expand options for women in abusive and controlling relationships. A systematic rapid review of peerreviewed published articles on PubMed and abstracts of fifteen HIV, women's health, or interpersonal violence-related conferences synthesized existing research focused on PrEP acceptability and use among women in abusive intimate relationships. Nine articles and conference abstracts were coded using a structured abstraction form and synthesized according to relevant themes. Review results indicate that intimate partner violence experience has implications on women's interest and willingness to use PrEP, perceived PrEP coercion, partner interference in use, interruptions in PrEP use, and adherence. Future research examining the intersection of intimate partner violence and PrEP is critical to inform a woman-centered PrEP intervention development with significant implications on women's health and well-being.

### **2.2 Introduction**

Extensive research highlights the co-occurrence of HIV and intimate partner violence among women (Centers for Disease Control and Prevention, 2014a; World Health Organization, 2004), underscoring the importance of interpersonal context when addressing HIV prevention. Despite advances in treatment and prevention, HIV continues to be a significant health issue for women worldwide. Globally, an estimated 18.2 million women are living with HIV, accounting for 52% of all adults living with HIV (UNAIDS, 2017). Women 15 years of age and older represent 48% of new HIV infections among adults globally (UNAIDS, 2017). Women's risk for heterosexual HIV infection is significantly influenced by male partner's HIV risk factors (e.g., injection drug use, sex with men or other women) (Centers for Disease Control and Prevention, 2013; World Health Organization, 2004).

More than one in three women have ever experienced some form of physical and/or sexual violence by a male intimate partner globally (World Health Organization, 2013). Intimate partner violence (IPV), defined as actual, attempted, or threatened physical, sexual, or psychological violence by a current or former intimate partner (Centers for Disease Control and Prevention, 2016), is associated with serious physical and mental health outcomes among women. Increased levels of depression, posttraumatic stress, and thoughts or attempts of suicide (Campbell, 2002; Chandra et al., 2009; Ellsberg et al., 2008; Varma et al., 2007); alcohol and drug abuse (Coker et al., 2002; Kinyanda et al., 2016); unintended pregnancy and unsafe abortions (Pallitto et al., 2013); and feelings of powerlessness, social isolation, and economic dependence (Antai et al., 2014; Matheson et al., 2015) are connected to women's experience of IPV.

Substantial research has addressed the intersection of IPV and HIV among women (Campbell et al., 2008; Centers for Disease Control and Prevention, 2014a; Gielen et al., 2007; Li

et al., 2014; Maman et al., 2000; Phillips et al., 2014; World Health Organization, 2004). In some settings, women who experienced IPV were 1.5 times more likely to acquire HIV compared to women who have not experienced partner violence (World Health Organization, 2013). The relationship between IPV and HIV is complex and involves multiple pathways. Direct pathways, including forced or coerced sex with risky partner, and indirect pathways of limited self-efficacy to enact behaviors to reduce HIV, increase risk among women who experience IPV (Coker, 2007; Dude, 2007; Dunkle & Decker, 2013; Li et al., 2014; Maman et al., 2000; Stockman et al., 2013; Wingood et al., 2000b). Further, acceptability and use of existing HIV prevention methods is difficult for women who are unable to negotiate safe sex, such as those in abusive and controlling relationships. Current (e.g., male and female condoms) and experimental (e.g., vaginal microbicides) HIV prevention options often fail to consider the context of abusive intimate relationships as the strategies are highly dependent on partner interest and cooperation in prevention (Choi et al., 2004; Doggett et al., 2015; Saul et al., 2004).

Pre-exposure prophylaxis (PrEP), a daily oral emtricitabine-tenofovir (Truvada) medication, is a promising biobehavioral HIV prevention method being used to reduce HIV incidence (Centers for Disease Control and Prevention, 2014b; Fonner et al., 2016; Food and Drug Administration, 2012). PrEP, a fixed-dose combination of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC), was approved by the FDA in 2012 (Food and Drug Administration, 2012), and was then recommended in 2015 by the World Health Organization as a biobehavioral prevention method to reduce HIV incidence among people who are uninfected but at high risk for HIV acquisition (World Health Organization, 2017). The emergence of PrEP presents a new opportunity for a woman-controlled prevention strategy (Chen et al., 2011; Koechlin et al., 2017; Rubtsova et al., 2013), and has several advantages over other options for women experiencing

IPV, including autonomous or covert use and not needing to be used at time of sexual activity (Braksmajer et al., 2016). However, PrEP use among women remains relatively low. For example, women in the United States represent 19% of all new HIV diagnoses and only 7% of PrEP users (AIDSVu, 2018).

Violence in an intimate relationship has been found to place constraint on the acceptability, uptake and use of HIV prevention methods including condom use and vaginal microbicides. Violence or fear of violence has frequently been found to limit a woman's ability and self-efficacy to request or negotiate condom use (Bergmann & Stockman, 2015; Decker et al., 2014; Wingood & DiClemente, 1997) or acceptability of microbicides (Flash et al., 2014; Weeks et al., 2004). Decker and colleagues (2014) found that women with recent IPV (previous three months) were more likely to report involuntary condom non-use (AOR = 1.87; 95% CI: 1.51-2.33) and fears of requesting condoms (AOR = 4.15; 95% CI: 2.73-6.30) compared to women not disclosing recent IPV. Other studies report the varied acceptability of vaginal microbicides among women with a history of partner violence. Women were interested in vaginal microbicides over female condoms in one study (Stockman et al., 2014), whereas another (Weeks et al., 2004) found women's microbicide acceptability scores were negatively related to having experienced either physical or sexual violence (p < 0 .03). Additionally, vaginal gels may create added lubrication, causing concerns by women that their partner would be able to tell when they were used (Flash et al., 2014; Weeks et al., 2004).

While there is a growing recognition of the value of PrEP as a component of HIV prevention and increasing research focusing on women's use of PrEP, there is a substantial gap in the literature that explicitly examines the intersection of PrEP acceptability and IPV among

women. The purpose of this systematic rapid review is to identify and synthesize existing research focused on PrEP acceptability and use among women in abusive intimate relationships.

### 2.3 Methods

# Search Strategy

A systematic rapid review process was used to identify peer-reviewed published articles through systematic searches conducted in PubMed. Rapid reviews have emerged as valuable approach to provide actionable and relevant evidence in a timely manner (Tricco, Langlois, & Straus, 2017). A type of knowledge synthesis where systematic review processes are accelerated and methods are streamlined to complete the review more quickly (Tricco et al., 2017), a rapid review is an appropriate level of review for this topic in order to inform research and practice recommendations rapidly. Relevant literature was identified using the following terms: ('preexposure prophylaxis' OR 'preexposure prophylaxis' OR 'PrEP' OR 'PREP') AND ('women' OR 'female') AND ('intimate partner violence' OR 'domestic violence' OR 'gender-based violence' OR 'marital violence' OR 'spousal abuse' OR 'spousal violence' OR 'violence against women'). The keywords used in the search were selected based on a review of relevant literature and identification of terms used in previous literature reviews within the field broadly (e.g., (Koechlin et al., 2017; Young & McDaid, 2014). Both approved (daily oral TDF/FTC) and experimental (vaginal microbicide gel or ring) PrEP delivery methods were included to better understand the extent of research on this topic. The process, including search, review, and coding, were all conducted by the lead author (TLO), who has considerable experience and multiple publications in this literature review approach. The search was initially conducted in January 2018, and then updated in November 2018 and January 2019. All publications dates were considered for inclusion. A Public Health Informationist at the University of Pittsburgh's Health Sciences Library System provided input and guidance regarding the search strategy.

In addition to the published articles, the search included a review of available abstracts (in English) from six national and international conferences related to HIV, women's health, or interpersonal violence. Conference abstracts play an important role in research dissemination (Kelly, 1998), and as PrEP is a growing research area, they provide a valuable opportunity to access current research. Using available online conference abstract systems, the abstracts were searched using keywords (e.g., ('intimate partner violence' OR 'domestic violence') AND ('preexposure prophylaxis' OR 'preexposure prophylaxis' OR 'PrEP' OR 'PREP')) across the following six conferences: International AIDS Conference; Conference on HIV Pathogenesis, Treatment, and Prevention; Conference on Retroviruses and Opportunistic Infections; International Workshop on HIV & Women; Society for Advancement of Violence and Injury Research National Conference; and National Conference on Health and Domestic Violence. Conferences were reviewed back to 2015 to allow approximately three years between conference presentation and publication in peer-reviewed literature and represented 15 separate conference events. Studies reporting original data on PrEP and IPV among women were included in the review.

DistillerSR, a systematic review management software, was used throughout the review process (Evidence Partners, Ottawa, Canada). The lead author conducted the review through an initial title and abstract screening to ensure selected studies broadly reflected inclusion and exclusion criteria. Full text documents of articles and abstracts meeting inclusion criteria were then obtained and reviewed for final eligibility.

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# Inclusion Criteria

Articles and conference abstracts that were included had to meet the following criteria: (1) focused on both PrEP and IPV experiences among women, (2) presented primary data, (3) peerreviewed, and (4) written in English language. Studies that did not report data findings (e.g., literature review, commentary) were excluded.

#### Data Extraction and Analysis

The final set of articles and conference abstracts were reviewed by one coder (TLO). Descriptive information was abstracted by the reviewer from each study on setting and context, study design and objectives, recruitment process, sample characteristics, PrEP and IPV indicators assessed, and reported key findings around the intersection of IPV and PrEP among women. The reviewer used summary tables to compare variables of interest and associated outcomes across studies. A conference abstract and article reporting the same results were considered a single study and only the article was included in the analysis. The reviewer resolved any inclusion verification and coding concerns in collaboration with another author (JGB).

## 2.4 Results

The systematic rapid-review search yielded 55 records eligible for preliminary screening; of those, 19 articles and 3 conference abstracts were excluded from the full-text screening. Thirty-three underwent full-text screening and nine were deemed eligible for review inclusion. Articles and conference abstracts excluded did not focus on women, IPV, PrEP for HIV prevention (e.g., focused on emergency or disaster preparedness, discussed HIV prevention but not PrEP

specifically), or did not include primary data collection (e.g., literature review, commentary). Figure 2-1 displays the flowchart of the rapid review process.

## Descriptive Characteristics

The included studies contained quantitative (n=4; 44%), qualitative (n=4; 44%), and mixed-methods (n=1; 11%) designs, the majority of which were cross-sectional (n=7; 77%). Samples ranged across studies and included 26 (Braksmajer, Leblanc, El-Bassel, Urban, & McMahon, 2018) to 1785 women participating in a prospective cohort clinical trial (Roberts et al., 2016). Four studies were conducted in the United States and other study settings included work in Kenya, South Africa, Tanzania, and Uganda; three were conducted at multiple sites.

Almost an equal number of studies focused on hypothetical PrEP use and actual PrEP use. Four studies examined potential PrEP use through such things as awareness of, interest in, or willingness or intentions to use PrEP, and all of these were conducted in the United States. For example, several studies focused on interest or willingness to use PrEP (Braksmajer et al., 2018; T. Willie, Kershaw, Campbell, & Alexander, 2017; T. C. Willie et al., 2018; T. C. Willie, Stockman, Overstreet, & Kershaw, 2017). One study also explored perceived barriers to PrEP use among women reporting IPV experience in the previous six months (Braksmajer et al., 2018). Five studies involved actual PrEP use, all conducted in non-U.S. settings, and examined things around accessing PrEP, experience using, and adherence or interruption in PrEP use. Three of these studies were associated with larger clinical trials (i.e., Partners PrEP (Roberts et al., 2016); VOICE, MTN-003 (Hartmann et al., 2016); MTN-020/ASPIRE trial (Hartmann et al., 2018)). Two were part of demonstration projects, including one which sought to assess the feasibility and acceptability of integrating gender-based violence screening and support into HIV counselling for adolescent girls and young women accessing oral PrEP in South Africa and Tanzania (Colombini et al., 2018).

Different types of violence (e.g., physical, sexual, psychological, economic) were explored across studies included in this review. For example, two studies specifically examined physical and sexual IPV (T. C. Willie et al., 2018; T. C. Willie et al., 2017), one focused on sexual IPV (i.e., forced sex) (Braksmajer et al., 2018), and one explored a history of controlling or violent partner behaviors (Hartmann et al., 2018). Assessment of the timing of abuse also varied across studies. For example, four studies examined recent (e.g., previous 6 or 12 months, since last study visit) experience of partner violence (Braksmajer et al., 2018; Cabral et al., 2018; Roberts et al., 2016; T. C. Willie et al., 2018) and four focused on any IPV experience throughout participants' lifetime (Colombini et al., 2018; Hartmann et al., 2016; Hartmann et al., 2018; T. Willie et al., 2017). One study assessed both recent and lifetime IPV experience (T. C. Willie et al., 2017). Despite this variation, findings suggest that a history of IPV was common among the women sampled. Thirty-two percent of women aged 16 to 24 years accessing oral PrEP in an open-label PrEP demonstration project in South Africa and Tanzania reported lifetime experience of violence (Colombini et al., 2018). And over half (57%) of a sample of women in the United States who reported IPV within the previous six months were currently in abusive relationships (Braksmajer et al., 2018).

The PrEP constructs that were assessed varied by study and primarily focused on factors across categories of: (1) awareness of and willingness to use PrEP (e.g., knowledge, interest, intention to use) and (2) PrEP use experience (e.g., interruption in PrEP use, adherence). When focusing on women's awareness and interest in using PrEP, Willie et al. (2017) found that among 109 women surveyed through an online participant recruitment tool in the United States, PrEP
awareness was moderate (12%), but participants were interested in using PrEP (25%). Additionally, a study involving in-depth interviews with 26 women in the United States report that approximately half of participants expressed interest in taking PrEP, while others reported ambivalence or not being interested in taking PrEP (Braksmajer et al., 2018). Among those studies focusing on PrEP use experience, Hartmann et al. (2018) report that women in South Africa described either categories of feeling fearful or empowered when using the dapivarine vaginal ring. Furthermore, a study in Uganda and Kenya around recent and/or past exposure to IPV and PrEP adherence found that PrEP pill count was high among participants (mean = 95.3%) (Roberts et al., 2016).

## Intersection of IPV and PrEP among Women

Results from the studies included in this review suggests that IPV is associated with women's PrEP-related outcomes. Studies are further discussed below and are grouped by: (1) awareness of and willingness to use PrEP and (2) PrEP use experience (see Table 2-1).

## Awareness of and Willingness to Use PrEP

Four studies addressed hypothetical PrEP use and found that awareness of and willingness to use PrEP were connected to women's IPV experience. While exploring the impact of IPV on PrEP interest among women and men recruited through an online participant tool in the United States, Willie and colleagues (2017) found that past-year physical IPV was associated with participants being interested in using PrEP (AOR = 4.53; 95% CI: 1.85-11.11, p < 0.001). Another study focused on willingness to use PrEP among urban-dwelling, low-income young Black women in the United States found that IPV was indirectly related to PrEP acceptability through reproductive coercion (i.e., partner uses power and control to influence reproductive health outcomes) (indirect effect = 0.08; p < 0.05) (T. Willie et al., 2017). They found that women who were willing to use PrEP were more likely to have experienced birth control sabotage (i.e., direct interference with use of contraception), compared to those not willing or indecisive about PrEP (T. Willie et al., 2017). Pregnancy coercion (i.e., verbal pressure and threats to promote pregnancy), however, was not found to have a significant indirect effect from IPV to PrEP acceptability.

Willie and colleagues (2018) examined how IPV experiences modify the association between participants' social network characteristics and PrEP awareness, interest, intentions, and perceived candidacy among women recruited through online and community flyers in the United States. They found that compared to women with no recent IPV experience (past 6 months), women experiencing recent IPV had the highest prevalence of PrEP interest (44.7% vs. 30.2%; p= 0.03), intentions (42.4% vs. 28.3%; p = 0.04), and perceived candidacy (47.1% vs. 26.4%; p = 0.003). However, women experiencing recent IPV reported smaller social networks and less support of potential PrEP use across their network, compared to women without recent IPV experiences. The authors report that the findings suggest that IPV modified the effect of social network characteristics on PrEP interest and intentions. Among women experiencing IPV, a higher percentage of PrEP-aware alters (i.e., individuals participant perceived to be close to) was associated with lower PrEP interest (p = 0.02) and intentions to use (p = 0.001) (T. C. Willie et al., 2018).

Braksmajer et al.'s interviews (2018) among women in violent intimate relationships in the United States found that a third of participants described potential partner interference as a barrier to PrEP use, that most women would not use PrEP covertly, and that many feared increased violence if their partner were to discover covert use. Similarly, IPV experience was found to influence perceived PrEP coercion, or believing that your current or most recent partner would prevent you from using PrEP if you were using it, among women and men in the United States (T. C. Willie et al., 2017). In particular, when examining whether type and timing of IPV impacted perceived PrEP coercion differently, Willie et al. (2017) found that lifetime sexual (AOR = 3.69; 95% CI: 1.62-8.40, p < 0.001) and psychological IPV (AOR = 4.70; 95% CI: 1.01-21.89, p < 0.05), and past-year sexual IPV (AOR = 3.01; 95% CI: 1.10-8.27, p < 0.05) were positively associated with perceived PrEP coercion among the entire sample.

## PrEP Use Experience

Five studies found that women's experiences using PrEP, including interruptions in PrEP use and adherence, were related to IPV experience. An open-label PrEP demonstration project in South Africa and Tanzania examined the feasibility of integrating gender-based violence screening and support among young women (16-24 years) accessing PrEP (Colombini et al., 2018). While women who disclosed IPV reported it was helpful and reassuring to talk with counsellors who were friendly and non-judgmental, clinical staff described initial discomfort asking about violence and facilitating disclosure of suspected cases, and concerns about length of time to complete sessions and offering help to those who refuse referrals. Additional description of PrEP outcomes and IPV screening were not provided in the conference abstract.

Hartmann and colleagues' interviews (2018) focused on experience using the dapivirine vaginal ring among women who reported social harms during trial participation in South Africa (i.e., reported a partner-related social harm or adverse event, withdrew from the trial for partner-related reasons, or had any other documented partner-related opposition to the trial/product) and

their male partners. They found that the use of the PrEP vaginal ring/study participation was linked to IPV through exacerbating pre-existing violence due to such things as women spending time away from home (i.e., at the clinic), STI testing and disclosing to partner the need for treatment, and using a product that a partner disapproved or was not aware of. Women also described that the vaginal ring became a new mechanism for partners to perpetrate violence and used it to humiliate (e.g., it smelled and turned him off of sex) and accuse of distrust. One male partner reported that his partner's study participation led him to stop perpetrating violence due to a concern that study staff would be able to identify signs of abuse. Feeling either fearful or empowered also emerged towards vaginal ring use and violence. Women who feared their partners' reactions reported discontinuing ring use, tactics to retreat from or avoid ring-related conflict, or removing the ring when with partners. Women who felt empowered by ring use described a sense of power linked to the protection the ring was perceived to provide in risky relationships (Hartmann et al., 2018).

Hartmann et al.'s (2016) interviews and focus group discussions with multiple participant groups examined PrEP use and potential socio-cultural barriers and facilitators to PrEP among women in South Africa. The authors report that rape was frequently mentioned and was used as an expression of women's vulnerability to HIV and to also support use of female-initiated HIV prevention technologies like PrEP. For example, a "gender accommodating" view was found to be a dominant theme where participants rationalized the need to increase women's sexual agency in order to protect themselves against HIV in a way that did not suggest they were behaving improperly or immorally.

A PrEP demonstration project in Uganda and Kenya among HIV-negative partners in highrisk HIV serodiscordant heterosexual relationships examined the association between IPV and self-reported interruptions in PrEP use (i.e., deliberate decision to stop using PrEP) (Cabral et al.,

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2018). Experience of verbal, physical, or economic IPV within the previous three months was significantly associated with interruption in oral PrEP use (AOR = 2.6; 95% CI: 1.2-6.0, p = -0.002). Roberts and colleagues (2016) found that women were more likely (50%) to have low PrEP adherence at visits where recent IPV (past 3 months) was reported, compared to visits with no IPV to date. This association was found regardless of measuring adherence by pill count (aRR = 1.49; 95% CI: 1.17-1.89, p = 0.001) or by plasma tenofovir (aRR = 1.51; 95% CI: 1.06-2.15, p = 0.02). However, this association was not found to continue for more than three months after the violence, with the authors suggesting that the effects of IPV on PrEP adherence may be, "acute and time-limited" through factors such as stress, being forced to leave the home, or a partner trying to take or throw away pills as described by women in qualitative interviews (Roberts et al., 2016, p. 318).

## **2.5 Discussion**

Several existing commentaries discuss the potential of PrEP for women in abusive and controlling relationships (e.g., (Andersson, 2006; Braksmajer et al., 2016; Chen et al., 2011; Kofman & Adashi, 2014; Van der Wal & Loutfi, 2018) and underscore the relevance and importance of additional work in this area. However, results from this systematic rapid review highlight the paucity of studies focused on IPV and PrEP among women; we found only eight empirically-based published articles and one conference abstract exploring the intersection of IPV and PrEP among women. This systematic rapid review expands previous work by Young & McDaid, Koechlin and colleagues, and Bailey and colleagues, which primarily focused on acceptability, values, and preferences of PrEP broadly (Koechlin et al., 2017; Young & McDaid,

2014) or among women specifically (Bailey, Molino, Vega, & Badowski, 2017), and extends it to explore the particular impact of IPV experience on women's PrEP-related outcomes.

Our findings illustrate that while existing evidence is relatively limited in scope, IPV seems to have implications on women's PrEP acceptability and use. In particular, the studies reviewed demonstrate that IPV has been shown to impact women's interest and willingness to use PrEP; perceived PrEP coercion or partner interference; interruptions in PrEP use; and PrEP adherence. Other studies exploring women's PrEP outcomes, while not explicitly focused on the impact of IPV, provide additional insight around the potential implications of these complex issues. For example, Rubtsova et al. (2013) found that young women who experience several HIV risk factors, including IPV, may be likely PrEP candidates. Specifically, they report that young women 20 to 29 years who experienced lifetime IPV were three times more likely to report potential PrEP uptake than those who did not disclose IPV (aOR = 3.22; p < 0.001 vs. aOR = 1.92; p < 0.01). Garfinkel et al. (2017) found however, that among women seeking care at a family planning clinic, PrEP acceptability was significantly lower among women with a history of IPV relative to women without an abuse history (57% vs. 62%, AOR = 0.71; 95% CI: 0.59-0.85, p < 0.001) and suggest that women may not connect IPV experiences with increased HIV risk.

This review highlights the significant gaps in current literature and areas in need of further research and publication attention. An expanded understanding of the ways that IPV-related experiences (e.g., reproductive coercion) may influence women's needs for expanded HIV prevention options is necessary. For example, women that reported willingness to use PrEP were more likely to have experienced birth control sabotage compared to women not willing or indecisive about PrEP (indirect effect from IPV to PrEP acceptability = 0.08; p < 0.05) (T. Willie et al., 2017). Little is known about how type and timing of partner violence may also impact

women's PrEP decision-making and product use experience. For example, Willie and colleagues (2017) report that only certain types and timing of IPV were associated with participants' interest in using PrEP, as well as their perceived PrEP coercion. In particular, interest in using PrEP was significantly associated with past-year physical IPV, and lifetime and past-year sexual IPV and lifetime psychological IPV were associated with believing a partner would attempt to control their use of PrEP. Furthermore, risk of low PrEP adherence was found to increase with each increasing frequency of recent physical (aRR = 1.09 for each additional episode within the reporting period; 95% CI: 1.04-1.14, p < 0.001) and verbal IPV (aRR = 1.02 for each additional episode; 95% CI: 1.02-1.03, p < 0.001) (Roberts et al., 2016).

Further work to expand our understanding of the unique barriers and facilitators to PrEP decision-making and engagement in PrEP care among women in abusive and controlling intimate relationships is critical. Evidence of barriers/facilitators to women's use of other current and experimental HIV prevention strategies (e.g., male and female condoms, microbicides) include such things as cost (Gallo et al., 2012; Goparaju et al., 2017), ease of use (e.g., insertion/extraction) (Artz et al., 2002; Artz et al., 2000; Sly et al., 1997), male partners (e.g., beliefs, preferences) (Doggett et al., 2015; Hoffman et al., 2004), violence or fear of violence (Bergmann & Stockman, 2015), and stigma (Auerbach et al., 2015; Bailey et al., 2017; Goparaju et al., 2017). PrEP has the potential to expand HIV prevention options for women in violent relationships and research exploring the associated considerations regarding PrEP discussion, delivery, and care that reflects the context of IPV is crucial. Young and McDaid recommend that future research should broaden the examination of PrEP acceptability to include perceptions and management of risk and the impact of broader social structural factors on the potential uptake and sustained effectiveness of PrEP (e.g., social stigma, social pressures regarding sexual relationships, mistrust of medical

settings, financial barriers) (Young & McDaid, 2014). For example, results from this review suggest that women who have experienced IPV may be concerned about or experienced a partner interfering with their PrEP use (Roberts et al., 2016; T. Willie et al., 2017). Future investigation should include an examination of factors such as how IPV may impact women's PrEP decision-making and adherence concerns, fears associated with partners, or underestimated need for HIV prevention.

Consistently high rates of IPV among women and the persistent HIV incidence rates among women make understanding the HIV risk context and needs of women in abusive and controlling relationships critical (UNAIDS, 2017; World Health Organization, 2013). The co-occurring and intersecting issues of IPV and HIV reduces women's ability to use HIV protective behaviors (World Health Organization, 2004). Further, existing woman-controlled HIV prevention methods remain underused and inadequate (Doggett et al., 2015; Moore L et al., 2015). PrEP, however, as a discreet, woman-controlled strategy has the potential to dramatically expand HIV prevention options for women in abusive and controlling relationships (Braksmajer et al., 2016).

#### Implications for Future Research and Practice

An improved understanding of the intersection of IPV and PrEP among women is critical to support a woman-centered PrEP intervention development. Only one known study has explicitly explored the associated considerations regarding PrEP delivery and implementation of care that reflects the context of IPV (Braksmajer et al., 2018). Additional research is needed to inform a woman-centered PrEP intervention that takes into account the context of IPV. (Aaron et al., 2018). For example, questions remain around what messaging is appropriate to help women understand and explain their need for PrEP, where and by whom should PrEP be discussed and distributed,

how should medication be packaged and identified on medical and health insurance records, and a potential need for additional services to support medication adherence and safety within an abusive relationship. For example, staff from a domestic violence organization described that safety planning with clients regarding PrEP use may need to take place and the frequent medical visits recommended might present a barrier for some women (Collier et al., 2017). Further work is needed to understand appropriate settings for discussing PrEP. Women's health care settings, such as OB/GYN practitioners and family planning clinics, may provide an important setting for discussing IPV and PrEP (Hoover, 2014). Sexual and reproductive health care settings are often women's source of usual care (Frost, 2013), where women seek care regularly and for a variety of services (e.g., contraception, STI testing and treatment, pregnancy-related services, cancer screening, referrals) (Frost, Gold, & Bucek, 2012), and identified as a comfortable setting to discuss PrEP and sexual health behavior (Auerbach et al., 2015; Garfinkel et al., 2017). Moreover, family planning clinics often provide services to un- or under-insured women who may not be sceking healthcare elsewhere (Frost, 2013; Frost et al., 2012).

#### Limitations

A systematic rapid review process was used to identify and summarize existing research in a timely manner, yet there are limitations to this approach that should be noted (Tricco et al., 2015). While we consider our search to be comprehensive and conducted in collaboration with a health sciences librarian with expertise in systematic reviews, we may have missed relevant studies due to search terms and one database used. In addition, a single reviewer was responsible for the search, review, and coding. However, this reviewer has considerable experience and multiple publications involving a similar literature review approach. Given this is a growing research area, conference abstracts provide valuable information on current research, yet, they present an abbreviated summary of the work and details on results are often limited. Accordingly, we made as few assumptions regarding meaning as possible when reviewing abstracts, which resulted in missing data. Finally, the use of qualitative methods to summarize key findings limits applications of results, but until more studies demonstrate PrEP outcomes for women who experience IPV, this is an appropriate step to inform future research and practice.

## Conclusions

The high rates of IPV and persistent HIV incidence among women emphasize the urgency for a woman-centered HIV prevention option that's feasible within abusive and controlling relationships. Current HIV prevention options remain underused and fail to consider the context of IPV. PrEP presents an opportunity to expand HIV prevention strategies for women in abusive and controlling intimate relationships. This systematic rapid review explored the impact of IPV on women's PrEP acceptability and use and found a death of research. Yet, the review findings provide a foundation for developing an enhanced understanding of the considerations of IPV for women's PrEP delivery and care. Further research attention is critical for development of PrEP interventions that appropriately address the context of IPV with significant implications on women's health and well-being.

# 2.6 Tables and Figures



Figure 2.1 Flowchart of rapid review process

# Table 2.1 Peer-reviewed articles and conference abstracts on PrEP and IPV among women

Peer-reviewed articles and conference abstracts on PrEP and IPV among women (N=9)					
Author (year), Objective	Study details	Participants	IPV and PrEP Outcomes	Intersection of IPV and PrEP	
Awareness of and Willingne	ss to Use PrEP	•	•	•	
Braksmajer et al. (2018) To explore barriers to PrEP use among women experiencing IPV, and identify concerns that might be addressed with PrEP education and counseling.	Cross-sectional; in-depth interviews. Flyer and social media recruitment from IPV shelter, county STD clinic, local non- profit PrEP provider, and emergency department in United States. PrEP (acceptability, feasibility) and IPV (forced sex; previous 6 months) assessed.	26 women; average age 40 years. A majority identified as African-American/Black (81%) followed by White (8%), multiracial (8%), and Native American (4%). A majority (54%) had not finished high school, received public assistance (100%), and had Medicaid insurance (81%). All participants were in a relationship with a primary male partner during the past 6 months.	57% (n=15) of women were currently in abusive relationships (physically hurt, insulted, threatened with harm, or screamed at). Many participants reported childhood sexual abuse, sexual assault, or prior violent relationships. Approximately half of participants expressed interest in taking PrEP. Others reported ambivalence or not	A third of women described potential partner interference as a barrier to PrEP use. Most women reported they would not use PrEP covertly, and many feared increased violence if their partner were to discover covert use. Some women prioritized coping with IPV over HIV prevention, which combined with low risk perception, resulted in decreased willingness to use PrEP. Fear of side effects and long-term health consequences	
			PrEP.	also impacted women's PrEP decision-making.	
Willie et al. (2018) To examine the association	Cross-sectional; self- administered online or in- person survey.	191 women; 18 to 35 years of age. Most identified as non- Hispanic white (43%). A	Current physical and/or sexual IPV (within the past 6 months) was reported by 44%	Women experiencing IPV reported high PrEP interest (44% vs. 20%), intentions (42% vs. 28%) and perceived candidact	
characteristics and	Online and community flyer	employed (60%) and had an		(47% vs. 26%) compared to	
the PrEP care continuum and examine how IPV experiences modify the association between social network characteristics and	Facebook, beauty salons, and community health clinics in Connecticut, United States. Women experiencing IPV were oversampled.	or more (57%). 91% were currently in a relationship.	A quarter (24%) OT participants were aware of PrEP and over a third were interested in learning more about PrEP (37%) and intended to use PrEP (34%); 2% reported using PrEP	Further, women experiencing IPV. Further, women experiencing IPV reported less support of potential PrEP use across their network (10.48 vs.13.48, t=2.33, p=0.02). IPV modified the effect of social	
outcomes of PrEP care continuum.	Prep (awareness, interest, intentions, and perceived		previously.	interest and intentions. A higher	
	PrEP candidacy) and IPV			percentage of PrEP-aware alters	

	(physical, sexual; past 6-			was associated with lower PrEP
	months) assessed.			interest (B =04. SE =
				.01, p = 0.02) and PrEP intentions
				(B =05, SE = .02, p = 0.01)
				among women experiencing IPV.
Willie et al. (2017)	Cross-sectional: online	210 participants (n=109	Past-vear IPV experiences	Past-vear physical IPV (AOR =
	survey.	women. n=101 men): average	included physical (31.2%).	4.53: 95% CI: 1.85-11.11. p <
To examine the association		age 35.4 years. A majority	sexual (19.5%), and	0.001) was associated with
between lifetime and	Participants were recruited	identified as White (76%).	psychological (68.8%)	interest in using PrEP. Past-year
past-year physical, sexual,	across the United States	followed by Hispanic (9%).	violence. Lifetime IPV	sexual IPV (AOR = 3.01: 95% CI:
and psychological IPV	through Mechanical Turk	Black (5%), and other (9%).	experiences included physical	1.10-8.27. p < 0.05) was
experiences on PrEP-	(MTurk), an online participant	More than half had finished	(46.7%), sexual (17.1%), and	associated with PrEP coercion.
related outcomes.	recruitment tool.	college or attended graduate	psychological (78.6%)	Lifetime sexual (AOR = 3.69; 95%
		school (60%). 73% were in a	violence.	Cl: 1.62-8.40, <i>p</i> < 0.001) and
	PrEP (awareness, interest,	romantic relationship.		psychological (AOR = 4.70; 95%
	and perceived coercion) and		Among women, PrEP	Cl: 1.01-21.89, <i>p</i> < 0.05) IPV was
	IPV (physical, sexual, and		awareness was moderate	associated with PrEP coercion. No
	psychological; lifetime, past-		(12.8%), but participants were	significant associations were
	year) assessed.		interested in using PrEP	found between any forms of
			(25.7%). Almost a quarter	lifetime and past-year IPV and
			(21.7%) believed their	PrEP awareness.
			current/most recent partner	
			would prevent them from	No gender differences were
			using PrEP.	observed among lifetime or
				recent IPV and PrEP awareness,
				interest, and perceived PrEP
				coercion ( $ps > 0.5$ ).
Willie et al. (2017)	Cross-sectional; self-	147 Black women; average age	More than one in two (52%)	IPV was indirectly related to PrEP
	administered electronic	21.28 years. A majority had not	of women reported ever	acceptability through birth
To describe the prevalence	survey that lasted 20-30	finished high school (52%) and	experiencing physical or	control sabotage (indirect effect
and associations of IPV,	minutes.	had an average household	sexual IPV. Those who	= 0.08; <i>p</i> < 0.05). Results suggest
reproductive coercion		income of 13,496 USD. 61% of	reported IPV were more likely	that women with IPV experiences
experiences, and PrEP	Women recruited through	participants reported dating	to report birth control	were more willing to use PrEP
acceptability among	direct and flyer recruitment	one person and 4% were dating	sabotage ( $p < 0.01$ ) and	given their experience of birth
urban-dwelling low-	from youth education and	more than one person; 31%	pregnancy coercion ( $p < 0.01$ ).	control sabotage. Pregnancy
income young Black	employment programs (n=2),	were single and 5% were		coercion was not found to have a
women and examine birth	WIC programs (n=3), and	married.		significant indirect effect from
control sabotage and	health care and insurance			IPV to PrEP acceptability.

pregnancy coercion as mediators of the association between IPV and PrEP acceptability.	community-based organization (n=1) in an urban city in the United States. PrEP (willingness to use) and IPV (physical and sexual; lifetime) assessed.		Over three-quarters (77%) of participants were willing to use PrEP.	
PrEP Use Experience		1	1	
Cabral et al. (2018) Partners Demonstration Project To examine whether there is an association between IPV and self- reported interruptions in PrEP use.	Prospective cohort; baseline questionnaire and quarterly interview-administered follow-up assessments up to 24 months at 4 sites in Uganda and Kenya. Direct recruitment of HIV- negative partners in high-risk HIV serodiscordant heterosexual relationships. PrEP (interruption) and IPV (verbal, physical, economic; past 3-months) assessed.	1013 participants (n=334 women, n=679 men); approximately half of participants were aged 29 years or younger (55% of women, 47% of men). Almost all couples (95%) reported being married; over 97% living together and median length of partnership was approximately 5 years for couples with an HIV- negative woman.	<ul> <li>53 follow-up visits included reports of IPV by 49 participants, which included verbal abuse (50%), physical (25%), and economic (22%)</li> <li>IPV. 53% of reports were made by women; most physical abuse reports were made by women, while verbal abuse reports were made by women and men at similar rates.</li> <li>24.5% (n=249) participants reported PrEP interruption (deliberate decision to take a break from PrEP), with a median length of 28 days; 65% of reports were from men.</li> </ul>	IPV was associated with PrEP interruption (adjusted OR = 2.6, 95% CI: 1.2-6.0, <i>p</i> = 0.02) among HIV-negative participants in a known serodiscordant partnership.
Colombini et al. (2018)	Cross-sectional; in-depth	431 women enrolled in the	32% (n=141) reported lifetime	Challenges when screening for
EMPOWER study Assess the feasibility and acceptability of	interviews (n=39 participant; n=13 clinical staff) and counselling session observations (n=10). Counselling session	study; participants were 16-24 years of age. All women were HIV-negative.	experiences of violence. Women who reported abuse described that it was reassuring and helpful to talk	GBV reported by clinical staff counsellors included initial discomfort asking about violence, facilitating disclosure of suspected cases, length of time
integrating gender-based	observations were only		to counsellors who were	taken to complete the sessions.
violence screening and	conducted in South Africa: in-		friendly and non-judgmental.	and offering help when
support into HIV	depth interviews were		, ,	

counselling for adolescent	administered in both South			participants did not want any
girls and young women	Africa and Tanzania.			referrals.
accessing oral PrEP in an				
open-label PrEP	Recruitment methods not			
demonstration project.	described.			
	PrEP access and exposure to			
	gender-based violence (GBV)			
	were assessed.			
Hartmann et al. (2018)	Cross-sectional; in-depth	42 participants (n=14 social	Lifetime experience of partner	Two categories of feelings and
	interviews.	harm (SH) women, n=14 non-	violence was described by all	actions toward ring use and
MTN-020/ASPIRE trial		SH women, and n=14 male	SH women and the majority	violence emerged: felt fearful or
	Purposive sampling across	partners); average age 30 years	of non-SH women;	empowered. Women who feared
To explore how	three groups: former ASPIRE	(SH), 32.1 years (non-SH), and	psychological violence was	their partners' reactions reported
dapivirine vaginal ring	(MTN-020) participants who	36.8 years (male partners).	the most common form	actions of discontinuing ring use,
use and partnership	reported partner-related	Almost all women had a current	experienced by all women.	tactics to retreat from or avoid
dynamics interacted.	challenges (i.e., "social	sexual partner. A majority of	Women reported physical	ring-related conflict, or removing
	harms") during trial	women were still with their	violence (50%; n=7), sexual	the ring when with partners.
	participation, those who did	ASPIRE partner; this was less	violence (35%; n=5), and	Women who felt empowered by
	not, and male partners of	common among SH women	economic violence (14%;	ring use described a sense of
	ASPIRE participants.	(55% vs. 70%).	n=2).	power linked to the protection
	Interviews were conducted			the ring was perceived to provide
	at a single ASPIRE site in		Three ways in which	in risky relationships.
	Johannesburg, South Africa.		study/dapivirine ring use was	
			related to violence was	
	PrEP (use of dapivirine		described: it exacerbated pre-	
	vaginal ring) and IPV (history		existing violence, it served as	
	of controlling or violent		a new mechanism for	
	partner behaviors,		perpetrating violence, and it	
	relationship between partner		decreased violence. Triggers	
	behaviors and ring use)		to violence experiences	
	assessed.		included spending time away	
			from home (i.e., at the clinic),	
			being tested and disclosing to	
			partners a need for STI	
			treatment, or using a product	
			that a male partner was not	
			aware of/disapproved of.	

Hartmann et al. (2016)	Cross-sectional; in-depth	164 participants (n=102	Rape was frequently	A "gender accommodating" view
	interviews and focus group	women, n=22 male partners,	mentioned across participant	was dominant in the data where
VOICE, MTN-003 trial	discussions. Data collection	n=17 advisory board members,	group; one fifth of discussions	participants rationalized the need
	modalities pre-assigned	n=23 community stakeholders);	among female participants,	to increase women's sexual
To explore the broader	based on participant group.	average age 26.8 years. A	half of discussions among	agency in order to protect
context of gender-based		majority of women had	advisory board, and two-	themselves against HIV in a way
violence through	Direct recruitment by study	completed secondary school or	thirds discussions with	that did not suggest they were
participants' discussions	staff and varied by	more (68%) and earned an	community stakeholders.	behaving improperly or
of rape and to examine	participant group (n=4).	income (57%). All were married	Male partners were the only	immorally. A 'gender
how this reflects on the	Women were randomly pre-	or had a primary partner.	group to not specifically	transformative' view that sees
context of <b>gender</b>	selected parent study		mention rape.	PrEP as empowering women to
inequality and	participants, male partners			prevent HIV was not present in
intersection with PrEP	were recruited from parent		Two themes emerged around	the discussions.
product use.	study participants who had		rape: it was used as an	
	provided permission for		expression of women's overall	
	partners to be contacted,		vulnerability to HIV and to	
	community members		legitimize the use of female-	
	advisory board members		initiated HIV prevention	
	recruited from existing		technologies. Participants	
	board, and community		discussions highlighted	
	stakeholders identified by		several ways women perceive	
	study staff in Johannesburg,		and explain the role of PrEP	
	South Africa.		including protecting them	
			against sexual violence	
	PrEP (experience with		victimization and assuaging	
	product) and IPV (anything		social and male partner	
	about violence or violent		criticisms of women's	
	behaviors, including actual		sexuality.	
	experiences or discussion of			
	potential risk, in relation to			
	anyone) was assessed.			
Roberts et al. (2016)	Prospective cohort; baseline	1785 women; average age 33.2	16.1% of women reported IPV	Women were more likely (50%)
	questionnaire, interview-	years. An average of 5.6 years	at 437 visits (0.7% total visits).	to have low PrEP adherence at
Partners PrEP trial	administered follow-up	of school had been completed	Most women reported	visits with IPV in past 3 months
	assessments and PrEP pill	and over two thirds (69%) had	multiple types of IPV; verbal	compared to visits with no IPV to
To examine whether	count (monthly), plasma	earned income in the past 3	IPV was the most common	date, regardless of measuring by
recent and/or past	tenofovir concentration	months. Almost all participants	(reported at 376 visits),	pill count (aRR = 1.49; 95% CI:
exposure to IPV is	(months 1, 3, and quarterly	(99%) were married;	followed by physical (235	1.17-1.89, <i>p</i> = 0.001) or plasma

associated with low PrEP	thereafter), and in-depth	relationship duration average	visits) and economic (212	tenofovir (aRR = 1.51; 95% CI:
adherence among HIV	interviews.	was 12.9 years.	visits).	1.06-2.15, <i>p</i> = 0.02). The effect of
uninfected women				recent (past 3 mos.) verbal (aRR =
participating in a clinical	Recruitment methods not		Pill count coverage was high	1.65; 95% CI: 1.17-2.33, <i>p</i> =
trial of PrEP.	described. Interviews were		among women regardless of	0.005) and economic IPV (aRR =
	only collected at a single		IPV experience (mean =	1.48; 95% CI: 1.14-1.92, <i>p</i> =
	study site in Uganda; all		95.3%).	0.003) was associated with pill
	other methods assessed in			count coverage. Frequency of IPV
	Kenya.			since last study visit was higher
				for verbal IPV (mean 4.1
	PrEP (adherence, experience			episodes) than for physical IPV
	taking) and IPV (physical,			(mean 1.7 episodes), however,
	verbal, economic; since last			the risk of low adherence
	study visit) assessed.			increased with increasing
				frequency of recent physical IPV
				(aRR = 1.09 for each additional
				episode within the reporting
				period; 95% CI: 1.04-1.14, <i>p</i> <
				0.001) and verbal IPV (aRR = 1.02
				for each additional episode; 95%
				Cl: 1.02-1.03, <i>p</i> < 0.001).
				IPV was raised during interviews
				around adherence challenges and
				included themes of: stress,
				leaving home without study drug,
				and partner throws away or
				threatens to take study drugs.

#### **3.0 Research Methods**

# 3.1 Overview of Study Design

In order to investigate the intersection of intimate partner violence and PrEP acceptability among urban women, and the potential barriers to PrEP acceptability, a cross-sectional survey was administered among women seeking care at an urban family planning clinic. This chapter outlines the methodology of the study, including a description of the setting and population of interest. The methods of study recruitment and enrollment, measures, data management, and analysis strategy are also presented.

This study examines quantitative and qualitative data from a mix of closed and open-ended questions using cross-sectional survey data. A concurrent mixed-methods study design was used, where one method was dominant (quantitative; "QUAN") over the other (qualitative; "qual") (i.e., QUAN+qual). Public health research using QUAN+qual designs often involve researchers collecting, "qualitative data to enliven or illustrate quantitative findings, for example, excerpts from responses to open-ended questions or case vignettes" (Padgett, 2012, p. 51). Gaps in current research highlight contextual factors (e.g., relationship, community or social) as important areas in enhancing our understanding of PrEP acceptability, specifically how women's choices to use PrEP may be constrained or enabled by relationship or social context (Young & McDaid, 2014). Given the dearth of research specifically focused on PrEP acceptability and use among women experiencing IPV, a survey was selected as an appropriate first step to investigate the opinions and experiences of a large sample of women. Further, the inclusion of open-ended questions in the

survey is complementary and well-suited to enhance our initial exploration of this area and allow for the voices, experiences, and perspectives of participants to emerge.

## 3.2 Setting and Population

Planned Parenthood of Western Pennsylvania (PPWP) provides reproductive health care, sex education, and information to women, men, and young people through their mission to "provide comprehensive and complementary health care to those in need of services; disseminate information about human sexuality and the need for family planning and responsible parenthood; and advocate public policies which guarantee these rights and ensure access to such services (Planned Parenthood of Western Pennsylvania). PPWP serves a variety of communities in Pittsburgh and surrounding counties and has seven family planning health centers in the region. Over 17,500 patients sought health care at PPWP health clinics in 2016-17, of which over 93% were women (Planned Parenthood of Western Pennsylvania, 2017). A majority of their patients are low-income; among 2015-16 female patients who reported income, 77% were living below 150% of the poverty line (Planned Parenthood of Western Pennsylvania, 2017). A majority of their patients a number of important health services including Pap tests, breast exams, STI testing, and birth control. In 2017, PPWP began offering PrEP in all of their family planning health centers for free or at low-cost to those who do not have health insurance.

The sample of women included in this study were recruited over a four-month period (September 2018 to January 2019) from one PPWP family planning clinic in Pittsburgh, Pennsylvania. Eligible women who presented for care during times of data collection were recruited to participate in a survey prior to their clinic visit. Participants were eligible for the study

if they were female, 18 years of age or older, able to read English, reported sex with a male partner within the previous 12 months, and a concern for HIV infection or interest in HIV prevention.

#### 3.3 Recruitment and Informed Consent

Clinic staff shared study recruitment flyers with all women at check-in. The flyers provided a brief description of the study, the inclusion criteria, a statement about compensation, and next steps for those interested. Women were given the choice to complete the survey at the clinic using an electronic tablet or online; an online survey link was included on the flyer for those interested in completing the survey outside of the clinic setting. The principal investigator (PI), Teagen O'Malley who conducted this research for her dissertation, was at the study clinic during the recruitment period and provided additional information to those who expressed interest or had questions about the study. The PI was at the study clinic during set times based on weekly clinic hours, and on average, was at the clinic 4 days a week (6 hours per day). Days when the PI was unable to be at the clinic, check-in staff continued to distribute flyers to all women and encouraged them to complete the online survey.

Informed consent and the eligibility screening were completed prior to survey administration. Informed consent, eligibility screening, and the survey were all done using the secure, web-based survey service Qualtrics (Qualtrics, Provo, UT). Eligible participants completed a self-administered brief anonymous survey that took 10-15 minutes to complete and included closed and open-ended questions (survey presented in Appendix B). Women who participated inperson utilized a password protected electronic tablet in the clinic waiting room; those who participated outside the clinic via the online survey link utilized personal electronic devices. Following survey completion, participants were provided with a list of local resources (e.g., support services for IPV, mental health, and HIV) (Appendix B) and given a \$10 thank you gift for their participation (cash for in-person survey completion and an electronic gift card to Amazon for online completion). A total of 147 women met eligibility criteria and completed the survey. Study materials were reviewed by PPWP clinic staff prior to data collection to ensure appropriateness of proposed approach and language used. All materials and protocols were approved by the University of Pittsburgh Institutional Review Board and Planned Parenthood Federation of America.

## **3.4 Measures**

Survey questions addressed sociodemographic characteristics, HIV risk factors, intimate partner violence experience, PrEP awareness and previous use, PrEP acceptability, and barriers to PrEP acceptability. All data were self-reported, and measures included were selected based on existing PrEP acceptability evidence, known factors influencing HIV risk, and when available, established valid and reliable measures. Open-ended questions were included to capture context around willingness to use PrEP and perceptions about the barriers to PrEP acceptability. A summary of survey constructs is presented in Appendix B.

<u>Sociodemographic characteristics.</u> Items assessed participant characteristics and were used to describe the sample. Participants were asked their age, race and ethnicity, education level, annual income, relationship status, and type of health insurance. Additional items included assessed sexual orientation, live-in male sexual partner, preferred birth control method, primary reason for seeking care at the clinic, and total distance travelled to the clinic. <u>HIV risk factors.</u> HIV risk factors were measured with questions of number of male sexual partners, condom use, STI diagnosis, transactional sex, sex with male partner of unknown HIV status, and male sexual partner at risk of HIV through sexual or drug using behavior. All items were measured for within the previous 12 months. HIV risk perception was measured through questions of previous HIV testing, HIV worry in the next six months, and previous use of PEP (post-exposure prophylaxis). Measures included were modified from existing relevant work when available or developed by the study team.

Intimate partner violence. Intimate partner violence experience was assessed with items drawn from the Revised Conflict Tactics Scale Short Form (Straus & E.M., 2004) and existing relevant work (Decker et al., 2014). Eight items assessed experience of physical (2 items; e.g., "partner pushed, shoved, or slapped you"), sexual (4 items; e.g., "partner insisted on sex when you did not want to"), and psychological (2 items; e.g., "partner insulted or swore or shouted or yelled at you") IPV by any male sexual partner (e.g., a date, boyfriend, husband, or any other sexual partner). Items asked for experience of IPV within the previous 12 months, as well at any point in life.

<u>PrEP awareness and use.</u> PrEP awareness and use were assessed via items around participants awareness of PrEP, know others who have used PrEP, and previous and current use of PrEP. Measures included were modified from existing relevant work when available or developed by the study team.

<u>PrEP acceptability.</u> PrEP acceptability was measured through a single item of willingness to use PrEP on a 4-point scale ranging from "no, definitely not" to "yes, definitely". Specifically, the item asked, "Would you be willing to take a pill every day if you could protect yourself from getting HIV during sex?" and was informed by previous work in the PrEP field (Eisingerich et al.,

2012; Garfinkel et al., 2017; T. Willie et al., 2017; T. C. Willie et al., 2017). A brief description of PrEP was provided immediately before the question and included facts on what PrEP is, how it is administered and functions, potential side effects, follow-up requirements, and associated costs. In addition, an open-ended question asked about reasons why participants would be willing or not willing to use PrEP and was based on their PrEP acceptability response. For example, additional description of why participants were willing to use PrEP was requested of those who indicated that they would "yes, probably" or "yes, definitely" be willing to use PrEP and were asked to respond to the following question: "We are interested in understanding more about your willingness to use PrEP. In the space below, please tell us more about why you would be willing to use PrEP." Those who indicated that they would "no, probably not" or "no, definitely not" be willing to use PrEP were asked to describe reasons why they were not willing to use PrEP.

Barriers to PrEP acceptability. Participants were asked to rate their agreement on 4-point scale ranging from "strongly disagree" to "strongly agree" to 34 statements about their attitudes towards willingness to use PrEP (Appendix B). Statements included nine categories of attitudes towards PrEP: (1) access/affordability (6 items; e.g., "I wouldn't be able to afford PrEP"), (2) stigma (5 items; e.g., "I would be concerned about my sexual partner(s) finding out if I started taking PrEP"), (3) partner reaction (4 items; e.g., "I would be concerned that my sexual partner(s) would think I was having sex with other people if I started taking PrEP"), (4) drug effects (5 items; e.g., "I am concerned about side effects or feeling sick from taking PrEP"), (5) perceived benefits (5 items; e.g., "Taking PrEP would be a good way to protect myself from getting HIV), (6) risk compensation (2 items; e.g., "I am concerned that I would take more sexual risks if I started taking PrEP), (7) lack of perceived need (2 items; e.g., "I don't need PrEP because I'm not at risk for getting HIV"), (8) mistrust (2 items; e.g., "I don't trust drug companies"), and (9) adherence (3

items; e.g., "It would be difficult for me to remember to take PrEP every day"). PrEP acceptability statements were informed by previous work (Holloway et al., 2017), and adapted to be reflective of women's HIV prevention within an IPV context (e.g., covert use, in control of HIV prevention) (Braksmajer et al., 2018; Braksmajer et al., 2016; Flash et al., 2014; Goparaju et al., 2017). An additional category (partner reaction) composed of known factors related to women's use of HIV prevention strategies (e.g., suggestion of infidelity, dishonesty, or a casual attitude toward one's partner) explored attitudes towards partner reactions impacting women's PrEP acceptability (Braksmajer et al., 2016; Goparaju et al., 2017).

Three open-ended questions asked participants to describe perceived factors, such as relationship, community, or society factors, impacting women's willingness to use PrEP. Specifically, the open-ended questions asked: "What are some other relationship things that may impact, positively or negatively, a woman's willingness to use PrEP?", "What are some other community or social things that may impact, positively or negatively, a woman's willingness to use PrEP?", and "Any other things that may impact, positively or negatively, a woman's willingness to use PrEP?".

## 3.5 Data Management

Once the recruitment period was complete, both datasets (in-person survey and online survey) were downloaded as .CSV files from Qualtrics. After a preliminary review of each to ensure completeness, the two datasets were merged into one, which served as the full dataset for analyses, and imported into StataSE (v.15.1). A participant ID variable was created for each response, as well as a survey type variable to distinguish between type of survey completed.

Additional data cleaning steps occurred related to formatting (e.g., changing variables to the appropriate format (string vs. numeric), removing extra spacing carried over from Qualtrics, and revising select variable names (e.g., eligibility screening questions)). Appropriate data values were assigned to all variables and subsequent collapsing of variables was determined through frequencies. For example, categories were collapsed if no responses were selected or if the sample size was small (e.g., less than 10). Additionally, continuous variables (e.g., age) were recoded as categorical variables with categories based on cumulative percentage. Key independent and dependent variables, including IPV experience, HIV worry, PrEP acceptability, and barriers to PrEP acceptability, were recoded prior to analysis. In particular, summary dichotomous variables were created for any experience of IPV, as well as across each of the three types of violence. For example, recent IPV was indicated by a yes to any IPV experience in the past 12 months, lifetime IPV was indicated by a yes to any IPV experienced within participant's lifetime, and past IPV was indicated by a yes to any IPV experienced within participant's lifetime, but not within the past 12 months. A summary dichotomous variable was created for HIV worry, where HIV worry was indicated by "worried a little" or "very worried" about HIV in the next six months. A summary dichotomous PrEP acceptability variable was created where acceptability was indicated by "yes to probably" or "yes, definitely" willing to use PrEP. The 34 statements around barriers to PrEP acceptability were reverse coded so that all scores reflected less willingness to use PrEP. A summary dichotomous variable was created for the nine types of barriers. For example, stigma as a barrier to PrEP acceptability was indicated by an agree or strongly agree to any of the five stigma items.

Individual Stata do-files were used throughout to manage and track syntax. Multiple dofiles were created and used to distinguish between data management or analysis step (e.g., cleaning, recoding variables, preliminary analysis, summary statistics, bivariate, multivariable regression). In addition, detailed notes were taken tracking progress, questions, and decisions made and stored in Apple Notes, a notetaking application (Apple Inc).

QSR International's Nvivo 12 qualitative data analysis software (QSR International, 2018) was used to manage and code the five open-ended questions. The full, cleaned Stata dataset was uploaded as a .CSV file to Nvivo in order to allow for characterizing and comparing of text responses across participant variable (e.g., age, race, IPV experience). After a preliminary review of the dataset to ensure completeness and appropriate formatting of the codable fields, initial word frequency queries were run to explore potential themes among survey responses. Text responses from the open-ended questions were then categorized using thematic codes consistent with study aims. Specific codes related to the topic of interest (e.g., perceived barriers to PrEP acceptability) were then examined for recurring themes (e.g., fear of side of effects). Detailed notes were taken to track progress, questions, and decisions made and stored in Apple Notes, a notetaking application (Apple Inc).

#### **3.6 Analysis Strategy**

#### Paper Two Analysis Strategy

Paper two analysis was guided by the aims of the study to: (1) assess the prevalence of recent and lifetime IPV and PrEP acceptability (i.e., willingness to use) among a sample of women seeking care at an urban family planning clinic, and (2) evaluate the impact of IPV experience on women's PrEP acceptability. Frequencies and distribution statistics was first conducted to get an overall sense of the data and to check for missing data. Two participants were dropped as

approximately 50% of the survey was completed and included missing data for intimate partner violence experience. As a result, all analyses focused on a sample of 145 women. Analyses were then conducted to answer the research study aims and are further described below. Analyses were conducted in StataSE (v.15.1), and statistical significance was set at  $p \le 0.05$ .

<u>Descriptive analyses.</u> Frequency and distribution statistics were calculated for all variables of interest. The frequencies and percentages of all categorical variables and the mean and range of all continuous variables were calculated. The co-occurrence of IPV experience by type of abuse was calculated using a three-way cross-tabulation of physical, sexual, and psychological IPV variables. Co-occurrence of IPV types was conducted for both recent and lifetime IPV.

<u>Bivariate analyses.</u> Bivariate associations between PrEP acceptability and IPV experience, HIV risk factors, and demographic characteristics were determined using simple logistic regression. Unadjusted associations between each of the explanatory variables (IPV experience, HIV risk factors, age, race, education level) and the outcome variable (PrEP acceptability) were calculated using logistic regression. A post-hoc analysis examined the association between HIV worry and IPV experience. Unadjusted associations between each of the explanatory variables (IPV experience) and the outcome variable (HIV worry) were calculated using simple logistic regression. P-values  $\leq 0.05$  were considered a statistically significant association.

## Paper Three Analysis Strategy

Paper three analysis was guided by the aims of the study to: (1) investigate perceptions about the barriers to PrEP acceptability among a sample of women seeking care at an urban family planning clinic, (2) evaluate the relationship between barriers and women's reports of PrEP acceptability (i.e., willingness to use), and (3) determine if the association of barriers to PrEP and PrEP acceptability vary by women's IPV experience. Frequencies and distribution statistics was first conducted to get an overall sense of the data and to check for missing data. Two participants were dropped as approximately 50% of the survey was completed and included missing data for barriers to PrEP acceptability and intimate partner violence experience. As a result, all analyses focused on a sample of 145 women. Analyses was then conducted to answer the research study aims and are further described below. Analyses were conducted in StataSE (v.15.1), and statistical significance was set at  $p \le 0.05$ .

<u>Descriptive analyses.</u> Frequency and distribution statistics were calculated for all variables of interest. The frequencies and percentages of all categorical variables and the mean and range of all continuous variables were calculated. The co-occurrence of IPV experience by type of abuse was calculated using a three-way cross-tabulation of physical, sexual, and psychological IPV variables. Co-occurrence of IPV types was conducted for both recent and past IPV.

<u>Bivariate analyses.</u> Bivariate associations between barriers to PrEP acceptability and recent and past IPV experience were determined using simple logistic regression. Unadjusted associations between each of the explanatory variables (IPV experience) and the outcome variable (barriers to PrEP acceptability) were calculated using logistic regression. P-values  $\leq 0.05$  were considered a statistically significant association.

<u>Multivariable analyses.</u> Multiple logistic regression models were used to examine the adjusted association between PrEP acceptability and explanatory variables (barriers to PrEP acceptability), stratified by total sample, recent IPV, and past IPV experience. Model building was conducted by each of the nine barriers to PrEP acceptability variables individually, controlling for age, race, and education. P-values  $\leq 0.05$  were considered a statistically significant association.

<u>Qualitative analyses</u>. Crosstab queries were run across each of the five coded open-ended questions by participant variables (e.g., recent IPV experience) to explore potential differences. Data tables of crosstab queries were organized by primary theme and iillustrative quotes were then selected to elaborate on and provide context to specific findings from the quantitative analysis answering the research study aims.

# 4.0 Intersection of intimate partner violence and pre-exposure prophylaxis (PrEP): Exploring HIV worry and PrEP acceptability among women

#### 4.1 Abstract

Extensive research highlights the co-occurrence of HIV and intimate partner violence (IPV) among women, underscoring the importance of prevention options tailored to interpersonal context. Existing HIV prevention options for women remain underused and inadequate. Preexposure prophylaxis (PrEP), a valued component of HIV prevention, has the potential to expand options for women at risk of HIV, specifically those in abusive and controlling relationships. A cross-sectional survey among women (N=145) assesses the prevalence of recent and lifetime IPV and association with PrEP acceptability among women seeking care at an urban family planning clinic. Over 40% of women reported recent IPV and 71% disclosed lifetime IPV. Almost a third (31%) of participants reported being worried about HIV risk, 70% were willing to take PrEP, and 71% of women who disclosed recent IPV were willing to use PrEP. These findings show that while women's PrEP awareness is low, once learning more willingness to use PrEP was high and did not vary by IPV. Significant work is needed to expand awareness of PrEP as a HIV prevention strategy for women, including women with IPV experience. Results suggest that women with a history of IPV may require support to discuss HIV concerns and help identifying appropriate prevention options tailored to their interpersonal contexts. Current PrEP eligibility guidelines, which do not include perceived HIV risk/worry or IPV, might not identify all women who may benefit from PrEP and additional screening questions could be appropriate. Additional research is needed to

more completely explore the context of IPV to focus development of a woman-centered PrEP intervention.

## **4.2 Introduction**

Globally, an estimated 18.2 million women are living with HIV, accounting for 52% of all adults living with HIV (UNAIDS, 2017). Women 15 years of age and older represent 48% of new HIV infections among adults worldwide (UNAIDS, 2017). In the United States, close to a fifth (19%) of new HIV diagnoses are among women (Centers for Disease Control and Prevention, 2017; U.S. Department of Health & Human Services, 2017). A wealth of research has addressed the intersection of intimate partner violence (IPV) and HIV among women (Campbell et al., 2008; Gielen et al., 2007; Li et al., 2014; Maman et al., 2000; Phillips et al., 2014), underscoring the importance of interpersonal context when addressing HIV prevention. The relationship between IPV and HIV is complex and involves multiple pathways. Direct pathways, including forced or coerced sex with risky partner, and indirect pathways of limited self-efficacy to enact behaviors to reduce HIV risk, increase HIV risk among women who experience IPV (Coker, 2007; Dude, 2007; Dunkle & Decker, 2013; Li et al., 2014; Maman et al., 2000; Stockman et al., 2013; Wingood et al., 2000b). Despite extensive research illustrating the multiple pathways between IPV and increased HIV risk, work remains to develop acceptable woman-controlled HIV prevention strategies that can be effectively utilized by women in abusive and controlling relationships. Preexposure prophylaxis (PrEP) is a discreet, woman-controlled strategy that has the potential to expand HIV prevention options for women in violent relationships (Chen et al., 2011; Koechlin et al., 2017; Rubtsova et al., 2013), however, research specifically examining the complexities of PrEP use among women in abusive and controlling relationships is limited.

IPV, defined as actual, attempted, or threatened physical, sexual, or psychological violence by a current or former intimate partner (Centers for Disease Control and Prevention, 2016), reduces women's ability to enact behaviors to reduce their risk for HIV (World Health Organization, 2004). More than one in three women have ever experienced some form of physical and/or sexual violence by a male intimate partner globally (World Health Organization, 2013). Almost half (44%) of women in the United States have experienced sexual violence in their lifetime (e.g., rape, sexual coercion, and/or unwanted sexual contact) (Smith et al., 2015). Current (e.g., male and female condoms) and experimental (e.g., vaginal microbicides) HIV prevention options for women often fail to consider the context of abusive intimate relationships as strategies are highly dependent on partner interest and cooperation (Choi et al., 2004; Doggett et al., 2015; Saul et al., 2004). Violence in an intimate relationship has been found to place constraint on the acceptability, uptake, and use of HIV prevention methods including condoms and vaginal microbicides. Violence or fear of violence has frequently been found to limit a woman's ability and self-efficacy to request or negotiate condom use (Bergmann & Stockman, 2015; Decker et al., 2014; Wingood & DiClemente, 1997) or acceptability of microbicides (Flash et al., 2014; Weeks et al., 2004).

PrEP, a daily oral emtricitabine-tenofovir (Truvada) medication, is a valued component of HIV prevention and research is increasingly exploring women's PrEP interest and use. PrEP, a fixed-dose combination of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC), was approved by the FDA in 2012 and recommended by the CDC in 2014 as a biobehavioral prevention method to reduce HIV incidence among people who are uninfected but at high risk for HIV acquisition (Centers for Disease Control and Prevention, 2014b; Fonner et al., 2016; Food and

Drug Administration, 2012); however, the use of PrEP among women remains low. In the United States, women represent 19% of all new HIV diagnoses, yet only 7% of PrEP users are women (AIDSVu, 2018). Results from a nationally representative survey of U.S. women found a high acceptability of PrEP, where 64% of women aged 20-29 years and 59% of women aged 30-45 years reported they would take a daily pill to prevent HIV (Rubtsova et al., 2013). Women's health care settings, such as OB/GYN practitioners and family planning clinics, have been identified as trusted places to receive PrEP information and services and may serve an important role for better understanding women's PrEP acceptability (Auerbach et al., 2015; Garfinkel et al., 2017).

Compared to other HIV prevention methods, PrEP has several advantages for women experiencing IPV, including autonomous or covert use and not needing to be taken at time of sexual activity (Braksmajer et al., 2016). For example, PrEP, unlike condoms, is not partner dependent, allowing women to use without their partner's involvement or knowledge. Further, oral PrEP allows women to discreetly use the prevention method and is likely preferred over other PrEP formulations, such as topical gels which may create additional lubrication causing concerns that partners would be able to tell when they were used (Flash et al., 2014; Weeks et al., 2004). The fact that PrEP does not need to be taken right at the time of sexual activity for prevention is also important as women experiencing IPV may not have control over when or how a sexual encounter occurs. Despite the potential of PrEP as a woman-controlled HIV prevention method, the existing limited research in this area suggests that IPV may have implications on PrEP acceptability and use and that abuse experience is an important aspect to consider when examining women's views and interest in PrEP. In particular, IPV experience may uniquely impact women's willingness to use PrEP (T. Willie et al., 2017; T. C. Willie et al., 2018), and may affect women's actual PrEP use and adherence (Cabral et al., 2018; Roberts et al., 2016). The existing high rates of IPV and

the persistent HIV incidence rates among women worldwide make understanding the HIV risk context and prevention needs of women in abusive and controlling relationships critical.

The current study: (1) assesses the prevalence of recent and lifetime IPV and PrEP acceptability (i.e., willingness to use) among a sample of women seeking care at an urban family planning clinic, and (2) evaluates the impact of IPV experience on women's PrEP acceptability.

## 4.3 Methods

#### Study Design

This study examines cross-sectional data collected from women seeking care at a family planning clinic in Pittsburgh, Pennsylvania from September 2018 to January 2019. Eligible women who presented for care during data collection were recruited to participate in this survey prior to their clinic visit. Participants were eligible for the study if they were female, 18 years of age or older, able to read English, reported sex with a male partner within the previous 12 months, and a concern for HIV infection or interest in HIV prevention. Clinic staff shared study recruitment flyers with all women at check-in. The flyers provided a brief description of the study, the inclusion criteria, a statement about compensation, and next steps for those interested. Women were given the choice to complete the survey at the clinic using an electronic tablet or online; an online survey link was included on the flyer for those interested in completing the survey outside of the clinic setting. The PI (TLO) was at the study clinic during the recruitment period and provided additional information to those who expressed interest or had questions about the study.

Informed consent and eligibility screening were completed prior to survey administration. Informed consent, eligibility screening, and the survey were all done using the secure, web-based survey service Qualtrics (Qualtrics, Provo, UT). Eligible participants completed a selfadministered brief anonymous survey that took 10-15 minutes to complete and included closed and open-ended questions. Women who participated in-person utilized a password protected electronic tablet in the clinic waiting room; those who participated outside the clinic via the online survey link utilized personal electronic devices. Survey questions addressed sociodemographic characteristics, sexual behavior, HIV risk perception, intimate partner violence experience, and PrEP awareness and acceptability. Following survey completion, participants were provided with a list of local resources (e.g., support services for IPV, mental health, and HIV) and given a \$10 thank you gift for their participation. All study materials and protocols were approved by the University of Pittsburgh Institutional Review Board and Planned Parenthood Federation of America.

#### Measures

All data were self-reported, and measures included were selected based on existing PrEP acceptability evidence, known factors influencing HIV, and when available, established valid and reliable measures.

<u>PrEP acceptability.</u> PrEP acceptability was measured through a single item of willingness to use PrEP on a 4-point scale ranging from "no, definitely not" to "yes, definitely". Specifically, the item asked, "Would you be willing to take a pill every day if you could protect yourself from getting HIV during sex?" and was informed by previous work in the PrEP field (Eisingerich et al., 2012; Garfinkel et al., 2017; T. Willie et al., 2017; T. C. Willie et al., 2017). A brief description of PrEP was provided immediately before the question and included facts on what PrEP is, how it is administered and functions, potential side effects, follow-up requirements, and associated costs. A summary dichotomous PrEP acceptability variable was created where acceptability was indicated by yes to probably or definitely willing to use PrEP.

Intimate partner violence. Intimate partner violence experience was assessed with items drawn from the Revised Conflict Tactics Scale Short Form (Straus & E.M., 2004) and existing relevant work (Decker et al., 2014). Eight dichotomous (yes/no) items assessed experience of physical (2 items; e.g., "partner pushed, shoved, or slapped you"), sexual (4 items; e.g., "partner insisted on sex when you did not want to"), and psychological (2 items; e.g., "partner insulted or swore or shouted or yelled at you") IPV by any male sexual partner (e.g., a date, boyfriend, husband, or any other sexual partner). Items asked for experience of IPV within the previous 12 months, as well at any point in life. Summary dichotomous variables were created for any experience of IPV, as well as across each of the three types of violence. For example, recent IPV was indicated by a yes to any IPV experience in the past 12 months, and lifetime IPV was indicated by a yes to any IPV experienced within participant's lifetime.

<u>HIV risk factors and PrEP awareness and use.</u> HIV risk factors were measured with questions of number of male sexual partners, condom use, STI diagnosis, transactional sex, and sex with partner of unknown HIV status. All items were assessed for within the previous 12 months. HIV risk perception was measured through questions of previous HIV testing and HIV worry in the next six months. PrEP awareness and use were assessed via items around aware of PrEP, know others who have used PrEP, and previous use of PrEP. Measures included were modified from existing relevant work when available or developed by the study team.

Sociodemographic characteristics. Participant characteristics collected included age, race, education, income, relationship status, and health insurance.
Analysis

Frequencies of PrEP acceptability, IPV, and sample demographics were generated. Bivariate associations between PrEP acceptability and IPV experience, HIV risk factors, and sociodemographic characteristics were determined using logistic regression. A post-hoc analysis was then conducted to examine the association between IPV and HIV worry using bivariate logistic regression. Analyses were conducted in StataSE (v.15.1), and statistical significance was set at  $p \le 0.05$ .

## 4.4 Results

#### *Participant characteristics*

Table 4-1 presents descriptive characteristics of the 145 female study participants. The average age of participants was 25 years. Approximately half had a college degree or more (55%), earned less than \$20,000 annually (57%), and almost two-thirds identified as straight (66%). A majority identified as White (72%), while 16% identified as Black or African-American and 12% identified as multiracial, Asian, or another race. Close to half of participants were in a serious relationship (42%), while the others described their relationship status as casually dating (40%) or single (18%). Approximately a fifth (19%) of participants did not have health insurance, and 38% received Medicaid/Medical Assistance. One fifth of participants (20%) reported coming to the clinic for STI testing and services.

## HIV risk

A third of women (33%) reported more than two male sexual partners in the past 12 months. Over three-quarters (86%) engaged in inconsistent or no condom use in the past 12 months. Past-year STI diagnosis was reported by 15%. One-fifth (21%) of women reported sex in the past-year with a male partner whose HIV status was unknown; 6% reported their current partner at risk of HIV through sexual or drug using behavior; and 2% had traded sex or sexual acts in the past 12 months in exchange for money, drugs, shelter, gifts, or other resources. A majority (80%) of women had received a HIV test in their lifetime. Almost a third (31%) of women were a little or very worried about HIV infection in the next six months.

# PrEP use, awareness, and acceptability

Two participants reported using PrEP previously. A little over a third (35%) had heard of PrEP prior to study participation, and 13% reported knowing someone who had taken PrEP previously. Approximately 70% of participants reported that they would be willing to take PrEP to protect against HIV.

#### Intimate partner violence experience

Over 40% of women reported recent (past 12 months) experience of psychological, physical, or sexual violence by an intimate partner (Table 4-2). Most women (33%) reported recent psychological partner violence, followed by sexual violence (20%); approximately 10% of women had a recent history of physical violence. Close to three quarters of the women (71%) disclosed lifetime experience of psychological, physical, or sexual violence by an intimate partner. Over half (51%) reported lifetime sexual violence, and almost a third (31%) of women reported lifetime

physical violence. There was considerable co-occurrence of multiple types of IPV among women. Almost a fifth (18%) of women had recently experienced two or more types of violence, and almost half (49%) had experienced two or more types of violence within their lifetime. Approximately 6% of women reported recent experience of psychological, physical, and sexual partner violence.

# *PrEP acceptability*

PrEP acceptability was similar across all the participants; 71% of women who had experienced any recent IPV reported a willingness to use PrEP and 70% of the total sample were willing to use PrEP. No statistically significant relationship was found between recent and lifetime IPV and PrEP acceptability (Table 4-3). HIV worry was significantly associated with women's PrEP acceptability. Women who were a little or very worried about HIV in the next six months had 3.98 greater odds of willingness to use PrEP compared to women not worried about HIV (OR = 3.98; 95% CI: 1.54-10.2, p = 0.004). Women with more than two male sexual partners in the previous 12 months had less odds of willingness to use PrEP compared to women with two partners or less (OR = 0.40; 95% CI: 0.19-0.83, p = 0.014).

#### HIV worry

Lifetime sexual violence was significantly associated with HIV worry (Table 4-4). Women who reported lifetime experience of sexual IPV had 2.9 greater odds of being worried about HIV in the next six months compared to women who did not report lifetime sexual IPV (OR = 2.9; 95% CI: 1.39-6.18, p = 0.005). Further, other IPV variables were approaching statistical significance with HIV worry. In particular, recent sexual IPV (OR = 2.02; 95% CI: 0.91-4.63, p = 0.081), any

recent IPV (psychological, physical, and sexual) (OR = 1.88; 95% CI: 0.91-3.79, p = 0.088), and any lifetime IPV (OR = 2.27; 95% CI: 0.95-5.43, p = 0.064) approached significance.

#### 4.5 Discussion

This study contributes valuable information about IPV and women's PrEP acceptability, and to the growing discussion of the potential for PrEP to expand HIV prevention options for women in abusive and controlling relationships. These results provide insights into HIV worry, PrEP acceptability, and the context of IPV among women. The study also supports the feasibility of studying PrEP interest and IPV experiences with women and provides suggested areas for future research.

High rates of IPV were disclosed among this sample of women seeking care at an urban family planning clinic; over 40% of women reported experience of any violence by an intimate partner in the previous 12 months, and 71% reported any violence by an intimate partner within their lifetime. Additionally, these findings on types of abuse highlight that women rarely experienced only one act of violence and that a significant co-occurrence of abuse experience exists. Among this sample, approximately 18% of women disclosed two or more types of IPV within the past 12 months and 6% reported recent experiences of all three (psychological, physical, and sexual). In addition, almost half of the women had a history of two or more types of IPV in their lifetime and 23% reported ever experiencing all three. The rates of IPV uncovered in this sample are slightly higher than rates reported in existing prevalence research on this topic. For example, Decker et al. (2014) found lower rates among a similar population of women seeking care at 24 free-standing Title X family planning clinics in Western Pennsylvania with recent (past

three months) physical or sexual IPV reported among 11% of the participants (N=3504). While the differences in the specific measurement tools used to assess recent IPV experience make direct comparisons between the two studies difficult, both show that IPV is a significant health issue among women seeking care at family planning clinics in the region.

IPV is a known HIV risk factor among women through multiple, complex direct and indirect pathways (Centers for Disease Control and Prevention, 2014a; World Health Organization, 2004). Existing HIV prevention options have remained inadequate for use within abusive and controlling relationships, and limited research has examined the relationship between women's abuse experiences and willingness to use PrEP for HIV risk reduction. These findings show that while women's PrEP awareness is low, once participants learned more about the HIV prevention method their reported willingness to use PrEP was high and these findings did not vary by women's abuse experience. For example, only 27% of women reporting recent IPV were aware of PrEP prior to study participation, but 71% were willing to take PrEP to protect against HIV. These results are fairly consistent with existing research. Among 191 U.S. women recruited through online and community flyers, approximately a quarter (25%) of those who reported IPV within the past six months were aware of PrEP, 45% were interested in learning more about PrEP, and 42% intended to take PrEP (T. C. Willie et al., 2018). Braksmajer et al.'s (2018) study involving in-depth interviews with 26 women disclosing IPV within the past six months in the United States found that approximately half of participants expressed interest in taking PrEP.

No statistical significance was found between the relationship of IPV experience and PrEP acceptability in this study. This is likely due to the lack of variation of PrEP acceptability observed among the sample; PrEP acceptability was consistently high. However, other research, though relatively limited in scope, suggests that IPV impacts women's interest and willingness to use

PrEP. For example, among women recruited online and through community flyers in the United States, women experiencing IPV (past six months) had the highest reported rates of PrEP interest (44.7% vs. 30.2%; p = 0.03) and intentions (42.4% vs. 28.3%; p = 0.04) compared to those reporting no IPV experience (T. C. Willie et al., 2018). In addition, past-year physical IPV was associated with being interested in using PrEP (AOR = 4.53; 95% CI: 1.85-11.11, p < 0.001) among women and men recruited through an online participant tool in the United States (T. C. Willie et al., 2017). Other studies exploring women's PrEP outcomes, while not explicitly focused on the impact of IPV, provide additional insights into the relationship between IPV and PrEP acceptability. Rubtsova et al. (2013) found that young women who experience several HIV risk factors, including IPV, may be likely PrEP candidates and report that young women 20 to 29 years who experienced lifetime IPV were three times more likely to report potential PrEP uptake than those who did not disclose IPV (AOR = 3.22; p < 0.001 vs. AOR = 1.92; p < 0.01). Garfinkel et al. (2017) found, however, that among women seeking care at a family planning clinic, PrEP acceptability was significantly lower among women with a history of IPV relative to women without an abuse history (57% vs. 62%, AOR = 0.71; 95% CI: 0.59-0.85, p < 0.001).

The results showing that women who report IPV are more worried about HIV compared to women who do not disclose violence experience provides some insights into the relationship of IPV and HIV among this sample of female family planning patients. Participants who report lifetime experience of sexual IPV had 2.9 greater odds of being worried about HIV in the next six months compared to women who do not report lifetime sexual IPV (OR = 2.9; 95% CI: 1.39-6.18, p = 0.005). The fact that an association was found between lifetime sexual IPV and HIV worry, yet no significant association was identified between IPV and PrEP acceptability, suggests that women with a history of partner violence may require support to discuss their HIV concerns and

help identifying appropriate HIV prevention options tailored to their interpersonal contexts. Further, this study found that women who are worried about HIV had higher odds of PrEP acceptability, suggesting that in a larger sample we may be able to detect significant associations between IPV and PrEP acceptability. Taken together, the addition of screening questions around IPV and HIV worry and risk to PrEP eligibility guidelines appears to be appropriate. This is supported by other work that recommends both questions of perception of HIV risk acquisition and sexual violence be included in PrEP screening and eligibility efforts (Patel et al., 2018). Current CDC eligibility guidelines, which do not address perceived HIV risk or IPV experiences, might not identify all women who may benefit from PrEP. Results from this study provide some insights into the relationship between IPV and PrEP, but the generalizability of our work is limited by the relatively small sample size. Future research should focus on incorporating PrEP screening and care that recognizes the impact of violence in women's lives; values women's decision-making and control; and supports women's health, well-being, and safety.

This study supports the feasibility of discussing PrEP and IPV experiences with women and provides needed information about the complexities of HIV prevention and possibility of PrEP within the context of IPV. Surprisingly, women in our study reporting more than two male sexual partners in the past-year are less willing to use PrEP compared to women with two or less partners. Though we do not fully know the context of women's sexual encounters in this study, and this finding indicates the need for additional research. The high rates of IPV disclosure suggest that women were comfortable disclosing IPV, and consistent with previous work, emphasize women's health care settings like family planning clinics as a comfortable setting for discussing sexual behavior, IPV, and HIV prevention (Auerbach et al., 2015; Garfinkel et al., 2017; Hoover, 2014). In addition, women receive a variety of services from family planning clinics (e.g., contraception, STI testing and treatment, pregnancy-related services, cancer screening, referrals) and use such clinics as their usual source for health care (Frost, 2013; Frost et al., 2012). Moreover, family planning clinics often provide services to un- or under-insured women who may not be seeking health care elsewhere (Frost, 2013; Frost et al., 2012). Future work should continue to explore the importance of family planning clinics and other women's health care settings for engaging women around PrEP and IPV discussions and care.

There are limitations to this study worth noting. The study may be limited by the relatively homogenous sample of women. Future research should examine how IPV impacts willingness to use PrEP among women with varied sociodemographic backgrounds including age, race, and income. The relatively small sample size also limited our ability to identify statistically significant differences between groups including comparisons between women based on IPV experiences. Additionally, women may have underreported their behavior and experiences of violence due to the sensitive and stigmatized nature of sexual behavior and IPV. However, the high rates of reported IPV suggest that this was likely not an issue and the approach used is consistent with guidelines for assessing IPV. Finally, findings are likely not generalizable to all women. Family planning clinics provide an appropriate setting for discussing sexual behavior and HIV prevention, yet results may not be reflective of women who may benefit from PrEP but are not engaged in care at family planning clinics.

Despite select limitations, this study provides valuable information about IPV and PrEP acceptability among women attending an urban family planning clinic. As the discussion of PrEP as a valued component of HIV prevention for women continues, these findings contribute to our understanding of the impact of IPV on women's PrEP acceptability. Study findings highlight the urgency and need for expanded screening and services supporting women in discussing their HIV

concerns and help identifying appropriate HIV prevention options tailored to their interpersonal contexts. Finally, additional research should explore a woman-centered PrEP intervention development that takes into account the context of IPV to ensure that programming is appropriate (Aaron et al., 2018; Braksmajer et al., 2018). Questions remain around such things as what messaging is appropriate to support women's understanding and potential need for PrEP, where and by whom should PrEP be discussed and distributed, potential use considerations to ensure women's safety (e.g., unmarked packaging, medical and health insurance records), and additional services to support medication adherence, health, and well-being (e.g., safety planning, covert use, burden of follow-up visits required).

# 4.6 Tables

# Table 4.1 Characteristics of women seeking care at a family planning clinic

	Total ( <i>n</i> = 145) n (%)	Recent IPV ( <i>n</i> = 59) n (%)	Lifetime IP∨ ( <i>n</i> = 104) n (%)
Age, years (mean (range))	25.2 (18-45)	24.9 (18-40)	25.8 (18-45)
Race			
Black / African-American	23 (15.8)	9 (15.2)	18 (17.3)
White	104 (71.7)	42 (71.1)	77 (74.0)
Other (Multiracial, Asian)	18 (12.4)	8 (13.5)	9 (8.65)
Education completed			
Less than college	64 (44.1)	36 (61.0)	55 (52.8)
College degree or more	81 (55.8)	23 (38.9)	49 (47.1)
Income status			
Less than \$20,000	82 (56.9)	35 (59.3)	58 (56.3)
\$20,000 or more	62 (43.1)	24 (40.6)	45 (43.7)
Relationship status			
Single	26 (17.9)	11 (18.6)	15 (14.4)
Casually dating	57 (39.3)	23 (38.9)	45 (43.3)
Serious relationship, including marriage	62 (42.7)	25 (42.3)	44 (42.3)
HIV Risk Factors			
Sexual partners			
2 or less	88 (60.6)	33 (55.9)	62 (59.6)
More than 2	57 (39.3)	26 (44.1)	42 (40.4)
Condom use			
Never or inconsistently	124 (85.5)	58 (98.3)	95 (91.3)
Every time	21 (14.4)	1 (1.69)	9 (8.65)
STI diagnosis			
None	122 (84.1)	49 (83.1)	86 (82.6)
At least once	23 (15.8)	10 (6.9)	18 (17.3)
Sex with partner of unknown HIV status			
None	115 (79.3)	44 (74.5)	81 (77.9)
At least once	30 (20.6)	15 (25.4)	23 (22.1)
HIV worry			
Not worried at all	100 (68.9)	36 (61.0)	67 (64.4)
A little or very worried	45 (31.0)	23 (38.9)	37 (35.6)
PrEP Awareness and Acceptability			
Aware of PrEP			
No	94 (64.8)	43 (72.8)	68 (65.4)
Yes	51 (35.1)	16 (27.1)	36 (34.6)
Know others who have used PrEP			
No	126 (86.8)	11 (68.7)	23 (63.9)
Yes	19 (13.1)	5 (31.2)	13 (36.1)
Willing to use PrEP			
No	44 (30.3)	17 (28.8)	34 (32.7)
Yes	101 (69.6)	42 (71.1)	70 (67.3)
	· · ·		

	Total ( <i>N</i> =145)	
	Recent IPV n (%)	Lifetime IPV n (%)
Psychological Violence		
Partner insulted or swore or shouted or yelled	48 (33.1)	85 (58.6)
Partner destroyed something or threatened to hit	14 (9.66)	42 (28.9)
Any psychological violence	49 (33.7)	87 (60.0)
Physical Violence		
Partner pushed, shoved, or slapped	14 (9.66)	45 (31.0)
Partner punched, kicked, or beat	6 (4.14)	15 (10.3)
Any physical violence	14 (9.66)	45 (31.0)
Sexual Violence		
Partner used force (like hitting, holding down, or using a weapon) to have sex	5 (3.45)	24 (16.5)
Partner insisted on sex or insisted on sex without a condom	27 (18.6)	66 (45.5)
Afraid to ask partner to use a condom	13 (8.97)	26 (17.9)
Afraid to refuse sex with a sexual partner	12 (8.28)	41 (28.2)
Any sexual violence	32 (20.1)	74 (51.0)
Any psychological, physical, or sexual violence	59 (40.7)	104 (71.7)
Co-occurrence of two or more types of violence	26 (17.9)	71 (48.9)
Co-occurrence of all three types of violence	9 (6.21)	33 (22.7)

# Table 4.2 Intimate partner violence experience among women seeking care at a family planning clinic

	( <i>N</i> = 14	-5)
	Bivariate OR (95% CI)	<i>p</i> -value
Age, years	.99 (.93,1.05)	.823
Race		
Other (Multiracial, Asian)	-ref-	
Black / African-American	1.8 (.44, 7.25)	.408
white	1.07 (.37, 3.11)	.893
Education	<b>f</b>	
Loss than college	-ret-	FCC
	1.25 (.60, 2.50)	.300
HIV Risk Factors		
Sexual partners	f	
2 of less	-ret-	014
	.40 (.19, .85)	.014
Condom use	rof	
Every unite Never or inconsistently	-iei- /19 (15 1 56)	221
	.45 (.15, 1.50)	.231
SII diagnosis	rof	
At least once	-151- 1 28 ( 46 3 50)	629
	1.20 (.40, 5.50)	.025
Sex with partner of unknown HIV status		
At least once	-rei- 1 97 ( 74 5 23)	172
	1.37 (.74, 5.23)	.172
HIV worry Not worriged at all	rof	
A little or very worried	-101-	004
	5.56 (1.54, 16.2)	1004
No.	rof	
Yes	1 13 ( 54 2 33)	740
Recent psychological IPV	1.13 (.0 1, 2.55)	., 10
No	-ref-	
Yes	1.13 (.53, 2.41)	.740
Recent physical IPV		
No	-ref-	
Yes	1.09 (.32, 3.71)	.879
Recent sexual IPV		
No	-ref-	
Yes	1.14 (.48, 2.73)	.757
Lifetime IPV	r	
NO	-ret-	220
tes Lifetime neuchological IDV	.00 (.29, 1.51)	.529
No	_ref_	
Yes	.80 (.38, 1.66)	.556
Lifetime physical IPV	.00 (.00, 1.00)	
No	-ref-	
Yes	.81 (.38, 1.73)	.600
Lifetime sexual IPV		
No	-ref-	
Yes	.93 (.45, 1.89)	.844

# Table 4.3 Associations with PrEP acceptability among women seeking care at a family planning clinic

Bolded values indicate statistical significance; significance was set at  $p \leq 0.05$ .

	( <i>N</i> = 145	5)
IPV History	Bivariate OR (95% CI)	<i>p</i> -value
Recent IPV		
No	-ref-	
Yes	1.88 (.911, 3.79)	.088
Recent psychological IPV		
No	-ref-	
Yes	1.70 (.82, 3.53)	.152
Recent physical IPV		
No	-ref-	
Yes	1.76 (.57, 5.43)	.319
Recent sexual IPV		
No	-ref-	
Yes	2.02 (.91, 4.63)	.081
Lifetime IPV		
No	-ref-	
Yes	2.27 (.95, 5.43)	.064
Lifetime psychological IPV		
No	-ref-	
Yes	1.14 (.55, 2.35)	.714
Lifetime physical IPV		
No	-ref-	
Yes	1.00 (.47, 2.14)	.989
Lifetime sexual IPV		
No	-ref-	
Yes	2.9 (1.39, 6.18)	.005

# Table 4.4 Associations with HIV worry among women seeking care at a family planning clinic

Bolded values indicate statistical significance; significance was set at  $p \le 0.05$ .

# 5.0 Intimate partner violence, HIV pre-exposure prophylaxis (PrEP) acceptability, and perceived barriers to PrEP use willingness: Perspectives of women seeking care at a family planning clinic

#### 5.1 Abstract

The emergence of pre-exposure prophylaxis (PrEP) presents a new opportunity for a woman-controlled HIV prevention strategy, with a unique opportunity to expand prevention options for women experiencing intimate partner violence (IPV). However, PrEP use among women in the United States remains low and significant research gaps exist in our understanding of potential barriers to PrEP acceptability and use, particularly among women in violent intimate relationships. A cross-sectional survey among women (N=145) assesses perceptions about the barriers to PrEP acceptability and the relationship between barriers and PrEP acceptability among women seeking care at an urban family planning clinic. Over 40% of women reported recent IPV, and 31% disclosed past IPV. Approximately 70% of all participants, including those who had experienced IPV, reported a willingness to take PrEP. While a high percentage of women were willing to use PrEP, a number of potential barriers were identified. Among women reporting recent IPV, a majority identified drug effects (96%), access/affordability (76%), and adherence (74%) as barriers to PrEP acceptability; over 50% reported issues connected with intimate partner reaction. Mistrust of drug companies and healthcare providers was associated with reduced PrEP acceptability among women reporting recent IPV. The limited awareness of PrEP and misconceptions around PrEP (e.g., effectiveness, side effects, who is able to use) found in this study support the need to increase PrEP awareness and understanding. Results highlight the value of a woman-centered PrEP intervention and additional research is needed to focus intervention development that reflects the context of IPV.

#### **5.2 Introduction**

Pre-exposure prophylaxis (PrEP), a daily oral emtricitabine-tenofovir (Truvada) medication, is a promising biobehavioral HIV prevention method used to reduce HIV incidence among people who are uninfected but at high risk for HIV infection (Centers for Disease Control and Prevention, 2014b; Fonner et al., 2016; Food and Drug Administration, 2012). The emergence of PrEP presents a new opportunity for a woman-controlled HIV prevention strategy (Chen et al., 2011; Koechlin et al., 2017; Rubtsova et al., 2013), yet use remains low. In the United States, only 7% of PrEP users are women despite representing 19% of all new HIV diagnoses (AIDSVu, 2018). As recognition of the value of PrEP use for HIV prevention among women grows, researchers are increasingly exploring issues related to women's PrEP acceptability and willingness to use the medication (Auerbach et al., 2015; Collier et al., 2017; Flash et al., 2014; Rubtsova et al., 2013; Wingood et al., 2013). Existing evidence from U.S. research suggests that women are interested in using PrEP once they learn about it, yet have often not heard of PrEP prior to study participation. A nationally representative survey of U.S. women found a high acceptability of PrEP, with over half of both women aged 20-29 years (64%) and 30-45 years (59%) willing to take PrEP (Rubtsova et al., 2013). Focus group findings among women in six U.S. cities (New York, Dallas, Atlanta, Newark, Chicago, and New Orleans) report low awareness of PrEP before study participation (less than 10%), and that participants were even frustrated that they had not heard about PrEP prior to the study, and those who had heard of PrEP, reported that they did not know it was available for women (Auerbach et al., 2015).

Existing research on barriers to women's acceptability and use of existing and experimental HIV prevention strategies (e.g., male and female condoms, vaginal microbicides, PrEP) shows that issues of cost (Gallo et al., 2012; Goparaju et al., 2017), ease of use (e.g., insertion/extraction) (Artz et al., 2002; Artz et al., 2000; Sly et al., 1997), male partners (e.g., beliefs, preferences) (Doggett et al., 2015; Hoffman et al., 2004), and stigma (Auerbach et al., 2015; Bailey et al., 2017; Goparaju et al., 2017) all reduce the likelihood of women's use of such strategies. Literature examining the use of woman-controlled prevention strategies, including those still experimental such as vaginal microbicides, provide guidance on acceptability and barriers of such methods. For example, women described negative experiences with the female condom including discomfort, difficulty of insertion/extraction, time-intensive, unappealing appearance, messiness, and sexual dissatisfaction (Stockman et al., 2014). A literature review examining the impact of gender norms, roles, and relations on women's ability to access and use vaginal microbicides found that influencing factors fell into categories of norms related to women's and men's sexuality and power dynamics within intimate relationships (Doggett et al., 2015). Additionally, other predictors of women's acceptance and use of microbicides include male partner preference, or perceived preference, around product and product characteristics (i.e., wetness) (Domanska & Teitelman, 2012). Evidence of facilitators to women's interest in using PrEP suggests that HIV risk perception, social influence, and healthcare provider recommendation impact women's openness or interest in using PrEP (Kwakwa et al., 2016; Rubtsova et al., 2013; Wingood et al., 2013). A nationally representative survey of U.S. women found that younger and African-American women were significantly more likely to report potential PrEP uptake if recommended by a healthcare

provider and if they thought that many of their female friends would also use PrEP (Rubtsova et al., 2013).

Violence in an intimate relationship has been found to place additional constraint on the acceptability, uptake, and use of HIV prevention methods (Bergmann & Stockman, 2015; Decker et al., 2014; Flash et al., 2014; Stockman et al., 2014; Weeks et al., 2004; Wingood & DiClemente, 1997). Violence or fear of violence has frequently been found to limit women's ability and self-efficacy to request or negotiate condom use (Bergmann & Stockman, 2015). Decker and colleagues (2014) found that women with recent partner violence (previous three months) were more likely to report involuntary condom non-use (AOR = 1.87; 95% CI: 1.51-2.33) and fears of requesting condoms (AOR = 4.15; 95% CI: 2.73-6.30) than those who did not report recent IPV. Women with a history of IPV were interested in vaginal microbicides over female condoms in one study (Stockman et al., 2014), whereas another (Weeks et al., 2004) found women's microbicide acceptability scores were negatively related to having experienced either physical or sexual violence (p < 0.03).

PrEP may have the potential to expand HIV prevention options for women in abusive or controlling relationships. In particular, PrEP offers several advantages over other existing prevention strategies for women experiencing IPV, including autonomous or covert use and not needing to be taken at time of sexual activity (Braksmajer et al., 2016). For example, PrEP, unlike condoms, is not partner dependent, allowing women to use without their partner's involvement or knowledge. Further, oral PrEP allows women to discreetly use the prevention method and is likely preferred over other PrEP formulations (e.g., vaginal microbicides) which may create additional lubrication causing concerns that partners would be able to tell when they were used (Flash et al., 2014; Weeks et al., 2004). Since PrEP does not need to be taken right at the time of sexual activity

for prevention is also important as women experiencing IPV may not have control over when or how a sexual encounter occurs.

While existing acceptability evidence of other HIV prevention options provide important insight of women's use and preferences, limited research has explicitly focused on the complex and intersecting issues of PrEP acceptability among women in violent intimate relationships, despite its potential as a woman-controlled HIV prevention method. An enhanced understanding of the considerations necessary for PrEP delivery and implementation, including potential barriers to PrEP acceptability, that reflects the context of IPV is crucial. For example, existing research suggests that women who have experienced IPV may be concerned about their partner interfering with their PrEP use (Roberts et al., 2016; T. Willie et al., 2017) and that IPV may have implications on PrEP adherence (Roberts et al., 2016). Future investigation should include an examination of factors such as how IPV may impact women's PrEP decision-making and adherence concerns, fears associated with partner, or underestimated risk of HIV and prevention.

The current study uses quantitative and qualitative data to: (1) investigate perceptions about the barriers to PrEP acceptability among a sample of women seeking care at an urban family planning clinic, (2) evaluate the relationship between the barriers and women's reports of PrEP acceptability (i.e., willingness to use), and (3) determine if the association of barriers and PrEP acceptability vary by women's IPV experience.

## 5.3 Methods

#### Study Design

This study examines quantitative and qualitative cross-sectional data collected using surveys from women seeking care at a family planning clinic in Pittsburgh, Pennsylvania from September 2018 to January 2019. Eligible women who presented for care during data collection were recruited to participate in this concurrent mixed-methods study prior to their clinic visit. Participants were eligible for the study if they were female, 18 years of age or older, able to read English, reported sex with a male partner within previous 12 months, and a concern for HIV infection or interest in HIV prevention. Clinic staff shared study recruitment flyers with all women at check-in. The flyers provided a brief description of the study, the inclusion criteria, a statement about compensation, and next steps for those interested. Women were given the choice to complete the survey at the clinic using an electronic tablet or online; an online survey link was included on the flyer for those interested in completing the survey outside of the clinic setting. The PI (TLO) was at the study clinic during the recruitment period and provided additional information to those who expressed interest or had questions about the study.

Informed consent and eligibility screening were completed prior to survey administration. Informed consent, eligibility screening, and the survey were all done using the secure, web-based survey service Qualtrics (Qualtrics, Provo, UT). Eligible participants completed a selfadministered brief anonymous survey that took 10-15 minutes to complete and included closed and open-ended questions. Women who participated in-person utilized a password protected electronic tablet in the clinic waiting room; those who participated outside the clinic via the online survey link utilized personal electronic devices. Following survey completion, participants were provided with a list of local resources (e.g., support services for IPV, mental health, and HIV) and given a \$10.00 thank you gift for their participation. All study materials and protocols were approved by the University of Pittsburgh Institutional Review Board and Planned Parenthood Federation of America.

#### Measures

The surveys included a mix of closed and open-ended questions and all data were selfreported. Close-ended measures were selected based on existing PrEP acceptability evidence, known factors influencing HIV risk, and when available, established valid and reliable measures. Open-ended questions were developed for this study and designed to capture context around barriers to PrEP acceptability.

<u>PrEP acceptability.</u> PrEP acceptability was measured through a single item of willingness to use PrEP on a 4-point scale ranging from "no, definitely not" to "yes, definitely". Specifically, the item asked, "Would you be willing to take a pill every day if you could protect yourself from getting HIV during sex?" and was informed by previous work in the PrEP field (Eisingerich et al., 2012; Garfinkel et al., 2017; T. Willie et al., 2017; T. C. Willie et al., 2017). A brief description of PrEP was provided immediately before the question and included facts on what PrEP is, how it is administered and functions, potential side effects, follow-up requirements, and associated costs. A summary dichotomous PrEP acceptability variable was created where acceptability was indicated by yes to probably or definitely willing to use PrEP.

An open-ended question asked about reasons why participants would be willing/not willing to use PrEP and was based on their PrEP acceptability response. For example, additional description of why participants were willing to use PrEP was requested of those who indicated that they would "yes, probably" or "yes, definitely" be willing to use PrEP and were asked to respond to the following question: "We are interested in understanding more about your willingness to use PrEP. In the space below, please tell us more about why you would be willing to use PrEP."

Barriers to PrEP acceptability. Participants were asked to rate their agreement on 4-point scale ranging from "strongly disagree" to "strongly agree" to 34 statements about their attitudes towards willingness to use PrEP. Statements included nine categories of attitudes towards PrEP: (1) access/affordability (6 items; e.g., "I wouldn't be able to afford PrEP"), (2) stigma (5 items; e.g., "I would be concerned about my sexual partner(s) finding out if I started taking PrEP"), (3) partner reaction (4 items; e.g., "I would be concerned that my sexual partner(s) would think I was having sex with other people if I started taking PrEP"), (4) drug effects (5 items; e.g., "I am concerned about side effects or feeling sick from taking PrEP"), (5) perceived benefits (5 items; e.g., "Taking PrEP would be a good way to protect myself from getting HIV), (6) risk compensation (2 items; e.g., "I am concerned that I would take more sexual risks if I started taking PrEP), (7) lack of perceived need (2 items; e.g., "I don't need PrEP because I'm not at risk for getting HIV"), (8) mistrust (2 items; e.g., "I don't trust drug companies"), and (9) adherence (3 items; e.g., "It would be difficult for me to remember to take PrEP every day").

PrEP barrier statements were informed by previous work (Holloway et al., 2017), and adapted to be reflective of women's HIV prevention within an IPV context (e.g., covert use, in control of HIV prevention) (Braksmajer et al., 2018; Braksmajer et al., 2016; Flash et al., 2014; Goparaju et al., 2017). An additional category (partner reaction) composed of known factors related to women's use of HIV prevention strategies (e.g., suggestion of infidelity, dishonesty, or a casual attitude toward one's partner) explored attitudes towards partner reactions impacting women's PrEP acceptability (Braksmajer et al., 2016; Goparaju et al., 2017). Items were reverse coded so that all scores reflected less willingness to use PrEP. A summary dichotomous variable was created for the nine types of barriers. For example, stigma as a barrier to PrEP acceptability was indicated by an agree or strongly agree to any of the five stigma items.

Open-ended questions asked participants to describe perceived factors, such as relationship, community, or society factors, impacting women's willingness to use PrEP. For example, participants were asked: "What are some other relationship things that may impact, positively or negatively, a woman's willingness to use PrEP?".

Intimate partner violence. Intimate partner violence experience was assessed with items drawn from the Revised Conflict Tactics Scale Short Form (Straus & E.M., 2004) and existing relevant work (Decker et al., 2014). Eight dichotomous (yes/no) items assessed experience of physical (2 items; e.g., "partner pushed, shoved, or slapped you"), sexual (4 items; e.g., "partner insisted on sex when you did not want to"), and psychological (2 items; e.g., "partner insulted or swore or shouted or yelled at you") IPV by any male sexual partner (e.g., a date, boyfriend, husband, or any other sexual partner). Items asked for experience of IPV within the previous 12 months, as well at any point in life. Summary dichotomous variables were created for any experience of IPV within the previous 12 months and more than 12 months ago, as well as across each of the three types of violence. For example, recent IPV was indicated by a yes to any IPV experienced within participant's lifetime, but not within the past 12 months.

<u>HIV risk factors and PrEP awareness and use.</u> HIV risk factors were measured with questions of number of male sexual partners, condom use, STI diagnosis, transactional sex, and sex with partner of unknown HIV status. All items were assessed for within the previous 12 months. HIV risk perception was measured through questions of previous HIV testing and HIV worry in the next six months. PrEP awareness and use were assessed via items around aware of

PrEP, know others who have used PrEP, and previous use of PrEP. Measures included were modified from existing relevant work when available or developed by the study team.

Sociodemographic characteristics. Participant characteristics collected included age, race, education, income, relationship status, and health insurance.

## Analysis

Quantitative. Responses to the close-ended measures were used to generate frequencies of PrEP acceptability, barriers to PrEP acceptability, IPV, and sample characteristics. Bivariate associations between barriers to PrEP acceptability and recent and past IPV experience were determined using logistic regression. Multiple logistic regression models were then conducted to examine whether barriers predicted PrEP acceptability (i.e., willingness to use), adjusted for potentially confounding variables. Multivariate logistic models were generated for recent IPV and past IPV separately, controlling for age, race, and education. Analyses were conducted in StataSE (v.15.1), and statistical significance was set at  $p \le 0.05$ .

Qualitative. Text responses from the open-ended questions were classified by the project PI (TLO) using broad thematic codes consistent with study aims. Specific codes related to the topic of interest (e.g., perceived barriers to PrEP acceptability) were then examined for recurring sub-themes (e.g., fear of side of effects). Illustrative qualitative quotes are used in the results section to elaborate on and provide context to the quantitative findings addressing PrEP acceptability and barriers. QSR International's Nvivo 12 qualitative data analysis software (QSR International, 2018) was used to manage, code and extract the text data.

## **5.4 Results**

#### Participant characteristics

Table 5-1 presents descriptive characteristics of the 145 female study participants. A majority of participants had a college degree or more (55%), earned less than \$20,000 annually (57%), and identified as straight (66%) and white (72%). The average age of participants was 25 years. Approximately a fifth (19%) of the participants did not have health insurance, and 38% received Medicaid/Medical Assistance. Close to half of the participants were in a serious relationship (42%), while the others described their relationship status as casually dating (40%) or single (18%). One fifth of participants (20%) reported coming to the clinic for STI testing and services.

## HIV risk

A third of women (33%) reported more than two male sexual partners in the past 12 months (Table 5-1). Over three-quarters (86%) engaged in inconsistent or no condom use in the past 12 months. Past-year STI diagnosis was reported by 15%. One-fifth (21%) of women reported sex in the past 12 months with a male partner whose HIV status was unknown; 6% reported their current partner at risk of HIV through sexual or drug using behavior; and 2% had traded sex or sexual acts within the past 12 months in exchange for money, drugs, shelter, gifts, or other resources. A majority (80%) of women had received a HIV test in their lifetime. Almost a third (31%) were a little or very worried about HIV infection in the next six months.

# Use, awareness of, and willingness to use PrEP

Two participants reported using PrEP previously (Table 5-1). A little over a third (35%) had heard of PrEP prior to study participation, and 13% reported knowing someone who had taken PrEP previously. Approximately 70% of participants reported that they would be willing to take PrEP. When asked to describe, in response to an open-ended question, reasons why they would be willing to use PrEP, participants' responses included description of poor outcomes from sex such a previous STI diagnosis, as well as an identification of their risk and concern for their sexual health. For example, one participant described the following as why they would be willing to use PrEP:

I am someone who usually participate[s] in unprotected sex. I was in a relationship for over a year and was active with just that person. He recently cheated and gave me gonorrhea. We broke up but occasionally and stupidly I have casual sex with this individual. So, I worry about my health sometimes due to our history. Also, before reading the information about HIV I never really thought about my chances of getting it because I thought it's commonly found in the LGBT community.

Women also described how their own HIV risk behaviors affected their interest in using PrEP: "I would be willing to use due to [my] inconsistent usage of condoms and amount of partners in the past 12 months", "I am very interested in protecting myself in any way I can. I casually date and some of my male partners also have had male partners in the past and I would like to be as safe as possible", and "I am sexually active and the person I am with has no interest in using condoms though I have them". A lack of communication with sexual partners or not knowing when partners lie, and opportunity to be in control of one's HIV prevention, was also described as reasons for a willingness to use PrEP:

I do not always talk to my partners about their sexual history before having sex. I also don't always know if my partners are telling me the whole truth about their sexual histories. I would feel more in control of my own health by taking PrEP.

# Perceived barriers to PrEP acceptability

Women identified a range of barriers to PrEP acceptability (Table 5-2). PrEP drug effects was the most frequently chosen barrier to willingness to use PrEP, reported by 93% of participants. When asked, in an open-ended question, to further explain potential barriers to PrEP acceptability, women described specific concerns for perceived drug effects, including the short and long-term side effects and newness of PrEP. For example, one participant stated the following:

One of my main concerns before taking any medicine is of the short and long-term side effects. Especially in new medications that haven't been around for a long time, it is pretty much impossible to know all of the side effects and there are numerous examples in history of drugs that seemed safe being devastatingly the opposite. Anyway, I would just want to know what's in the drug before I take it, and all available info so I could feel fully informed of the decision and the accompanying risks I would be taking. Which is funny because it's not like I am this careful about other stuff I put in my body.

Over half of women identified adherence (63%) as a barrier to PrEP acceptability and frequently described in the open-ended questions issues around prescription requirement (e.g., daily dosing) and frequency of follow-up visits. For example, one participant wrote, "I would be more willing to use [PrEP] if it wasn't a daily pill. If it was a shot I would be more willing" and another reported, "My willingness to take PrEP may be affected just by the amount of times I would need to see a doctor". Issues of PrEP access/affordability was often identified as a barrier, with 61% of women indicating it would impact their willingness to use PrEP. In the qualitative

data, women described concerns of cost, insurance, and transportation to doctors' visits when elaborating on perceived barriers to PrEP acceptability.

Almost half of women selected partner reaction (44%) as a barrier to their willingness to use PrEP and frequently expressed in open-ended questions accusations of cheating, mistrust by partners, and fear of partner finding out about PrEP use as impacting women's PrEP decisionmaking: "A woman's significant other can accuse her of cheating or leave her if they found out or take offense" and "They might be afraid to tell their partner or them finding out". As illustrated in the following quote, women's concern about their partner's reaction to taking PrEP might influence her decision to use PrEP even when there were HIV risk concerns:

Partners jealousy or suspicion I feel would likely make women less likely to want to take PrEP even if she was possibly [at] risk [for HIV].

#### Intimate partner violence, barriers, and PrEP acceptability

Over 40% of women reported any recent (past 12 months) intimate partner violence. Most women who reported recent IPV specified psychological partner violence (33%), followed by sexual violence (20%); approximately 10% of women had a recent history of physical violence. Almost a third (31%) of women disclosed experiencing any IPV in their past (at some point in their life more than 12 months ago). Women who reported past IPV identified psychological IPV (80%), followed by sexual (67%) and physical (38%) IPV.

Table 5-2 describes the relationship between participants' experiences with recent and past IPV and their identified barriers to PrEP acceptability. The barriers most frequently selected among women with recent IPV included drug effects (96%), access/affordability (76%), adherence

(74%), partner reaction (54%), and stigma (49%). Lack of perceived need was identified the least (28%). Barriers most frequently selected among women who reported past partner violence included drug effects (91%), adherence (58%), access/affordability (53%), and lack of perceived need (49%); perceived benefits was identified the least (29%).

Recent IPV experience was associated with a number of barriers to PrEP acceptability in bivariate analyses (Table 5-3). Recent IPV experience was significantly associated with access/affordability as a barrier to PrEP acceptability (OR = 3.21; 95% CI: 1.54-6.69, p < 0.01), and specific factors of price, insurance, and unreliable healthcare were described by women with recent IPV as barriers to PrEP acceptability. Recent IPV experience was significantly associated with stigma as a barrier to PrEP acceptability (OR = 2.00; 95% CI: 1.01-3.95, p < 0.05). Stigma around HIV and women's sexuality were specifically described in the open-ended responses of women with recent IPV as factors impacting women's willingness to use PrEP. For example, one participant noted, "Society may think [a] woman already has HIV rather than prevention" and another stated, "The stigma of women hav[ing] many sexual partner[s] plays a part in women taking advantage of things like this".

Women reporting recent IPV were also significantly more likely to identify partner reaction as a barrier to PrEP acceptability compared to women not disclosing recent IPV (OR = 2.00; 95% CI: 1.01-3.92, p < 0.05). Qualitative text from women who reported recent IPV experience highlights accusations of cheating as barriers to women's PrEP acceptability: "If their partner was abusive emotionally or physically he or she may accuse them of things they aren't guilty of." As illustrated in the following quote, abusive partners in general were also described as impacting women's willingness to use PrEP: The type of relationship, monogamous or open/casual, as well as the safety and degree of open mindedness within the relationship (for example, a partner who is manipulative or pressures the other into doing things sexual or otherwise). Also, the uncomfortable discussion it may bring up.

Interestingly, among participants who did not disclose recent IPV, their descriptions of factors impacting women's willingness to use PrEP included specific concerns of the context of abusive and controlling intimate partners. For example, one woman stated the following:

A woman in a controlling relationship may have a hard time taking PrEP without being confronted by her partner. It will most likely discourage her from using it, and she will be more at risk of HIV.

Women reporting recent IPV were also more likely to identify adherence as a barrier to PrEP acceptability compared to women who did not report recent IPV (OR = 2.43; 95% CI: 1.18-5.01 p < 0.05). Consistent healthcare, high pill burden, and follow-up required were described in the open-ended questions as specific adherence barriers among women disclosing recent IPV. One participant stated, "Women already face much of the responsibility for birth control so adding another pill to their regimen might be a pain."

Results from multivariable logistic regression analyses of barriers on PrEP acceptability are presented in Table 5-4. Among women who reported recent IPV, those who identified mistrust of drug companies and healthcare providers as a barrier to PrEP acceptability were less willing to use PrEP compared to those who did not identify mistrust as a barrier (AOR = 0.25; 95% CI: 0.07-0.89, p < 0.05) when controlling for age, race, and education. Among women who reported past IPV, those who identified lack of perceived benefits as a barrier were less willing to use PrEP compared to those who did not identify perceived benefits as a barrier (AOR = 0.12; 95% CI: 0.02-0.59, p < 0.01). Lack of perceived need was statistically significant with PrEP acceptability regardless of IPV experience. The qualitative text comments in response to open-ended questions highlight how many women do not perceive a need for PrEP because they do not consider themselves at risk for HIV. For example, one participant notes: "Many women may think that being heterosexual is a protective factor against HIV". And another points to the continued need for information and education to help women understand HIV risk: "I think most women aren't fully aware of their risk of HIV. So if more women learned about their risk I think it would be good for society as more people are protected."

# 5.5 Discussion

This study contributes important information about IPV and barriers to women's PrEP acceptability, and to the increasing research investigating the potential for PrEP to expand HIV prevention options for women in abusive and controlling relationships. These results provide guidance on barriers to women's PrEP acceptability and potential use, and into the relationship between PrEP acceptability and IPV. This study also supports the feasibility of discussing IPV experiences and PrEP interest with women, as well as the perceived barriers to PrEP decision-making within the context of IPV.

PrEP acceptability was high with 70% of this sample of women seeking care at an urban family planning clinic reporting a willingness to use PrEP to protect against HIV. While awareness of PrEP was low prior to study participation, women were supportive of PrEP once learning more.

The open-ended survey questions provide context of how women's willingness to use PrEP is related to such things as a STI diagnosis, inconsistent condom use, number of partners, and lack of or dishonest conversations with partners. Study results are fairly consistent with existing research. A nationally representative survey of U.S. women found a high acceptability of PrEP, where 64% of women aged 20-29 years and 59% of women aged 30-45 years reported they would take a daily pill to prevent HIV (Rubtsova et al., 2013). Among 191 U.S. women recruited through online and community flyers, approximately a quarter (25%) of those who reported IPV within the past six months were aware of PrEP and 45% were interested in learning more about PrEP (T. C. Willie et al., 2018). Braksmajer et al.'s (2018) study involving in-depth interviews with 26 women disclosing IPV within the past six months in the United States found that approximately half of participants expressed an interest in taking PrEP.

Women identified perceived drug effects, adherence, access/affordability, and partner reaction as primary barriers to PrEP acceptability. Women's description of barriers to PrEP acceptability in the open-ended questions illustrate specific concerns of things such as short and long-term side effects, newness of PrEP, drug prescription requirements (e.g., daily dosing), frequency of follow-up visits required, cost, insurance, and transportation to doctor visits. Study results are consistent with existing research, which highlights that a lack of interest or openness to PrEP among women has involved similar things including low risk perception, medicine concerns (e.g., high pill burden, side effects), cost, mistrust of medical institutions or pharmaceutical companies, newness of drug, stigma, and lack of communication among community members and healthcare providers (Auerbach et al., 2015; Flash et al., 2014; Goparaju et al., 2017; Kwakwa et al., 2016). This study also found partner reaction as an important barrier to PrEP acceptability among all women and accusations of cheating, mistrust by partners, and fear of partner finding out

about PrEP use were specifically described in open-ended questions as factors impacting women's willingness to use PrEP. Focus groups in Washington, D.C. also report that a concern of hostile reactions or suspicions towards those who take PrEP and allegations of infidelity and mistrust by partners were described by women (Goparaju et al., 2017). While partner reaction was not originally included in the scale of barriers to PrEP acceptability, study findings, together with existing research, underscore that partner reaction is an important area in understanding women's PrEP acceptability and decision-making.

Considerably high rates of IPV were disclosed among this sample with 41% of women reporting recent experience of physical, sexual, or psychological violence by an intimate partner. Perceived PrEP acceptability barriers of access/affordability, stigma, partner reaction, and adherence were significantly associated with recent IPV in bivariate analyses. Descriptions of a lack of consistent healthcare, a high pill burden, the follow-up required, and accusations of cheating from the qualitative open-ended questions provide important insight into specific barriers perceived to impact PrEP acceptability among women with recent IPV. Further, abusive and controlling behaviors of partners were frequently described, both by women reporting recent IPV and those not disclosing recent IPV, as factors impacting women's willingness to use PrEP. While PrEP offers several advantages over other existing HIV prevention strategies (e.g., autonomous or covert use and not needing to be taken at time of sexual activity), and has the potential to expand prevention options for women in abusive and controlling relationships, IPV experiences and fears associated with partner may impact women's PrEP decision-making and use. These study findings contribute to the growing discussion of potential implications of abusive partners on women's willingness to use PrEP. For example, existing research suggests that women who have experienced IPV may be concerned about their partner interfering with their PrEP use (Braksmajer

et al., 2018; T. C. Willie et al., 2017). Braksmajer et al.'s interviews (2018) among women in violent intimate relationships in the United States found that a third of participants described potential partner interference as a barrier to PrEP use, that most women would not use PrEP covertly, and that many feared increased violence if their partner were to discover covert PrEP use. Another study found that past-year sexual IPV and lifetime psychological IPV were associated with believing a partner would prevent your PrEP use among women and men in the United States (T. C. Willie et al., 2017). Additional research is needed to further understand the considerations necessary for engaging women in PrEP discussions and implementing PrEP care that prioritizes women's safety.

Mistrust of drug companies and healthcare providers also emerged as a barrier to PrEP use among women who reported recent IPV and is consistent with existing research (Auerbach et al., 2015; Flash et al., 2014; Goparaju et al., 2017; Kwakwa et al., 2016). In-depth interviews with 26 women disclosing IPV within the past six months in the United States report that women's concerns of long-term health outcomes combined with medical mistrust resulted in disinterest in using PrEP, leading the authors to recommend that medical mistrust be openly discussed among women when assessing PrEP acceptability (Braksmajer et al., 2018). Future PrEP intervention development may need clear information and discussions around such things as medical and pharmaceutical mistrust, women's HIV risk perceptions, as well as perceived issues of short and long-term side effects. Further research is also needed to fully understand the considerations necessary for engaging women in PrEP discussions and implementing PrEP care that prioritizes women's safety. The use of qualitative research methods, such as in-depth interviews, should be used to investigate women's recommendations and suggestions for a woman-centered PrEP intervention that takes into account the context of IPV. For example, questions remain around what messaging is appropriate to help women understand and explain their need for PrEP, where and by whom should PrEP be discussed and distributed, potential uptake considerations including the importance of unmarked packaging and medical and health insurance records, and suggested services to support adherence and retention in care (e.g., safety planning, covert use, burden of follow-up visits required). Our study findings of concerns related to the frequent medical followups is supported by existing work (Collier et al., 2017), which also identified that safety planning with women regarding PrEP use may need to take place.

This study successfully recruited and surveyed 145 female family planning patients in a short timeframe and doing so supports the feasibility of discussing IPV experiences, PrEP acceptability, and perceived barriers. Consistent with previous work, women's health care settings like family planning clinics provide a comfortable setting for discussing sexual behavior, IPV, and HIV prevention (Auerbach et al., 2015; Garfinkel et al., 2017; Hoover, 2014). Women receive a variety of services from family planning clinics (e.g., contraception, STI testing and treatment, pregnancy-related services, cancer screening, referrals) and use such clinics as their usual source for health care (Frost, 2013; Frost et al., 2012). Moreover, family planning clinics often provide services to un- or under-insured women who may not be seeking health care elsewhere (Frost, 2013; Frost et al., 2012). Future work should continue to explore the importance of family planning clinics and other women's health care settings in engaging with women around PrEP and IPV discussions and care.

This study has limitations worth noting. The relatively small sample size limited our ability to identify statistically significant differences between groups, including comparisons between women based on abuse experiences. The fairly homogenous sample of women included may have also limited the study. Future research should examine whether IPV and barriers to PrEP acceptability vary between women with different sociodemographic backgrounds (e.g., age, race, income) or geographic setting (e.g., non-urban clinics). A potential for underreporting of sensitive and stigmatized behaviors such as experience of violence may also be present. However, the high rates of IPV reported suggest that this was likely not an issue and the approach used is consistent with guidelines for assessing IPV. Also, most participants had not heard of PrEP prior to study participation and were then asked to offer their thoughts about perceived barriers impacting their to willingness to use PrEP. Perceptions of barriers to PrEP acceptability may have varied if participants were more familiar with PrEP or were given additional time to consider it. The inclusion of open-ended survey questions provided context of barriers to women's PrEP acceptability; however, it was not possible to probe or ask follow-up questions to elicit additional information. Future research should include qualitative methods to more fully examine perceived barriers to women's PrEP acceptability. Finally, findings may not necessarily be generalizable to all women. While family planning clinics provide an appropriate setting for discussing sexual behavior and HIV prevention, results might not be reflective of all women who may benefit from PrEP but are not engaged in care at family planning clinics.

This study provides valuable insights into PrEP acceptability barriers among women in abusive relationships. These findings illustrate that IPV is important to screen for and address when exploring and discussing women's PrEP acceptability and decision-making. While a high percentage of women were willing to use PrEP, a number of potential barriers were identified. The limited awareness of PrEP and misconceptions around PrEP (e.g., effectiveness, side effects, who is able to use) support the need to increase PrEP awareness and understanding among all women, including women with IPV experience. Additional research should investigate a woman-centered PrEP intervention that reflects the context of IPV (Aaron et al., 2018; Braksmajer et al., 2018).

Study findings suggest that clear information and discussions around things such as medical and pharmaceutical mistrust, HIV risk perception, concerns and fears around intimate partner reaction, as well as issues of perceived short and long-term side effects are important for women's PrEP acceptability. Additional intervention development questions remain, however, and research around advertisement, access, uptake, and adherence is necessary to focus development of a woman-centered PrEP intervention that reflects the context of IPV.
## 5.6 Tables

## Table 5.1 Characteristics of women seeking care at a family planning clinic

	Total n = 145 (100%) n (%)	Current IPV n = 59 (40.7%) n (%)	Past IPV n = 45 (31.0%) n (%)
Age, years (mean (range))	25.2 (18-45)	24.9 (18-40)	27.0 (19-45)
Race			
Black or African American	23 (15.9)	9 (15.2)	9 (20.0)
White	104 (71.7)	41 (71.2)	35 (77.3)
Asian, Multiracial, and All Other Races	18 (12.4)	8 (13.6)	1 (2.20)
Education completed			
Less than college	64 (44.1)	36 (61.0)	19 (42.2)
College degree or more	81 (55.8)	23 (38.9)	26 (57.7)
Income status			
Less than \$20,000	82 (56.9)	35 (59.3)	23 (52.2)
\$20,000 or more	62 (43.1)	24 (40.6)	21 (47.7)
Relationship status			
Single	26 (17.9)	11 (18.6)	2 (8.89)
Casually dating	57 (39.3)	23 (38.9)	22 (48.8)
Serious relationship, including marriage	62 (42.7)	25 (42.3)	19 (42.2)
Sexual partners			
2 or less	88 (60.6)	33 (55.9)	29 (64.4)
More than 2	57 (39.3)	26 (44.1)	16 (35.5)
Condom use			
Never or inconsistently	124 (85.5)	58 (98.3)	37 (82.2)
Every time	21 (14.4)	1 (1.69)	8 (17.7)
STI diagnosis			
None	122 (84.1)	49 (83.1)	37 (82.2)
At least once	23 (15.8)	10 (16.9)	17.7 (8)
Sex with partner of unknown HIV status			
None	115 (79.3)	44 (74.5)	37 (82.2)
At least once	30 (20.6)	15 (25.4)	8 (17.7)
HIV worry			
Not worried at all	100 (68.9)	36 (61.0)	31 (68.8)
A little or very worried	45 (31.0)	23 (38.9)	14 (31.1)
Aware of PrEP			
No	94 (64.8)	43 (72.8)	25 (55.5)
Yes	51 (35.1)	16 (27.1)	20 (44.4)
Know others who have used PrEP			
No	126 (86.8)	11 (68.7)	12 (60.0)
Yes	19 (13.1)	5 (31.3)	8 (40.0)
Willing to use PrEP			
No	44 (30.3)	17 (28.8)	17 (37.7)
Yes	101 (69.6)	42 (71.1)	28 (62.2)

Barriers to PrEP Acceptability	Total n = 145 (100%) n (%)	Recent IPV n = 59 (40.7%) n (%)	Past IPV n = 45 (31.0%) n (%)
Access/Affordability	88 (60.6)	45 (76.2)	24 (53.3)
Stigma	57 (39.3)	29 (49.1)	17 (37.7)
Partner Reaction	64 (44.1)	32 (54.2)	20 (44.4)
Drug Effects	135 (93.1)	57 (96.6)	41 (91.1)
Perceived Benefits	46 (31.7)	19 (32.2)	13 (28.8)
Risk Compensation	64 (44.1)	26 (44.1)	20 (44.4)
Lack of Perceived Need	53 (36.5)	17 (28.8)	22 (48.8)
Mistrust	50 (34.4)	25 (42.3)	16 (35.5)
Adherence	91 (62.7)	44 (74.5)	26 (57.7)

Table 5.2 Barriers to PrEP acceptability among women seeking care at a family planning clinic

Total ( <i>N</i> =145)	Access/ Affordability	Stigma	Partner Reaction	Drug Effects	Perceived Benefits	Risk Compensation	Lack of Perceived Need	Mistrust	Adherence
	OR (95% CI)	OK (95% CI)	OK (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)	01 (95% CI)
Recent IPV									
No	-ref-	-ref-	-ref-	-ref-	-ref-	-ref-	-ref-	-ref-	-ref-
Yes	3.21 (1.54, 6.69)**	2.00 (1.01, 3.95)*	2.00 (1.01, 3.92)*	2.92 (.59, 14.2)	1.03 (.50, 2.11)	0.99 (.51, 1.93)	0.56 (.27, 1.14)	1.79 (.89, 3.59)	2.43 (1.18, 5.01)*
Past IPV									
No	-ref-	-ref-	-ref-	-ref-	-ref-	-ref-	-ref-	-ref-	-ref-
Yes	0.64 (.31, 1.31)	0.91 (.44, 1.87)	1.01 (.50, 2.06)	0.65 (.17, 2.44)	0.82 (.38, 1.77)	1.01 (.50, 2.06)	2.12 (1.03, 4.38)*	1.07 (.51, 2.23)	0.73 (.35, 1.51)
* <i>p</i> < 0.05									
p < 0.01									

Table 5.3 Bivariate associations between IPV experience and barriers to PrEP acceptability among women seeking care at a family planning clinic

	Total ( <i>n</i> = 145)	Recent IPV (n = 59)	Past IPV $(n = 45)$
Models <sup>a</sup>	AOR (95% CI)	AOR (95% CI)	AOR (95% CI)
Access/Affordability			
Not a barrier	-ref-	-ref-	-ref-
Barrier	1.12 (.54, 2.32)	0.64 (.14, 2.83)	2.11 (.60, 7.43)
Stigma			
Not a barrier	-ref-	-ref-	-ref-
Barrier	0.92 (.44, 1.91)	1.13 (.35, 3.58)	0.48 (.12, 1.78)
Partner Reaction			
Not a barrier	-ref-	-ref-	-ref-
Barrier	.93 (.45, 1.91)	1.02 (.32, 3.21)	0.79 (.22, 2.87)
Drug Effects <sup>b</sup>	-	-	-
Perceived Benefits			
Not a barrier	-ref-	-ref-	-ref-
Barrier	0.36 (.17, .76)**	0.33 <sup>+</sup> (.09, 1.16)	0.12** (.02, .59)
Risk Compensation			
Not a barrier	-ref-	-ref-	-ref-
Barrier	0.91 (.44, 1.88)	0.63 (.20, 2.01)	0.56 (.15, 1.96)
Lack of Perceived Need			
Not a barrier	-ref-	-ref-	-ref-
Barrier	0.13 (.06, .30)***	0.08*** (.02, .34)	0.14** (.03, .58)
Mistrust			
Not a barrier	-ref-	-ref-	-ref-
Barrier	0.57 (.26, 1.22)	0.25* (.07, .89)	5.13 <sup>†</sup> (.99, 26.5)
Adherence <sup>b</sup>			
Not a barrier	-ref-	-	-ref-
Barrier	0.36 (.15, .83)*		0.61 (.16, 2.24)

Table 5.4 Multivariable logistic regression of barriers on PrEP acceptability among women with IPV experience

<sup>a</sup> Models were run for each barrier individually, and all were adjusted for age, race, and education completed. <sup>b</sup> Variable was not included in model due to little variation in data.

<sup>+</sup> *p* < 0.1

\* *p* < 0.05

, \*\* p < 0.01

\*\*\* *p* < 0.001

### 6.0 Discussion

## 6.1 Overview

The ultimate goal of this dissertation research was to inform public health efforts to enhance HIV prevention options for women in abusive relationships by examining evidence of the intersection of PrEP acceptability and intimate partner violence (IPV) in existing research and among a sample of women attending a family planning clinic in Southwestern Pennsylvania. The research results contribute to furthering our understanding of the unique HIV prevention context and needs of women in abusive and controlling relationships. It provides needed insights into the potential of PrEP within the context of IPV, including PrEP acceptability and perceived barriers to acceptability. This knowledge is critical for the development of PrEP interventions that appropriately incorporate the risk context and needs of women with IPV experience. This discussion chapter summarizes the results and offers conclusions according to each dissertation study aim.

## 6.2 Summary of Findings

# Study Aim 1: To identify and synthesize existing research focused on PrEP acceptability and use among women in abusive relationships.

In paper 1, the results of a systematic rapid review and synthesis of peer-reviewed published articles on PubMed and abstracts of fifteen conferences are presented to address study aim one. Nine studies focused on PrEP acceptability and use among women in abusive relationships and were eligible for review. These studies assessed the connection of IPV experience with women's awareness of and willingness to use PrEP and PrEP use experience. Study results highlight the paucity of research focused on IPV and PrEP among women; only eight empirically-based published articles and one conference abstract exploring PrEP and IPV among women were found. This systematic rapid review expands previous work by Young & McDaid, Koechlin and colleagues, and Bailey and colleagues, which primarily focused on acceptability, values, and preferences of PrEP broadly (Koechlin et al., 2017; Young & McDaid, 2014) or among women specifically (Bailey et al., 2017), and extends it to explore the particular impact of IPV experience on women's PrEP-related outcomes. Several existing commentaries discuss the potential of PrEP for women in abusive and controlling relationships (e.g., (Andersson, 2006; Braksmajer et al., 2016; Chen et al., 2011; Kofman & Adashi, 2014; Van der Wal & Loutfi, 2018) and underscore the relevance and importance of additional work in this area.

Findings of this systematic rapid review illustrate that while existing evidence is relatively limited in scope, IPV seems to have implications on women's PrEP acceptability and use experience. In particular, studies reviewed demonstrate that IPV has been shown to impact women's interest and willingness to use PrEP, perceived PrEP coercion and partner interference, experience using PrEP, interruptions in PrEP use, and PrEP adherence. Other studies exploring women's PrEP outcomes, while not explicitly focused on the impact of IPV, provide additional insight around the potential implications of these complex issues. For example, Rubtsova et al. (2013) found that young women who experience several HIV risk factors, including IPV, may be likely PrEP candidates. Specifically, the authors report that young women 20 to 29 years who experienced lifetime IPV were three times more likely to report potential PrEP uptake than those who did not disclose IPV (AOR = 3.22; p < 0.001 vs. AOR = 1.92; p < 0.01). Garfinkel et al. (2017) found however, that among women seeking care at a family planning clinic, PrEP acceptability was significantly lower among women with a history of IPV relative to women without an abuse history (57% vs. 62%, AOR = 0.71; 95% CI: 0.59-0.85, p < 0.001) and suggest that women may not connect IPV experiences with increased HIV risk.

Results of this rapid review also highlight the significant gaps in current research and areas in need of further attention. An expanded understanding of the ways that IPV-related experiences (e.g., reproductive coercion) may influence women's needs for expanded HIV prevention options is necessary. For example, an included study that focused on willingness to use PrEP among urbandwelling, low-income young Black women in the United States found that IPV was indirectly related to PrEP acceptability through reproductive coercion (i.e., partner uses power and control to influence reproductive health outcomes) (indirect effect = 0.08; p < 0.05) (T. Willie et al., 2017). The authors found that women who were willing to use PrEP were more likely to have experienced birth control sabotage (i.e., direct interference with use of contraception), compared to those not willing or indecisive about PrEP (T. Willie et al., 2017). Little is known about how type and timing of partner violence may also impact women's PrEP decision-making and product use experience. For example, Willie and colleagues (2017) report that only certain types and timing of IPV were associated with interest in using PrEP, as well as perceived PrEP coercion, among women and men recruited through an online participant tool in the United States. In particular, among the entire sample, interest in using PrEP was significantly associated with past-year physical IPV (AOR = 4.53; 95% CI: 1.85-11.11, p < 0.001), and lifetime sexual (AOR = 3.69; 95% CI: 1.62-8.40, p < 0.001) and psychological IPV (AOR = 4.70; 95% CI: 1.01-21.89, p < 0.05), and pastyear sexual IPV (AOR = 3.01; 95% CI: 1.10-8.27, p < 0.05) were positively associated with

believing a partner would attempt to control their use of PrEP. Furthermore, risk of low PrEP adherence was found to increase with each increasing frequency of recent physical (ARR = 1.09 for each additional episode within the reporting period; 95% CI: 1.04-1.14, p < 0.001) and verbal IPV (ARR = 1.02 for each additional episode; 95% CI: 1.02-1.03, p < 0.001) among women participating in a clinical trial in Uganda and Kenya (Roberts et al., 2016).

Further work to expand our understanding of the unique barriers and facilitators to PrEP decision-making and engagement in PrEP care among women in abusive and controlling intimate relationships is critical. Evidence of barriers/facilitators to women's use of other current and experimental HIV prevention strategies (e.g., male and female condoms, microbicides) include such things as cost (Gallo et al., 2012; Goparaju et al., 2017), ease of use (e.g., insertion/extraction) (Artz et al., 2002; Artz et al., 2000; Sly et al., 1997), male partners (e.g., beliefs, preferences) (Doggett et al., 2015; Hoffman et al., 2004), violence or fear of violence (Bergmann & Stockman, 2015), and stigma (Auerbach et al., 2015; Bailey et al., 2017; Goparaju et al., 2017). PrEP has the potential to expand HIV prevention options for women in violent relationships and research exploring the associated considerations regarding PrEP discussions and delivery that reflects the context of IPV is crucial. Young and McDaid recommend that future research should broaden the examination of PrEP acceptability to include perceptions and management of risk and the impact of broader social structural factors on the potential uptake and sustained effectiveness of PrEP (e.g., social stigma, social pressures regarding sexual relationships, mistrust of medical settings, financial barriers) (Young & McDaid, 2014). For example, results from this systematic rapid review suggest that women who have experienced IPV may be concerned about or experienced a partner interfering with their PrEP use (Roberts et al., 2016; T. Willie et al., 2017). Future investigation should include an examination of factors such as how IPV may impact women's

PrEP decision-making and adherence concerns, fears associated with partners, or underestimated need for HIV prevention.

An improved understanding of the intersection of IPV and PrEP among women is critical to support a woman-centered PrEP intervention development. Only one known study has explicitly explored the associated considerations regarding PrEP delivery and implementation of care that reflects the context of IPV (Braksmajer et al., 2018). Additional research is needed to inform a woman-centered PrEP intervention that takes into account the context of IPV. (Aaron et al., 2018). For example, questions remain around what messaging is appropriate to help women understand and explain their need for PrEP, where and by whom should PrEP be discussed and distributed, how should medication should be packaged and identified on medical and health insurance records, and a potential need for additional services to support medication adherence and safety within an abusive relationship. For example, staff from a domestic violence organization in New York City described that safety planning with clients regarding PrEP use may need to take place and the frequent medical visits recommended might present a barrier (Collier et al., 2017). Further work is needed to understand appropriate settings for discussing PrEP. Women's health care settings, such as OB/GYN practitioners and family planning clinics, may provide an important setting for discussing IPV and PrEP (Hoover, 2014). Family planning clinics are often women's source of usual care (Frost, 2013), where women seek care regularly and for a variety of services (e.g., contraception, STI testing and treatment, pregnancy-related services, cancer screening, referrals) (Frost et al., 2012), and provide a comfortable setting to discuss PrEP and sexual health behavior (Auerbach et al., 2015; Garfinkel et al., 2017). Moreover, family planning clinics often provide services to un- or under-insured women who may not be seeking health care elsewhere (Frost, 2013; Frost et al., 2012).

This systematic rapid review asserts that IPV is important to consider when examining women's PrEP acceptability and use, however, there is a dearth of research. The high rates of IPV and persistent HIV incidence among women emphasize the urgency for a woman-centered HIV prevention option that's feasible within abusive and controlling relationships. Further research is critical to understand PrEP intervention development that appropriately reflects the context of IPV with significant implications on women's health and well-being. Future research is needed to: (1) more fully investigate the connection between IPV experience and PrEP acceptability and use among women, (2) identify barriers to PrEP interest and use for women with IPV experience, and (3) explore women's PrEP messaging and programming recommendations within contexts of IPV to focus intervention development.

Study Aim 2: To assess the prevalence of recent and lifetime IPV and its association with PrEP acceptability (i.e., willingness to use) among a sample of women seeking care at an urban family planning clinic.

Findings from a quantitative analysis of cross-sectional data collected from women seeking care at a family planning clinic in Pittsburgh, Pennsylvania are presented in paper 2. Descriptive and bivariate logistic regression analyses were conducted on data from 145 women to assess the prevalence of recent and lifetime IPV and PrEP acceptability (i.e., willingness to use), and evaluate the impact of IPV experience on women's PrEP acceptability. This study contributes valuable information about IPV and women's PrEP acceptability, and to the growing discussion of the potential for PrEP to expand HIV prevention options for women in abusive and controlling relationships. These results provide insights into HIV worry, PrEP acceptability, and the context

of IPV among women. The study also supports the feasibility of studying PrEP interest and IPV experiences with women and provides suggested areas for future research.

High rates of IPV were disclosed among this sample of women seeking care at an urban family planning clinic; over 40% of women reported recent (past 12 months) experience of any violence by an intimate partner, and 71% reported any violence by an intimate partner within their lifetime. Additionally, these findings on types of abuse highlight that women rarely experienced only one act of violence and that a significant co-occurrence of abuse experience exists. Among this sample, approximately 18% of women disclosed recent experience of two or more types of IPV and 6% reported recent experiences of all three (psychological, physical, and sexual). In addition, almost half of the women had a history of two or more types of IPV in their lifetime and 23% reported ever experiencing all three. The rates of IPV uncovered in this sample are slightly higher than rates reported in existing prevalence research on this topic. For example, Decker et al. (2014) found lower rates among a similar population of women seeking care at 24 free-standing Title X family planning clinics in Western Pennsylvania with recent (past three months) physical or sexual IPV reported among 11% of the participants (N=3504). While the differences in the specific measurement tools used to assess recent IPV experience make direct comparisons between the two studies difficult, both show that IPV is a significant health issue among women seeking care at family planning clinics in the region.

IPV is a known HIV risk factor among women through multiple, complex direct and indirect pathways (Centers for Disease Control and Prevention, 2014a; World Health Organization, 2004). Existing HIV prevention options have remained inadequate for use within abusive and controlling relationships, and limited research has examined the relationship between women's abuse experiences and willingness to use PrEP for HIV risk reduction. These study

findings show that while women's PrEP awareness is low, once participants learned more about the HIV prevention method their reported willingness to use PrEP was high and these findings did not vary by women's abuse experience. For example, only 27% of women reporting recent IPV were aware of PrEP prior to study participation, but 71% were willing to take PrEP to protect against HIV. These results are fairly consistent with existing research. Among 191 U.S. women recruited through online and community flyers, approximately a quarter (25%) of those who reported IPV within the past six months were aware of PrEP, 45% were interested in learning more about PrEP, and 42% intended to take PrEP (T. C. Willie et al., 2018). Braksmajer et al.'s (2018) study involving in-depth interviews with 26 women disclosing IPV within the past six months in the United States report that approximately half of participants expressed interest in taking PrEP.

No statistical significance was found between the relationship of IPV experience and PrEP acceptability in this study. This is likely due to the lack of variation of PrEP acceptability observed among the sample; PrEP acceptability was consistently high. However, other research, though relatively limited in scope, suggests that IPV impacts women's interest and willingness to use PrEP. For example, among women recruited online and through community flyers in the United States, women experiencing IPV (past 6 months) had the highest reported rates of PrEP interest (44.7% vs. 30.2%; p = 0.03) and intentions (42.4% vs. 28.3%; p = 0.04) compared to those reporting no IPV experience (T. C. Willie et al., 2018). In addition, past-year physical IPV was associated with being interested in using PrEP (AOR = 4.53; 95% CI: 1.85-11.11, p < 0.001) among women and men recruited through an online participant tool in the United States (T. C. Willie et al., 2017). Other studies exploring women's PrEP outcomes, though not explicitly focused on the impact of IPV, provide additional insights into the relationship between IPV and PrEP acceptability. Rubtsova et al. (2013) found that young women who experience several HIV

risk factors, including IPV, may be likely PrEP candidates and report that young women 20 to 29 years who experienced lifetime IPV were three times more likely to report potential PrEP uptake than those who did not disclose IPV (AOR = 3.22; p < 0.001 vs. AOR = 1.92; p < 0.01). Garfinkel et al. (2017) found, however, that among women seeking care at a family planning clinic, PrEP acceptability was significantly lower among women with a history of IPV relative to women without an abuse history (57% vs. 62%, AOR = 0.71; 95% CI: 0.59-0.85, p < 0.001).

The study results showing that women who report IPV are more worried about HIV compared to women who do not disclose violence experience provide some insights into the relationship of IPV and HIV among this sample of female family planning patients. Participants who report lifetime experience of sexual IPV had 2.9 greater odds of being worried about HIV in the next six months compared to women who do not report lifetime sexual IPV (OR = 2.9; 95%) CI: 1.39-6.18, p = 0.005). The fact that an association was found between lifetime sexual IPV and HIV worry, yet no significant association was identified between IPV and PrEP acceptability, indicates that women with a history of partner violence may require support to discuss their HIV concerns and help identifying appropriate HIV prevention options tailored to their interpersonal contexts. Further, this study found that women who are worried about HIV had higher odds of PrEP acceptability, suggesting that in a larger sample a significant association between IPV and PrEP acceptability may be detected. Taken together, the addition of screening questions around IPV and HIV worry and risk to PrEP eligibility guidelines appears to be appropriate. This is supported by other work that recommends both questions of perception of HIV risk acquisition and sexual violence be included in PrEP screening and eligibility efforts (Patel et al., 2018). Current CDC eligibility guidelines, which do not address perceived HIV risk or IPV experiences, might not identify all women who may benefit from PrEP. Results from this study provide some

insights into the relationship between IPV and PrEP, but the generalizability of our work is limited by the relatively small sample size. Future research should focus on incorporating PrEP screening and care that recognizes the impact of violence in women's lives; values women's decision-making and control; and supports women's health, well-being, and safety.

This study supports the feasibility of discussing IPV experience and PrEP interest with women and provides needed information about the possibility of PrEP within the context of IPV. Surprisingly, women in our study reporting more than two male sexual partners in the past-year were less willing to use PrEP compared to women with two or less partners. Though we do not fully know the context of women's sexual encounters in this study, and this finding highlights the need for additional research. The high rates of IPV disclosure suggest that women were comfortable disclosing IPV, and consistent with previous work, emphasize family planning clinics as a comfortable setting to discuss sexual behavior, IPV, and PrEP (Auerbach et al., 2015; Garfinkel et al., 2017; Hoover, 2014). In addition, women receive a variety of services from family planning clinics (e.g., contraception, STI testing and treatment, pregnancy-related services, cancer screening, referrals) and use such clinics as their usual source for health care (Frost, 2013; Frost et al., 2012). Moreover, family planning clinics often provide services to un- or under-insured women who may not be seeking health care elsewhere (Frost, 2013; Frost et al., 2012). Future work should continue to explore the importance of family planning clinics and other women's health care settings for engaging women around PrEP and IPV discussions and care.

This study provides valuable information about IPV and PrEP acceptability among women attending an urban family planning clinic. As the discussion of PrEP as a valued component of HIV prevention for women continues, these findings contribute to our understanding of the impact of IPV on women's PrEP acceptability. Study findings highlight the urgency and need for expanded screening and services supporting women in discussing their HIV concerns and help identifying appropriate HIV prevention options tailored to their interpersonal contexts. Finally, additional research should explore a woman-centered PrEP intervention development that takes into account the context of IPV to ensure that programming is appropriate (Aaron et al., 2018; Braksmajer et al., 2018). Questions remain around such things as what messaging is appropriate to support women's understanding and potential need for PrEP; where and by whom should PrEP be discussed and distributed; potential use considerations to ensure women's safety (e.g., unmarked packaging, medical and health insurance records); and additional services to support medication adherence, health, and well-being (e.g., safety planning, covert use, burden of follow-up visits required).

Study Aim 3: To explore perceptions about the barriers to PrEP acceptability among a sample of women seeking care at an urban family planning clinic, and examine the association of barriers to PrEP acceptability (i.e., willingness to use) and potential differences by IPV experience.

Findings from a quantitative and qualitative analysis of cross-sectional data collected from women seeking care at a family planning clinic in Pittsburgh, Pennsylvania are presented in paper 3. Descriptive, bivariate, and multivariable analyses were conducted on data from 145 women to investigate perceptions about the barriers to PrEP acceptability among a sample of women seeking care at an urban family planning clinic, evaluate the relationship between the barriers and women's reports of PrEP acceptability (i.e., willingness to use), and determine if the association of barriers and PrEP acceptability vary by women's IPV experience. Qualitative analysis of open-ended survey questions was conducted to provide context to and elaborate on specific findings from the

quantitative analysis. This study contributes important information about IPV and barriers to women's PrEP acceptability, and to the increasing research investigating the potential for PrEP to expand HIV prevention options for women in abusive and controlling relationships. These results provide guidance on barriers to women's PrEP acceptability and potential use, and into the relationship between PrEP acceptability and IPV. This study also supports the feasibility of discussing IPV experiences and PrEP acceptability with women, as well as the perceived barriers to PrEP decision-making within the context of IPV.

PrEP acceptability was high with 70% of this sample of women seeking care at an urban family planning clinic reporting a willingness to use PrEP to protect against HIV. While awareness of PrEP was low prior to study participation, women were supportive of PrEP once learning more. The open-ended survey questions provide context of how women's willingness to use PrEP is related to such things as a previous STI diagnosis, inconsistent condom use, number of partners, and lack of or dishonest conversations with sexual partners. Study results are fairly consistent with existing research. A nationally representative survey of U.S. women found a high acceptability of PrEP, where 64% of women aged 20-29 years and 59% of women aged 30-45 years reported they would take a daily pill to prevent HIV (Rubtsova et al., 2013). Among 191 U.S. women recruited through online and community flyers, approximately a quarter (25%) of those who reported IPV within the past six months were aware of PrEP and 45% were interested in learning more about PrEP (T. C. Willie et al., 2018). Braksmajer et al.'s (2018) study involving in-depth interviews with 26 women disclosing IPV within the past six months in the United States found that approximately half of participants expressed an interest in taking PrEP.

In this study, women identified perceived drug effects, adherence, access/affordability, and partner reaction as primary barriers to PrEP acceptability. Women's description of barriers to PrEP

acceptability in the open-ended questions illustrate specific concerns of things such as short and long-term side effects, newness of PrEP, drug prescription requirements (e.g., daily dosing), frequency of follow-up visits required, cost, insurance, and transportation to doctor visits. Study results are consistent with existing research, which highlights that a lack of interest or openness to PrEP among women has involved similar things including risk perception, medicine concerns (e.g., high pill burden, side effects), cost, mistrust of medical institutions or pharmaceutical companies, newness of drug, stigma, and lack of communication among community members and healthcare providers (Auerbach et al., 2015; Flash et al., 2014; Goparaju et al., 2017; Kwakwa et al., 2016). This study also found partner reaction as an important barrier to PrEP acceptability among all women and accusations of cheating, mistrust by partners, and fear of partner finding out about PrEP use were specifically described in open-ended questions as factors impacting women's willingness to use PrEP. Focus groups in Washington, D.C. also report that a concern of hostile reactions or suspicions towards those who take PrEP and allegations of infidelity and mistrust by partners were described by women (Goparaju et al., 2017). While partner reaction was not originally included in the scale assessing barriers to PrEP acceptability, study findings, together with existing research, underscore that partner reaction is an important area in understanding women's PrEP acceptability and decision-making.

Considerably high rates of IPV were disclosed among this sample with 41% of women reporting recent (past 12 months) experience of physical, sexual, or psychological violence by an intimate partner. Perceived PrEP acceptability barriers of access/affordability, stigma, partner reaction, and adherence were significantly associated with recent IPV in bivariate analyses. Descriptions of a lack of consistent healthcare, a high pill burden, the follow-up required, and accusations of cheating from the qualitative open-ended questions provide important insight into specific barriers perceived to impact PrEP acceptability among women reporting recent IPV experience. Further, abusive and controlling behaviors of partners were frequently described, both by women reporting recent IPV and those not disclosing recent IPV, as factors impacting women's willingness to use PrEP. While PrEP offers several advantages over other existing HIV prevention strategies (e.g., autonomous or covert use and not needing to be taken at time of sexual activity), and has the potential to expand prevention options for women in abusive and controlling relationships, IPV experiences and fears associated with partner may impact women's PrEP decision-making and use. These study findings contribute to the growing discussion of potential implications of abusive partners on women's willingness to use PrEP. For example, existing research suggests that women who have experienced IPV may be concerned about their partner interfering with their PrEP use (Braksmajer et al., 2018; T. C. Willie et al., 2017). Braksmajer et al.'s interviews (2018) among women in violent intimate relationships in the United States found that a third of participants described potential partner interference as a barrier to PrEP use, that most women would not use PrEP covertly, and that many feared increased violence if their partner were to discover covert PrEP use. Another study among women and men in the United States found that past-year sexual IPV and lifetime psychological IPV were associated with believing a partner would prevent your PrEP use (T. C. Willie et al., 2017). Additional research is needed to further understand the considerations necessary for engaging women in PrEP discussions and implementing PrEP care that prioritizes women's safety.

Mistrust of drug companies and healthcare providers also emerged as a barrier to PrEP use among women who reported recent IPV and is consistent with existing research (Auerbach et al., 2015; Flash et al., 2014; Goparaju et al., 2017; Kwakwa et al., 2016). In-depth interviews with 26 women disclosing IPV within the past six months in the United States report that women's concerns of long-term health outcomes combined with medical mistrust resulted in disinterest in using PrEP, leading the authors to recommend that medical mistrust be openly discussed among women when assessing PrEP acceptability (Braksmajer et al., 2018). Future PrEP intervention development may need clear information and discussions around such things as medical and pharmaceutical mistrust, women's HIV risk perceptions, as well as perceived issues of short and long-term side effects. Further research is also needed to fully understand the considerations necessary for engaging women in PrEP discussions and implementing PrEP care that prioritizes women's safety. The use of qualitative research methods, such as in-depth interviews, should be used to investigate women's recommendations and suggestions for a woman-centered PrEP intervention that takes into account the context of IPV. For example, questions remain around what messaging is appropriate to help women understand and explain their need for PrEP, where and by whom should PrEP be discussed and distributed, potential uptake considerations including the importance of unmarked packaging and medical and health insurance records, and suggested services to support adherence and retention in care (e.g., safety planning, covert use, burden of follow-up visits required. Our study findings of concerns related to the frequent medical followups is supported by existing work (Collier et al., 2017), which also identified that safety planning with women regarding PrEP use may need to take place.

This study successfully recruited and surveyed 145 female family planning patients in a short timeframe and doing so supports the feasibility of discussing IPV experiences, PrEP acceptability, and perceived barriers. Consistent with previous work, women's health care settings, such as family planning clinics, provide a comfortable setting for discussing sexual behavior, IPV, and HIV prevention (Auerbach et al., 2015; Garfinkel et al., 2017; Hoover, 2014). Women receive a variety of services from family planning clinics (e.g., contraception, STI testing and treatment,

pregnancy-related services, cancer screening, referrals) and use such clinics as their usual source for health care (Frost, 2013; Frost et al., 2012). Moreover, family planning clinics often provide services to un- or under-insured women who may not be seeking health care elsewhere (Frost, 2013; Frost et al., 2012). Future work should continue to explore the importance of family planning clinics and other women's health care settings in engaging with women around PrEP and IPV discussions and care.

This study provides valuable insights into PrEP acceptability barriers among women in abusive relationships. These findings illustrate that IPV is important to screen for and address when exploring and discussing women's PrEP acceptability and decision-making. While a high percentage of women were willing to use PrEP, a number of potential barriers were identified. The limited awareness of PrEP and misconceptions around PrEP (e.g., effectiveness, side effects, who is able to use) support the need to increase PrEP awareness and understanding among all women, including women with IPV experience. Additional research should investigate a woman-centered PrEP intervention that reflects the context of IPV (Aaron et al., 2018; Braksmajer et al., 2018). Study findings suggest that clear information and discussions around things such as medical and pharmaceutical mistrust, HIV risk perception, concerns and fears around intimate partner reaction, as well as issues of perceived short and long-term side effects are important for women's PrEP acceptability. Additional intervention development questions remain, however, and research around advertisement, access, uptake, and adherence is necessary to focus development of a woman-centered PrEP intervention that reflects the context of IPV.

## 6.3 Study Limitations

This study has limitations worth noting. A systematic rapid review process was used to identify and summarize existing research in a timely manner, yet there are limitations to this approach that should be noted. While the search was considered to be comprehensive and conducted in collaboration with a health sciences librarian with expertise in systematic reviews, relevant studies may have been missed due to search terms and only one database used. In addition, a single reviewer was responsible for the search, review, and coding. However, this reviewer has considerable experience and publications involving similar literature review approaches. Given this is a growing research area, conference abstracts provide valuable information on current research, yet, they present an abbreviated summary of the work and details on results are often limited. Accordingly, few assumptions were made regarding meaning as possible when reviewing abstracts, which resulted in missing data. Finally, the use of qualitative methods to summarize key findings limits applications of results, but until more studies demonstrate PrEP outcomes for women who experience IPV, this is an appropriate step to inform future research and practice. The findings from this systematic rapid review provide a foundation for developing a better understanding of the impact of IPV on women's PrEP acceptability and use.

Additional limitations related to the cross-sectional survey among women seeking care at an urban family planning clinic should also be noted. The relatively small sample size limited our ability to identify statistically significant differences between groups, including comparisons between women based on abuse experiences. In addition, women may have underreported their sexual behavior and experiences of violence due to the sensitive and stigmatized nature of sexual behavior and IPV. An underreporting of behaviors or IPV experiences may have also occurred according to an inability to recall if or when they occurred. The high rates of reported IPV, however, suggest that this was likely not an issue and the approach used was consistent with guidelines for assessing IPV. Further, most participants had not heard of PrEP prior to study participation and were then asked to offer their thoughts about perceived barriers impacting their to willingness to use PrEP. Perceptions of barriers to PrEP acceptability may have varied if participants were more familiar with PrEP or were given additional time to consider it. The inclusion of open-ended survey questions provided context of perceived barriers to women's willingness to use PrEP, however, there was no ability to probe or ask follow-up questions to elicit additional information. Future work should include qualitative research methods to more fully examine barriers to women's willingness to use PrEP. Finally, study findings may not be generalizable to all women and may not reflect the experiences of all women seeking care at an urban family planning clinic. The sampling method included only one study clinic and the short recruitment period means that some women were also missed based on their timing of care at the clinic. Future research should include multiple clinic settings, including those in a varied geographic setting (e.g., clinic outside of the city), and a longer recruitment period, to expand our understanding of women's perceptions of barriers to PrEP acceptability and willingness to use. The results may also not be reflective of the experiences of women not engaged in care at family planning clinics, and while family planning clinics provide an appropriate setting for discussing sexual behavior and HIV prevention, additional work could explore IPV and PrEP acceptability in other healthcare settings (e.g., OB/GYN practitioners).

## 6.4 Study Strengths

This dissertation research is novel and is one of a few that examines the intersection of IPV and PrEP acceptability among women. The study successfully recruited and surveyed 147 female family planning patients in a short timeframe and doing so supports the feasibility of discussing IPV experiences, PrEP acceptability, and perceived barriers to PrEP use among women. The qualitative analysis of open-text survey questions contributes important context to women's perceived barriers to PrEP acceptability and elaborates on the quantitative findings. A successful collaboration history with Planned Parenthood of Western Pennsylvania supported the use of a partnered and engaged research approach throughout and ensured that contextually relevant data were collected. In addition, lay-language materials to be shared with PPWP leadership and staff will promote discussion of study recommendations and potential next steps with direct implications on women's health promotion and intervention development. This dissertation contributes to filling an existing gap and offers several suggested areas for future research and practice recommendations.

#### **6.5 Research Implications**

Findings from this dissertation indicate several opportunities for future research. This study provides insights into the intersection of IPV and PrEP acceptability among women, but additional research is needed to more completely understand the implications of IPV on women's PrEP acceptability, use, and care. The specific issues for consideration in future research include:

- Existing Evidence and Knowledge: As discussions of the importance of PrEP as an HIV prevention option for women in abusive and controlling relationships grows, access to existing research evidence and knowledge is critical to inform research and practice supporting women's health. Quick publication of study findings and improved access to conference abstracts is important for up to date research.
- Sample Size: While this study heard from 147 women seeking care at an urban family planning clinic, research that includes a larger sample of women (e.g., 250 women) could allow for analysis between groups, including comparisons between women based on abuse experiences.
- **Sample Diversity:** PrEP acceptability and perceptions around barriers to use may differ among women not represented in this study. Future research should include diverse settings to broaden our understanding of the intersection of IPV and PrEP among women (e.g., clinics outside of the city, non-family planning clinics).
- Intervention Development: Low HIV risk perception, mistrust of drug companies and • healthcare providers, concerns about intimate partner, including fear of finding out about PrEP use, emerged throughout this study as important for women's PrEP acceptability. However, specific implications for intervention development is unclear and questions remain. Intervention development around research awareness/advertisement (e.g., what messaging is appropriate for women), access (e.g., where and by whom should PrEP be discussed and distributed), uptake (e.g., potential use considerations including unmarked packaging and medical and health insurance records), and adherence (e.g., additional support services such as safety planning, covert use, burden of follow-up visits). Future research may also want to explore the

appropriateness of incorporating a trauma-informed approach to a woman-centered PrEP care continuum.

## **6.6 Practice Implications**

The findings from this dissertation suggests several practice implications to enhance PrEP as a woman-controlled HIV prevention method including the following:

- Education: Increased PrEP awareness among all women, as well as women with IPV experience, is necessary. This research identified limited awareness of PrEP and misconceptions about PrEP (e.g., effectiveness, side effects, who is able to use). Significant work is needed to expand general awareness of PrEP as a HIV prevention strategy for women, and to increase accurate understanding of its use.
- Screening: This research identified that women with a lifetime experience of sexual IPV were worried about HIV in the next six months and that women who are worried about HIV were more likely to report a willingness to use PrEP, suggesting that additional screening questions around IPV and HIV worry/risk to PrEP eligibility guidelines may be appropriate. Current CDC eligibility guidelines do not address perceived HIV risk/worry or IPV experiences and are likely not identifying all women who may benefit from PrEP. In addition, screening guidelines or protocols that also encourage discussion of HIV risk and prevention, including PrEP as a woman-controlled risk-reduction option, to IPV screening or when women report IPV should be implemented in women's health care settings.

- **Provider Training:** Women's healthcare providers should be aware that women with a history of IPV may require support to discuss their HIV concerns and help identifying appropriate HIV prevention options tailored to their interpersonal contexts.
- Expanded Services: Continued work within family planning clinics or other women's healthcare settings is important to enhance PrEP care for women. Women receive a variety of services from family planning clinics (e.g., contraception, STI testing and treatment, pregnancy-related services, cancer screening, referrals) and use such clinics as their usual source for health care, highlighting a critical setting for engaging with women around PrEP and IPV discussion and care.

#### 6.7 Conclusion

IPV and HIV are serious public health issues that significantly impact the health and wellbeing of women. Existing HIV prevention options for women remain underused and inadequate. PrEP, an already valued component of HIV prevention for other populations (e.g., MSM), has the potential to expand options for women at risk of HIV, specifically those in abusive relationships. Efforts to understand the intersection of IPV and PrEP acceptability and use is critical to improve HIV prevention within contexts of violence. This dissertation research used the results from a systematic rapid literature review and cross-sectional survey data to provide important insights and suggestions for future research, intervention development, and practice that appropriately incorporates the risk context and needs of women with IPV experience. Findings from this dissertation highlight public health and healthcare efforts necessary to develop and implement a woman-centered PrEP intervention that recognizes the impact of violence in women's lives; values women's decision-making and control; and supports women's health, well-being, and safety.

# Appendix A PrEP Guidelines and Efficacy Trials

<b>CDC/USPHS</b> (Centers for Disease Control and Prevention, 2018)	<b>WHO*</b> (World Health Organization, 2017)
Indications for PrEP Eligibility	
<ul> <li>HIV-positive sexual partner</li> <li>Recent bacterial STI (gonorrhea, syphilis)</li> <li>High number of sexual partners</li> <li>History of inconsistent or no condom use</li> <li>Commercial sex work</li> <li>In high HIV prevalence area or network</li> </ul>	<ul> <li>HIV-negative, AND</li> <li>Sexual partner with HIV who is not virally suppressed, OR</li> <li>Sexually active in a high HIV incidence/prevalence population AND any of the following:         <ul> <li>Vaginal or anal sexual intercourse without condoms with more than one partner, OR</li> <li>A sexual partner with one or more HIV risk factors, OR</li> <li>A history of STI by lab testing or self-report or syndromic STI testing, OR</li> <li>Use of PEP, OR</li> <li>Requests PrEP</li> </ul> </li> </ul>
Clinical Eligibility for PrEP	· · · · · · · · · · · · · · · · · · ·
<ul> <li>Negative HIV test</li> <li>No symptoms or signs of acute HIV infection</li> <li>Normal renal function</li> <li>No contraindicated medications</li> <li>Hepatitis B virus infection and vaccination status</li> </ul>	<ul> <li>Negative HIV test</li> <li>No suspicion of acute HIV infection</li> <li>No contraindication to PrEP medicines</li> <li>Willingness to use</li> <li>Hepatitis B virus infection and vaccination status</li> </ul>
Recommended PrEP Medication and Follow-up	
<ul> <li>Daily, continuous, oral doses of TDF/FTC (Truvada); no more than a 90-day supply</li> <li>Every 3-month follow-up:         <ul> <li>HIV test</li> <li>Pregnancy intent and test for women</li> <li>Medication adherence counseling, behavioral risk reduction support, side- effect assessment</li> </ul> </li> <li>At 3 months, then every 6 months:         <ul> <li>Renal function</li> </ul> </li> <li>Every 6 months:             <ul> <li>STD testing (syphilis, chlamydia, gonorrhea)</li> </ul> </li> </ul>	<ul> <li>Daily, continuous, oral doses of TDF/FTC (Truvada)</li> <li>Every 3-month follow-up:         <ul> <li>HIV test</li> <li>Address side-effects</li> <li>Adherence counselling</li> </ul> </li> <li>Every 6-months:             <ul> <li>Estimated creatinine clearance</li> </ul> </li> <li>As needed:             <ul> <li>STI screening, condoms, contraception or safer or conception services</li> <li>Counselling regarding effective PrEP use, prevention of STIs, recognition of symptoms of STIs, and issues related to mental health, IPV,</li> </ul> </li> </ul>

## Table A.1 Summary of PrEP Guideliens for Heterosexual Women and Men

\* Risk groups not differentiated

## Table A.2 Summary of PrEP Efficacy Trials

Trial					
(Sponsor)	Intervention	Population	Countries	Outcome	
Sample Size					
iPrEx	Daily oral TDF/FTC	MSM, transgender women	Brazil, Ecuador, Peru,	44% risk reduction	
(NIH; Gates			Thailand, USA, South		
Foundation)			Africa		
n=2499					
Partners PrEP	Daily oral TDF/FTC,	Heterosexual	Kenya, Uganda	TDF/FTC = 75% efficacy	
(Gates Foundation)	TDF	serodiscordant couples		TDF = 67% efficacy	
n=4758 couples					
TDF2	Daily oral TDF/FTC	Heterosexual men and	Botswana	62% efficacy	
(CDC)		women			
n=1219					
Bangkok Tenofovir	Daily oral TDF	Injection drug users	Thailand	73.5% risk reduction	
(CDC)					
n=2413					
FEM-PrEP	Daily oral TDF/FTC	Heterosexual women	Kenya, South Africa,	Drug detected in <50% of	
(USAIDS; Gates, FHI			Tanzania	participants; trial discontinued.	
360)				Poor adherence may have likely	
n=1951				been the primary issue.	
VOICE	Daily oral TDF/FTC,	Heterosexual women	South Africa,	Drug detected in <30% of	
(MTN-003)	TDF,		Uganda, Zimbabwe	participants; groups receiving oral	
n=5029	1% tenofovir gel			TDF and tenofovir gel were	
	(topical vaginal)			discontinued after interim	
				analyses suggested futility.	
Source: Centers for Disease Control and Prevention (2018), Preexposure prophylaxis for the prevention of HIV infection in the United					
States—2017 Update: a clinical practice guideline (Centers for Disease Control and Prevention, 2018).					

## **Appendix B Cross Sectional Survey Documents**

## **B.1 Survey**

## Introduction Script

This study is being conducted by researchers from the University of Pittsburgh. The purpose of this research is to learn about the sexual health and relationship health, HIV prevention experiences, and PrEP acceptability of women attending family planning clinics. The information you share will be used to better understand women's sexual health and improve services for other women seeking care at clinics like Planned Parenthood.

If you agree to participate, we will ask you to complete a survey that asks about your background (e.g., age, race, education) and your sexual behaviors, experience, and health. The questionnaire takes about 10-15 minutes to complete. We will not ask for your name or contact information on the survey. All information you provide us will be anonymous, which means that your name and any other identifying information will not be linked to your responses.

All of your information will be uploaded to a secure storage system, and the data will only be accessed through security password. Any presentation or publication of findings will be based on accumulated data and will not refer to participants individually.

There are minimal risks associated with this study, primarily that someone may learn that you completed this survey or may access your survey results. However, we have taken numerous steps to make sure that this does not happen. There is a small risk that you may feel some emotional discomfort when answering questions. There are no costs or direct benefits for taking part in this study.

A first set of questions will determine whether you are eligible to participate in the survey. Those who are eligible will then be asked to complete the survey. Participants will receive \$10.00 upon completion of the entire survey as a thank you for their time.

Again, this survey is anonymous. And your participation is voluntary. You may change your mind at any point during the survey. Not taking part or not completing the survey will not harm your relationship with Planned Parenthood or the University of Pittsburgh.

This study is being led by Teagen O'Malley who can be reached at tlo8@pitt.edu if you have any questions. Or if you have a concern about this study, you may also contact the University of Pittsburgh at 1-866-212-2668.

By clicking on the continue button below you consent to participate in this study. Are you still interested in continuing?

- I do not wish to continue
- Continue

## **Eligibility Screen**

Thank you for your interest in the PrEP Her Project. Before starting, we have a few questions to determine whether or not you are eligible for the study. Participation in the survey is completely voluntary, and you do not have to participate if you don't want to.

Are you 18 years of age or older?

- Yes
- o No

Can you read English?

- Yes
- o No

In the past 12 months, have you had sex with a man?

- Yes
- o No

How concerned or worried about HIV are you?

- Not at all concerned
- Slightly concerned
- Somewhat concerned
- Moderately concerned
- Extremely concerned

## How interested in HIV prevention are you?

- Not at all interested
- Slightly interested
- Somewhat interested
- Moderately interested
- Extremely interested

## Survey Introduction

Based on your responses, you are eligible to complete this survey. The survey should take approximately 10-15 minutes to complete.

What is the main reason you are at the health center today?

- Birth control
- Pregnancy testing
- HIV testing
- STD testing and services
- Other women's health care (such as Pap test, urinary tract infection, vaginal infection)
- LGBTQ services (such as resources, referrals)
- Other \_\_\_\_\_

How old are you?\_\_\_\_\_

How would you describe your current relationship status?

- Single
- Casually dating
- Serious relationship (including marriage)

How many male sexual partners have you had in the past 12 months?\_\_\_\_\_

In the past 12 months, how often did you use a condom during sex (vaginal or anal) with a man?

- Every time
- Most of the time
- Occasionally
- Never

In the past 12 months, how many times have you tested positive for a sexually transmitted infection (been told by a doctor or other health care professional that you had a sexually transmitted infection)? By sexually transmitted infection (STI) we mean, for example, chlamydia, gonorrhea (also known as the clap), syphilis, herpes, genital warts, or Hepatitis B.

- None
- 1 to 3
- 4 to 6
- 7 to 10
- More than 10

In the past 12 months, how many times have you had sex (vaginal or anal) with a man who has HIV, or with a man whose HIV status you did not know?

- None
- 1 to 3
- o 4 to 6
- 7 to 10
- More than 10

In the past 12 months, how many times have you traded sex or sexual acts in exchange for money, drugs, shelter, gifts, or other resources?

- None
- 1 or 3
- 4 to 6
- 7 to 10
- More than 10

Have you ever heard of HIV-negative persons using HIV medicines before sex to reduce their chances of getting HIV?

- Yes
- o No

*Skip To: Q13 If Have you ever heard of HIV-negative persons using HIV medicines before sex to reduce their chance... = No* 

Do you know anyone who has taken HIV medicines before sex to reduce their chances of getting HIV?

- Yes
- o No

Skip To: Q13 If Do you know anyone who has taken HIV medicines before sex to reduce their chances of getting HIV? = No\_\_\_\_\_

Have you ever used HIV medicines before sex to reduce your chances of getting HIV?

- O Yes
- o No

Skip To: Q13 If Have you ever used HIV medicines before sex to reduce your chances of getting HIV? = No

Are you currently using HIV medicines before sex to reduce your chances of getting HIV?

- Yes
- o No

**PrEP** stands for **Pre-Exposure Prophylaxis and is a daily pill (sometimes called Truvada) that HIV-negative people, including women, can take to reduce their risk of becoming HIV positive by over 90% when used properly. <b>PrEP** can help women to feel more in control of their HIV prevention. **PrEP** does not protect against STDs, protect against pregnancy, or work as a treatment for someone living with HIV. **PrEP** may cause side effects like nausea, loss of appetite, and headaches. These side effects aren't dangerous and usually get better with time, once your body gets used to **PrEP**. **PrEP** requires doctor visits every three months and lab tests to make sure the medication is working. Most insurance plans cover **PrEP**. Costs may vary depending on the insurance company and plan. If you don't have health insurance, there are programs that may help cover costs. *Source: The Well Project and AIDS Free Pittsburgh* 

Would you be willing to take a pill every day if you could protect yourself from getting HIV during sex?

- Yes, definitely
- Yes, probably
- No, probably not
- No, definitely not

#### Display This Question:

If PrEP stands for Pre-Exposure Prophylaxis and is a daily pill (sometimes called Truvada) that HIV-... = Yes, definitely

Or PrEP stands for Pre-Exposure Prophylaxis and is a daily pill (sometimes called Truvada) that HIV-... = Yes, probably

We are interested in understanding more about your willingness to use PrEP. In the space below, please tell us more about why you would be willing to use PrEP. \_\_\_\_\_

### Display This Question:

If PrEP stands for Pre-Exposure Prophylaxis and is a daily pill (sometimes called Truvada) that HIV-... = No, probably not

Or PrEP stands for Pre-Exposure Prophylaxis and is a daily pill (sometimes called Truvada) that HIV-.. = No, definitely not

We are interested in understanding more about your willingness to use PrEP. In the space below, please tell us more about why you are not willing to use PrEP. \_\_\_\_\_
The following questions ask about your attitudes towards willingness to use **PrEP**. Please read the following statements and **select one response that best indicates your level of agreement or disagreement with each statement.** There is a total of 35 statements. Please read each carefully and make sure your response reflects your attitude.

	Strongly Disagree	Disagree	Agree	Strongly Agree
I wouldn't be able to take PrEP because I don't have a doctor or healthcare provider	0	0	0	0
I wouldn't be able to take PrEP because I don't have health insurance	0	0	0	0
I don't know how to enroll in health insurance so I can start taking PrEP	0	0	0	0
l wouldn't be able to afford PrEP	0	0	0	0
I don't know how to find a doctor who can give me a PrEP prescription	0	0	0	0
I don't know where to go to get a PrEP prescription	0	0	0	0
I would be concerned about my sexual partner(s) finding out if I started taking PrEP	0	0	0	0
I would be concerned about family members finding out if I started taking PrEP	0	0	0	0
I would be concerned about friends finding out if I started taking PrEP	0	0	0	0
I would be uncomfortable asking a doctor for PrEP prescription	0	0	0	0
I would be uncomfortable talking to a doctor about my sexual behavior	0	0	0	0
I would be concerned about sexual partners finding out if I started taking PrEP	0	0	0	0

The following questions ask about your attitudes towards willingness to use **PrEP**. Please read the following statements and **select one response that best indicates your level of agreement or disagreement with each statement**.

	Strongly Disagree	Disagree	Agree	Strongly Agree
My sexual partner(s) would argue with me about PrEP if I started taking it	0	0	0	0
I would be concerned that my sexual partner(s) would think I was having sex with other people if I started taking PrEP	0	0	0	0
My sexual partner(s) would support me if I started taking PrEP	0	0	0	0
I would be concerned that my sexual partner(s) would think I was accusing him of having sex with other people if I started taking PrEP	0	0	0	0
Not knowing if there are long-term side effects of taking PrEP makes me very uncomfortable	0	0	0	0
I am concerned about side effects or feeling sick from taking PrEP	0	0	0	0
l am concerned that PrEP is only partially effective	0	0	0	0
I would be very uncomfortable taking HIV medicines when I don't have HIV	0	0	0	0
I would take PrEP if there weren't any side effects	0	0	0	0

The following questions ask about your attitudes towards willingness to use **PrEP**. Please read the following statements and **select one response that best indicates your level of agreement or disagreement with each statement**.

	Strongly Disagree	Disagree	Agree	Strongly Agree
Taking PrEP would be a good way to protect myself from getting HIV	0	0	0	0
PrEP would help me worry less about getting HIV	0	0	0	0
PrEP use should be encouraged to prevent the spread of HIV	0	0	0	0
PrEP would allow me to be in control of protecting myself from getting HIV	0	0	0	0
I would use condoms less if I started taking PrEP	0	0	0	0
I am concerned that I would take more sexual risks if I started taking PrEP	0	0	0	0
l think people who take PrEP will take more sexual risks	0	0	0	0

The following questions ask about your attitudes towards willingness to use **PrEP**. Please read the following statements and **select one response that best indicates your level of agreement or disagreement with each statement**.

	Strongly Disagree	Disagree	Agree	Strongly Agree
I don't need PrEP because I always use condoms	0	0	0	0
I don't need PrEP because I'm not at risk for getting HIV	0	0	0	0
I don't trust doctors or healthcare providers	0	0	0	0
I don't trust drug companies	0	0	0	0
It would be difficult for me to remember to take PrEP every day	0	Ο	0	0
It would be difficult for me to take a pill every day because I would hide it from my sexual partner(s)	0	0	0	0
It would be difficult for me to see my doctor every 2-3 months for follow-up if I started taking PrEP	0	0	0	0

We are interested in understanding more about how relationships may impact women's willingness to use PrEP. In the space below, please tell us what else about **romantic or sexual relationships** may impact, positively or negatively, women's willingness to use PrEP? \_\_\_\_\_\_

We are interested in understanding more about how community or society may impact women's willingness to use PrEP. In the space below, please tell us what else about **community or society** may impact, positively or negatively, women's willingness to use PrEP?

We are interested in understanding more about how anything else may impact women's willingness to use PrEP. In the space below, please tell us about **anything else** that may impact, positively or negatively, women's willingness to use PrEP? \_\_\_\_\_\_

## **IPV Introduction**

No matter how well a couple gets along, there are times when they disagree, get annoyed with the other person, want different things from each other, or just have spats or fights because they are in a bad mood, are tired or for some other reason. Couples also have many different ways of trying to settle differences. The following questions include things that might happen when you have differences.

We know these are personal questions, so we do not ask your name or other identifying information. Your information is completely confidential.

Please select one response after each statement to indicate if any male sexual partner, such as a date, boyfriend, husband, or any other sexual partner, has ever done the following to you within the **past 12 months.** 

	Yes	No
Partner insulted or swore or shouted or yelled at you?	0	0
Partner pushed, shoved, or slapped you?	0	0
Partner punched, kicked, or beat you up?	0	0
Partner destroyed something belonging to you or threatened to hit you?	0	0
Partner used force (like hitting, holding down, or using a weapon) to make you have sex?	0	0
Partner insisted on sex when you did not want to or insisted on sex without a condom (but did not use physical force)?	0	0
You were afraid to ask your partner to use a condom?	0	0
You were afraid to refuse sex with a sexual partner?	0	0

Please select one response after each statement to indicate if any male sexual partner, such as a date, boyfriend, husband, or any other sexual partner, has ever done the following to you at **any point in your life.** 

	Yes	No
Partner insulted or swore or shouted or yelled at you?	0	0
Partner pushed, shoved, or slapped you?	0	0
Partner punched, kicked, or beat you up?	0	0
Partner destroyed something belonging to you or threatened to hit you?	0	0
Partner used force (like hitting, holding down, or using a weapon) to make you have sex?	0	0
Partner insisted on sex when you did not want to or insisted on sex without a condom (but did not use physical force)?	0	0
You were afraid to ask your partner to use a condom?	0	0
You were afraid to refuse sex with a sexual partner?	0	0

There are a few additional questions about your sexual health and HIV prevention experiences.

Have you ever been tested for HIV?

- Yes, within the past 6 months
- Yes, greater than 6 months ago
- No, never

## Display This Question:

If Have you ever been tested for HIV? = Yes, within the past 6 months

Or Have you ever been tested for HIV? = Yes, greater than 6 months ago

What was the result of your most recent HIV test?

- Negative
- Positive

Have you ever used **PEP** (post-exposure prophylaxis) because you were nervous you had been exposed to HIV during sex or sharing needles? **PEP** is a medicine that may be taken after a suspected exposure like condomless sex with someone who may have HIV or a sexual assault.

- Yes, within the past 6 months
- Yes, greater than 6 months ago
- No, never

Are any of your current male sexual partners at risk of HIV, through sexual or drug using behavior?

- Yes
- o No

How worried are you about HIV in the next 6 months?

- Not worried at all
- Worried a little
- Very worried

The following questions ask about your background.

Are you currently living with a male sexual partner?

- Yes
- o No

What is your preferred birth control method?

- o Implant
- Patch
- o Pill
- o Shot
- Sponge (Today Sponge)
- Vaginal ring (NuvaRing)
- O Diaphragm
- Male condom
- Female condom
- IUD (hormonal or copper)
- Spermicide
- Other

What type or types of health insurance do you have? Check all that apply.

- Medicaid/Medical Assistance
- Private health insurance
- Medicare
- None
- □ Other

What is the highest grade or level of education you have completed?

- Less than high school diploma
- High school diploma/GED
- Trade/Technical school
- Some college
- College degree
- Master's degree or higher

What would you say your annual income is?

- Less than \$10,000
- \$10,000 to \$19,999
- \$20,000 to \$29,999
- \$30,000 to \$49,999
- \$50,000 to \$69,999
- \$70,000 to \$99,999
- \$100,000 or more

How would you describe your race? Check all that apply.

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White
- Other. Please specify: \_\_\_\_\_\_

Would you consider yourself to be Hispanic or Latina?

- Yes
- o No

Do you think of yourself as: (please check only one)

- Heterosexual or Straight
- Homosexual or Lesbian or Gay
- Bisexual
- Other (please specify): \_\_\_\_\_\_
- Don't know

Approximately how many miles did you travel to get to the clinic today? For example, 5 miles.

# **B.2 Resource List**

Food As	sistance
Greater P	ittsburgh Community Food Bank
Food assis	stance, Supplemental Nutrition Assistance Program (SNAP)
assistance	e, summer program for kids 18 and under, online portal of food
assistance	e throughout the region
Duquesne	e   412-460-3663
II nited W	av of Southwestern PA
Emergeno	
Informati	on on health and human services in the region   dial 2-1-1
internati	
Housing	Support
Communi	itv Human Services
Housing a	issistance programs food pantry youth programs
Strip Dist	rict. Oakland   412-246-1600
•	
Urban Lea	ague of Greater Pittsburgh
Housing, t	family support, employment assistance, youth leadership
developm	ient
Downtow	n   412-227-4802
Mental	Health Support
Peroluo (	inicia Services
Homowo	anais Services
24/7 Hotl	ino: 1.888-7. VOLLCAN (1.888-706-8226)
24/7 1100	III - 1-000-7-10-0-0414 (1-000-7-5-0-02-2-0)
Family Lir	ıks
Mental he	ealth, substance use, housing, service coordination
East Liber	ty   412-343-7166
Davie II.	
Drug Us	er narm Reduction
Preventio	n Point
Needle ex	change, STI testing, overdose prevention, intervention counseling
Liakland a	ind Perry Hilltop, Hill District, and East Liberty regularly throughout
Oakialiu a	

Front page of resource booklet

#### Women's Health & Wellness Planned Parenthood of Western PA

STI testing and treatment, birth control and pregnancy testing, PrEP prescriptions, gynecological care Downtown | 412-692-8971 Other locations: Bridgeville, Greensburg, Moon Township, Johnstown, Somerset

#### YWCA of Greater Pittsburgh

Women's resource center, housing, health and wellness, child care Downtown, Homewood-Brushton | 412-391-5100

Women's Center and Shelter of Greater Pittsburgh Emergency shelter, legal and medical advocacy, support groups, children programs 412-687-8017 | 24/7 Hotline: 412-687-8005

#### Center for Victims

Emergency shelter, transitional housing, medical advocacy, children's advocacy and counseling Southside | 412-482-3240 24/7 Hotline: 1-866-644-2882

## PAAR (Pittsburgh Action Against Rape)

Victim response and rights services, therapy Southside | 412-431-5665 24/7 Hotline: 1-866-END-RAPE (1-866-363-7273)

### National Domestic Violence Hotline

24/7 Hotline: 1-800-799-SAFE (1-800-799-7233) 24/7 Chat at <u>http://www.thehotline.org/</u>

### Women's Law Project

Telephone Counseling guidance around legal issues of domestic violence, custody, housing 215-928-9801, extension 5760

HIV/AIDS

#### Allies for Health + Wellbeing Testing, counseling, PrEP prescriptions, medical and behavioral health East Liberty | 412-248-0550

UPMC PrEP Clinic HIV risk assessment, testing, PrEP prescriptions Oakland | 412-647-7228

## Positive Health Clinic (Allegheny Health Network)

HIV risk assessment, testing, PrEP prescriptions Northside, Aliquippa, Monroeville | 412-359-3360

## UPMC Shadyside Family Health Center

HIV risk assessment, testing, PrEP prescriptions Shadyside | 412-623-2287

#### Forbes Family Medicine

HIV risk assessment, testing, PrEP prescriptions Monroeville | 412 457-1100

#### AIDS Free Pittsburgh

Information, connection to community resources preppgh.com | 412-773-1120

The Well Project Online resource on women and HIV http://www.thewellproject.org

#### HIVE

Online resource on reproductive and sexual wellness and HIV http://hiveonlie.org

Inside pages of resource booklet

Construct	Description	Questions	Source/Citation
Sociodemographic Data to Characteristics age, rel educati	Data to describe the sample (e.g., age, relationship status, education, income, health	What is the main reason you are at the health center today?	Services available at downtown Pittsburgh PPWP clinic according to website
	insurance, reason for clinic visit)	How old are you?	Developed by study team
		How would you describe your current relationship status?	Developed by study team
		Are you currently living with a male sexual partner?	Developed by study team
		What is your preferred birth control method?	Adapted from the birth control methods listed as offered by the Pittsburgh PPWP clinic
		What type or types of health insurance do you have?	Developed by study team
		What is the highest grade or level of education you have completed?	Developed by study team
	What would you say your annual income is?	Developed by study team	
		How would you describe your race?	Developed by study team
		Would you consider yourself to be Hispanic or Latina?	Developed by study team
		Sexual orientation	Developed by study team
		Approximately how many miles did you travel to get to the clinic today?	Developed by study team
PrEP Awareness	Aware of PrEP, know others on PrEP	Have you ever heard of HIV-negative persons using HIV medicines before sex to reduce their chances of getting HIV?	Adapted from (Holloway et al., 2017; T. C. Willie et al., 2017)
		Do you know anyone who has taken HIV medicines before sex to reduce their chances of getting HIV?	Adapted from (Holloway et al., 2017; T. C. Willie et al., 2017)
PrEP Use	Previous or current PrEP use	Have you ever used HIV medicines before sex to reduce your chances of getting HIV?	Developed by study team
		Are you currently using HIV medicines before sex to reduce your chances of getting HIV?	Developed by study team

# Table B.3 Survey Constructs

Intimate Partner Violence Experience	Recent (past 12 months) and lifetime experience of sexual,	Partner insulted or swore or shouted or yelled at you? [psychological]	(Straus & E.M., 2004)
	physical, psychological violence by an intimate partner	Partner pushed, shoved, or slapped you? [physical]	(Straus & E.M., 2004)
		Partner punched, kicked, or beat you up? [physical]	(Straus & E.M., 2004)
		Partner destroyed something belonging to you or threatened to hit you? [psychological]	(Straus & E.M., 2004)
		Partner used force (like hitting, holding down, or using a weapon) to make you have sex? [sexual]	(Straus & E.M., 2004)
		Partner insisted on sex when you did not want to or insisted on sex without a condom (but did not use physical force)? [sexual]	(Straus & E.M., 2004)
		You were afraid to ask your partner to use a condom? [sexual]	Adapted from (Decker et al., 2014)
		You were afraid to refuse sex with a sexual partner? [sexual]	Adapted from (Decker et al., 2014)
HIV Risk Perception	HIV testing, HIV status, PEP use, HIV risky partner, HIV worry,	Have you ever been tested for HIV?	Developed by study team
		What was the result of your most recent HIV test?	Developed by study team
		How worried are you about HIV in the next 6 months?	Adapted from (Garfinkel et al., 2017)
		Have you ever used <b>PEP</b> ( <b>p</b> ost- <b>e</b> xposure <b>p</b> rophylaxis) because you were nervous you had been exposed to HIV during sex or sharing needles? <b>PEP</b> is a medicine that may be taken after a suspected exposure like condomless sex with someone who may have HIV or a sexual assault.	Developed by study team
		Are any of your current male sexual partners at risk of HIV, through sexual or drug using behavior?	Adapted from CDC indicator for PrEP eligibility among heterosexual women
HIV Risk Factors	Previous STI diagnosis, condom	How many male partners have you had in the past 12 months?	Developed by study team
	us	In the past 12 months, how often did you use a condom during sex (vaginal or anal) with a man?	Developed by study team

		In the past 12 months, how many times have you tested positive for a sexually transmitted infection (been told by a doctor or other health care professional that you had a sexually transmitted infection)? By sexually transmitted infection (STI) we mean, for example, chlamydia, gonorrhea (also known as the clap), syphilis, herpes, genital warts, or Hepatitis B.	Adapted from (Decker et al., 2014)
		In the past 12 months, how many times have you had sex (vaginal or anal) with a man who has HIV, or have you had sex with a man whose HIV status you did not know?	Adapted from CDC indicator for PrEP eligibility among heterosexual women
		In the past 12 months, how many times have you traded sex or sexual acts in exchange for money, drugs, shelter, gifts, or other resources?	Adapted from CDC indicator for PrEP eligibility among heterosexual women
Dependent Variable			
PrEP Acceptability Willingness to use Open-ended ques requesting reason willing/not willing	Willingness to use PrEP. Open-ended questions requesting reasons for	Would you be willing to take a pill every day if you could protect yourself from getting HIV during sex?	Adapted from (Eisingerich et al., 2012; Garfinkel et al., 2017; T. Willie et al., 2017; T. C. Willie et al., 2017)
	willing/not willing to use PrEP.	We are interested in understanding more about your willingness to use PrEP. In the space below, please tell us more about why you would be willing to use PrEP. [free text]	Developed by study team
		We are interested in understanding more about your willingness to use PrEP. In the space below, please tell us more about why you are not willing to use PrEP. [free text]	Developed by study team
Barriers to PrEP Acceptability	Attitudes towards PrEP	Access/Affordability (6 items)	(Holloway et al., 2017)
	acceptability assessed across 34 statements and nine categories	Stigma (5 items)	(Holloway et al., 2017)
C a c v	Open-ended questions explored additional factors (relationship, community social) influencing women's willingness to use PrEP.	Partner Reaction (4 items)	Developed by study team; informed by factors impacting HIV prevention among women in IPV contexts (Braksmajer et al., 2016; Goparaju et al., 2017)
		Drug Effects (5 items)	(Holloway et al., 2017)
		Perceived Benefits (5 items)	(Holloway et al., 2017) + "being in control" developed by study team

Table B.3 Continued

	Risk Compensation (2 items)	(Holloway et al., 2017)
-	Lack of Perceived Need (2 items)	(Holloway et al., 2017)
-	Medical Mistrust (2 items)	(Holloway et al., 2017)
-	Adherence (3 items)	(Holloway et al., 2017) + "hide from sexual partners" developed by study team
-	We are interested in understanding more about how relationships may impact women's willingness to use PrEP. In the space below, please tell us what else about <b>romantic or sexual relationships</b> may impact, positively or negatively, women's willingness to use PrEP? [free text]	Developed by study team
	We are interested in understanding more about how community or society may impact women's willingness to use PrEP. In the space below, please tell us what else about <b>community or society</b> may impact, positively or negatively, women's willingness to use PrEP? [free text]	Developed by study team
-	We are interested in understanding more about how anything else may impact women's willingness to use PrEP. In the space below, please tell us about <b>anything else</b> that may impact, positively or negatively, women's willingness to use PrEP? [free text]	Developed by study team

Factor	Item
1. Access/Affordability	I wouldn't be able to take PrEP because I don't have a doctor or healthcare provider
(6 items)	I wouldn't be able to take PrEP because I don't have health insurance
	I don't know how to enroll in health insurance so I can start taking PrEP
	I wouldn't be able to afford PrEP
	I don't know how to find a doctor who can give me a PrEP prescription
	I don't know where to go to get a PrEP prescription
2. Stigma	I would be concerned about my sexual partner(s) finding out if I started taking PrEP
(5 items)	I would be concerned about family members finding out if I started taking PrEP
	I would be concerned about friends finding out if I started taking PrEP
	I would be uncomfortable asking a doctor for PrEP prescription
	I would be uncomfortable talking to a doctor about my sexual behavior
3. Partner Reaction	My sexual partner(s) would argue with me about PrEP if I started taking it*
(4 items)	I would be concerned that my sexual partner(s) would think I was having sex with other people if I started taking PrEP*
	My sexual partner(s) would support me if I started taking PrEP*
	I would be concerned that my sexual partner(s) would think I was accusing him of having sex with other people if I started taking PrEP*
4. Drug Effects	Not knowing if there are long-term side effects of taking PrEP makes me very uncomfortable
(5 items)	I am concerned about side effects or feeling sick from taking PrEP
	I am concerned that PrEP is only partially effective
	I would be very uncomfortable taking HIV medicines when I don't have HIV
	I would take PrEP if there weren't any side effects
5. Perceived Benefits	Taking PrEP would be a good way to protect myself from getting HIV
(5 items)	PrEP would help me worry less about getting HIV
	PrEP use should be encouraged to prevent the spread of HIV
	PrEP would allow me to be in control of protecting myself from getting HIV*
	I would use condoms less if I started taking PrEP
6. Risk Compensation	I am concerned that I would take more sexual risks if I started taking PrEP
(2 items)	I think people who take PrEP will take more sexual risks
7. Lack of Perceived Need	I don't need PrEP because I always use condoms
(2 items)	I don't need PrEP because I'm not at risk for getting HIV
8. Mistrust	I don't trust doctors or healthcare providers
(2 items)	I don't trust drug companies
9. Adherence	It would be difficult for me to remember to take PrEP every day
(3 items)	It would be difficult for me to take a pill every day because I would hide it from my sexual partner(s)*
	It would be difficult for me to see my doctor every 2-3 months for follow-up if I started taking PrEP
* Indicates items created o	r modified by study team.

# Table B.4 Barriers to PrEP Acceptability

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