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Factors Associated with Awareness of Pre-exposure Prophylaxis for HIV Among Persons Who Inject Drugs in Philadelphia: National HIV Behavioral Surveillance, 2015

Alexis Roth¹ · Nguyen Tran² · Brogan Piecara¹ · Seth Welles² · Jennifer Shinefeld³ · Kathleen Brady³

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Abstract

Persons who inject drugs (PWID) continue to experience disproportionate HIV burden. Though studies demonstrate PWID find pre-exposure prophylaxis (PrEP) acceptable, awareness and uptake remains low. Data from the 2015 PWID cycle of the National HIV Behavioral Surveillance (n=612) in Philadelphia, Pennsylvania (USA) were analyzed to evaluate how socio-demographics and behavioral factors impact PrEP awareness. Only 12.4% of PWID surveyed were PrEP-aware and 2.6% reported receiving a prescription. Factors associated with PrEP awareness included having at least some college education (aOR 2.13, 95% CI 1.03, 4.43), sharing paraphernalia (aOR 2.37, 95% CI 1.23, 4.56), obtaining syringes/needles primarily from a syringe exchange program (aOR 2.28, 95% CI 1.35, 3.87), STI testing (aOR 1.71, 95% CI 1.01, 2.89) and drug treatment (aOR 2.81, 95% CI 1.62, 4.87). Accessing prevention and health services increased the odds of being PrEP-aware; however, awareness was low overall. Additional promotion efforts are warranted.

Keywords Pre-exposure prophylaxis \cdot People who inject drugs (PWID) \cdot PrEP awareness \cdot HIV prevention \cdot Harm reduction

Introduction

Nearly 6.5 million persons living in the United States have injected drugs in their lifetime [1]. Persons who inject drugs (PWID) are disproportionally impacted by HIV in the United States. They comprised about 3% of adults but accounted for 6% of new HIV infections and 23% of persons living with HIV nationwide in 2015 [2, 3]. Recent estimates indicate that 1 in 23 women and 1 in 36 men who inject drugs will acquire HIV if nothing is done to prevent these infections [3]. HIV among PWID has decreased dramatically over time in large part due to the proliferation of syringe exchange

Alexis Roth amr395@drexel.edu

programs (SEP), which reduce parenteral exposures from syringe sharing [4–6]. However, PWID continue to experience a disproportional vulnerability to HIV.

Pre-exposure prophylaxis (PrEP) is a promising biomedical HIV prevention strategy that involves the daily use of antiretroviral medications by HIV-negative individuals to reduce their risk of acquiring HIV. In 2013, the Centers for Disease Control and Prevention (CDC) recommended emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) as PrEP for PWID as one HIV prevention option in this population [7]. However, research and programs to bring PrEP to scale have yet to focus on PWID. Therefore, research is necessary to identify strategies to successfully promote engagement in PrEP care among at-risk PWID. This study addresses this gap by assessing factors associated with PrEP awareness, the first step in engagement in PrEP care, among PWID in Philadelphia, the most prominent heroin market in the mid-Atlantic region of the United States [8–10].

Drug Use and HIV Among PWID in Philadelphia

In 1991, more than 33% of persons diagnosed with AIDS in Philadelphia were PWID [11]. To combat blood-borne

¹ Department of Community Health and Prevention, Dornsife School of Public Health, Drexel University, 3215 Market Street, Room 454, Philadelphia, PA 19104, USA

² Department of Epidemiology and Biostatistics, Dornsife School of Public Health, Drexel University, Philadelphia, PA, USA

³ Philadelphia Department of Public Health, AIDS Activities Coordinating Office, Philadelphia, PA, USA

transmission of HIV, Prevention Point Philadelphia (PPP) began to clandestinely operate an SEP in the city. In 1992, PPP was officially sanctioned to operate an SEP [11, 12]. In addition to their SEP, PPP began offering HIV education, testing, linkage to care, and case management. In 2015, PPP served approximately 5700 unduplicated clients (J. Benitez, personal communication, January 31, 2018). Scale-up of their services, along with other SEPs in the city like Project SAFE, is correlated with decreasing HIV incidence among PWID, who represented only 5.6% of new diagnoses in 2016 [13]. Similar trends in decreasing HIV incidence have been associated with the introduction of SEP programs worldwide [4–6].

Awareness and Acceptability of PrEP Among PWID

The Bangkok Tenofovir Study showed that PrEP was 49–74% effective at preventing HIV acquisition among PWID taking once daily TDF as PrEP with highest rates of effectiveness among those most adherent [14]. Other clinical trials demonstrated the effectiveness of PrEP to reduce HIV transmission with use of once daily FTC/TDF among MSM [15–17] and heterosexual men and women [18, 19]. Compared to MSM, relatively few studies have assessed acceptability of PrEP among PWID [20]. Those that have demonstrate low PrEP awareness but high acceptability once PWID are educated about PrEP [21–28].

Study Objectives

Research that identifies strategies to successfully promote engagement in PrEP care is central to the development of high impact, cost-effective PrEP interventions. Engagement in the PrEP care continuum includes (1) awareness and willingness to use PrEP, (2) ability to access PrEP care, (3) receiving a PrEP prescription, (4) adhering to PrEP, and (5) remaining engaged in care [29]. We assessed factors associated with engagement in the PrEP continuum among PWID participating in the Philadelphia arm of the 2015 NHBS IDU-4 [30–32]. Our primary outcome was PrEP awareness. Secondary outcomes were discussing PrEP with a health care provider and receiving a PrEP prescription, which were assessed among only those who were aware of PrEP.

Methods

Sampling Design and Recruitment

Data are from the 2015 NHBS survey in Philadelphia among PWID. Participants were recruited using Respondent Driven Sampling (RDS) [30]. NHBS and RDS methods have been previously described in detail [31, 32]. Briefly, RDS is a

modified chain recruitment strategy that utilizes social networks to tap into and derive population estimates from 'hidden populations' such as PWID. Study staff recruited a small number of seeds (8-10 individuals) through focus groups and community outreach. These seeds completed the survey, were offered optional HIV and Hepatitis C (HCV) testing, and were then asked to recruit up to five peers who also inject drugs. Peer respondents were offered the opportunity to be screened for eligibility; if found eligible they were also surveyed and asked to recruit up to five peers. The recruitment process continues until the desired sample size (n = 500) is achieved at the end of the study period. All participants were offered optional HIV and HCV testing and at the end of the survey were asked to recruit additional peers. Participants were compensated \$25 for completing the survey, \$25 for optional HIV testing, and \$10 per recruit; no additional incentive was offered for HCV testing. The NHBS protocol was approved by the City of Philadelphia Institutional Review Board.

Eligible participants were 18 years of age or older, able to complete the interview in English or Spanish, in possession of a valid RDS coupon (coded, non-replicable coupons that link the recruiter and the recruit), currently living in the Philadelphia Metropolitan Statistical Area defined as: Philadelphia County, Delaware County, Montgomery County, Bucks County and Chester County, and reported injecting drugs in the 12 months prior to the interview. Participants were asked to show physical evidence of their injection (e.g., track marks). If unable to provide this, they were asked a series of in-depth injection practice questions. After consenting, eligible participants completed the procedures described above.

Measures

NHBS includes questions on socio-demographics, HIVrelated risk behavior, access to and engagement in health and prevention services. For this analysis, age, current gender identity, race/ethnicity, and sexual orientation were categorized into: 18-29, 30-39, 40-49, 50 and older; male or female; non-Hispanic White, non-Hispanic Black, Hispanic/ Latinx, and other; and heterosexual/straight or lesbian/gay/ bisexual, respectively. Education was categorized into three groups: less than high school, high school degree/GED, and college or above. Homelessness was defined as living in the streets, a shelter, a single room occupancy hotel, or a car at any point in the past 12 months. Engagement in prevention and health services included yes/no responses to: having health insurance, any medical visit within 12 months, sexually transmitted infection (STI) testing within 12 months, and drug treatment within 12 months. Most common source of syringes in the past 12 months, our primary exposure of interest, was categorized into SEP, clinic/pharmacy, and secondary sources (e.g., friend, relative, sex partner, dealer, shooting gallery, or off the streets). We choose this variable as opposed to SEP access within 12 months because we hypothesized that there may be a dose relationship between accessing one HIV prevention service and the awareness of another, namely PrEP.

HIV risk behavior questions used a 12-month recall with yes/no responses unless otherwise noted. These included: condomless vaginal or anal sex, transactional sex, non-injection drug use, and poly-injection drug use. Use of injection drugs were categorized based on the frequency of drug use, including daily drug use vs. non-daily drug use. Sharing drug equipment in the past 12 months was categorized as, "does not share any drug equipment" (i.e., participants indicated not sharing syringes, cookers, cottons, or water), "share syringe only" (i.e., participants that indicated only sharing syringes) "sharing paraphernalia only" (i.e., participants that indicated sharing only paraphernalia such as cookers, cottons, or water), and "sharing syringes/paraphernalia" (i.e., participants that indicated sharing both syringes and paraphernalia).

The main outcome of interest was PrEP awareness defined as: "Before today, have you ever heard of people who do not have HIV taking PrEP, the antiretroviral medicine taken every day for months or years to reduce the risk of getting HIV?" Secondary outcomes, assessed among those who were aware of PrEP, included discussing PrEP with a health care provider (yes/no) and receiving a PrEP prescription (yes/no).

Analyses

Data presented here represent unweighted, cross-sectional data. γ^2 tests and Fisher's Exact tests (for expected small cell size < 5) were performed to describe the sample and assess the relationship between demographic characteristics, HIV risk behaviors, healthcare engagement, and PrEP awareness. Multicollinearity of HIV risk behaviors were assessed using variance inflation factor. No major concerns for multicollinearity were detected as estimates of variance inflation were less than 2.5. Backwards stepwise multivariable models were then manually built. All predictor variables with significance level ≤ 0.10 from the bivariate analyses were included and with covariates with significance level > 0.05 were removed after assessing for goodness of fit (i.e., Hosmer-Lemeshow goodness-of-fit test) and potential confounding (i.e., changes in effect estimates $\geq 10\%$). Thus, covariates with significance level > 0.05 were included in the final model if change in estimate was > 10%. Gender was included in the final multivariable model as a confounder regardless of statistical significance. All analyses were conducted using SAS 9.4 (Cary, N.C.).

Results

A total of 849 PWID were recruited. Of these, 662 participants met eligibility criteria and were screened and enrolled in the 2015 IDU IV cycle. PWID with invalid responses (n = 16), incomplete survey data (n = 10), self-reported as HIV positive either during the survey or counseling (n = 18), or those who identified as transgender (n = 5) were excluded from our analysis. In total, 612 participants with complete survey data were included in the final analysis.

The sociodemographic characteristics, frequency and type of drug use, healthcare engagement, and HIV risk behaviors of the sample (n = 612) are detailed in Table 1. Our sample was relatively diverse in sociodemographic characteristics: 25.3% were female, 32.0% were persons of color (10.6% were non-Hispanic Black, 19.0% were Hispanic/Latinx, and 2.4% were other racial/ethnic groups), 13.7% identified as lesbian/gay/bisexual, 41.7% were age 30-39, and 71.2% had at least a high school education; various forms of health utilization and HIV risk factors were also relatively high among PWID. Of the 612 participants, only 76 (12.4%) were aware of PrEP. Of those, 14 (18.4%) PWID indicated they had discussed PrEP with a health care provider. Participants who reported being aware of PrEP compared to those unaware of PrEP were more likely to be women (35.5% vs. 23.9%, p = 0.03), lesbian/gay/bisexual participants (21.0% vs. 12.7%, p = 0.05) and have at least some college education (32.9% vs. 21.5%, *p*=0.04). PrEP-aware PWID were also more likely to report attending drug treatment (71.1% vs. 47.0%, p < 0.01), receiving an STI test (56.6% vs. 39.7%, p < 0.01), sharing paraphernalia only (52.6% vs. 31.3%, p < 0.01), using non-injection drugs (86.8% vs. 73.1%, p = 0.01), and obtaining syringes primarily from an SEP (61.8% vs. 44.0%, p < 0.01). Obtaining syringes from other sources, including obtaining syringes from a clinic/ pharmacy (8.2% vs. 2.6%, p = 0.08) and from secondary sources (47.8% vs. 35.5%, p = 0.05) were significantly associated with being unaware of PrEP.

After adjusting for gender in our multivariable model, significant predictors associated with PrEP awareness (see Table 2) included: higher educational attainment [adjusted odds ratio (aOR) 2.13; 95% confidence interval (CI) 1.03, 4.43], having an STI test in past 12 months (aOR 1.71; 95% CI: 1.01, 2.89), sharing paraphernalia only in past 12 months (aOR 2.0; 95% CI 1.35, 3.87), obtaining syringes primarily from an SEP in past 12 months (aOR 2.28; 95% CI 1.35, 3.87), and participating in a drug treatment program in past 12 months (aOR 2.81; 95% CI 1.62, 4.87).

Additional analyses were conducted to understand the relationship between equipment sharing behaviors and

Table 1PrEP awareness by
demographic and behavioral
characteristics of persons
who inject drugs (PWID)
Philadelphia, NHBS 2015
(n = 612)

Variable	Total		Aware of PrEP (n=76)		Unaware of PrEP (n=536)		χ^2 statistic	p value
	n	%	n	%	n	%		
Age							1.97	0.58
18–29	160	26.1	18	23.7	142	26.5		
30–39	255	41.7	35	46.1	220	41.0		
40-49	115	18.8	16	21.0	99	18.5		
50 and older	82	13.4	7	9.2	75	14.0		
Current gender identity							4.77	0.03
Female	155	25.3	27	35.5	128	23.9		
Race							1.68	0.64
White, non-Hispanic	416	68.0	54	71.1	362	67.5		
Black, non-Hispanic	65	10.6	6	7.9	59	11.0		
Hispanic/Latinx	116	19.0	13	17.1	103	19.2		
Other ^a	15	2.4	3	3.9	12	2.3		
Sexual orientation							3.93	0.05
Lesbian, gay, or bisexual	84	13.7	16	21.0	68	12.7		
Education attainment							6.28	0.04
Less than high school	176	28.8	15	19.7	161	30.0		
High school or GED	296	48.3	36	47.4	260	48.5		
Some college or above	140	22.9	25	32.9	115	21.5		
Homeless ^b	429	70.1	57	75.0	372	69.4	0.99	0.32
Currently insured	470	76.8	64	84.2	406	75.8	2.68	0.10
Health care utilization								
Any medical visit ^b	440	71.9	52	68.4	388	72.4	0.52	0.47
Drug treatment ^b	306	50.0	54	71.1	252	47.0		< 0.01
STI test ^b	256	41.8	43	56.6	213	39.7	7.76	< 0.01
HIV risk factors								
Condomless vaginal or anal sex ^b	471	77.0	60	79.0	411	76.7	0.19	0.66
Transactional sex ^b	158	25.8	26	34.2	132	24.6	3.19	0.07
Frequency of injection drug use ^b							0.09 ^c	0.30
Daily use	574	93.8	69	90.8	505	94.2		
Non-daily use	38	6.2	7	9.2	31	5.8		
Poly injection drug use ^b	456	74.5	60	79.0	396	73.9	0.89	0.34
Non-injection drug use ^b	458	74.8	66	86.8	392	73.1	6.64	0.01
Sharing drug equipment ^b							13.52	< 0.01
Does not share any drug equipment	209	34.1	19	25.0	190	35.5		
Share paraphernalia only	208	34.0	40	52.6	168	31.3		
Share syringe only	15	2.5	e	e	14	2.6		
Share syringe/paraphernalia	180	29.4	16	21.1	164	30.6		
Most common syringe source ^b								
Syringe exchange program	283	46.3	47	61.8	236	44.0	8.49	< 0.01
Clinic/pharmacy	46	7.5	e	e	44	8.2	2.97	0.08
Secondary sources ^d	283	46.2	27	35.5	256	47.8	4.01	0.05

^aCategory includes Category includes Native American/Alaskan Native, Asian/Pacific Islander

^bIndicates within the past 12 months

^cFisher's Exact Test

^dSecondary sources include friend, relative, sex partner, dealer, shooting gallery, or off the streets

^eCounts less than 6 are not reported

Table 2Multivariable logistic regression examining PrEP awarenessamong persons who inject drugs (PWID) in Philadelphia: NationalHIV Behavioral Surveillance system injection drug user cycle, 2015:reduced model (n = 612)

	Adjusted odds ratio ^b (95% CI)			
Education attainment				
Less than high school	Ref			
High school or GED	1.52 (0.77, 2.97)			
Some college or above	2.13* (1.03, 4.43)			
STI test ^a				
Yes	1.71* (1.01, 2.89)			
No	Ref			
Sharing drug equipment ^a				
No sharing	0.94 (0.45, 1.95)			
Paraphernalia only	2.37** (1.23, 4.56)			
Syringes only	1.07 (0.13, 9.06)			
Shared syringes and paraphernalia	Ref			
Most common source of syringes-SI	$\mathbb{E}\mathbf{P}^{a}$			
Yes	2.28** (1.35, 3.87)			
No	Ref			
Participated in drug treatment program	n ^a			
Yes	2.81** (1.62, 4.87)			
No	Ref			

SEP syringe exchange program

^aIndicates within the past 12 months

^bFinal reduced model included gender as a confounder

*p < 0.05; **p < 0.01 based on Wald's χ^2 test

most common sources of syringes (see Table 3). PWID obtaining their syringes primarily from the SEP were less likely to share syringes and paraphernalia (unadjusted OR 0.61; 95% CI 0.43, 0.87) compared to those acquiring syringes from clinics/pharmacy/secondary sources. Furthermore, PWID reporting secondary sources as their most common source of syringes were 50% more likely (unadjusted OR 1.50; 95% CI 1.07, 2.10) and 76% more likely (unadjusted OR 1.76; 95% CI 1.24, 2.49) to share any drug equipment as well as share both syringes and paraphernalia, respectively.

Discussion

Despite high levels of ongoing injection and sexual HIV risk behaviors among PWID, PrEP awareness in this population remains very low. In our Philadelphia-based study, only one in eight (12.4%) participants reported ever hearing of PrEP. This low rate of PrEP awareness is similar to other NHBS samples in NY and Washington D.C. from the IDU-3 survey conducted in 2012 (8.9% and 13.4%, respectively) [22, 28] prior to the CDC's endorsement of PrEP to prevent HIV among PWID in 2013 [7]. However, PrEP

awareness in this sample is lower than among women who inject drugs in the New York City MSA from the same NHBS cycle in 2015 (12.4% in Philadelphia vs. 31.4% in NY) [23]. This signals a need to increase efforts to promote PrEP to this vulnerable population.

When we assessed for the independent predictors of PrEP awareness, not surprisingly, PWID who had engaged with harm and risk reduction programs such as the SEP (aOR 2.28; 95% CI 1.35, 3.87), drug treatment (aOR 2.81; 95% CI 1.62, 4.87), and sexual health services (aOR 1.71; 95% CI 1.01, 2.89) were nearly twice as likely to be aware of PrEP compared to PWID who did not access these programs within the past year. Access to an SEP had the greatest impact on PrEP awareness. Among those PrEP aware, a higher percentage reported obtaining syringes most commonly from the SEP compared to secondary sources or a clinic/pharmacy. While SEP engagement is associated with higher PrEP awareness, additional efforts are still needed to promote PrEP within these sites.

Interestingly, in a multivariable model, PWID who reported sharing only paraphernalia were significantly more likely to be PrEP aware compared to participants sharing both syringes and paraphernalia. PWID that share syringes face a greater risk for HIV acquisition than those sharing only paraphernalia since HIV can survive for 6 weeks or more within a syringe and results in infected blood being injected directly into the bloodstream [33, 34]. Further exploration of this association illustrated that PWID reporting lower risk for HIV (i.e., those endorsing no sharing or sharing only paraphernalia) were more likely to obtain their syringes from SEPs compared to those sharing paraphernalia and syringes. SEPs have long been leaders in HIV prevention to this population so it is not surprising they may lead the charge in promoting PrEP to this community.

Conversely, a greater proportion of those obtaining syringes from a secondary source such as friend, relative, sex partner, dealer, shooting gallery, or off the streets were PrEP unaware. These PWID have fewer opportunities to benefit from interaction with SEP staff or educational programs/materials at the SEP. Research has also shown that primary and secondary SEP users have a different risk profile with secondary SEP clients being more vulnerable than primary clients who directly access SEPs [35, 36].

Our findings indicate that there is untapped potential to provide PrEP education within the population of PWID that primarily utilize secondary sources for syringes. Peer-topeer interventions are a well-established strategy for HIV prevention with this population and potentially could also work for the dissemination of PrEP information [37–40]. However, no research to date has explored the feasibility or acceptability of this approach. Despite this, we hypothesize this strategy could have great potential for reaching a large

Most common source of syringes, past 12 months	Any sharing (n=403)	No sharing $(n=209)$	p value	Unadjusted Odds Ratio (95% CI)
Syringe exchange program	177 (43.9%)	106 (50.7%)	0.11	0.76 (0.54, 1.06)
Clinic/pharmacy	26 (6.5%)	20 (9.6%)	0.17	0.65 (0.36, 1.20)
Secondary sources	200 (49.6%)	83 (39.7%)	0.02	1.50 (1.07, 2.10)
	Shared only paraphernalia (n=208)	Did not share paraphernalia $(n = 404)$		
Syringe exchange program	106 (51.0%)	177 (43.8%)	0.09	1.33 (0.95, 1.86)
Clinic/pharmacy	12 (5.8%)	34 (8.4%)	0.24	0.67 (0.34, 1.32)
Secondary sources	90 (43.3%)	193 (47.8%)	0.29	0.83 (0.60, 1.17)
	Shared only syringes $(n=15)$	Did not share syringes $(n = 597)$		
Syringe exchange program	3 (20%)	280 (46.9%)	0.06	0.28 (0.08, 1.01)
Clinic/pharmacy	3 (20.0%)	43 (7.2%)	0.10	3.22 (0.88, 11.9)
Secondary sources	9 (60.0%)	274 (45.9%)	0.28	1.77 (0.62, 5.03)
	Shared both syringes and para- phernalia (n = 180)	Did not share syringes and para- phernalia (n=432)		
Syringe exchange program	68 (37.8%)	215 (49.8%)	0.007	0.61 (0.43, 0.87)
Clinic/Pharmacy	11 (6.1)	35 (8.1)	0.39	0.74 (0.37, 1.49)
Secondary sources	101 (56.1%)	182 (42.1%)	0.002	1.76 (1.24, 2.49)

Table 3Univariable logistic regression of drug equipment sharing behaviors by most common sources of syringes among persons who injectdrugs (PWID) in Philadelphia: National HIV Behavioral Surveillance system injection drug user cycle, 2015 (n = 612)

The bold values represent statistically significant values

Secondary sources include friend, relative, sex partner, dealer, shooting gallery, or off the streets

p value based on Wald's χ^2 test

number of at-risk persons who might benefit from learning about, and potentially utilizing, PrEP.

Greater efforts are also needed to educate and prescribe PrEP in non-traditional medical settings such as STD clinics and drug treatment facilities. While research on the viability of drug treatment facilities to distribute PrEP has yet to be conducted, STD clinics are increasingly being utilized to educate and enroll vulnerable patients in PrEP services, though the focus has been primarily on MSM [41]. Although we found access to STD testing and drug treatment was associated with higher PrEP awareness, access to medical care was not. In this sample, the majority of participants had attended any medical visit, including ER visits, in the last 12 months, yet they were not more likely to know about PrEP than their peers who had not. Previous research has found that primary care providers (PCP) do not feel comfortable prescribing PrEP, which may be exacerbated for PWID who often face stigma within health care settings [42, 43]. Additional outreach to clinicians serving PWID may be needed in order to encourage them to educate and prescribe PrEP to this population. While the ER may not be the appropriate place to prescribe and follow persons on PrEP, a basic PrEP referral could be provided in this setting with appropriate follow-up.

Our data must be interpreted with the limitations of the study design and measurement. All of the data presented are self-reported and are subject to social desirability and recall biases. Since PWID were recruited from Philadelphia with a low HIV prevalence among PWID [13], findings from our MSA might not be generalizable to other cities with a higher HIV prevalence in this population. Finally, our survey did not capture detailed information on source of PrEP awareness (i.e., how participants learned about PrEP) nor whether secondary sources were safe (i.e., new syringes provided via secondary exchange or bought on the street) or not. More information in these areas would help us to better understand PrEP dissemination and the potential for other outreach and educational strategies. Additional limitations include presenting unweighted estimates of association that do not account for peer network size or clustering within recruitment chains. However, there is no reason to assume this would impact our outcome of interest given the distribution of PrEP awareness.

Conclusion

In this sample of vulnerable PWID, PrEP awareness, the first step in the continuum of PrEP care, was low. While greater efforts should be made to promote PrEP to all PWID,

tailored interventions may be needed to penetrate into networks of PWID who do not access SEPs. One possible mechanism is via secondary exchange networks. This may be crucial given this subpopulation representing unserved PWID is consistently found to be disproportionately vulnerable to PWID. With additional promotional efforts, PrEP will have greater potential to prevent HIV among this vulnerable population.

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Compliance and Ethical Standards

Conflict of interest The authors report no conflict of interest.

Ethical Approval All procedures involving human participants were reviewed and approved by the City of Philadelphia Institutional Review Board. This study does not contain animals.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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