HIV Rapid Testing and Counseling in Drug Abuse Treatment Programs in the U.S. CTN 0032

Lisa Metsch, Ph.D.

Grant Colfax, M.D.

Florida Node Alliance and Western States Node

National Institute on Drug Abuse

Clinical Trials Network

The White House

Office of the Press Secretary

For Immediate Release March 14, 2012

President Obama Announces Grant Colfax as New Director of the Office of National AIDS Policy

WASHINGTON, DC – Today, President Obama announced the appointment of one of the nation's leading public health policy experts as the Director of the Office of National AIDS Policy (ONAP). Grant Colfax, MD, Director of the HIV Prevention Section in the San Francisco Department of Public Health will coordinate the continuing efforts of the government to reduce the number of HIV infections across the United States. A component of the White House Domestic Policy Council, ONAP emphasizes prevention through wide-ranging education initiatives and helps to coordinate the care and treatment of citizens with HIV/AIDS.

"Grant Colfax will lead my Administration's continued progress in providing care and treatment to people living with HIV/AIDS," said **President Obama**. "Grant's expertise will be key as we continue to face serious challenges and take bold steps to meet them. I look forward to his leadership in the months and years to come."

ONAP coordinates with the National Security Council and the Office of the Global AIDS Coordinator, and works with international bodies to ensure that America's response to the global pandemic is fully integrated with other prevention, care, and treatment efforts around the world. Through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) initiative, the U.S. has made enormous progress in responding to the global HIV/AIDS pandemic, working with countries heavily impacted by HIV/AIDS to help expand access to treatment, care, and prevention.

Grant Colfax, MD, was most recently Director of the HIV Prevention Section in the San Francisco Department of Public Health. Dr. Colfax is a graduate of Harvard Medical School and completed his medical residency at the University of California, San Francisco. His work focuses on collaborating with community stakeholders to implement sustainable, evidence-based HIV prevention and treatment interventions and policies in public health settings and measuring their effectiveness. Under his leadership, San Francisco greatly expanded HIV testing and treatment support was also an NIH- and CDC supported scientist studying HIV testing strategies, dependence, and biomedical HIV prevention interventions. Dr. Colfax was a pr San Francisco's premier public HIV clinic.

Special Thanks

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HIV in the United States

HIV infected	1,106,400
Unaware of their HIV infection	232,700 (21%)
Annual incidence	50,000

Prejean et al., 2011
Campsmith M et al, JAIDS April 2010

Drug Use Continues to Contribute to New HIV Infections

May 1, 2007 45(1)

The Relationship between Methamphetamine and Popper use and Risk of HIV Seroconversion in the Multicenter AIDS Cohort Study

MW Plankey, DG Ostrow et al.

July1, 2009 51(3)

Specific Sex Drug Combinations Contribute to the Majority of Recent HIV Seroconversions among MSM in the MACS

DG Ostrow, MW Plankey et al.

Benefits of HIV Testing

- Decreases HIV transmission
  - HIV diagnosis is associated with reduction in high risk sexual and injection behaviors
- Improves survival
  - Linkage to care and treatment
  - Lower viral load associated with decreased infectivity

"HIV Treatment as Prevention"

- Advances in HIV Rapid Testing Technologies

Marks 2005; Quinn 2000; Cohen 2011

What about HIV Testing in Drug Abuse Treatment Centers?

- Fewer than one-third of U.S drug treatment programs offer HIV testing and counseling. *

- Fewer than half of CTN community treatment programs made HIV testing available either in the CTP, or through referral.**

Abraham et al., 2012; SAMSHA, 2004, Pollack and D'Aunno, 2010 *

Abraham et al., 2011; Brown et al. JSAT, 2006, AJPH, 2007 *

Patient characteristics and availability of onsite non-rapid and rapid HIV testing in US substance use disorder treatment programs

Amanda J. Abraham, Ph.D.[a, b], Lauren A. O'Brien, Ph.D.[a], Hannah K. Knudsen, Ph.D.[c], Brian E. Bride, Ph.D.[d], G. Rush Smith, Ph.D.[a], Paul M. Roman, Ph.D.[a, b]

[a] Owens Institute for Behavioral Research, University of Georgia, Athens GA, USA

[b] Department of Sociology, University of Georgia, Athens GA, USA

[c] Department of Behavioral Science and Center on Drug and Alcohol Research, University of Kentucky, USA

[d] School of Social Work, University of Georgia, Athens GA, USA

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Abstract

Racial and ethnic minorities and injection drug users (IDUs) are at increased risk of HIV infection. However, the associations between these caseload characteristics and the availability of onsite HIV testing in substance use disorder treatment programs are unknown. This study uses data collected in 2008–2009 from 198 program administrators of treatment programs participating in the National Institute on Drug Abuse's Clinical Trials Network to address this gap in the literature. Results show positive associations between the percentages of African American, Hispanic, and IDU patients and the odds of offering non-rapid onsite HIV testing versus no onsite testing. The associations between racial/ethnic composition and the availability of rapid HIV testing were more complicated. These findings suggest that many programs are responding to the needs of at-risk populations. However, programs and their patients may benefit from greater adoption of rapid testing which is less costly and better ensures that patients receive their results.

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HIV testing and counseling in the nation's outpatient substance abuse treatment system, 1995–2005

Harold A. Pollack, (Ph.D.)[a], Thomas D'Aunno, (Ph.D.)[b,*]

[a]*University of Chicago, Chicago, IL, USA*
[b]*Columbia University, New York, NY, USA*

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Abstract

This article examines the extent to which U.S. outpatient substance abuse treatment (OSAT) facilities provide HIV counseling and testing (C&T) to clients between 1995 and 2005. We also examine organizational and client characteristics associated with OSAT facilities' provision of HIV C&T. Data were collected from a nationally representative sample of outpatient treatment facilities in 1995 ($n = 618$), 2000 ($n = 571$), and 2005 ($n = 566$). Results show that in 1995, 26.8% of OSAT clients received HIV C&T; by 2005, this proportion had increased, but only to 28.8%. Further, results from random-effects interval regression analysis show that C&T is especially widespread in public and nonprofit facilities, in methadone facilities, and in units that serve injection drug users and commercial sex workers. HIV C&T was also more widespread in units that employed formal intake protocols. Despite widespread efforts to increase HIV C&T services in OSAT care, only a small and stable minority of clients receive these services. Adoption of formal intake procedures may provide one vehicle to increase provision of C&T services.

Keywords: HIV counseling and testing; Substance abuse treatment; Opiate; Managed care

Pollack & D'Aunno Analysis

Journal of Substance Abuse Treatment, 2010

- Analyzed data from three waves of the National Drug Abuse Treatment Survey (NDATSS)
  - Examined the percent of treatment clients who actually receive HIV testing (on-site or off-site) at outpatient treatment facilities
  - Examined the proportion of out-patient treatment units which reported at least 1% of clients were tested.

Pollack & D'Aunno Analysis

Journal of Substance Abuse Treatment, 2010

	1995 (N=568)	2005 (N=500)
Percentage of clients who receive on-site HIV tests	26.8%	28.8%
Percentage of units, weighted by caseload, which provide at least some on-site HIV testing.	36.2%	35.3%

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HIV/AIDS Services in Private Substance Abuse Treatment Programs

Amanda J. Abraham[a,c,*], L
[a] Center for Research on Be
[b] School of Social Work, Un
[c] Department of Sociology,

Abstract

Background—HIV infe
States. Little research, hov
abuse treatment programs.

Methods—This study ex
representative sample of 3
collected via face-to-face i
programs in 2007–2008.

Results—Results show t
African American and inje
AIDS support groups and
reveals that the odds of offering onsite HIV testing services were higher for hospital based programs, programs providing medical services onsite, and programs with higher percentages of African American patients, relative to the odds of offering no HIV testing or referring patients to an external provider for HIV testing services. The odds of providing onsite testing were lower for outpatient-only treatment programs, relative to the odds of offering no HIV testing or referring patients to an external provider for HIV testing services.

Conclusions—Our findings highlight critical barriers to the adoption of onsite HIV/AIDS services and suggest treatment programs are missing the opportunity to significantly impact HIV-related health outcomes.

Keywords

substance abuse treatment; HIV/AIDS services; HIV testing

1. Introduction

HIV infection among substance abusers is a growing concern in the United States (Des Jarlais et al., 2007; NIDA, 2006; Strathdee and Stockman, 2010; Volkow and Montaner, 2010). While injection drug use (IDU) has been a primary mode of HIV transmission since

Correspondence Author: Amanda J. Abraham, Institute for Behavioral Research, 112 Barrow Hall, University of Georgia, Athens GA 30602-2401, Tel: (706) 542-6090, Fax: (706) 542-6436, aabraham@uga.edu.

HIV/AIDS Services in Private Substance Abuse Treatment Programs

Amanda J. Abraham[a,c,*], Lauren A. O'Brien[a], Brian E. Bride[a,b], and Paul M. Roman[a,c]
[a] Center for Research on Behavioral Health and Human Services Delivery, University of Georgia
[b] School of Social Work, University of Georgia, 310 E. Campus Road, Athens, GA 30602
[c] Department of Sociology, University of Georgia, 115 D. W. Brooks Drive, Athens, GA 30602

What about Pre-test Counseling?

- *The efficacy of pre-test counseling in the rapid testing era is unknown.*
- RESPECT trial: 1993-1995
  - Brief client-centered counseling reduced STD incidence among STD clinic patients.
- CDC Testing Guidelines: 2006
  - Recommended routine HIV testing in medical settings without requiring counseling.

Primary Questions

- In substance use treatment centers, what is most effective HIV testing strategy:

  (1) To increase receipt of HIV test results?

  (2) To decrease HIV sexual risk behaviors?

Study Intervention Groups

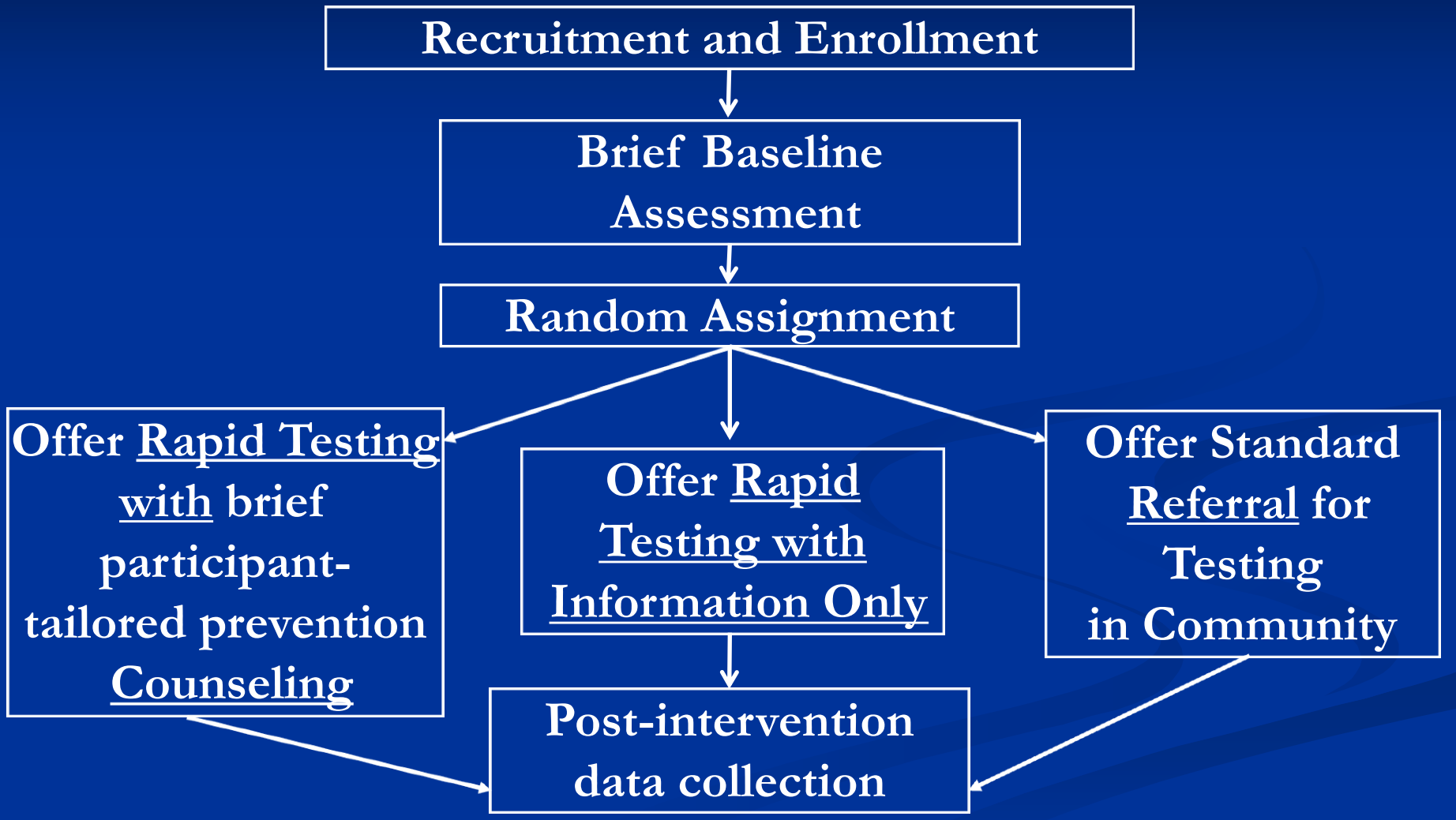
- Group 1

  (Rapid HIV Testing with RESPECT Counseling)
- Group 2

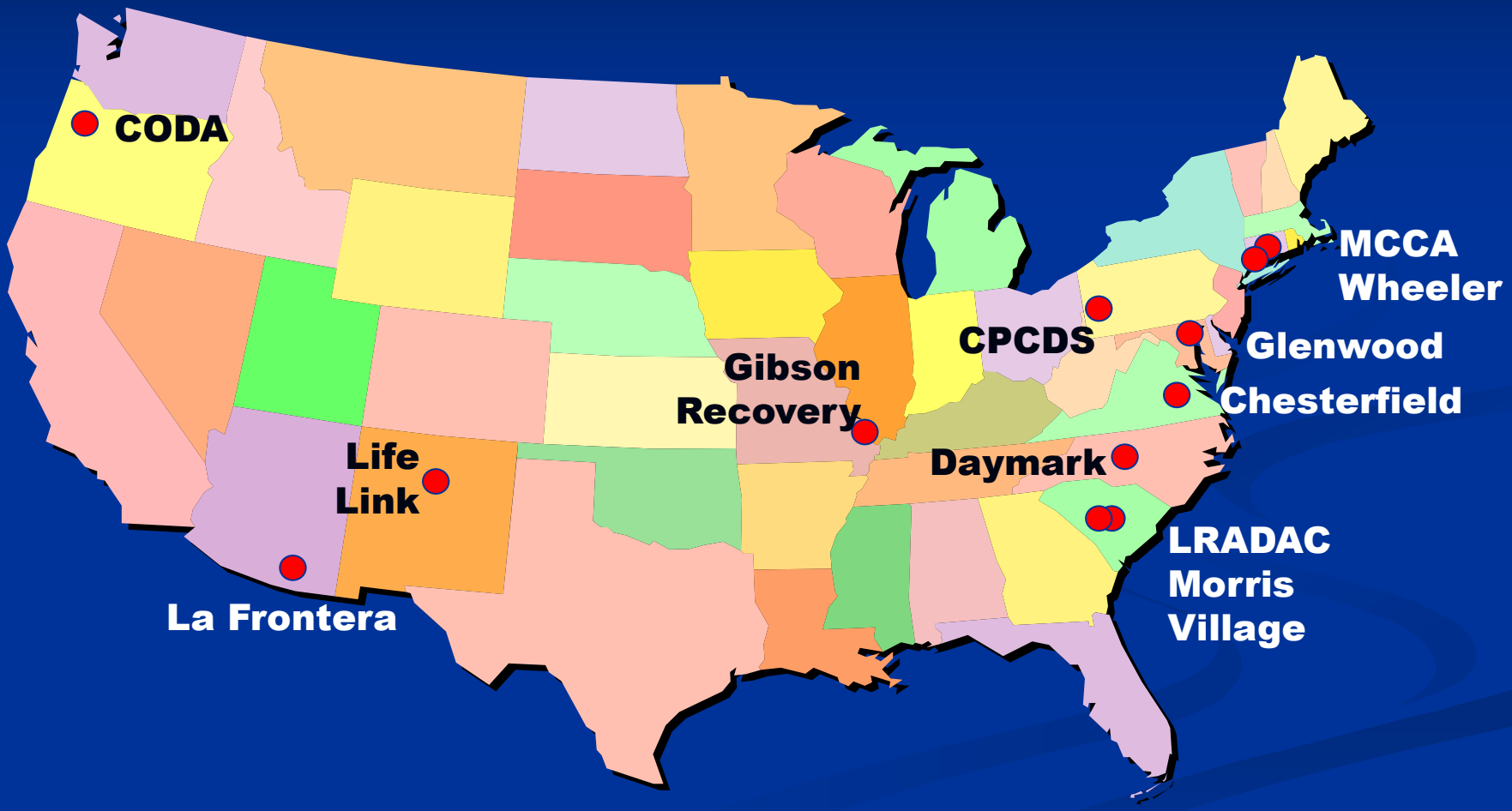
  (Rapid HIV Testing and Information Only)
- Group 3

  (Referral Only)

Overview of Study Design



Participating Sites



Study Population

- 1281 drug treatment clients enrolled at 12 CTPs in the U.S. in less than 5 months
- 12 sites randomized an average of 106 participants (ranging from 59 to 126 per site)
- Randomized participants were demographically similar (age, gender, race/ethnicity) to CTP demographics

Notable Inclusion Criteria

Participant must:

- Be seeking or currently receiving drug (inclusive of alcohol) abuse treatment services at the CTP
- Report being HIV-negative or HIV status unknown
- Report no receipt of results from an HIV test performed in the prior 12 months

Efficacy Assessments

- Primary Outcomes:
  - Self-reported receipt of HIV test results at one month follow-up
  - Self-reported sexual risk behavior at 6 month follow-up
- Data collected on web-based ACASI and Electronic Data Collection Form (eCRF)
- Emphasis on intervention fidelity and quality assurance

Follow-Up Visit Attendance

Randomized (n=1281)	n	%
Month 1	1257/1281	98.1
Month 6	1193/1281	93.1

Summary of Treatment Exposure

Treatment	n	%
Off-site referral	429/429	100
On-site HIV test with RESPECT-2	427/433	98.8
On-site HIV test with information only	419/419	100

Counseling Fidelity

Pre-results session	Overall (n=198)	
Adherence Rating	**n**	**%**
Unsatisfactory	0/198	0.0
Acceptable/Good	10/198	5.1
Excellent	188/198	94.9
Counseling content beyond treatment arm	5/131	3.8

Demographics (n=1281)

- Gender
  - 60.7% Male
  - 39.3% Female
- Age Range
  - 24.1% 18-29
  - 24.4% 30-39
  - 32.3% 40-49
  - 19.1% ≥ 50
- Race
  - 2.6% American Indian
  - 20.5% Black/African American
  - 64.5% White
  - 7.7% Multiracial
  - 4.7% Other*
- Ethnicity
  - 11.5% Hispanic

*Includes Asian, Native Hawaiian/Pacific Islander, and other

Baseline Drug Use

Baseline	%
Injected Drugs in Lifetime	48.6
Injected Drugs in Last 6 Mo	20.6
Used Opiates in Last 6 Mo	37.0
Used Stimulants in Last 6 Mo	43.6
High Drug Use Severity	53.6
Binge Drinking	71.8

Baseline Sex Risk and HIV Testing History

Risky Sexual Behavior	61.7%
Median Number of Risky Sexual Acts	5
Ever Tested for HIV	69.3%
Median Times HIV Tested	2

Primary Hypothesis Test: HIV Testing

Self-report receipt of HIV results at 1 month post-randomization

Treatment	n	%
Off-site Referral	78/424	18.4
On-site HIV test: RESPECT	338/424	79.7
On-site HIV test: Info Only	347/409	84.8

Comparison of groups

- Overall:
  - $p = .0032$*
- Off-site vs. On-site:
  - $p = .0007$*
- RESPECT vs. Info Only:
  - $p = .0425$

* ***A priori*** **alpha level significance at** $p < .025$

Primary Hypothesis Test: Risky Sexual Behavior

Number of risky sexual behaviors at 6 month post-randomization

Treatment	n	Mean (SD)
Off-site Referral	387	20.5 (49.8)
On-site HIV test: RESPECT-2	385	21.3 (47.6)
On-site HIV test: Info Only	371	21.3 (44.8)

Comparison Groups

- Overall:
  - $p = .6596$
- Off-site vs. On-site:
  - $p = .4348$
- RESPECT-2 vs. Info Only:
  - $p = .8697$

No Differences Found in Adjusted Efficacy Analyses

- Controlling for:
  - Age
  - Race/Ethnicity
  - Gender
  - Drug Use
    - Severity
    - Injection
    - Substances
  - HIV testing history
  - Treatment
  - Risky Sexual Behaviors

Subset of Participants with Reported Sex Risk at Baseline

- No significant difference between treatments

HIV Diagnoses

- 3 (0.4%) participants had reactive tests confirmed HIV positive by Western Blot
  - 2 in counseling
  - 1 in information only

Change in Needle Sharing from Baseline to Six Months

	Discontinued	No Change	Initiated
Counseling	32	369	1
Information Only	24	355	6
Referral	17	384	3

Full Sample: Fisher's Exact $p < .046$

Summary of Findings – CTN 0032

- HIV testing in substance use treatment centers increased testing and receipt of test results.
- Risk-reduction counseling did not reduce participants' sexual risk behaviors or increase their acceptance of HIV testing.
- Secondary analysis found counseling reduced needle/syringe sharing risk.

Implementing Rapid HIV Testing With or Without Risk-Reduction Counseling in Drug Treatment Centers: Results of a Randomized Trial

Lisa R. Metsch, PhD, Daniel J. Feaster, PhD, Lauren Gooden, PhD, Tim Mat
Susan Tross, PhD, Tiffany Kyle, PhD, Dianne Gallup, PhD, Andrzej S. Kosins
Moupali Das, MD, Robert Lindblad, MD, Sarah Erickson, PhD, P. Todd Kortl
José Szapocznik, PhD, Rochelle Walensky, MD, Bernard Branson, MD, and

Objectives. We e
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Methods. Betwe
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Results. We defi
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risk ratio = 4.52; 97
were no significant
combined on-site tes
[IRR] = 1.04; 97.5% CI = 0.95, 1.14) or the 2 on-site testing arms (*P* = .81; IRR = 1.03; 97.5% CI = 0.84, 1.26).
Conclusions. This study demonstrated on-site rapid HIV testing's value in drug treatment centers and found no additional benefit from HIV sexual risk-reduction counseling. (*Am J Public Health*. Published online ahead of print April 19, 2012: e1–e8. doi:10.2105/AJPH.2011.300460)

An estimated 56 300 Americans were newly infected with HIV in 2006.[1] Among the more than 1 million people living with HIV in the United States, approximately one fifth do not know they are infected.[2] This has led to expanded efforts to increase HIV testing, as recently outlined in the US National HIV/AIDS Strategy.[3] In 2006, the Centers for Disease Control and Prevention (CDC) recommended routine HIV screening of all adults and adolescents in health care settings,[4] with other medical groups following with similar recommendations.[5,6]

Medical care settings and community-based testing sites are where most testing occurs,[7] but the CDC and others have called for expanded testing in other locales serving high-risk persons, including drug treatment programs.[4] Previous studies have shown that, despite high HIV prevalence in drug treatment programs (ranging from more than 3% in noninjection drug users [non-IDUs] to 27% in IDUs[8,9]) and the well-established link among substance use, sexual risk behaviors, and HIV, fewer than half of US drug treatment programs offer HIV testing on site.[10–12]

The role of risk-reduction counseling in the HIV testing process remains a central question, because of both questions of efficacy in reducing HIV infection rates and its implications for the time and personnel required for the recommended scale-up of testing. In a major policy shift, the 2006 CDC testing guidelines specify that risk-reduction counseling should only be required for persons who test HIV-positive.

In the era of rapid HIV testing, the effectiveness of brief risk-reduction counseling for reducing risk behavior in persons who test HIV-negative is unknown. The seminal US trial, Project RESPECT[13] demonstrated that two 20-minute counseling sessions in conjunction with conventional HIV testing for sexually transmitted disease (STD) clinic patients including IDUs[14] significantly increased self-reported condom use and reduced STD incidence. However, in the 15 years since RESPECT, the context for HIV testing has changed dramatically: rapid testing is now widespread, effective treatment has greatly reduced HIV-related morbidity and mortality, and many people report having been tested for HIV at least once.

To examine the efficacy of on-site rapid testing and risk-reduction counseling in increasing receipt of results and reducing HIV risk behaviors in drug treatment program patients, the National Drug Abuse Treatment Clinical Trials Network (CTN) conducted the HIV Rapid Testing and Counseling Study (CTN 0032). The aims were to quantify the degree to which available on-site rapid HIV testing increases testing and receipt of results, and to determine whether counseling affects testing acceptance and reduces HIV risk behaviors.

METHODS

CTN 0032 was a randomized controlled trial conducted in 12 US community-based drug treatment programs that previously did not offer on-site HIV testing. Participants were randomized to (1) referral for off-site HIV testing, (2) brief, participant-tailored risk-reduction counseling with the offer of an on-site rapid HIV test, or (3) information only (description of the testing procedure) with the offer of an on-site rapid HIV test. Participants

Implementing Rapid HIV Testing With or Without Risk-Reduction Counseling in Drug Treatment Centers: Results of a Randomized Trial

Lisa R. Metsch, PhD, Daniel J. Feaster, PhD, Lauren Gooden, PhD, Tim Matheson, PhD, Raul N. Mandler, MD, Louise Haynes, MSW, Susan Tross, PhD, Tiffany Kyle, PhD, Dianne Gallup, PhD, Andrzej S. Kosinski, PhD, Antoine Douaihy, MD, Bruce R. Schackman, PhD, Moupali Das, MD, Robert Lindblad, MD, Sarah Erickson, PhD, P. Todd Korthuis, MD, Steve Martino, PhD, James L. Sorensen, PhD, José Szapocznik, PhD, Rochelle Walensky, MD, Bernard Branson, MD, and Grant N. Colfax, MD

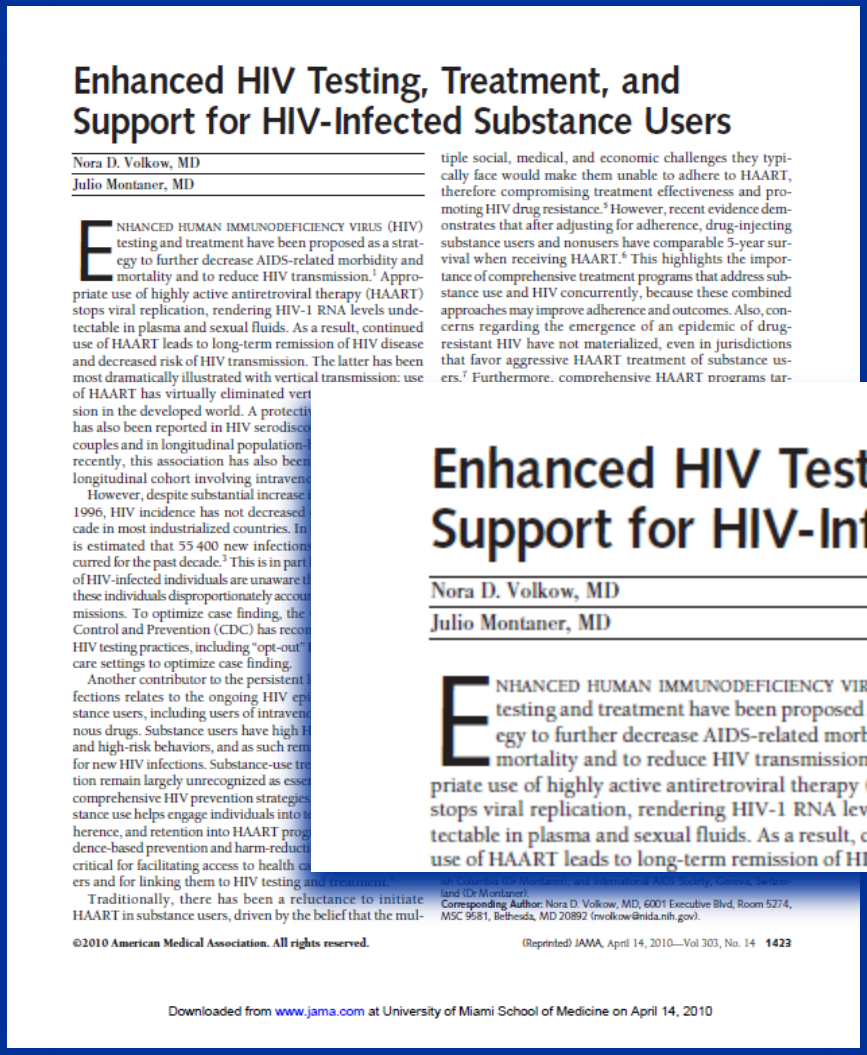
From Research to Policy: 0032 and the National HIV/AIDS Strategy

- National Strategy target: Increase from 79% to 90% of people living with HIV who know their status by 2015
  - "CDC will update and issue guidelines on the provision of HIV counseling and testing in nonclinical settings."
  - "SAMHSA and other relevant HHS agencies will consider guidance requiring Federally funded substance abuse and mental health treatment clinics to offer voluntary routine HIV testing to their clients."

HIV Testing Blending Product

- Video interviews with researchers, treatment providers, executive directors, and clients about the value of Onsite Rapid HIV Testing
- A Fact Sheet that provides details about the urgent need to provide routine onsite HIV testing and substantive information about the NIDA Study
- A Web Guide that provides links to valuable testing and other implementation resources

"Seek, Test, Treat, and Retain"



Enhanced HIV Testing, Treatment, and Support for HIV-Infected Substance Users

Nora D. Volkow, MD
Julio Montaner, MD

ENHANCED HUMAN IMMUNODEFICIENCY VIRUS (HIV) testing and treatment have been proposed as a strategy to further decrease AIDS-related morbidity and mortality and to reduce HIV transmission.[1] Appropriate use of highly active antiretroviral therapy (HAART) stops viral replication, rendering HIV-1 RNA levels undetectable in plasma and sexual fluids. As a result, continued use of HAART leads to long-term remission of HIV disease and decreased risk of HIV transmission. The latter has been most dramatically illustrated with vertical transmission: use of HAART has virtually eliminated vert
sion in the developed world. A protecti
has also been reported in HIV serodisco
couples and in longitudinal population-
recently, this association has also been
longitudinal cohort involving intraven

However, despite substantial increase
1996, HIV incidence has not decreased
cade in most industrialized countries. In
is estimated that 55 400 new infection
curred for the past decade.[3] This is in part
of HIV-infected individuals are unaware t
these individuals disproportionately accou
missions. To optimize case finding, the
Control and Prevention (CDC) has recon
HIV testing practices, including "opt-out"
care settings to optimize case finding.

Another contributor to the persistent
fections relates to the ongoing HIV ep
stance users, including users of intraven
nous drugs. Substance users have high H
and high-risk behaviors, and as such rem
for new HIV infections. Substance-use tr
tion remain largely unrecognized as esse
comprehensive HIV prevention strategies
stance use helps engage individuals into t
herence, and retention into HAART prog
dence-based prevention and harm-reducti
critical for facilitating access to health ca
ers and for linking them to HIV testing a

Traditionally, there has been a reluctance to initiate HAART in substance users, driven by the belief that the multiple social, medical, and economic challenges they typically face would make them unable to adhere to HAART, therefore compromising treatment effectiveness and promoting HIV drug resistance.[5] However, recent evidence demonstrates that after adjusting for adherence, drug-injecting substance users and nonusers have comparable 5-year survival when receiving HAART.[6] This highlights the importance of comprehensive treatment programs that address substance use and HIV concurrently, because these combined approaches may improve adherence and outcomes. Also, concerns regarding the emergence of an epidemic of drug-resistant HIV have not materialized, even in jurisdictions that favor aggressive HAART treatment of substance users.[7] Furthermore, comprehensive HAART programs tar-

land (Dr Montaner).

Corresponding Author: Nora D. Volkow, MD, 6001 Executive Blvd, Room 5274, MSC 9581, Bethesda, MD 20892 (nvolkow@nida.nih.gov).

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