



# Linkage and Retention in Care for Vulnerable Populations

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## Original Investigation

# Effect of Patient Navigation With or Without Financial Incentives on Viral Suppression Among Hospitalized Patients With HIV Infection and Substance Use

## A Randomized Clinical Trial

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**IMPORTANCE** Substance use is a major driver of the HIV epidemic and is associated with poor HIV care outcomes. Patient navigation (care coordination with case management) and the use of financial incentives for achieving predetermined outcomes are interventions increasingly promoted to engage patients in substance use disorders treatment and HIV care, but there is little evidence for their efficacy in improving HIV-1 viral suppression rates.

**OBJECTIVE** To assess the effect of a structured patient navigation intervention with or without financial incentives to improve HIV-1 viral suppression rates among patients with elevated HIV-1 viral loads and substance use recruited as hospital inpatients.

**DESIGN, SETTING, AND PARTICIPANTS** From July 2012 through January 2014, 801 patients with HIV infection and substance use from 11 hospitals across the United States were randomly assigned to receive patient navigation alone (n = 266), patient navigation plus financial incentives (n = 271), or treatment as usual (n = 264). HIV-1 plasma viral load was measured at baseline and at 6 and 12 months.

**INTERVENTIONS** Patient navigation included up to 11 sessions of care coordination with case management and motivational interviewing techniques over 6 months. Financial incentives (up to \$1160) were provided for achieving targeted behaviors aimed at reducing substance use, increasing engagement in HIV care, and improving HIV outcomes. Treatment as usual was the standard practice at each hospital for linking hospitalized patients to outpatient HIV care and substance use disorders treatment.

**MAIN OUTCOMES AND MEASURES** The primary outcome was HIV viral suppression ( $\leq 200$  copies/mL) relative to viral nonsuppression or death at the 12-month follow-up.

**RESULTS** Of 801 patients randomized, 261 (32.6%) were women (mean [SD] age, 44.6 years [10.0 years]). There were no differences in rates of HIV viral suppression versus nonsuppression or death among the 3 groups at 12 months. Eighty-five of 249 patients (34.1%) in the usual-treatment group experienced treatment success compared with 89 of 249 patients (35.7%) in the navigation-only group for a treatment difference of 1.6% (95% CI, -6.8% to 10.0%;  $P = .80$ ) and compared with 98 of 254 patients (38.6%) in the navigation-plus-incentives group for a treatment difference of 4.5% (95% CI -4.0% to 12.8%;  $P = .68$ ). The treatment difference between the navigation-only and the navigation-plus-incentives group was -2.8% (95% CI, -11.3% to 5.6%;  $P = .68$ ).

**CONCLUSIONS AND RELEVANCE** Among hospitalized patients with HIV infection and substance use, patient navigation with or without financial incentives did not have a beneficial effect on HIV viral suppression relative to nonsuppression or death at 12 months vs treatment as usual. These findings do not support these interventions in this setting.

**TRIAL REGISTRATION** [clinicaltrials.gov](http://clinicaltrials.gov) Identifier: NCT01612169

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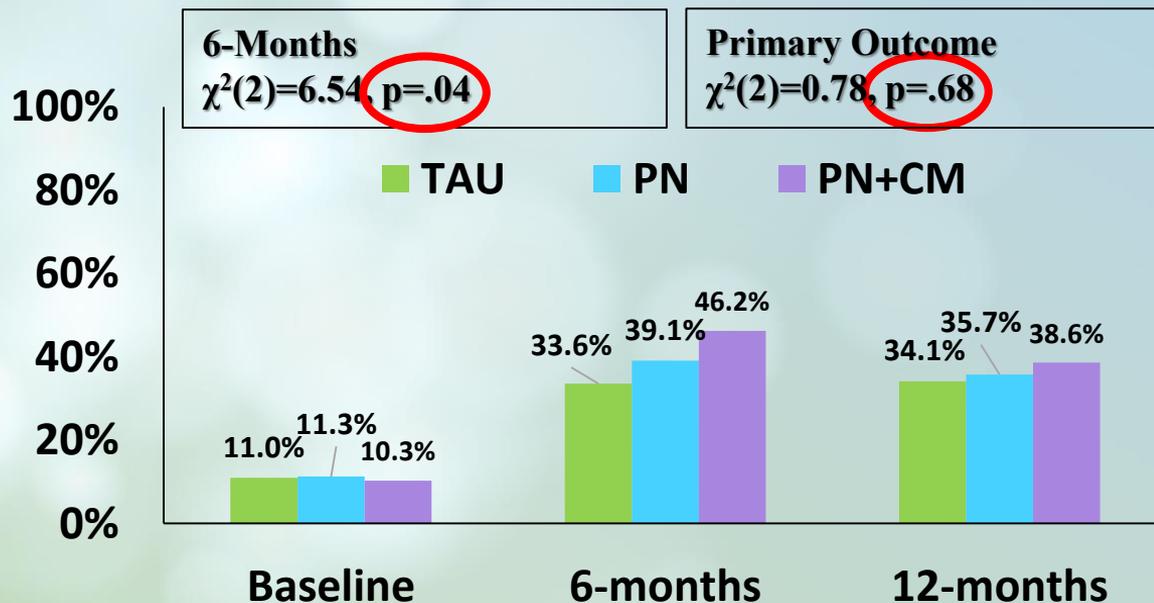
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# NIDA CTN 0049: Project HOPE

n=801 HIV-positive substance users,  
recruited from 11 hospitals in the US, 2012 - 2014

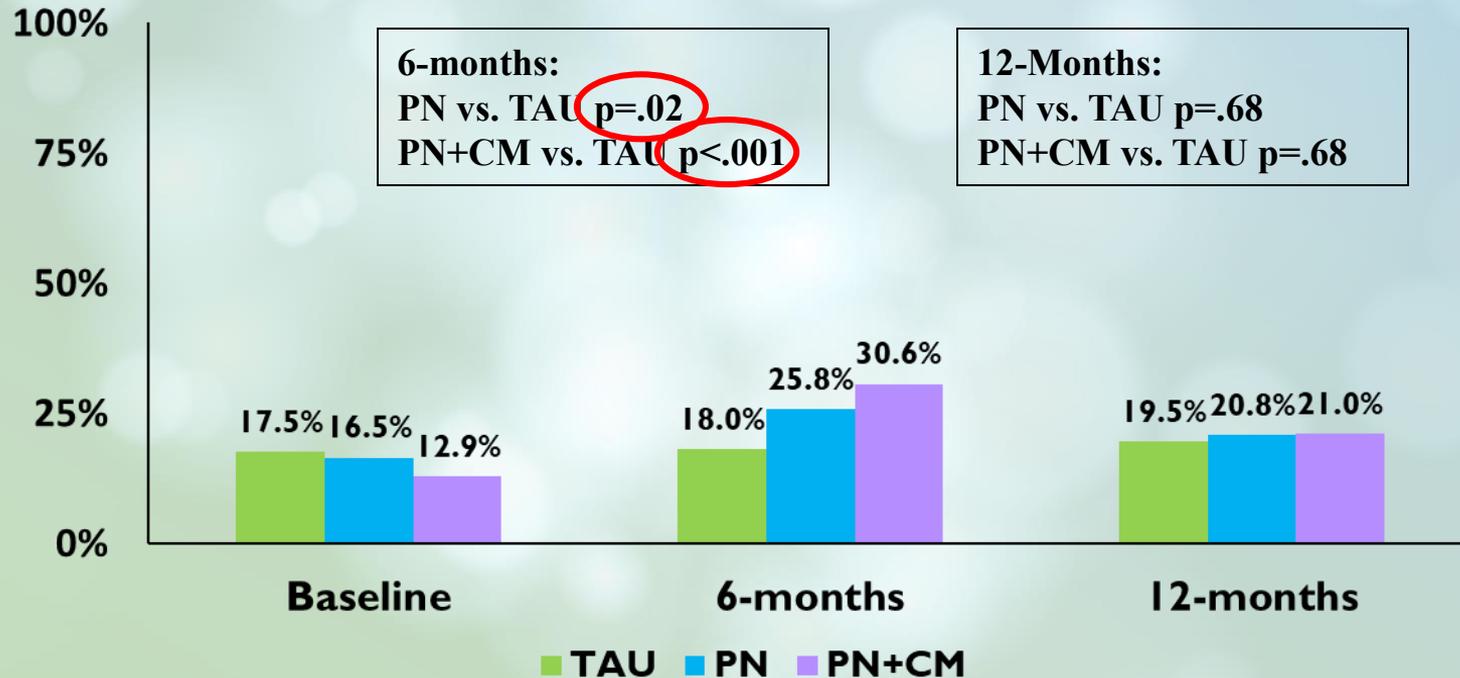
## Viral Suppression Rate



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# Substance Use Disorder Treatment\*

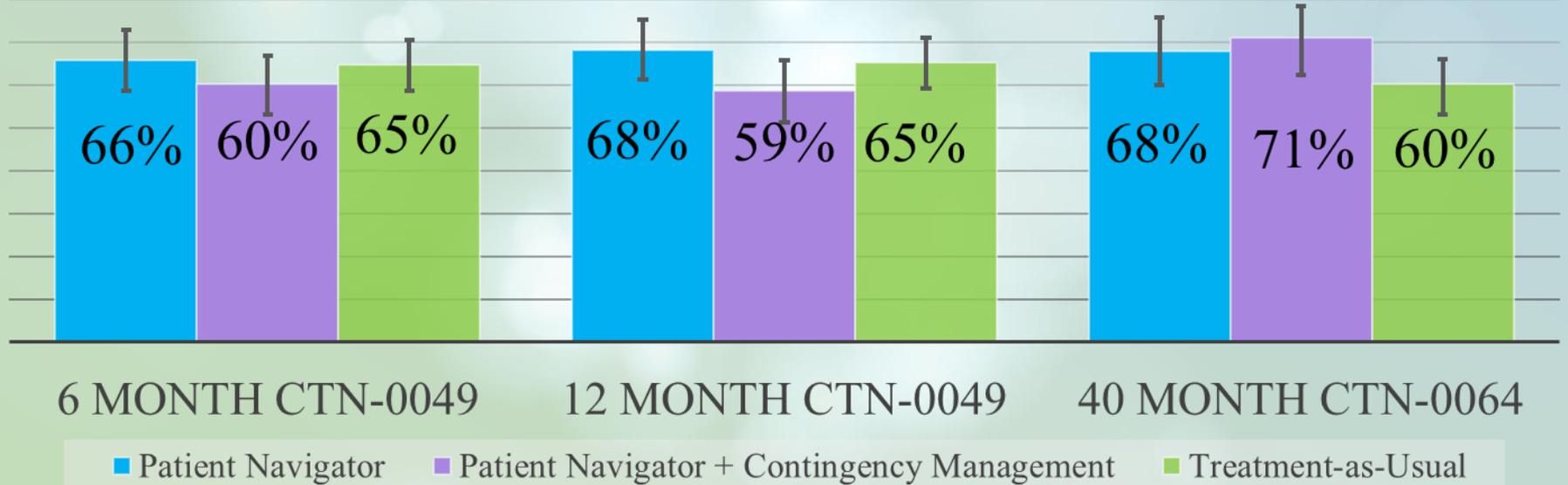


\*Self-report data



# Rates of Substance use Remain High after 3 Years

## Proportions Urinalysis Positive for Substance Use Over Time; Among Survivors





# Addressing Care Needs of Persons Living with HIV and Substance Use Disorders

- Integrated HIV care and Substance Use Treatment
- Addressing Provider-level barriers
- Harm reduction – “Habitus from the Margins” (Lekas et al.)



By Nora D. Volkow and Julio Montaner

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**ANALYSIS & COMMENTARY**

# **The Urgency Of Providing Comprehensive And Integrated Treatment For Substance Abusers With HIV**

**Poor access to  
effective substance  
abuse treatment is a  
major factor fueling  
HIV transmission.**



Full length article

## Faster entry into HIV care among HIV-infected drug users who had been in drug-use treatment programs

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### ABSTRACT

**Objective:** We evaluated whether being in drug use treatment improves linkage to HIV medical care for HIV-infected drug users. We assessed whether an evidence-based intervention for linkage to care [‘ARTAS’] works better for HIV-infected drug users who had been in drug use treatment than those who had not.

**Design:** Randomized trial.

**Methods:** 295 Participants in the Antiretroviral Treatment Access Study [‘ARTAS’] trial were followed for time to first HIV medical care. Drug use (injected and non-injected drugs) in the last 30 days and being in drug treatment in the last 12 months were assessed by audio-CASI. We used a proportional hazards model of time to care in drug users with and without drug treatment, adjusting for barriers to care, AIDS symptoms, and demographic factors. We tested whether drug treatment modified the intervention effect by using a drug use/drug treatment<sup>2</sup>intervention interaction term.

**Results:** Ninety-nine participants (30%) reported drug use in the 30 days before enrollment. Fifty-three (18%) reported being in a drug treatment program in the last 12 months. Drug users reporting methadone maintenance became engaged in care in less than half the time of drug users without a treatment history [HR 2.97 (1.20, 6.21)]. The ARTAS intervention effect was significantly larger for drug users with a treatment history compared to drug users without a treatment history (AHR 5.40, [95% CI, 2.03–14.38]).

**Conclusions:** Having been in drug treatment programs facilitated earlier entry into care among drug users diagnosed with HIV infection, and improved their response to the ARTAS linkage intervention.

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### 1. Introduction

Timely entry into HIV medical care after being diagnosed with HIV infection is essential in helping patients attain the full health benefits of antiretroviral therapy (ART). The 2020 National HIV/AIDS strategy (Office of National AIDS Policy, 2015) and the 2015 World Health Organization Guidelines (WHO, 2015) have a major focus on linkage to care; one of the United States (U.S.) indicators that will be used to measure success of the U.S. National HIV/AIDS strategy is linkage to HIV medical care within 30 days of HIV diagnosis.

One population group that has exhibited delay in linking to HIV care and difficulty being retained in care is persons who use illicit

- Methadone maintenance treatment had shortest time to care
- ARTAS care entry intervention effect larger for users with a drug treatment history

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# Clinic-Based Treatment of Opioid-Dependent HIV-Infected Patients Versus Referral to an Opioid Treatment Program

## A Randomized Trial

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**Background:** Opioid dependence is common in HIV clinics. Buprenorphine–naloxone (BUP) is an effective treatment of opioid dependence that may be used in routine medical settings.

**Objective:** To compare clinic-based treatment with BUP (clinic-based BUP) with case management and referral to an opioid treatment program (referred treatment).

**Design:** Single-center, 12-month randomized trial. Participants and investigators were aware of treatment assignments. (ClinicalTrials.gov registration number: NCT00130819)

**Setting:** HIV clinic in Baltimore, Maryland.

**Patients:** 93 HIV-infected, opioid-dependent participants who were not receiving opioid agonist therapy and were not dependent on alcohol or benzodiazepines.

**Intervention:** Clinic-based BUP included BUP induction and dose titration, urine drug testing, and individual counseling. Referred treatment included case management and referral to an opioid-treatment program.

**Measurements:** Initiation and long-term receipt of opioid agonist therapy, urine drug test results, visit attendance with primary HIV care providers, use of antiretroviral therapy, and changes in HIV RNA levels and CD4 cell counts.

**Results:** The average estimated participation in opioid agonist therapy was 74% (95% CI, 61% to 84%) for clinic-based BUP and 41% (CI, 29% to 53%) for referred treatment ( $P < 0.001$ ). Positive test results for opioids and cocaine were significantly less frequent in clinic-based BUP than in referred treatment, and study participants receiving clinic-based BUP attended significantly more HIV primary care visits than those receiving referred treatment. Use of antiretroviral therapy and changes in HIV RNA levels and CD4 cell counts did not differ between the 2 groups.

**Limitation:** This was a small single-center study, follow-up was only moderate, and the study groups were unbalanced in terms of recent drug injections at baseline.

**Conclusion:** Management of HIV-infected, opioid-dependent patients with a clinic-based BUP strategy facilitates access to opioid agonist therapy and improves outcomes of substance abuse treatment.

**Primary Funding Source:** Health Resources and Services Administration Special Projects of National Significance program.

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For author affiliations, see end of text.

www.annals.org

Opioid agonist treatment used to be available only in highly regulated programs. In 2002, the U.S. Food and Drug Administration approved the sublingual combination tablet buprenorphine–naloxone (BUP) for office-based treatment of opioid dependence (1, 2). Treatment of opioid dependence in medical settings has particular resonance in HIV care. Injection drug use is a major risk factor for HIV, and opioid dependence is highly prevalent in HIV clinics.

It is not known how treating opioid-dependent patients with BUP in an HIV clinic compares with the traditional model of referral to specialized opioid treatment

programs. To address this, we conducted a single-center, nonblinded, 12-month randomized trial comparing clinic-based treatment with BUP (clinic-based BUP) with case management and referral to an opioid treatment program (referred treatment) for opioid-dependent persons in an urban HIV clinic. We hypothesized that clinic-based BUP would improve engagement with and outcomes for both substance abuse and HIV treatment better than referred treatment.

## METHODS

### Setting

We performed this study in the Johns Hopkins HIV Clinic between November 2005 and April 2009. Our study was 1 of 10 sites supported by the Health Resources Services Administration Special Projects of National Significance to conduct demonstration projects that included the integration of BUP treatment into HIV primary care (www.bhives.org). The Johns Hopkins Medicine and New York Academy of Medicine institutional review boards approved this study.

Management of HIV-infected, opioid-dependent patients with a clinic-based buprenorphine strategy facilitates access to opioid agonist therapy and improves outcomes of substance abuse treatment.

### See also:

**Print**  
Editors' Notes ..... 705

**Web-Only**  
Appendix Figure  
Conversion of graphics into slides

# What is the effect of **office-based extended-release naltrexone (XR-NTX)** versus treatment as usual (TAU) on **HIV viral suppression** for people with HIV and untreated opioid use disorder (OUD)? (N=350)

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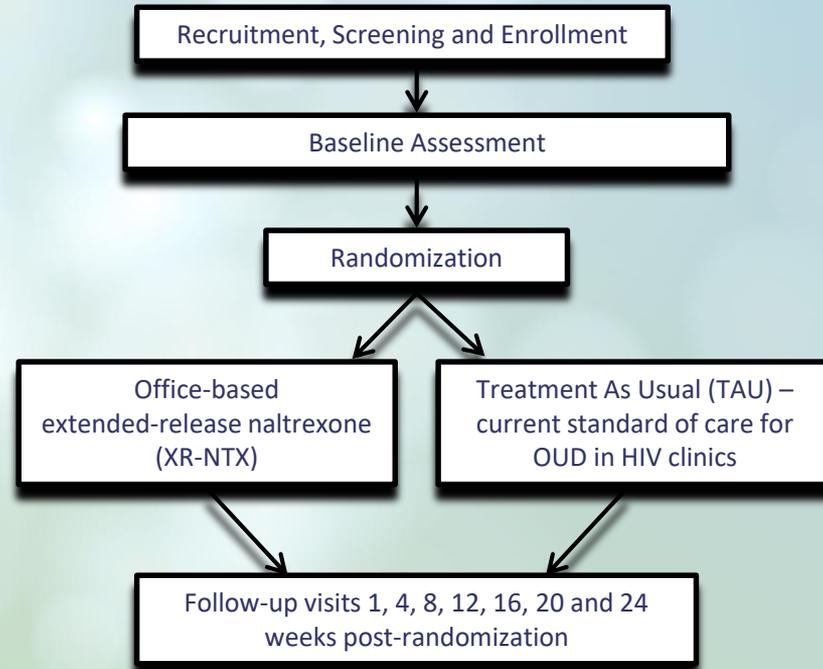


**NIDA CTN 0067**

**Lead Investigator: Todd Korthuis**

- Sites: 7 HIV clinics in the U.S.
- Study population: HIV-infected patients with untreated OUD and HIV RNA PCR  $\geq 200$  copies/mL at baseline
- Outcome: Viral suppression at 24 weeks

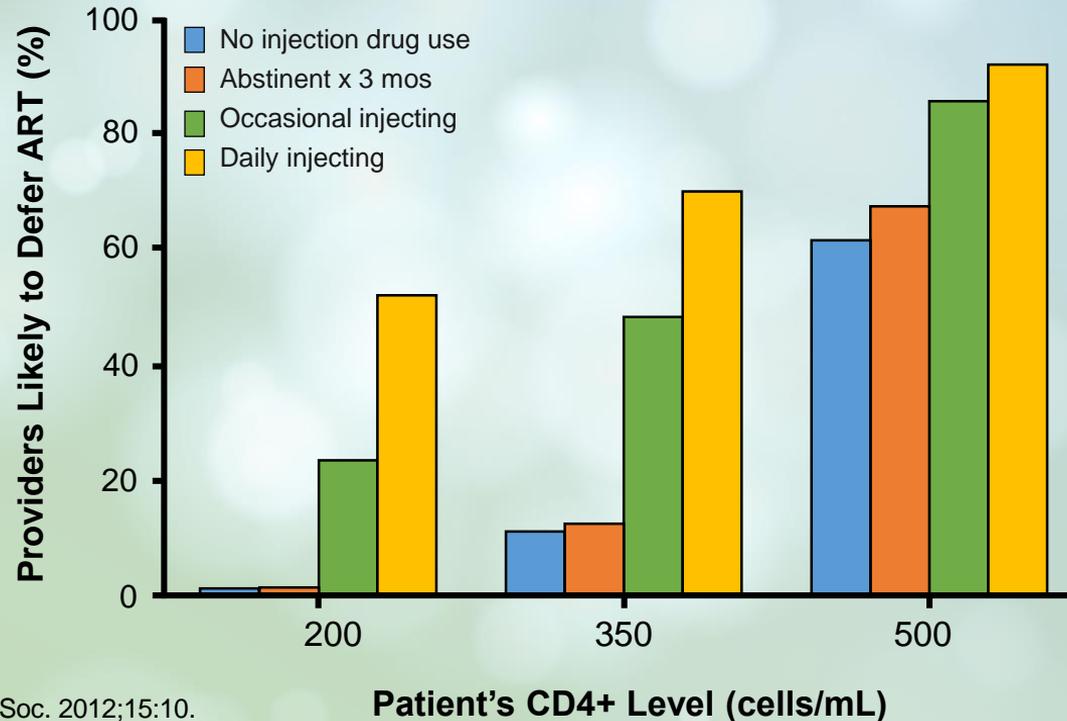
## STUDY DESIGN





# Reluctance to Initiate ART in PWID

Cross-sectional survey of ART prescribers in North America (N = 662)



## Provider barriers to prescribing HAART to medically-eligible HIV-infected drug users

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**Abstract** We aimed to identify factors associated with provider barriers to prescribing HAART to medically-eligible HIV-infected drug users. A cross-sectional survey queried 420 HIV care providers. Adjusted odds ratios (AOR) and 95% confidence intervals (CI) were estimated using logistic regression. Providers identified as resistant to prescribing HAART to injection drug users were more likely to be non-prescribers in populations with a high prevalence of both injection drug use (AOR = 1.82 95% CI: 1.04–3.55) and by patients' limited ability to keep appointments (AOR = 1.92; 95% CI: 1.04–3.55) and Providers working in populations with a high prevalence of non-injection drug use, alcohol use, and therapy refusal rates within their patient population. Providers who treat HIV-infected drug users from on-site drug treatment, mental health

### Introduction

Approximately, one-third of new human immunodeficiency virus (HIV) infections occurring in the USA can be attributed to injection drug use, taking into account both direct transmission of HIV due to the sharing of contaminated injection equipment and indirect transmission through sexual contact and mother-to-child transmission (CDC, 2001). Dual diagnoses of mental illness and substance abuse, in addition to other physical problems, further complicate the lives of illicit drug users and subsequently, their health care (Angelino *et al.*, 2001; Bing *et al.*, 2001; Burnam *et al.*, 2001; Ferrando *et al.*, 1996; Kilbourne *et al.*, 2001; Tyndall *et al.*, 2001). Urban injection drug users (IDUs) often are members of racial/

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# Provider barriers to prescribing HAART to medically-eligible HIV-infected drug users

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# Health Habitus from the Margins

- Pierre Bourdieu’s theory of habitus, a set of deeply ingrained perceptions, beliefs, and tendencies we have as a result of our life opportunities that shape our life choices and experience.
- In other words, habitus is habits rooted in our social circumstances, social constraints, and/or opportunities
- We put forth a theory of “health habitus from the margins” (Lekas, et al.)
- 120 qualitative interviews with HIV-positive patients in New York City Hospital



# Health Habitus From the Margins

A 41 year-old African American male described wanting to be treated like a “person.” He indicated that his continuation in HIV care was contingent upon his relationship with his provider because he lacked social support when growing up and this shaped his habitus.

*“The nurses in there, they acted like.. You understand. I want to be treated like a person. I know what I got, you know what you got, you don’t have to let it be known, oh, you got that... You know that has actually have stopped me from going to, to any, anything like that ‘cause, I grew up with no family, stuff like that, so it’s easy to hurt my feelings, you know what I’m saying...”*



# Health Habitus From the Margins

In her definition of a good doctor, a 40 year-old African American woman exposed her habitus at the margins that incorporated concern about being excluded and discredited. She indicated that she was looking for a provider that made her feel “comfortable.”

*“You know, somebody I could,  
somebody I could talk to about my  
problems. Nobody shovin’ me away. I  
could just be me.”*



# Health Habitus From the Margins

A 56 year-old African American man discusses why he does not disclose his drug use to his HIV provider:

*So, all these years that you've been with [Dr. S], he doesn't know that you use crack?*

*“Nope...I don't know. I just feel like he would treat me differently, you know? You don't wanna have a drug addict around you. (SNIFF) You know, they steal, and all kinds of – hmm, hmm.”*

*So, you think he may stigmatize you?*

*“Oh, no doubt.”*



# Going Forward...

- Increasing integrated substance use and mental health treatment with ART and PrEP
- Reducing Implicit Bias among Providers and Others
- Enhanced Awareness of “Habitus from the Margins”