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Acceptability and Correlates of Pre-Exposure Prophylaxis Use for HIV Prevention among High-Risk Drug Users in Treatment

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Acceptability and Correlates of Pre-Exposure Prophylaxis Use for HIV Prevention among High-Risk Drug Users in Treatment

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ABSTRACT

Background

Although people who use drugs (PWUD) are a key population recommended to receive pre-exposure prophylaxis (PrEP) to prevent HIV, few data are available to guide PrEP delivery in this underserved group. We therefore examined the willingness to initiate PrEP, the anticipation of HIV risk reduction while on PrEP, and the acceptability of PrEP based on a number of known PrEP attributes among high-risk PWUD.

Methods

In a cross-sectional study of 400 HIV-negative, opioid dependent individuals enrolled in a methadone program and reporting recent risk behaviors, we examined independent correlates of being willing to initiate PrEP. Participants also ranked the eight hypothetical PrEP program scenarios with varied combinations of six attributes related to PrEP (cost, dosing, efficacy, side-effects, treatment setting, and frequency of HIV testing).

Results

While only 72 (18%) were aware of PrEP, after being given a description of it, 251 (62.7%) were willing to initiate PrEP. Willingness to initiate PrEP was associated with having neurocognitive impairment (aOR=3.184, p=0.004) and higher perceived HIV risk (aOR=8.044, p<0.001). Among those willing to initiate PrEP, only 12.5% and 28.2%, respectively, indicated that they would always use condoms and not share

injection equipment while on PrEP. PrEP acceptability ranged from 30.6% to 86.3% with a mean acceptability of 56.2% across the eight hypothetical PrEP program scenarios. The PrEP program scenario with the highest acceptability had the following attribute levels: insurance covered, daily dosing, 95% effective, no side-effects, treatment at HIV clinic, and HIV testing needed every six months.

Conclusions

Our findings showed high acceptability of PrEP in response to different PrEP program scenarios with different attribute profiles. While willingness to initiate PrEP was high and correlated with being at elevated risk for HIV and having NCI, anticipated higher risk behaviors in this group even while on PrEP suggests that the next generation of HIV prevention approaches may need to combine biomedical and behavioral components to improve adherence to PrEP and to sustain HIV risk reduction over time.

INTRODUCTION

Background

HIV (Human Immunodeficiency Virus) continues to be a major global public health issue. Since the start of the epidemic, more than 70 million people have become infected with HIV globally and 35 million have died of AIDS-related illnesses. In 2016 alone, approximately 36.7 million people were living with HIV (PLWH), including 1.8 million children, with a global HIV prevalence of 0.8% among adults aged 15-49 years. The same year, there were roughly 1.8 million new HIV infections – a decline from 2.1 million new infections in 2015, and about 1 million deaths from HIV-related illnesses were reported in the same year (UNAIDS, 2017). The burden of the epidemic continues to vary considerably between countries and regions, with the vast majority of PLWH located in low- and middle- income countries.

HIV remains a persistent problem for the United States as well. The Centers for Disease Control and Prevention (CDC) estimated that a 1.1 million people in the United States were living with HIV at the end of 2014. Nearly one in seven of those are unaware of their HIV sero-status. In 2014, there were an estimated 37,600 new HIV infections, which represents a decline of 10% from 2010 (CDC, 2016b). The size of the epidemic is relatively small compared to the country's population, but is heavily concentrated among several key affected populations. Most new HIV infections occur among men who have sex with men (MSM), with African American/black men who have sex with men most affected. African American/black heterosexual women are also disproportionately affected (CDC, 2016b).

According to the recent CDC estimates, of the 1.1 million PLWH in the United States in 2014, an estimated 85% were diagnosed. This means that 15% (approximately 1 in 6 PLWH) were unaware of their infection and therefore not considering the care and treatment they need to stay healthy. Of those PLWH, 62% received HIV-related care, 48% were retained in care, and 49% had achieved viral suppression. In other words, approximately 3 out of 5 PLWH had the virus under control (CDC, 2016c). The CDC further estimated that 9 out of 10 HIV infections were transmitted by people who are not diagnosed or not in care. Reducing the number of undiagnosed HIV infections and getting more people into care present the greatest opportunities to improve viral suppression in America. This underscores the importance of continued and intensified efforts to reach more people with testing and to make sure that those with the HIV receive prompt, ongoing care and treatment to help them live longer, healthier lives and prevent the spread of HIV to others.

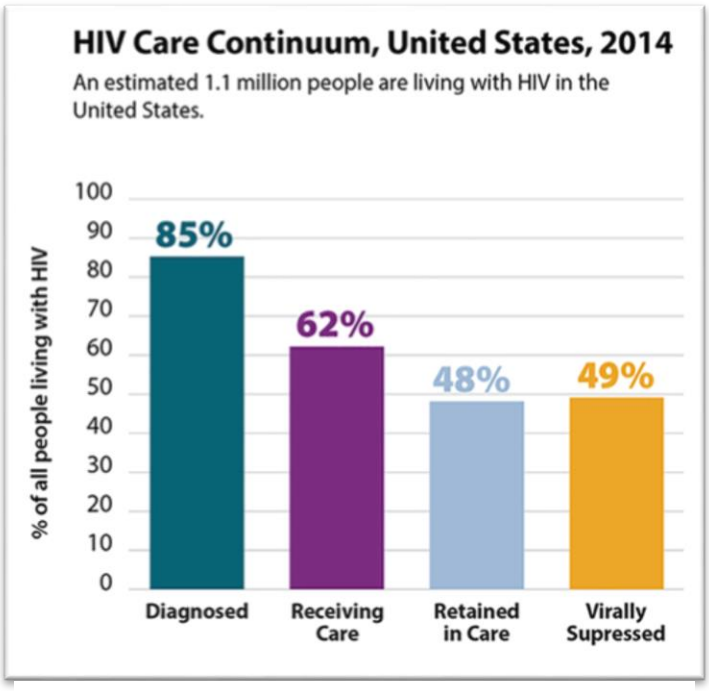

Figure 1: HIV continuum of care, U.S., 2014 (CDC, 2016c)

From the outset of the HIV epidemic, the use of substance, including alcohol use, injection drug use (IDU), and non-IDU, has been closely associated for its potential

influence on HIV disease progression (Degenhardt et al., 2013). Despite the recent decline in the proportion of HIV infections attributed to people who use drugs (PWUD) (CDC, 2016b), they still remain a priority population because of the potential for an increase in HIV transmission as a result of preventable drug-related (e.g., needle sharing) and sex-related (e.g., inconsistent condom use) risk behaviors (Alipour, Haghdoost, Sajadi, & Zolala, 2013; Marshall et al., 2014; Nadol et al., 2016; Strathdee et al., 2010; Volkow & Montaner, 2011). Failing to effectively intervene with PWUD has resulted in poor individual outcomes, and also threatens public health by increasing the likelihood of HIV transmission via PWUD. These high-risk individuals – and the communities in which they live – would greatly benefit from improving and expanding existing EBIs, and introducing new approaches to HIV prevention.

HIV oral pre-exposure prophylaxis (PrEP), which involves routine self-administration of antiretroviral medication, Truvada™ (Tenofovir/emtricitabine), represents a significant innovation in our public health response to reduce the HIV epidemic. Large-scale clinical trials have proven daily PrEP to be safe, well-tolerated, and efficacious for reducing HIV infection among those who are at substantial risk of acquiring HIV infection, such as men who have sex with men (MSM), people who inject drugs (PWID), sex workers, and transgender people (Baeten et al., 2012; Choopanya et al., 2013; Grant et al., 2010; Thigpen et al., 2012; Van Damme et al., 2012). Based on this evidence, the World Health Organization (WHO) and the US Centers for Disease Control and Prevention (CDC) have recommended PrEP for individuals at substantial risk for HIV infection (CDC, 2014; WHO, 2015), and the US National HIV/AIDS Strategy through 2020 priorities have expanded access to comprehensive PrEP services among

those who are interested and may benefit (The White House Office of National AIDS Policy, 2015).

Despite the unequivocal evidence and widespread PrEP availability in the US and its coverage by almost all insurance, its uptake among the most-at-risk populations, has been strikingly low (Kirby & Thornber-Dunwell, 2014), and non-existent among PWUD. The overall success of the PrEP strategy, which hinges heavily on PrEP uptake, involves a high level of user awareness, willingness to use it, and compliance (Peng et al., 2012). In recent years, there has been growth in studies examining attitudes, awareness, and willingness to use PrEP, especially among MSM, with limited research among high-risk PWUD (Ferrer et al., 2016; Goedel, Halkitis, Greene, & Duncan, 2016; Gredig, Uggowitzer, Hassler, Weber, & Nideröst, 2016; Hoagland et al., 2016; Holt et al., 2012; Kuo et al., 2016; Peng et al., 2012; Stein, Thurmond, & Bailey, 2014; Young, Li, & McDaid, 2013). Whether or not PWUD enrolled in substance abuse treatment would be willing to initiate PrEP, however, has not be explored. Furthermore, no prior studies have assessed individuals' anticipated likelihood of engaging in safer drug use (i.e., not sharing of needles/works) and safer sex (i.e., consistent condom use) while on PrEP among PWUD within a drug treatment setting (e.g., methadone maintenance program: MMP) where high risk individuals are concentrated.

PrEP programs developed based on stakeholders' preferences may improve successful identification, engagement, and adherence of individuals at substantial risk for HIV infection in PrEP care, as highlighted in the PrEP cascade. In this context, few studies have assessed information about individuals' attitudes and preferences of various attributes (e.g., cost, side-effects, dose, dispensing venue, etc.) of PrEP

programs. Those studies were, however, focused mostly among MSM (Eisingerich et al., 2012; Galea et al., 2011a; Wheelock et al., 2013), and no such studies have been conducted among PWUD within a drug treatment setting (e.g., methadone maintenance program: MMP) where high risk individuals are concentrated. As demonstration projects are beginning to develop, there is an urgent need to understand how high-risk PWUD value various aspects of PrEP programs.

A variety of behavioral, clinical, service delivery, socio-cultural, and other structural challenges represent a significant challenge to PrEP implementation among this underserved population. Prior studies have primarily focused on other risk populations, including MSM and transgender individuals, and no studies have been conducted among PWUD within a MMP to assess patients' willingness to use PrEP nor the influence of various attributes on PrEP program acceptability. A novel aspect of this thesis is that the results from this study will be the first to offer valuable insights that can help care providers implement PrEP more effectively among PWUD by focusing our efforts on the most critical aspects of PrEP treatment. Importantly, this study will provide preliminary evidence to inform the initiation of PrEP services and integration of additional strategies (e.g., behavioral interventions) within MMPs to optimize HIV prevention efforts.

Research Objectives

The overall objective of this study was to understand individuals' awareness and willingness to use PrEP and to investigate preferences about the delivery of the PrEP

program among high-risk PWUD in treatment. Specifically, three research aims were proposed to facilitate achieving the overall objective of the study:

- To assess awareness and willingness to use PrEP among high-risk PWUD in treatment.
- To assess demographic and behavioral correlates of willingness to use PrEP among high-risk PWUD in treatment.
- To investigate the acceptability of hypothetical PrEP programs and the impact of various PrEP attributes on PrEP program acceptability among high-risk PWUD in treatment.

LITERATURE REVIEW

Available HIV Prevention Strategies

Over the last three decades, research has led to a growing number of efficacious and cost-effective strategies to reduce the risk of HIV infection. Many of these approaches can be particularly effective when tailored to address the social, community, financial, and structural factors that place specific groups at risk. In the United States, proven strategies (CDC, 2016a) include:

HIV testing and linkage to care: Testing is a critical component of prevention efforts because when people learn they are infected, research shows that they take steps to protect their own health and prevent HIV transmission to others. Linkage to care helps ensure PLWH receive life-saving medical care and treatment, and helps reduce their risk of transmitting HIV (Christopoulos et al., 2011).

Antiretroviral therapy (ART): Treating PLWH early in their infection dramatically reduces the risk of transmitting the virus to others, underscoring the importance of HIV testing and access to medical care and treatment. Treatment as Prevention (TaP) has emerged as one of the ways for reducing the risk of transmission from HIV-infected pregnant women to their infants (Carpenter et al., 2000; WHO, 2012).Access to condoms and sterile syringes: In order for HIV prevention efforts to work, PWLH, or at risk for, HIV infection need to have access to effective prevention tools (CDC, 2016a).

Substance abuse treatment: Effective substance abuse treatment that helps PWUD stop injecting eliminates the risk of HIV transmission through injection drug use (CDC, 2016a).

Screening and treatment for other sexually transmitted infections: Many sexually transmitted infections (STIs) increase an individual's risk of acquiring and transmitting HIV, and STI treatment may reduce HIV viral load. Therefore, STI screening and treatment may reduce risk for HIV transmission (CDC, 2016a).

In addition, ***pre-exposure prophylaxis, or PrEP***, is a new prevention intervention in which HIV-uninfected people take a daily dose of antiretroviral medication to lower their chances of acquiring HIV (CDC, 2014; WHO, 2015). The efficacy of oral PrEP has been shown in recent randomized control trials and is highest when the drug is used as directed (Baeten et al., 2012; Choopanya et al., 2013; Grant et al., 2010; Thigpen et al., 2012; Van Damme et al., 2012).

Pre-Exposure Prophylaxis (PrEP)

The recent advent of PrEP has provided unprecedented opportunities in our public health response to curtail the HIV epidemic. Findings from recent PrEP trials have demonstrated that daily PrEP dose can significantly reduce the risk of HIV transmission among those who are at substantial risk of acquiring HIV infection, such as MSM, people who inject drugs (PWID), sex workers, and transgender people (Baeten et al., 2012; Choopanya et al., 2013; Grant et al., 2010; Thigpen et al., 2012; Van Damme et al., 2012). Based on these findings, the CDC released clinical practice guidelines on the use of PrEP for HIV prevention, identifying high-risk PWUD as one of the key populations that could benefit from the use of PrEP (CDC, 2014). The guidelines also indicate that PrEP should be given as an additional prevention choice

for people who are at substantial risk of HIV infection as part of combination HIV prevention approaches.

PrEP Guidelines

On the basis of this evidence, the Centers for Disease Control and Prevention (CDC) issued guidance on the use of PrEP in 2012 and published updated Clinical Practice Guidelines on 2014 (CDC, 2014). The major area covered by the guidelines are *(Table 1 in appendices)*:

- Daily oral PrEP has been shown to be effective in reducing the risk of HIV acquisition in adults.
- Current data on the efficacy and safety of PrEP for adolescents are not sufficient.
- HIV infection must be excluded by symptom history and HIV testing immediately before PrEP is prescribed.
- HIV infection should be assessed at least every 3 months and renal function at every 6 months after the patients is taking PrEP.
- Health care provider should provide access, directly or by facilitated referral to confirmed effective risk-reduction services.

In July 2015, the White House released an updated National HIV/AIDS Strategy for the United States, which highlights PrEP as a main tool in preventing HIV (The White House, 2015). In 2012, World Health Organization (WHO) endorsed the use of PrEP to MSM, sero-discordant couples, and transgender people (World Health Organization,

2012). Based on the findings of recent evidence of effectiveness of PrEP, in 2015 WHO broadened and developed the consolidated HIV guidelines to all groups of population incorporating MSM, IDUs, sex workers, transgender people, prisoners and other closed settings who are at substantial risk of acquiring HIV infection (WHO, 2015). Offering PrEP based on individual assessment rather than risk group is key factor in new recommendations. New recommendations also focuses on PrEP to be given as an additional prevention choice for people who are at substantial risk of HIV infection as part of combination HIV prevention approaches (WHO, 2015). Thus, the new recommendations facilitate a broader group of risk populations being positioned to benefit from this additional prevention alternative.

Key Evidences

Cost-effectiveness

A number of studies have evaluated the cost–effectiveness of oral antiretroviral PrEP, reporting results as the cost per infection averted, cost per life-year saved, cost per quality-adjusted life-year gained, cost per disability-adjusted life-year (DALY) averted and years on PrEP per infection averted (Hankins, 2014; WHO, 2015). A recent systematic review of 13 of the cost–effectiveness studies for PrEP found that PrEP could be a potentially cost-effective addition to HIV-prevention programs, particularly when those at highest risk of HIV exposure are prioritized, that is, where HIV incidence is highest. However, when the current price of drugs is high, as in Peru, PrEP may not be reasonable even if it could have a significant impact among MSM (Gomez et al., 2013). Studies have found PrEP to be cost-effective - depending on the cost of the drug

and delivery systems - when PrEP uptake is higher among people at substantial risk (Grant et al., 2014). The results vary widely depending on epidemic type, location and model parameters, including efficacy, cost, HIV incidence and target population (Alistar, Grant, & Bendavid, 2014; WHO, 2015). For example, while PrEP could have impact in key populations such as MSM, the first priority for PWIDs might be expanding access to antiretroviral treatment (ART) and opioid substitution therapy. In considering trade-offs, prioritizing PrEP for young women in southern Africa who are at alarmingly high risk of HIV acquisition can be cost-effective, especially when there are costly obstacles to recruiting HIV-positive people for treatment using the same drug (Hankins, Macklin, & Warren, 2015).

Equity and Acceptability

Averting HIV infection among PrEP users will contribute to equitable health outcomes by sustaining their health and the health of their sexual partners. Extending PrEP recommendations beyond narrowly defined groups (such as MSM and sero-discordant couples) allows for more equitable access and will reduce future treatment costs overall by preventing HIV infection in populations with a high incidence. PrEP acceptability has been reported in multiple populations: women, sero-discordant couples, female sex workers (FSWs), young women, PWID, transgender people, service providers and MSM (Ayala et al., 2013; Brooks et al., 2012; Ferrer et al., 2016; Frankis, Young, Lorimer, Davis, & Flowers, 2016; Galea et al., 2011b; Hosek et al., 2013; Jayakumaran, Aaron, Gracely, Schriver, & Szep, 2016; Mensch, Van Der Straten, & Katzen, 2012; Underhill et al., 2012; Van der Elst, Mbogua, Operario, Mutua, Kuo,

Mugo, Kanungi, Singh, Haberer, & Priddy, 2013; Yang et al., 2013). Population support for the provision of PrEP was based on the knowledge of safety and effectiveness and the compatibility of PrEP with other prevention strategies (WHO, 2015).

Feasibility

Large scale PrEP trials focused on various population groups have proven feasibility and safety in terms of administration among diverse trial settings and demonstration projects (Baeten et al., 2012; Grant et al., 2014; Grohskopf et al., 2013; Hosek et al., 2013; Marrazzo et al., 2015; Martin, Vanichseni, et al., 2014; Mayer et al., 2015; Peterson et al., 2007; Rajchgot et al., 2016; Thigpen et al., 2012; Van Damme et al., 2012). For example, the iPrEx OLE project and the Partners Demonstration project both showed that PrEP implementation is feasible for different populations, including men and women (Baeten et al., 2012; Choopanya et al., 2013). The PROUD study, conducted in the United Kingdom and designed to mimic real-life settings, demonstrated that PrEP is feasible and effective and is not associated with significant changes in behavioral risk (McCormack & Dunn, 2015). Similarly, PrEP trials in Botswana, South Africa, Thailand and the United States confirmed that protective levels of adherence are feasible for most PrEP users (Bekker et al., 2015; Henderson et al., 2015; Holtz et al., 2015; Liu, Cohen, Vittinghoff, & Anderson, 2015; Mannheimer, Hirsch-Moverman, & Loquere, 2015), although challenges remain to achieve optimal PrEP adherence, particularly among young people (Liu et al., 2015). Two placebo-controlled trials among women found significant barriers to uptake and adherence (Marrazzo et al., 2015; Van Damme et al., 2012). PrEP adherence among women has been high when open-label

PrEP is provided (HPTN 067 ADAPT Study and the TDF2 Open Label Extension) (Bekker et al., 2015; Thigpen et al., 2012).

Adherence to PrEP

Studies to date on daily oral PrEP indicate that medication adherence is the key to achieving the maximum prevention benefit from HIV acquisition (Baeten et al., 2012; Grant et al., 2014; Grohskopf et al., 2013; Marrazzo et al., 2015; Martin, Vanichseni, et al., 2014; Peterson et al., 2007; Thigpen et al., 2012; Van Damme et al., 2012). A recent review of the ART adherence studies over the past decade and adherence data from completed PrEP trials suggests various approaches to effectively support medication adherence (Koenig, Lyles, & Smith, 2013). These approaches include educating patients about their medications; helping them anticipate and manage side effects; helping them establish dosing routines that aligns with their work and social schedules; providing reminder systems and tools; addressing financial, substance abuse, or mental health needs that may impede adherence; and facilitating social support (Amico, Mansoor, Corneli, Torjesen, & Van Der Straten, 2013; CDC, 2014; Koenig, Lyles, & Smith; Tangmunkongvorakul et al., 2013; Ware et al., 2012).

METHOD

Participants

Between June and July 2016, a convenience sample of 400 participants was recruited at Connecticut's largest MMP. Screening eligibility included: i) being 18 years or older, ii) reporting HIV-uninfected, iii) reporting drug- or sex-related HIV risk behaviors in the past 6 months, and iv) being able to understand, speak, and read English. All patients were stabilized on methadone to treat opioid dependence. Among the 438 MMP clients approached, 28 did not meet eligibility criteria and an additional 10 either did not agree to study participation or chose not to complete the entire survey, leaving 400 individuals for the final analytical sample.

Study Setting and Procedures

We conducted a cross-sectional study of high-risk PWUD at Connecticut's largest addiction treatment program (APT Foundation, New Haven, Connecticut), which provides opioid agonist treatments (methadone and buprenorphine) and clinical care to over 7,000 opioid-dependent PWUD. Convenience sampling was used to recruit participants through flyers, peers, word-of-mouth, and direct referral from counselors. Screening was conducted by trained research assistants in a private room at APT Foundation or by phone. Individuals who met inclusion criteria and expressed interest in participating completed informed consent procedures in person and were administered a 45-minute survey (range: 40 - 60 minutes) using an audio computer-assisted self-interview (ACASI). All participants were reimbursed for the time and effort needed to

participate in the survey. The study protocol was approved by the Institutional Review Board at the University of Connecticut and received board approval from the APT Foundation, Inc.

Measures

In addition to demographic and social characteristics, we assessed health insurance status, visits to health care providers in the past 12 months and current methadone dose. We assessed whether participants were prescribed any medication (other than methadone) in the past 30 days and, for those who were, we assessed medication adherence using a self-reported, validated three-item scale developed by Wilson et al. (2016). Summary scales were calculated as the mean of the three individual items with higher score indicating better adherence (0 – 100) (Wilson, Lee, Michaud, Fowler, & Rogers, 2016).

Awareness and Willingness to Use PrEP

Participants were asked about their awareness and previous use of PrEP. Their willingness to use PrEP was assessed after providing a brief description of PrEP (Appendix). Participants were asked to respond to a statement "*I would be interested in taking PrEP to reduce my current risk of HIV infection*" on a five-point Likert scale. Their score was further dichotomized as "*Yes*" (strongly agree and agree) and "*No*" (strongly disagree, disagree, and neutral). Some further hypothetical questions were asked to assess participants' anticipation of engaging in HIV risk reduction behaviors while on PrEP: "*How confident are you that you would always use condoms while on PrEP?*",

and "*How confident are you that you would stop sharing needles or works completely while on PrEP?*" The 5-point Likert response ranged from "*Not at all confident*" to "*Completely confident*". This variable was further dichotomized as "*Yes*" (completely confident) and "*No*" (any other response, including being "not at all confident" to "very confident", but "not completely confident"). We chose to dichotomize these variables of interest for better interpretability and simplicity and in order to be more conservative in operationalizing the variables (i.e., consistently using condom and never sharing of injection equipment).

Correlates of Willingness to Use PrEP

Covariate measures included were based on prior research (refs here**). Neurocognitive impairment (NCI) was measured using the Brief Inventory of Neurocognitive Impairment (BINI), which is a brief, 54-item self-reported measure of neuropsychological symptoms (Copenhaver, Shrestha, Wickersham, Weikum, & Altice, 2016). The overall BINI score, which was obtained by summing responses to all items, was converted to standardized scores (i.e., z-scores). Participants with a z-score ≥ 0.5 were classified as moderately to severely neurocognitively "*impaired*", whereas those with a z-score < 0.5 were classified as "*not impaired*" (Dwan, Ownsworth, Chambers, Walker, & Shum, 2015). The overall internal consistency (Cronbach's alpha) for the BINI scale was 0.97. Depressive symptoms were assessed using the 20-item Center for Epidemiological Studies Depression Scale (CES-D), with ≥16 indicative of moderate to

severe depression (Radloff, 1977). The overall internal consistency (Cronbach's alpha) for the scale was 0.92.

Alcohol use disorders were measured using the validated 10-item Alcohol Use Disorders Identification Test (AUDIT), with standard cut-offs ≥ 8 for men and ≥ 4 for women suggestive of an AUD (Babor, Higgins-Biddle, Saunders, & Monteiro, 2001). The overall international consistency for the AUDIT was 0.92. Current drug- and sex-related risk was assessed for the past 30 days using an adapted version of the HIV risk-taking behavior scale (HRBS) (Ward, Darke, & Hall, 1990). Risk perception for HIV was measured by the question "*What do you think your current risk of getting HIV is?*" with possible options being "*no risk as all*", "*moderate risk*", or "*high risk*". Participants' satisfaction with previous HIV prevention methods was assessed using the question "*Are you satisfied with your current method of HIV protection (e.g., condom use, clean needle use)?*"

Conjoint Analysis

We used full-profile conjoint analysis approach to assess the acceptability of various hypothetical PrEP-related scenarios and to quantify the importance of key hypothetical and known PrEP attributes on acceptability. Briefly, conjoint analysis is a statistical technique often used to quantify consumer preferences for goods and services. It enables researchers to test what combination of program attributes is most critical in participants' decision-making and which attributes are most preferred (Bridges, 2003; Ryan et al., 2001). It has been applied successfully to measure preferences in economics and market research (Annunziata & Vecchio, 2013; Foxall, Menon, &

Sigurdsson, 2016; Uchida, Onozaka, Morita, & Managi, 2014) and recently has gained popularity in the health care studies (Bridges, Kinter, Kidane, Heinzen, & McCormick, 2008; Flynn, 2010; Kievit, Van Hulst, Van Riel, & Fraenkel, 2010; Lee, Newman, Comulada, Cunningham, & Duan, 2012; Marshall, McGregor, & Currie, 2010).

Based on themes that emerged from prior studies on PrEP acceptability (Eisingerich et al., 2012; Galea et al., 2011a; Shrestha, Altice, Karki, & Copenhaver, 2017; Wheelock et al., 2013) and input from PrEP experts, we composed six two-level PrEP program design attributes that included: Cost (*insurance covered* vs. *out-of-pocket*), dosing (*daily* vs. *on demand*), efficacy level at preventing HIV (*95%* vs. *75%*), side-effects (*none* vs. *nausea/dizziness*), treatment setting (*HIV clinic* vs. *drug treatment clinic*), and frequency of HIV testing needed (*every 6 months* vs. *every 3 months*) (Table 2).

A full-factorial design for six attributes, each with two levels, yielded 64 (26 = 64) different PrEP program scenarios. Since asking participants to rate all 64 scenarios would be difficult and burdensome, we used a fractional factorial orthogonal design (Ryan, McIntosh, & Shackley, 1998) to generate a subset of all of the possible combinations called an orthogonal array that allowed estimation of the part-worth utilities for all main effects. Part-worth utility is the value respondents attach to a specific level of a particular attribute. Relative importance reflects the influence of each attribute on a participant's decision-making. The 'Generate Orthogonal Design procedure' was used to generate an orthogonal array and is typically the starting point of a conjoint analysis. It is commonly used to reduce the number of profiles that have to be evaluated, while ensuring enough data are available for statistical analysis, resulting in

a carefully controlled set of "profiles" for the respondent to consider (Ryan et al., 1998). This resulted in an orthogonal main effects design, thus yielding as much statistical information as possible for estimating unbiased, precise preference parameters, such as ensuring the absence of multicollinearity between attributes (i.e. attributes included in the model are not correlated), equal preference weights in calculating efficiency. The statistical procedure involved removing from the original set of 64, scenarios that were linearly related to one other. We reduced the number of scenarios from 64 to 8 while ensuring that all of the attribute/level combinations appeared with the same frequency.

The attributes were described in lay language with examples to aid comprehension. Participants were then asked to rank the eight hypothetical PrEP program scenarios (Figure 1) from 1 (“*most likely to use*”) to 8 (“*least likely to use*”), which were presented concurrently, but none of the scenarios could share the same value. The scenarios were presented in random order to prevent potential biases related to order effects.

Data Analyses

All data analyses were performed using SPSS v. 23 (IBM Corp., 2015), and statistical significance was set at $p<0.05$.

Awareness and Willingness to Use PrEP

We computed descriptive statistics, including frequencies and percentages for categorical variables, and means and standard deviations for continuous variables.

Correlates of Willingness to Use PrEP

After conducting bivariate analyses for significant associations of participants' characteristics with their willingness to use PrEP, we conducted multivariate logistic regression analyses on bivariate associations found to be significant at $p<0.10$. We examined the correlates expressed as adjusted odds ratios (aORs) and their 95% confidence intervals (95% CI). The final model was ultimately selected based on goodness-of-fit using the Hosmer and Lemeshow Test (Hosmer, Hosmer, Le Cessie, & Lemeshow, 1997).

Conjoint Analysis

We used conjoint analysis to assess the acceptability of hypothetical PrEP scenarios and to quantify the impact of various PrEP attributes on acceptability. For the first conjoint analysis exercise, the acceptability of each of the eight hypothetical PrEP program scenarios was derived by averaging individual PrEP program acceptability ratings across respondents. Ratings from each PrEP program was transformed into a 0–100 scale, whereby ''*highly likely would accept*'' = 100 and ''*highly unlikely would accept*'' = 0. For the second conjoint analysis exercise, we used the "*conjoint*" procedure that utilizes the rankings of the different PrEP program scenarios for each participant to assess the impact of PrEP attributes. The conjoint procedure uses a set of linear regressions to generate utility scores for each attribute level. The utility score, called a part worth, is an estimate of the overall preference of utility associated with each attribute level used to define the PrEP program. The utility score for each factor level is analogous to regression coefficients and provide a quantitative measure of the

preference for each factor level, with larger values corresponding to greater preference. The relative importance score for each PrEP attribute provides a measure of how important the attribute is to overall preference with greater score playing a more significant role than those with smaller score. We expressed the utility scores on a common scale in percentage terms. We then calculated the relative importance score by taking the range of utility scores for any attribute levels (highest minus lowest), dividing this by the sum of all the utility ranges, and multiplying by 100 (IBM Corp., 2015; Ross, Avery, & Foss, 2003).

RESULTS

Participant Characteristics

Among the 400 participants, the average age of the participants was 40.9 ± 11.1 years and 58.5% were male. Self-reported HIV risk behaviors were highly prevalent with 57.5% reporting recent drug injection (past 30 days) with two-thirds of these reporting sharing needles/works. Of those who were sexually active (82.0%), 39.9% reported having multiple sexual partners, yet 85.1% reported condom less sex with casual sexual partners. Most participants reported having taken prescribed medication (other than methadone) in the past 30 days, with a mean medication adherence score of 73.3 (SD=15.4) on a scale of 0–100. Approximately one-third of participants were classified as being neurocognitively impaired, and 74.3% and 47.0% met screening criteria for depression and AUDs, respectively. Self-reported HIV risk behaviors were highly prevalent. Over half of participants reported being satisfied with their current method of HIV prevention and two-thirds perceived that they were at risk of acquiring HIV.

Awareness and Willingness to Use PrEP

Only 18% of participants reported having heard of PrEP as a method to prevent HIV transmission and 1.8% had ever used it. Conversations with friends (6.5%) and health care providers (4.8%) were noted as the top sources of PrEP knowledge (Figure 1). Nearly two-thirds of participants (62.7%) reported that they would be willing to use PrEP to reduce their risk of HIV infection. Participants willing to initiate PrEP were asked about their anticipated sexual and drug-related risk behaviors while on PrEP, and only

12.5% indicated that they would consistently use condoms while on PrEP. Regarding drug-related risk, only 28.2% of participants reported that they would not share injection equipment while on PrEP (Figure 1).

Correlates of Willingness to Use PrEP

While Table 2 shows the bivariate correlates of being willing to initiate PrEP, Table 3 shows the independent correlates associated with this outcome in multivariate modeling. Specifically, being neurocognitively impaired was associated with over a three-fold odds (aOR=3.184, p=0.004) of being willing to initiate PrEP. Additionally, compared to those who did not perceive themselves to be at risk for HIV, those with moderate (aOR=4.439, p<0.001) and high (aOR=8.044, p<0.001) perceived risk were significantly more likely to be willing to initiate PrEP.

Conjoint Analysis

PrEP acceptability ranged from 30.6% to 86.3% with a mean acceptability of 56.2% across the eight hypothetical PrEP program scenarios (Table 4). The PrEP program scenario with the highest acceptability (scenario 1) had the following attributes: lower cost (insurance covered), daily dosing, 95% effective, no side effects, prescription at a HIV clinic, and HIV testing every 6 months.

When the eight PrEP attributes were examined individually, however, the marginal utility for each attribute differed from the optimal program on several key attributes when comparing the preferred versus the non-preferred attributes. The cost associated with PrEP was the single most important attribute for participants.

Participants reported higher acceptability if the cost of PrEP was covered by insurance (Marginal utility score: *MUS*=1.43), compared to paying out-of-pocket (*MUS* = -1.43), yielding a net relative importance score (RIS) of 38.8. Efficacy of PrEP had the second-greatest impact on PrEP acceptability. Participants reported higher acceptability for PrEP when it was 95% effective (*MUS*=0.70) compared with 75% effective (*MUS* = -0.70), yielding a RIS of 20.5. Side effects had the third-greatest impact on PrEP acceptability with an overall RIS of 11.9. There was a notable preference for PrEP with no side effects (*MUS* = 0.29) compared to PrEP with even minor side effects (*MUS* = -0.29). Dosing frequency (*RIS* = 10.3), treatment location (*RIS* = 9.9), and frequency of associated HIV testing (*RIS* = 8.3) had relatively low influence on PrEP acceptability. Compared to taking PrEP *on demand* (*MUS* = -0.03), participants preferred taking PrEP on a *daily* basis (*MUS* = 0.03). Receiving PrEP in drug treatment clinics (*MUS* = 0.19) rather than in HIV clinics (*MUS* = -0.19) was preferred. The preferred frequency of associated HIV testing was every 6 months (*MUS* = 0.02) as opposed to every 3 months (MUS = -0.02) (Table 5 and Figure 3).

DISCUSSION

Given the dearth of literature examining the interest in or initiation of PrEP among PWUD, we sought to directly assess this risk group for their willingness to use PrEP and their perceptions about how PrEP might affect their drug and sexual risk behaviors. Furthermore, we aimed to assess PrEP acceptability, as well as utilizing conjoint analysis to quantify key attributes associated with PrEP acceptability in this key population. Overall, several important findings were gleaned from this study that have major implications for PrEP scale-up in MMP settings, where PrEP use among PWUD was originally examined (Choopanya et al., 2013).

Almost none of our participants (<2%) had ever taken PrEP and few (18%) were even aware of PrEP. This is especially concerning given that this is a population at high-risk for HIV, and who have frequent contact with various treatment providers (e.g., through MMPs and elsewhere). This represents missed opportunities to initiate, or at least discuss, PrEP among PWUD. Limited PrEP awareness and use among PWUD here is similar to that reported elsewhere among female sex workers in China (Peng et al., 2012) and among other studies of PWUD in the U.S. (Kuo et al., 2016; Stein et al., 2014), but PrEP awareness here was lower than that reported in studies of MSM (Ferrer et al., 2016; Goedel et al., 2016; Hoagland et al., 2016; Young et al., 2013). The higher level of knowledge about PrEP in MSM may stem from a number of PrEP initiatives that have primarily focused on MSM and HIV sero-negative partners in sero-discordant couples (Ware et al., 2012). Recent studies have also shown that many addiction treatment providers, with whom MMP patients are in daily contact, have limited

awareness of PrEP (Shrestha, Karki, Frederick, & Copenhaver, 2016; Spector, Remien, & Tross, 2015). In the context of clinical settings, including MMP patients in this study, treatment providers have great potential to engage their at-risk clients about PrEP through counseling, referrals, research trials, and may also effectively promote adherence to PrEP through counseling and monitoring. Our findings highlight the need for ongoing training for MMP providers, so they can refer clients to PrEP and promote PrEP adherence, as they would for other services (e.g., offer risk reduction items, HIV testing, referral) relevant to HIV prevention.

When information deficits about PrEP were corrected by describing its potential benefits, interest in initiating PrEP increased markedly, with nearly two-thirds (62.7%) of participants being willing to initiate PrEP. Importantly, those who stand to benefit the most from PrEP (i.e., those at highest risk for HIV) tended to be most interested in it. Specifically, those who accurately perceived themselves as being at higher risk for acquiring HIV were most willing to initiate it, as well as those with neurocognitive impairment, which is associated with higher HIV risk behaviors (Anand, Springer, Copenhaver, & Altice, 2010; Huedo-Medina, Shrestha, & Copenhaver, 2016; Shrestha & Copenhaver, 2016a). Together, these findings support PrEP expansion for PWUD enrolled in MMP.

The combination of high sex- and drug-related risk in MMP patients suggests that PrEP would be ideal for this risk group, just as reported in the original PrEP trial among PWID. In addition to the biomedical prevention benefits of PrEP, the structured nature of MMPs and the requirement for regular counseling suggests that MMP settings could

readily support the integration of PrEP into existing evidenced-based behavioral risk reduction strategies.

Furthermore, we found that higher willingness to initiate PrEP was associated with participants having NCI, which is highly prevalent (~30%) among this risk group (Shrestha, Huedo-Medina, Altice, Krishnan, & Copenhaver, 2016). In prior studies (Anderson, Higgins, Ownby, & Waldrop-Valverde, 2015; Attonito, Devieux, Lerner, Hospital, & Rosenberg, 2014; Becker, Thames, Woo, Castellon, & Hinkin, 2011), cognitive deficits have been associated with risky behaviors, poor medication adherence, and treatment disengagement (Anand et al., 2010; Shrestha, Huedo-Medina, & Copenhaver, 2015; Verdejo-Garcia & Perez-Garcia, 2007; Vo, Schacht, Mintzer, & Fishman, 2014). Given the relationship between NCI and higher HIV risk behaviors, this is an important group of PWUD who might benefit from PrEP. NCI may also undermine the efficacy of PrEP since high levels of adherence are required for its efficacy (Baeten et al., 2012; Choopanya et al., 2013; Grant et al., 2010; Shrestha, Karki, Huedo-Medina, & Copenhaver, 2016; Thigpen et al., 2012; Van Damme et al., 2012). For PWUD with NCI initiating PrEP, it is therefore crucial to couple PrEP with a behavioral approach to support medication adherence, such as cues and reminders or other cognitive remediation strategies (Barlati, Deste, De Peri, Ariu, & Vita, 2013; Cole-Lewis & Kershaw, 2010; Finitsis, Pellowski, & Johnson, 2014; Pop-Eleches et al., 2011).

Participants' overall perception of HIV risk was relatively high in this cohort of PWUD. We found that individuals who perceived themselves to be at higher risk of contracting HIV reported greater willingness to initiate PrEP, which is consistent with that reported in prior studies among MSM (Eisingerich et al., 2012; Golub, Gamarel,

Rendina, Surace, & Lelutiu-Weinberger, 2013; Wheelock et al., 2013; Young et al., 2013). The results suggest that participants are making rational judgments about their own risk levels when considering whether to initiate PrEP. This may indicate not only be a concern about risk of HIV infection but also a self-management response to their HIV risk behaviors (Young et al., 2013). Thus, self-management programs, which have been shown to have positive outcomes in a variety of long-term conditions (e.g., diabetes, hypertension, arthritis) (Martin, Chinnock, et al., 2014), may be of specific usefulness to promote self-management aspects of HIV prevention, such as HIV risk reduction strategies and PrEP. Alternatively, PrEP may be seen as an important HIV prevention approach in itself if, as our data suggest found, these individuals are unlikely to start using condoms more consistently (Holt et al., 2012). Overall, our findings suggest the need to consider how at-risk PWUD perceive and respond to their HIV risks as this may have a significant impact on the development and roll-out of PrEP-related programs targeting various risk populations.

Similar to other PrEP studies, findings here suggest that those who start PrEP are unlikely to then modify their risk behaviors. While these data do not support risk compensation as an anticipated behavioral response by PWUD, they do suggest that this population is ideal for PrEP and opens opportunities for integrating biomedical and behavioral interventions to enhance adherence and reduce other sexually transmitted infections (STIs) and blood-borne viral infections. Despite variable findings from other PrEP studies showing no risk compensation in clinical trials (Grant et al., 2010; McCormack et al.; Molina et al., 2015) but elevated risk-taking in other observational studies (Golub et al., 2013; Zhou et al., 2012), such responses should be closely

examined in further PrEP studies in PWUD. Furthermore, prior studies have shown that biomedical approaches to HIV prevention are optimized when they are combined with evidence-based behavioral strategies including structural interventions that increase access to services, decrease costs, and reduce stigma and discrimination to ensure broad scale implementation, teaching HIV risk reduction and PrEP adherence skills, routinely testing for HIV and STIs, and monitoring/supporting PrEP adherence over time.

Results from our conjoint analysis reveal variations in participants' attitudes and preferences of PrEP attributes that collectively or individually may help to strengthen the PrEP cascade (Liu et al., 2012). PrEP acceptability exceeded 80% for two case scenarios. Two key attributes were central to both scenarios – low cost and high (95%) efficacy – with other attributes varying between the two scenarios. It is not surprising that low cost (PrEP covered by insurance) dominated the individual program attributes, especially given the high unemployment level and 78% of the sample earning markedly below the poverty level for Connecticut. This finding also aligns with that from previous studies which identified cost as one of the major barriers to PrEP acceptability among MSM, female sex workers, and male-to-female transgendered individuals (Brooks et al., 2011; Galea et al., 2011a; Gersh et al., 2014; Schneider et al., 2010; Smith, Toledo, Smith, Adams, & Rothenberg, 2012). It is encouraging, however, that most private and public insurance plans in the U.S. cover the cost of PrEP, but this may be threatened if the Affordable Care Act is repealed, potentially leaving over 20 million people without insurance.

Efficacy was the second most important attribute, with 95% efficacy, as expected, being the preferred alternative, corroborating findings in Peru, a middle-income setting where patients must pay for their own medications (Galea et al., 2011a). In addition, prior studies reported similar findings, where MSM were willing to use PrEP with higher efficacy in preventing HIV (Golub, Kowalczyk, Weinberger, & Parsons, 2010; Mustanski, Johnson, Garofalo, Ryan, & Birkett, 2013); no such studies exist for PWUD. Notable here is while PrEP efficacy exceeds 90% in patients with high adherence, efficacy falls markedly at lower adherence levels (Baeten et al., 2012; Choopanya et al., 2013; Grant et al., 2010; Thigpen et al., 2012). While numerous factors contribute to medication adherence (Fisher, Amico, Fisher, & Harman, 2008), mean adherence for other medications in this sample was relatively low (Mean = 73.3). Prior research in this population suggests a high level of neurocognitive impairment (NCI) (Shrestha & Copenhaver, 2016b; Shrestha, Huedo-Medina, et al., 2016; Shrestha et al., 2015; Shrestha, Karki, Huedo-Medina, & Copenhaver, 2017), which has been associated with risky behaviors, poor medication adherence, and treatment disengagement (Anand et al., 2010; Huedo-Medina et al., 2016; Shrestha et al., 2015; Verdejo-Garcia & Perez-Garcia, 2007; Vo et al., 2014). Thus, NCI may undermine the effectiveness of PrEP if prescribed to cognitively impaired individuals, since high levels of adherence to PrEPis correlated with its efficacy (Baeten et al., 2012; Choopanya et al., 2013; Grant et al., 2010; Shrestha, Karki, Huedo-Medina, et al., 2016; Thigpen et al., 2012; Van Damme et al., 2012). One consideration for scaling up PrEP in PWUD would be to test and introduce empirically-based strategies that simultaneously address NCI and medication adherence to ensure higher PrEP efficacy. Alternatively, many more PrEP medications

are being developed and tested, including injectable, long-acting medications that can be administered once every 8-12 weeks (Landovitz, Kofron, & McCauley, 2016; Markowitz et al., 2016). In the absence of such data about adherence to PrEP medication and concomitant NCI, it may be beneficial to implement a combination HIV prevention package that includes evidence-based HIV risk reduction and PrEP adherence skills, routinely testing for HIV and STIs, and monitoring/ supporting PrEP adherence over time.

Experiencing side effects like nausea and dizziness had the third greatest impact on PrEP acceptability in the conjoint analysis. Not surprisingly, participants were concerned about potential side effects from PrEP, opting for scenarios without them. Previous studies have shown that potential side effects from PrEP medications as being one of the major barriers to uptake (Galea et al., 2011a; Gersh et al., 2014; Mack, Odhiambo, Wong, & Agot, 2014; Mustanski et al., 2013), yet numerous studies suggest that currently approved PrEP medications have few to no side effects (Baeten et al., 2012; Choopanya et al., 2013; Grant et al., 2010; Thigpen et al., 2012; Van Damme et al., 2012). Strategies like informed or shared decision-making can be useful to help guide patients to incorporate their preferences alongside evidence-based information in their decisions about initiating a medication like PrEP (Elwyn et al., 2012; Elwyn, Frosch, & Kobrin, 2016). To date, such decision aids are unavailable to at-risk individuals and pre-PrEP counseling could provide clients with skills, strategies, and support for minimizing adverse effects associated with taking PrEP (Van der Elst, Mbogua, Operario, Mutua, Kuo, Mugo, Kanungi, Singh, Haberer, Priddy, et al., 2013).

Low-threshold PrEP programs, however, may not have the luxury of extensive counseling sessions, favoring brief, evidence-based decision aids.

Participants preferred to receive treatment at an addiction treatment program (e.g., MMP) rather than a HIV clinic. Though not explored here, this finding may either represent a convenience factor for patients who might prefer integrated or co-located services (Sylla, Bruce, Kamarulzaman, & Altice, 2007), or alternatively, they perceived high levels of HIV stigma by attending such sites, even though they do not have HIV. For patients who preferred this attribute, there may be multiple advantages, including either combining supervised of methadone and PrEP medication, which has been successfully done for other diseases (Batki, Gruber, Bradley, Bradley, & Delucchi, 2002; Bruce et al., 2012; Litwin et al., 2009; Morozova, Dvoryak, & Altice, 2013; O'Connor et al., 1999), or when not feasible, to take advantage of the regular interaction with clinical staff supervising methadone administration to inquire about adherence and provide brief counseling when needed. Although HIV and TB services have been successfully integrated into addiction treatment settings (Bachireddy et al., 2014; Haddad, Zelenev, & Altice, 2013), further research is needed to ascertain the feasibility of integrating PrEP into such settings.

Consistent with national recommendations, participants in this study preferred PrEP to be taken on a daily basis, regardless of event-level risk-taking that would support PrEP taken *on-demand* only as needed. *On-demand* PrEP has only been documented to be effective in reducing HIV transmission only in MSM. Daily PrEP, however, is efficacious among all key populations (Baeten et al., 2012; Choopanya et al., 2013; Grant et al., 2010; Thigpen et al., 2012; Van Damme et al., 2012). This

finding aligns well with their interest in receiving PrEP at addiction treatment settings, like MMPs, where there is the potential for integration of services and daily supervision. Though integrating HIV testing at addiction treatment settings is an evidence-based practice (Metsch et al., 2012), many real-world treatment settings do not integrate such practices, preferring to refer offsite for either logistical or staffing reasons (Chadwick, Andrade, Altice, & Petry, 2014). Last, our sample generally preferred minimal testing and low levels of interaction with their healthcare provider. The desired frequency of HIV testing while on PrEP was every six months in this sample, similar to previous studies (Eisingerich et al., 2012; Wheelock et al., 2013), but inconsistent with national guidelines that recommend side-effect monitoring and testing for HIV and sexually transmitted infections every three months (CDC, 2014; WHO, 2015). Where guidelines are discordant with patient preferences, however, uptake or retention may be suboptimal, especially in PWUD who are presently uninformed about PrEP. In tailoring programs for this population, designing better PrEP program with brief follow-up calls or texting strategies may address their concerns about more frequently monitoring.

Our data further indicated that participants were willing to make trade-offs in exchange for having the PrEP program they prefer. For example, participants were willing to attend a HIV clinic or accept PrEP with lower efficacy to avoid side effects (i.e., nausea, dizziness) associated with PrEP. In other instances, participants were willing to pay out-of-pocket in exchange for a 20% increase in PrEP efficacy from 75% to 95%. Much has been learned from PrEP demonstration programs targeting MSM (Cohen et al., 2015; Hosek et al., 2017; Liu et al., 2014; Liu, Cohen, Vittinghoff, & et al., 2016), and many such lessons might be applied to PWUD, but nonetheless, the PrEP cascade will

be optimized, including satisfaction, if patient preferences are incorporated into treatment decision-making process.

Study Limitations

Our overall findings are not without limitations. As with all cross-sectional studies, we are only able to assess associations between variables rather than causal relationships. The use of self-reported measures may have resulted in participant underreporting of socially undesirable behaviors (e.g., drug- and sex-related risk behaviors) or inconsistently reporting (e.g., HIV status) because of stigma or fear of judgment. Additionally, our use of self-report measures may have resulted in participant underreporting or inconsistent reporting (e.g., HIV status) of socially undesirable behaviors. Although a brief explanation about PrEP was provided, we do not know the extent to which participants understood every attribute/aspect of PrEP (e.g., effectiveness, cost, side-effects, dispensing venue, adherence, etc.) when ranking the PrEP program scenarios and/or providing responses regarding their willingness to initiate PrEP. The participants in this study were high-risk PWUD enrolled in MMP; thus, our findings may not be generalizable to PWUD in other settings. PrEP characteristics modelled in our analysis did not include factors such as perception of HIV risk, trust in health care providers, stigma and discrimination, or satisfaction with current HIV prevention methods, which could also impact PrEP acceptability. We dichotomized our variables of interest (e.g., willingness to use PrEP), which may have resulted in the loss of some valuable information during the process. Finally, the use of the BINI, although a very user-friendly and convenient screening instrument for difficult-to-reach populations,

is not designed to measure as many cognitive domains as a comprehensive battery of tests.

SUMMARY AND FUTURE IMPLICATIONS

PrEP represents an important biomedical innovation in evidence-based primary HIV prevention among key risk populations. Although PWUD are one of the key risk populations who could benefit from the use of PrEP (CDC, 2014; Shrestha, Karki, Altice, et al., 2017; WHO, 2015), there have been no published studies conducted incorporating the use of PrEP into HIV prevention approaches targeting this underserved group. As part of our formative work, we conducted this study to understand whether high-risk PWUD are interested in taking PrEP and how these individuals value various aspects of PrEP treatment. As such, this study investigated the acceptability of PrEP based on a number of known PrEP attributes and factors related to willingness to use PrEP among high-risk PWUD in an addiction treatment setting. To our knowledge, this is also the first study to utilize conjoint analysis procedure to examine the preferences and future acceptability of attributes of PrEP program among high-risk PWUD in the context of a substance abuse treatment setting. Key findings include low knowledge about PrEP, but when informed, high levels of PrEP acceptability if PrEP delivery programs for PWUD are optimally designed. Findings further suggest that PWUD who would benefit from PrEP most were those most interested in receiving it. Moreover, the structured setting of MMPs provides an ideal clinical context in which to integrate biomedical and behavioral interventions in order to optimize HIV prevention efforts. The findings from this study provide preliminary evidence in support of the development and implementation of a PrEP program integrated into existing evidence-based HIV prevention efforts that target high risk PWUD. This will help guide

implementation of PrEP among high-risk PWUD in the context of common drug treatment settings and has the potential to significantly improve the PrEP continuum of care. Future studies are warranted to investigate the actual uptake of PrEP and to implement evidence-based interventions to improve PrEP continuum of care among this underserved population.

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Table 1: Characteristics of the participants (*N* = 400)

Variable	**Frequency**	**%**
Age: Mean (±SD)	40.9 (11.1)	
Gender		
Male	234	58.5
Female	166	41.5
Sexual orientation		
Heterosexual or straight	345	86.3
Homosexual, gay, or lesbian	16	4.0
Bisexual	39	9.7
Ethnicity		
White	253	63.2
African American	70	17.5
Hispanic or Latino	61	15.3
Other	16	4.0
Marital status		
Married	83	20.8
Divorced	111	27.8
Widowed	14	3.5
Single	192	48.0
High school graduate	293	73.3
Employed	69	17.3
Annual Income		
< $10,000	312	78.0
$10,000 - $19,999	57	14.2
≥ $20,000	31	7.8
Injected drugs *(past 30 days)*	230	57.5
Shared needles/works *(past 30 days)*	*n = 230*	
No	80	34.8
Yes	150	65.2
Sexually active *(past 30 days)*	328	82.0
Number of sexual partners *(past 30 days)*	*n = 328*	
1	197	60.0
2 – 5	116	35.4
≥ 6	15	4.6
Always used condom with casual partner	*n = 328*	
No casual partner	64	19.5
No	215	65.6
Yes	49	14.9
Taking prescribed medication	308	77.0
Medication adherence: Mean (SD)	73.3 (15.4)	
Heard about PrEP	72	18.0
Ever taken PrEP	7	1.8

Legend: SD: standard deviation; PrEP: pre-exposure prophylaxis

Table 2: Characteristics of participants and HIV transmission risk behaviors, stratified by their willingness to use PrEP

Variables	Willingness to use		OR (95% CI)	*p*
	No *(n = 149)*	**Yes** *(n = 251)*		
Characteristics of participants				
Age: Mean (SD)	39.7 (11.4)	41.8 (10.8)	1.017 (.999, 1.037)	0.070
Gender				
Male	94 (23.5)	140 (35.0)	-	-
Female	55 (13.8)	111 (27.8)	1.355 (.894, 2.053)	0.152
Sexual orientation				
Heterosexual or straight	137 (34.3)	208 (52.0)	-	-
Homosexual, gay, or lesbian	5 (1.3)	11 (2.8)	1.449 (.493, 4.262)	0.500
Bisexual	7 (1.8)	32 (8.0)	3.011 (1.292, 7.015)	0.011
Ethnicity				
Non-white	44 (11.0)	103 (25.8)	-	-
White	105 (26.3)	148 (37.0)	.602 (.391, .928)	0.022
Marital status				
Married	32 (8.0)	51 (12.8)	-	-
Divorced	33 (8.3)	78 (19.5)	1.483 (.813, 2.705)	0.199
Widowed	4 (1.0)	10 (2.5)	1.569 (.454, 5.426)	0.477
Single	80 (20.0)	112 (28.0)	.878 (.519, 1.488)	0.630
High school graduate				
No	32 (8.0)	75 (18.8)	-	-
Yes	117 (29.3)	176 (44.0)	.642 (.399, 1.032)	0.067
Employed				
No	277 (69.3)	54 (13.5)	-	-
Yes	51 (12.8)	18 (4.5)	1.054 (.615, 1.807)	0.848
Income level				
< $10,000	254 (63.5)	58 (14.5)	-	-
$10,000 - $19,999	52 (13.0)	5 (1.3)	.727 (.410, 1.288)	0.274
≥ $20,000	22 (5.5)	9 (2.3)	1.032 (.478, 2.232)	0.935
Currently have health insurance				
No	15 (3.8)	4 (1.0)	-	-
Yes	313 (78.3)	68 (17.0)	.768 (.286, 2.066)	0.601
Visited healthcare provider (past 12 months)				
No	29 (7.2)	5 (1.3)	-	-
Yes	299 (74.8)	67 (16.8)	1.198 (.586, 2.449)	0.621
Homeless (past 12 months)				
No	172 (43.0)	26 (6.5)	-	-
Yes	156 (39.0)	46 (11.5)	1.252 (.834, 1.879)	0.278
Methadone dose: Mean (SD), mg	81.3 (29.9)	81.3 (27.4)	1.000 (.993, 1.007)	0.982
Taking medication (past 30 days)				
No	38 (9.5)	54 (13.5)	-	-
Yes	111 (27.8)	197 (49.3)	1.249 (.776, 2.010)	0.360
Medication adherence: Mean (SD)	75.4 (15.8)	72.2 (15.2)	.986 (.970, 1.002)	0.076
Ever heard of PrEP				
No	120 (30.0)	208 (52.0)	-	-
Yes	29 (7.2)	43 (10.8)	.855 (.508, 1.441)	0.558
Neurocognitive impairment				
No	122 (30.5)	157 (39.3)	-	-
Yes	27 (6.8)	94 (23.5)	2.705 (1.659, 4.411)	<0.001
Moderate to Severe Depression				
No	48 (12.0)	55 (13.8)	-	-
Yes	101 (25.3)	196 (49.0)	1.694 (1.074, 2.671)	0.023
Alcohol use disorders				
No	87 (21.8)	125 (31.3)	-	-

Yes	62 (15.5)	126 (31.5)	1.437 (.940, 2.129)	0.097
HIV transmission risk behaviors				
During the past 30 days…				
Injected drugs				
No	72 (18.0)	98 (24.5)	-	-
Yes	77 (19.3)	153 (38.3)	1.460 (.969, 2.198)	0.070
Shared injection equipment				
No	32 (13.9)	48 (20.9)	-	-
Yes	45 (19.6)	105 (45.7)	1.556 (.882, 2.744)	0.127
Had sex				
No	28 (7.0)	44 (11.0)	-	-
Yes	121 (30.3)	207 (51.7)	1.089 (.645, 1.839)	0.751
Number of sexual partners				
1	83 (25.3)	114 (34.8)	-	-
2 – 5	35 (10.7)	81 (24.7)	1.685 (1.035, 2.742)	0.036
≥ 6	3 (0.9)	12 (3.7)	2.912 (.797, 10.647)	0.106
Always used condom with regular partner				
No	105 (34.1)	177 (57.5)	-	-
Yes	8 (2.6)	18 (5.8)	1.335 (.561, 3.177)	0.514
Always used condom with casual partner				
No	80 (30.3)	135 (51.1)	-	-
Yes	12 (4.5)	37 (14.0)	1.827 (.901, 3.707)	0.095
Diagnosed with STIs (past 12 months)				
No	128 (32.0)	218 (54.5)	-	-
Yes	21 (5.3)	33 (8.3)	.923 (.512, 1.663)	0.789
Perceived risk for HIV infection				
No risk at all	65 (16.3)	64 (16.0)	-	-
Moderate	57 (14.2)	88 (22.0)	1.568 (.970, 2.533)	0.065
High	27 (6.8)	99 (24.8)	3.724 (2.153, 6.441)	<0.001
Satisfied with current method of HIV prevention				
No	56 (14.0)	106 (26.5)	-	-
Yes	93 (23.3)	145 (36.3)	.824 (.544, 1.248)	0.360

Legend: PrEP: Pre-exposure prophylaxis; SD: Standard deviation; OD: Odds ratio; STIs: Sexually transmitted infections; OR: Odds ratio

Note: STIs in the past 12 months

Table 3: Multivariate logistic regression models of factors associated with willingness to use PrEP

Variables	Willingness to use PrEP		
	aOR	**95% CI**	***P***
Age	1.017	.986, 1.049	0.280
Sexual orientation			
Heterosexual or straight	-	-	-
Homosexual, gay, or lesbian	1.378	.279, 6.814	0.694
Bisexual	2.920	.930, 9.171	0.067
Ethnicity			
Non-white	-	-	-
White	1.188	.566, 2.496	0.648
High school graduate			
No	-	-	-
Yes	1.040	.482, 2.240	0.920
Neurocognitive impairment			
No	-	-	-
Yes	3.184	1.459, 6.949	0.004
Moderate to Severe Depression			
No	-	-	-
Yes	1.219	.535, 2.779	0.638
Alcohol use disorders			
No	-	-	-
Yes	1.023	.526, 1.986	0.948
Injected drugs			
No	-	-	-
Yes	.986	.483, 2.012	0.968
Number of sexual partners			
1	-	-	-
2 – 5	.714	.350, 1.455	0.353
≥ 6	.629	.126, 3.139	0.572
Always used condom with casual partner			
No	-	-	-
Yes	3.401	.940, 6.307	0.062
Perceived risk for getting HIV			
No risk at all	-	-	-
Moderate	4.439	1.959, 7.060	<0.001
High	8.044	3.012, 13.481	<0.001
Hosmer and Lemeshow Test: Chi-square = 5.439; $p = 0.710$			

Legend: aOR: Adjusted odds ratio

Table 4: Acceptability (Mean) of hypothetical pre-exposure prophylaxis (PrEP) scenarios with different attributes in order of decreasing acceptability among participants

PrEP Scenarios	PrEP Acceptability Mean	PrEP Attributes					
		Cost	Dose	Efficacy	Side Effects	Treatment Location	HIV Testing Needed
1	86.28	Insurance covered	Daily use	95%	None	HIV clinic	Every 6 months
2	82.09	Insurance covered	On demand	95%	Nausea/Dizziness	Drug treatment clinic	Every 3 months
3	70.75	Insurance covered	Daily use	75%	None	Drug treatment clinic	Every 3 months
4	57.25	Insurance covered	On demand	75%	Nausea/Dizziness	HIV clinic	Every 6 months
5	51.44	Out of Pocket	On demand	95%	None	Drug treatment clinic	Every 6 months
6	39.84	Out of Pocket	Daily use	95%	Nausea/Dizziness	HIV Clinic	Every 3 months
7	31.63	Out of Pocket	On demand	75%	None	HIV clinic	Every 3 months
8	30.56	Out of Pocket	Daily use	75%	Nausea/Dizziness	Drug treatment clinic	Every 6 months

Table 5: Relative importance and marginal utilities of PrEP attribute levels among participants

Attributes	Attribute Levels	Relative Importance Score (%)
Cost	Insurance Covered Out of pocket	38.8
Efficacy	95% 75%	20.5
Side-effects	None Nausea/dizziness	11.9
Dosing	Daily use On demand	10.3
Treatment location	Drug treatment clinic HIV clinic	9.9
HIV testing needed	Every 6 months Every 3 months	8.3

Legend: PrEP: pre-exposure prophylaxis, RIS: relative importance score

Figure 1: Variables of interest related to PrEP among participants (*N* = 400)

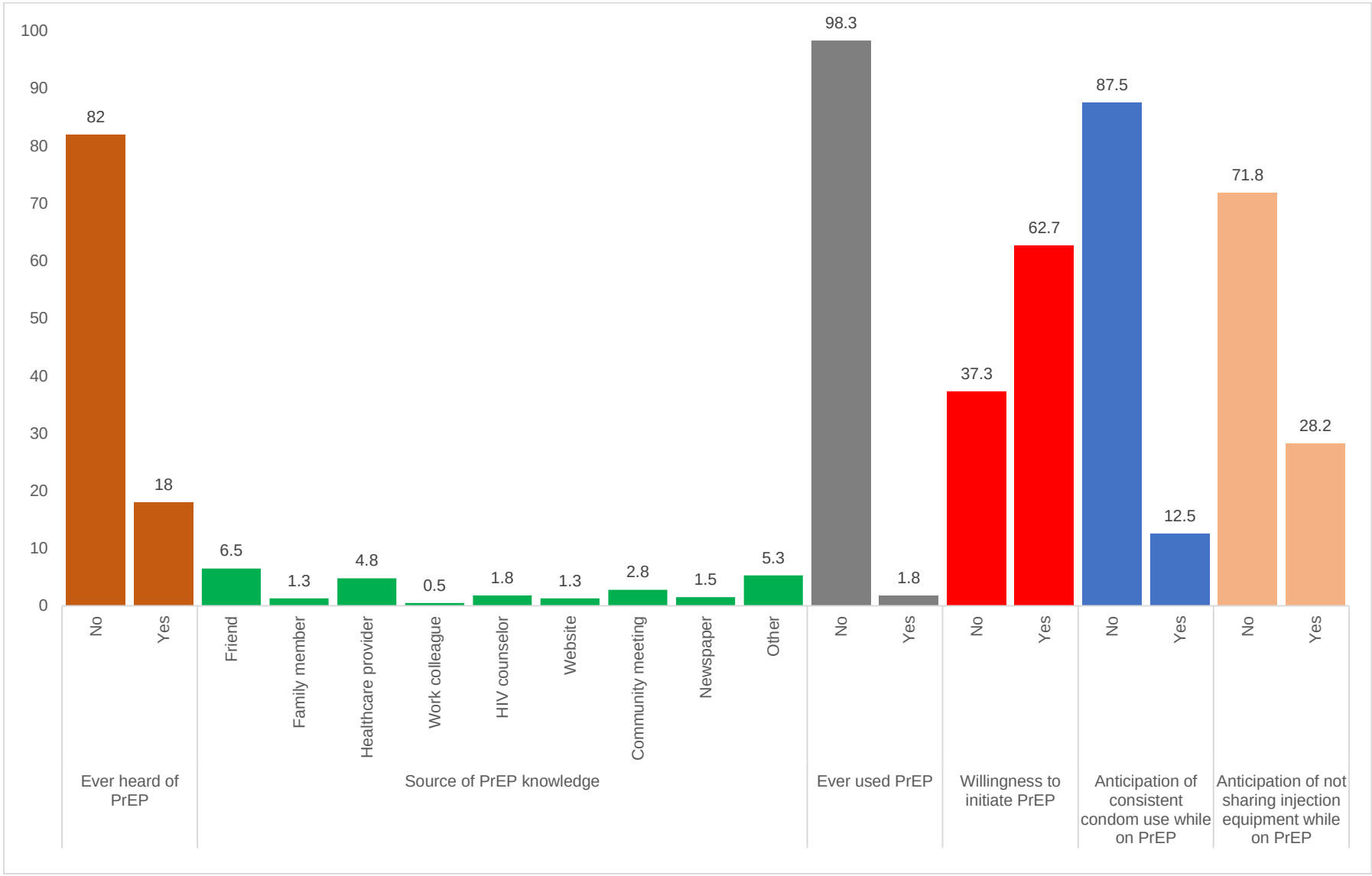


Figure 2: Example of full-profile conjoint task (hypothetical PrEP program scenarios)

On the cards, we show you next, are different hypothetical PrEP program scenarios. Please rank these hypothetical PrEP programs from 1 (=*most likely to use*) to 8 (=*least likely to use*).

[This is just your opinion, so there are no right or wrong answers.]

Scenario 1

Cost: *Out of pocket*
% Effective: *95%*
Dispensing Venue: *HIV clinic*
Dose: *Daily use*
Side Effect: *Nausea/Dizziness*
HIV Testing Associated: *Every 3 months*

Scenario 2

Cost: *Out of pocket*
% Effective: *75%*
Dispensing Venue: *HIV clinic*
Dose: *On demand*
Side Effect: *None*
HIV Testing Associated: *Every 3 months*

Scenario 3

Cost: *Insurance covered*
% Effective: *95%*
Dispensing Venue: *Drug treatment clinic*
Dose: *On demand*
Side Effect: *Nausea/Dizziness*
HIV Testing Associated: *Every 3 months*

Scenario 4

Cost: *Out of pocket*
% Effective: *75%*
Dispensing Venue: *Drug treatment clinic*
Dose: *Daily use*
Side Effect: *Nausea/Dizziness*
HIV Testing Associated: *Every 6 months*

Scenario 5

Cost: *Out of pocket*
% Effective: *95%*
Dispensing Venue: *Drug treatment clinic*
Dose: *On demand*
Side Effect: *None*
HIV Testing Associated: *Every 6 months*

Scenario 6

Cost: *Insurance covered*
% Effective: *95%*
Dispensing Venue: *HIV clinic*
Dose: *Daily use*
Side Effect: *None*
HIV Testing Associated: *Every 6 months*

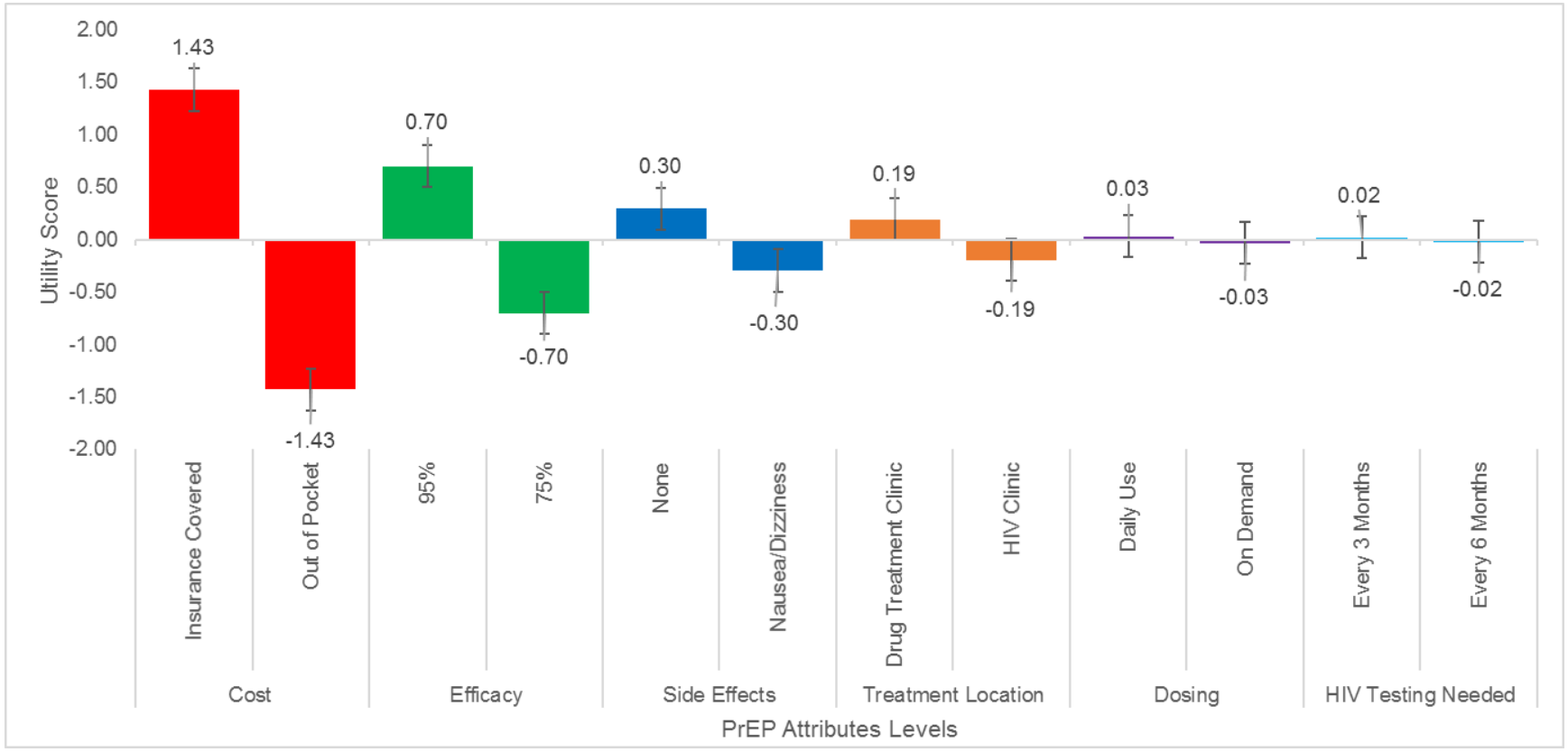
Scenario 7

Cost: *Insurance covered*
% Effective: *75%*
Dispensing Venue: *HIV clinic*
Dose: *On demand*
Side Effect: *Nausea/Dizziness*
HIV Testing Associated: *Every 6 months*

Scenario 8

Cost: *Insurance covered*
% Effective: *75%*
Dispensing Venue: *Drug treatment clinic*
Dose: *Daily use*
Side Effect: *None*
HIV Testing Associated: *Every 3 months*

Figure 3: Marginal utilities of pre-exposure prophylaxis (PrEP) attributes' levels among participants



Legend: PrEP: pre-exposure prophylaxis

* Constant: 4.467 (0.110)

Pearson's R: 0.998

Kendall's tau: 1.000

APPENDICES

Table 1: Summary of Guidance for PrEP Use

<table>
<tr><th></th><th>Men Who Have Sex with Men</th><th>Heterosexual Men and Women</th><th>Injection Drug Users</th></tr>
<tr><td>Detecting Substantial Risk of Acquiring HIV Infection</td><td>• HIV-positive sexual partner
• Recent bacterial STI
• Multiple sexual partners
• History of inconsistent or no condom use
• Commercial sex work</td><td>• HIV-positive sexual partner
• Recent bacterial STI
• Multiple sexual partners
• History of inconsistent or no condom use
• Commercial sex work
• High-prevalence area</td><td>• HIV-positive injecting partner
• Sharing needles and works
• Recent drug treatment (but currently injecting)</td></tr>
<tr><td>Clinically Eligible</td><td colspan="3">• Documented negative HIV test result before prescribing PrEP
• No signs/symptoms of acute HIV infection
• Normal renal function; no contraindicated medications
• Documented hepatitis B virus infection and vaccination status</td></tr>
<tr><td>Prescription</td><td colspan="3">Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply</td></tr>
<tr><td rowspan="2">Other Services</td><td colspan="3">Follow-up visits at least every 3 months to provide:
• HIV test, medication adherence counseling, behavioral risk reduction support.
• Side effect assessment, STI symptom assessment
• At 3 months and every 6 months thereafter, assess renal function
• Every 6 months, test for bacterial STIs</td></tr>
<tr><td>• Do oral/rectal STI testing</td><td>• Assess pregnancy intent
• Pregnancy test every 3 months</td><td>• Access to clean needles/syringes and drug treatment services</td></tr>
</table>

Table 2: Outcomes from Various PrEP RCTs

Study & Population	Protective Effect All Study Participants	Protective Effect Participants with Higher Adherence
Heterosexual men and women (Partners PrEP; TDF-2 study): Botswana, Kenya and Uganda	62% - 76%	Up to 90%
Gay men and other MSM (iPrEX study): Brazil, Ecuador, Peru, South Africa, Thailand and the United States	44%	90%
People who inject drugs (Bangkok Tenofovir Study)	49%	75%
FEM-PrEP: heterosexual women in Kenya, South Africa and the United Republic of Tanzania	<30% adherence, no effect	<30% adherence, no effect
VOICE heterosexual women in South Africa, Uganda and Zimbabwe	<30% adherence, no effect	<30% adherence, no effect

Brief description of pre-exposure prophylaxis (PrEP) provided to the participants

"*There is a new way to prevent HIV infection for people who may be exposed to the virus. It is called Pre-Exposure Prophylaxis or PrEP. It involves an HIV-negative person taking a pill daily, on an ongoing basis (starting before an exposure and continuing after for as long as the person is at risk) to reduce their risk of HIV infection. Research suggests that PrEP is generally safe and is highly effective (over 90%) in preventing HIV infection if taken every day. It is much less effective if not taken every day and does not protect against other sexually transmitted infections. Taking PrEP would require a visit to a doctor every three months in order to be tested for HIV, STIs and side effects*."

Flyer

University of Connecticut

Volunteers Wanted for a Research Study

Improving health care services during drug treatment

We are conducting a research study to assess what people think of Pre-Exposure Prophylaxis (PrEP) and how familiar people are with various kinds of communication technologies (i.e., landline phone, cell phone, and internet) and what tools would be the most helpful while in treatment to keep track of medical appointments or help remember to take medications. Upon meeting criteria, you will have to complete a survey that will take approximately 40-45 minutes.

You may be eligible to participate if ALL of the following apply to you:

- You are 18 years or older
- You are HIV-negative
- You are enrolled in methadone maintenance program
- You are available to participate in a survey
- You are able to understand, speak, and read English.

Participants will receive reimbursement for $25 for completing the survey.

To learn more about this research, please contact:
Brian, Jen, or Roman (Phone #: (203)-781-4690)

This research is conducted under the direction of Dr. Michael Copenhaver, Department of Allied Health Sciences, University of Connecticut.

UConn Protocol # H16-116

Research Study
UConn Protocol # H16-090
Contact Brian, Jen, or Roman
Phone #: 203-781-4690

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Informed Consent

Consent Form for Participation in a Research Study

UCONN
UNIVERSITY OF CONNECTICUT

Principal Investigator: Dr. Michael Copenhaver
Student Researcher: Roman Shrestha
Study Title: HIV prevention and PrEP adherence among high-risk drug users
Sponsor: National Institute on Drug Abuse

Introduction
First of all, thank you for taking the time to look over this invitation to participate in our study. You are invited to participate in a research study designed to provide us with information to improve our HIV prevention services. We are interested in hearing how familiar you are with a new treatment, Pre-exposure Prophylaxis (PrEP), and whether you believe that PrEP would be helpful as part of HIV prevention series while you are in drug treatment. We are also interested in hearing your opinion about the kinds of communication technologies (i.e., landline phone, cell phone, and internet) that you think may be helpful for you to use to support your health care while you are in drug treatment (e.g., medical appointment reminders). You have been asked to participate because you are HIV-negative and currently enrolled in drug treatment at the APT Foundation.

In order to decide whether or not you want to be a part of this study, you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, and potential benefits. We also encourage you to ask questions now and at any time. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this consent form, and you will be given a copy.

Why is this study being done?
The purpose of this research study is to hear your opinion about some ways to improve our HIV prevention services. We want to know how helpful you think the use of pre-exposure prophylaxis (PrEP) would be as part of HIV prevention in drug treatment, how familiar you are with various kinds of communication technologies (i.e., landline phone, cell phone, and internet), and what tools would be the most helpful while you're in drug treatment to keep track of when you have medical appointments or need to take medications.

What are the study procedures? What will I be asked to do?
If you agree to take part in this study, you will be asked to participate in a survey that ask you to answer questions about your knowledge and suggestions about PrEP, whether you own and use various communication devices (e.g., cell phone, smart phones), your use of the internet, as well as questions about memory challenges you may experience that may be improved by using communication devices while in drug treatment. The survey will last between 40-45 minutes and will be held in a private room at the APT Foundation.

What are the risks or inconveniences of the study?
We believe there are no known risks associated with this research study; however, a possible inconvenience may be the time it takes to complete the study and the possibility of experiencing discomfort regarding questions related to drug use and sexual risk behaviors in the survey. You are free not to answer such questions and also to withdraw yourself from participating in the research process at any time you like to do so.

If you would like to talk to a counselor about your feelings at any time, we can connect you with a counselor at the APT Foundation.

What are the benefits of the study?
You may not directly benefit from this research; however, we hope that your participation in the study may assist researchers to understand whether it will one day be helpful for care providers to develop PrEP programs and use communication technology (e.g., cell phone, smartphone) to help you remember things like when to take medications, come to medical appointments, and to get more out of your health care.

Will I receive payment for participation? Are there costs to participate?
Your participation is purely voluntary. There are no costs and you will be paid $25 in cash after the completion of the survey.

How will my personal information be protected?
We will make every effort to insure your privacy and confidentiality. If you do not choose to participate in this study, all information that you have given us will be destroyed immediately. If you do choose to participate, in all of our study records, you will be identified by a number and your name will be known only to the researcher. Your name will not appear in any publication or be released to anyone without your written consent. You should understand, however, that there is a risk that you will be recognized by other patients or staff involved in the study and that you may be recognized as a participant in a research program. But this is no greater than the usual risk of identification that occurs in your clinical care.

The following procedures will be used to protect the confidentiality of your data. The researchers will keep all study records (including any codes to your data) locked in a secure location. Research records will be labeled with a code. The code will be derived from a number (e.g. "sequential 3 digit code) that reflects how many people have enrolled in the study. A master key that links names and codes will be maintained in a separate and secure location. The master key will be destroyed after 3 years after the completion of this study. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. Data that will be shared with others will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

Data that we collect from you may be shared with other researchers in the future, but only after your name and all identifying information have been removed.

We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee 100% confidentiality. Your confidentiality cannot be guaranteed if your record is subpoenaed in a court of law or in the event the researcher determines that you are a clear and imminent danger to yourself and/or others. In addition, confidentiality cannot be guaranteed if you

disclose that you are intending to or currently sexually or physically abusing a child or an elderly person.

You should also know that the UConn Institutional Review Board (IRB) and Research Compliance Services may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

Can I stop being in the study and what are my rights?
You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate. You do not have to answer any question that you do not want to answer.

Whom do I contact if I have questions about the study?
Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this study or if you have a research-related problem, you may contact the principal investigator, Dr. Michael Copenhaver at (860) 486-2846 or the student researcher, Roman Shrestha at (203) 781-4690. If you have any questions concerning your rights as a research participant, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.

Documentation of Consent:
I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

_____	_____	_____
Participant Signature:	Print Name:	Date:
_____	_____	_____
Signature of Person Obtaining Consent	Print Name:	Date:

Screening Form

Screening Questionnaires

Interviewer: _____ Date: _____

Client name: _____ Contact: _____

1. Are you enrolled at the APT Foundation drug treatment program? Y_____ N _____

   If No, where? _____

   Dose _____

2. Are you a physician, counsellor, or other health care provider working with patients enrolled at the APT Foundation? Y____ N ____

   If No, where? _____

3. Do you currently drink alcohol? _____ (If yes, how much?) _____

4. Do you have children? _____ (If yes) Do you have custody? _____

5. Do you live in New Haven? _____ (If no, where)? _____

6. Do you have reliable transportation? _____

7. Have you ever been tattooed? _____

8. What is the highest level of school that you have completed? _____

9. Have you ever been tested for HIV? _____

   What year was the most recent test? _____

   What was the result of the test? _____

10. Have you seen a psychiatrist in the past 6 months? ____

    If yes, for what? Depression ___ PTSD _____ Schizophrenia _____

    Bipolar_____ Anxiety _____ Other_____

    If other, explain _____

11. Are you currently suicidal or homicidal? _____

Survey Questionnaires

Demographics

1. Interviewer: _____

2. Research staff, please fill in the participant number. _____

3. What year were you born? Please enter the four-digit year _____

4. What is your age? _____

5. What is your gender?
    a. Male
    b. Female
    c. Transgender

6. What is your sexual orientation?
    a. Heterosexual or straight
    b. Homosexual, gay, queer, or lesbian
    c. Bisexual
    d. Other

7. Which best describes you?
    a. White
    b. African American or Black
    c. Hispanic or Latino
    d. Asian or Pacific Islander
    e. Other

8. What is your current marital status?
    a. Now married or living with partner
    b. Divorced
    c. Separated
    d. Widowed
    e. Never married

9. What is the highest level of education you have completed?
    a. Middle School (Jr. High School) or Less
    b. Some High School, No Diploma
    c. High School Graduate / GED or Equivalent
    d. Junior (2-year) College
    e. Technical / Trade / Vocational School
    f. Some College (4-year college or university)
    g. College Graduate (4-year college or university)

10. What is your primary language?

a. English
b. Spanish
c. Other

11. What is your employment status?
    a. Working now (this includes full time work, part time work)
    b. Only temporarily laid off, sick leave or maternity leave
    c. Unemployed and looking for work
    d. Retired
    e. Disabled, permanently or temporarily
    f. Keeping house (full-time homemaker)
    g. Student
    h. Unemployed and not looking for work (not disabled or on medication)
    i. Other

12. Which is closest to your current income?
    a. Under $10,000
    b. $10,000 to $19,999
    c. $20,000 to $29,999
    d. $30,000 or more

13. Do you have health insurance?
    1. No
    2. Yes

14. What type of coverage do you have?
    a. Private health insurance
    b. Medicare
    c. Medi-gap
    d. Medicaid
    e. SCHIP
    f. Military healthcare
    g. Indian Health Service
    h. State Sponsored Plan
    i. Other government plan
    j. Single service plan
    k. Alliance
    l. Other coverage
    m. No coverage

15. Have you seen a doctor, nurse, or other health care provider in the past 12 months?
    1. No
    2. Yes

16. In the past 12 months, have you been homeless at any time? By homeless, I mean you were living on the street, in shelter, in a single room occupancy hotel, or in a car.
    1. No
    2. Yes

17. Are you currently homeless?
    1. No
    2. Yes

18. Are you currently on methadone maintenance program?
    1. No
    2. Yes

19. What is your current methadone dose? _____

20. What do you often use to help you remember take your medication?
    a. Pillbox
    b. Alarm
    c. Take it at the same time each day
    d. Ask family and friends
    e. Use a pill calendar or drug reminder chart
    f. Leave notes to remind yourself
    g. Email or calendar reminder
    h. Nurse call
    i. Text service
    j. None

Communication Technology and mHealth Scale

I. Access to and Frequency of Use of Communication Technology

1. Do you own or have access to the following devices on a daily basis (check all that apply)?

    a. Landline telephone
    b. Cell phone (without internet access)
    c. Cell phone (with internet access, i.e. a Smartphone)
    d. Tablet (e.g., iPad, Samsung Galaxy Tab, Kindle Fire etc.)
    e. Laptop
    f. Personal Computer (PC)
    g. Other devices (please write all other type of communication/mobile devices you own or have daily access to; e.g.,Personal Digital Assistant, Google Glass, Samsung Smartwatch etc.)

2. On a scale from 1 to 6 (with 1=never, 2=rarely, 3=sometimes, 4=often, 5=all the time, and 6=do not own), how often do you use the following ?

    Note: If yo do not own one of the following devices, select 'Do not own'; if you own the device but do not use it, select 'Never'.

	1 Never	2 Rarely	3 Sometimes	4 Often	5 All the time	6 Do not own
Landline						
Cell phone						
Smartphone						

Tablet						
Laptop						
PC						
Other						

II. Cell Phone/Smartphone Use

1. How many cell phones (including Smartphones) have you **ever owned**? ☐
2. How many cell phones (including Smartphones) do you own **currently**? ☐
3. Given below are different types of activities that cell phones can be used for. On a scale from 1 to 5 (with 1=never, 2=rarely, 3=sometimes, 4=often, 5=all the time), please indicate how often you engage in the following activities on your cell phone or Smartphone.

   Note: If your cell phone does not have a particular feature allowing you to carry out one or more of the following activities, select 'N/A'; however, if your cell phone has the feature but you do no use it for that activity, then select 'Never'. For example, if your cell phone does not have internet capability, select N/A for internet-related activities like accessing the internet, sending or receiving emails, online banking etc. However, if your cell phone has internet capability and you do not use it, then select 'Never'.

	Never	Rarely	Sometimes	Often	All the time	N/A
Make or receive phone calls						
Take a picture						
Record video						
Send or receive text messages						
Access the internet						
Send or receive emails						
Download applications						
Listen to music						
Watch videos						
Online banking						
Play games						
Online social networking (e.g., Facebook, Twitter, etc.)						
Use health-related apps						
Reading e-books						

III. mHealth Acceptance

Mobile technologies such as cell phones can be used in several ways to influence health outcomes, such as assessing health markers, reminding patients about medication intake and tracking health behaviors. This use of mobile technology in health research is called mHealth.

1. On a scale from 1 to 5 (with 1 being 'not interested at all' and 5 being 'extremely interested'), how interested would you be in using mHealth to remind you to take your medication?

1	2	3	4	5
Not interested at all	Slightly interested	Somewhat interested	Moderately interested	Extremely interested

IF 'NOT INTERESTED AT ALL', SKIP TO QUESTION 4.

2. How frequently are you interested to receive reminders (via phone calls, text messaes, and/or emails) to remind you to take your medication?

Daily Weekly Monthly

3. Which of the following would you prefer the most to receive a reminder to take your medication? (choose one)

Phone call Text messages Emails They are all equally fine

4. On a scale from 1 to 5 (with 1 being 'not interested at all' and 5 being 'extremely interested'), how interested would you be in using mHealth devices to receive information about HIV?

1	2	3	4	5
Not interested at all		Somewhat interested		Extremely interested

IF 'NOT INTERESTED AT ALL', SKIP TO QUESTION 7.

5. How frequently are you interested to receive information about HIV using mHealth devices (via phone calls, text messaes, and/or emails)?

Daily Weekly Monthly

6. Which of the following would you prefer the most to receive information about HIV (choose one):

Phone call Text messages Emails They are all equally fine

7. On a scale from 1 to 5 (with 1 being 'not interested at all' and 5 being 'extremely interested'), how interested would you be in using mHealth in assessing your health behaviors?

1	2	3	4	5
Not interested at all		Somewhat interested		Extremely interested

IF 'NOT INTERESTED AT ALL', SKIP TO SECTION V.

8. On a scale from 1 to 5 (with 1 being 'not interested at all' and 5 being 'extremely interested'), how interested would you be in using mHealth in assessing drug use behaviors?

1	2	3	4	5
Not interested at all		Somewhat interested		Extremely interested

9. On a scale from 1 to 5 (with 1 being 'not interested at all' and 5 being 'extremely interested'), how interested would you be in using mHealth in assessing your sexual behaviors?

1	2	3	4	5
Not interested at all		Somewhat interested		Extremely interested

Brief Inventory of Neurocognitive Impairment (BINI) Scale

Below is a list of problems which some people have. Please read each one carefully, and ask yourself how much that statement applies to you, in the past month.

Statements	0 Not at all	1 Slightly	2 Somewhat	3 Moderately	4 Extremely
I have trouble concentrating.					
My mind won't stay on any one thing.					
I have difficulty paying attention.					
My mind tends to wander.					
I often feel restless.					
I am easily distracted.					
I have trouble making up my mind.					
I have difficulty making decisions.					
I forget what I read.					
I feel frustrated quite often.					
My judgment is poor.					
Something is wrong with my mind.'					
I have trouble remembering important things.					
My thinking becomes blocked.					
I fall apart under pressure.					
I tend to give up easily.					
I forget where I put things.					
I feel everything is an effort.					
I often lose things.					
I get lost easily.					
My mind frequently goes blank.					
My reactions are slow.					
My arithmetic is poor.					
Doing simple math problems in my head is difficult.					
I count with my fingers.					
I do things slowly.					
My mind is dull.					
I forget the names of common things.					
I have trouble learning new things.					

I have forgotten much what learned in school.					
My words get mixed up.					
I have trouble writing sentences.					
My mind works slowly.					
My hearing has become worse.					
I have trouble following conversations.					
I have serious memory problems.					
I am forgetful.					
I have trouble remembering people's names.					
I have forgotten many things from my childhood.					
I am very clumsy.					
I drop things frequently.					
I bump into things.					
I fall down sometimes.					
I faint sometimes.					
I have trouble with the left side of my body.					
Part of my body is paralyzed.					
Part of my body feels numb.					
I have trouble walking.					
I have trouble with the right side of my body.					
I have a bad temper.					
I have urges to break and smash things.					
I get into arguments frequently.					
I have trouble sleeping.					
I suffer from severe pain.					
I have severe headaches.					
I have had a head injury.					
I have been knocked unconscious.					

Pre-Exposure Prophylaxis (PrEP)

There is a new way to prevent HIV infection for people who may be exposed to the virus. It is called Pre-Exposure Prophylaxis or PrEP. The use of anti-HIV medication can keep HIV negative people from becoming infected. When taken properly, PrEP is safe and highly effective (up to 99%) in preventing HIV infection. The key is taking one pill every day.

1. Before participating in this survey, have you ever heard about PrEP?
   0 No 1 Yes

2. Where did you hear about PrEP? Check all that apply.
   a. A friend
   b. A family member

c. A healthcare provider
d. A work colleague
e. An HIV prevention counselor
f. On a website
g. At a community meeting
h. From a newspaper
i. Other

3. Have you ever used PrEP?

0	1
No	Yes

IMB Items for PrEP

Information

1. Uninfected individuals who are at high risk of HIV infection (e.g., through unsafe sex or needle sharing) should take PrEP.

0	1
False	True

2. PrEP is highly effective for preventing HIV if it is taken on a daily basis.

0	1
False	True

3. Before taking PrEP, people need to be tested to confirm that they are not already infected with HIV.

0	1
False	True

4. When on PrEP, I don't need to use new or clean needles.

0	1
False	True

5. PrEP provides protection against other sexually transmitted infections (STIs), like gonorrhea and chlamydia.

0	1
False	True

6. When on PrEP, I don't need to use condoms.

0	1
False	True

7. I can stop taking PrEP if my risk of getting HIV infection becomes low because of changes in my life.

0	1
False	True

8. While I'm on PrEP, I will need to go for regular doctor visits.

0	1
False	True

9. The cost associated with the PrEP medication is not covered by the insurance.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

10. PrEP does not provide complete protection against HIV.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

11. Taking PrEP means I am putting myself at risk for HIV.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

12. The short-term side-effects of PrEP may include nausea and dizziness.

0	1
False	True

Motivation

1. It is important to me to not to get sexually transmitted infections (STIs), including HIV, in the next year.

0	1	2	3	4
Not important at all	Slightly important	Neutral	Very important	Extremely important

2. How satisfied are you with your current method of HIV protection (e.g., condom use, clean needle use)?

0	1	2	3	4
Very dissatisfied	Dissatisfied	Unsure	Satisfied	Very satisfied

3. If I were on PrEP, I'm sure that PrEP would be effective in protecting me from HIV-infection

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

4. I think I would be less worried about HIV infection if I were on PrEP.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

5. If I were on PrEP, it would take the worry out of the sex.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

6. If I were on PrEP, I would NOT be concerned about the potential side-effects of PrEP.

0	1	2	3	4

Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

7. I feel uncomfortable being prescribed a new medication.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

8. If I were on PrEP, taking it properly as prescribed would be hard.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

9. If I were on PrEP, I won't have to worry about using condoms.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

10. If I were on PrEP, I won't have to worry about sharing needles and works.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

11. If I were on PrEP, I won't have to worry about my partner's HIV status.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

12. I'm not concerned about the cost associated with PrEP medication.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

13. I would take PrEP if I know someone (e.g., friend, family member) who is currently taking it.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

14. I have a responsibility to contribute to HIV prevention efforts by using PrEP.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

15. I have family members or friends to encourage me to take PrEP properly.

0	1	2	3	4
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

16. If I disclose that I'm on PrEP to my sex partner, he/she will be comfortable with it.

0	1	2	3	4

Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

Behavioral Skills

Questions	0 Not at all confident	1 Somewhat confident	2 Moderately confident	3 Very confident	4 Completely confident
How confident are you that you would remember to take PrEP every day?					
How confident are you that you would stick to your PrEP regimen even if you have some side-effects (e.g., nausea)?					
How confident are you that you could make PrEP part of your daily routine?					
How confident are you that you could get PrEP refills before you run out?					
How confident are you that you could fill your PrEP prescription no matter what it costs?					
How confident are you that you could continue with your PrEP regimen even if getting to your clinic appointments is a major hassle?					
How confident are you that you would use condoms while on PrEP?					
How confident are you that you would stop sharing needles or works while on PrEP?					
How confident are you that you could continue with your PrEP regimen even when people close to you say it isn't a good idea.					
How confident are you that you could discuss using PrEP with your partner.					
How confident are you that you could use PrEP even if your partner didn't like it.					

Intent to use PrEP

1. I would be interested in taking PrEP to reduce my current risk of HIV infection.

0	1
No	Yes

Drug use

The next section will contain some questions about your use of drugs.

1. Have you used any illicit drugs in the pasts 3 months?

a. Yes
b. No

2. In the last 3 months, which illicit drug have you used?
    a. Heroin
    b. Cocaine
    c. OxyContin
    d. Crystal meth
    e. Percocet
    f. Marijuana
    g. others

3. In the last 3 months, what has been your primary method of illicit opiate use?
    a. IV injection
    b. Smoke
    c. Snort
    d. Oral
    e. Non-IV injection

4. In the last 3 months, have you injected any illicit drugs?
    a. Yes
    b. No

The HIV Risk-Taking Behavior Scale (HRBS)

Now, I'm going to ask you a few questions about your drug use for the last month, and, The next part of the questionnaire concerns your sex life over the last month.

Questions	0	1	2	3	4	5
How many times have you hit up (i.e. injected any drugs) in the last month?	Hasn't hit up	Once a week or less	More than once a week (but less than once a day)	Once a day	2-3 times a day	More thaan 3 times a day
How many times in the last month have you used a needle after someone else had already used it?	No times	One time	Two times	3-5 times	6-10 times	More than 10 times
How many different people have used a needle before you in the last month?	None	One person	Two people	3-5 people	6-10 people	More than 10 people
How many times in the last month has someone used a needle after you have used it?	None	One person	Two people	3-5 people	6-10 people	More than 10 people
How often, in the last month, have you cleaned needles before re-using them?	Doesn't re-use	Every time	Often	Sometimes	Rarely	Never
Before using needles again, how often in the last month did you use bleach to clean them?	Doesn't re-use	Every time	Often	Sometimes	Rarely	Never

How many people, including clients, have you had sex with in the last month?	None	One person	Two people	3-5 people	6-10 people	More than 10 people
How often have you used condoms when having sex with your regular partner(s) in the last month?	No regular partner	Every time	Often	Sometimes	Rarely	Never
How often did you use condoms when you had sex with casual partners?	No casual partners	Every time	Often	Sometimes	Rarely	Never
How often have you used condoms when you have been paid for sex in the last month?	No paid sex	Every time	Often	Sometiems	Rarely	Never
How many times did you have anal sex in the last month?	No times	One time	Two times	3-5 times	6-10 times	More than 10 times

1. What do you think your current risk of getting HIV is? Please consider your involvement in HIV transmission risk behaviors (e.g., needle sharing, no condom use) if applicable.
    a. No risk at all
    b. A little bit of risk
    c. More than a little bit of risk
    d. A lot of risk

2. Have you ever been diagnosed with any sexually transmitted infections (other than HIV) in the last 12 months? For example: Chlamydia, gonorrhea, syphilis, herpes, genital warts, etc.
    a. Yes
    b. No

Medication Adherence

1. In the last 30 days, haave you taken any medications?
    a. Yes
    b. No

2. In the last 30 days, on how many days did you miss at least one dose of any of the medication you are taking?

3. In the last 30 days, how often did you take your medication in the way you were supposed to?
    1. Never
    2. Rarely
    3. Sometimes
    4. Usually
    5. Almost always
    6. Excellent

4. In the last 30 days, how good a job did you do at taking your medication in the way you were supposed to?

1. Very poor
2. Poor
3. Fair
4. Good
5. Very good
6. excellent