

HIV Testing in Drug Abuse Treatment: New Paradigms

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Today's Presentation

- Update on revised CDC guidelines for HIV screening in health care settings
- Describe benefits of HIV testing and counseling
- Present latest technologies to conduct HIV testing and counseling
- Describe opportunity for providing HIV testing and counseling in drug abuse treatment
- Introduce CTN 0032 – HIV testing and counseling study in drug abuse treatment in U.S.

Criteria that justify routine screening

- Serious health disorder that can be detected before symptoms develop
- Treatment is more beneficial when begun before symptoms develop
- Reliable, inexpensive, acceptable screening test
- Costs of screening are reasonable in relation to anticipated benefits

Principles and Practice of Screening for Disease
-WHO Public Health Paper, 1968

Revised CDC recommendations: Adults and adolescents - I

- Routine, voluntary HIV screening for all persons 13-64 in health care settings, not based on risk
- Repeat HIV screening of persons with known risk at least annually
- Include HIV consent with general consent for care; separate signed informed consent not recommended
- Prevention counseling in conjunction with HIV screening in health care settings is not required

Revised CDC recommendations: Adults and adolescents - II

- Intended for all health care settings, including inpatient services, EDs, urgent care clinics, STD clinics, TB clinics, public health clinics, community clinics, substance abuse treatment centers, correctional health facilities, primary care settings
- Provide clinical HIV care or establish reliable referral to qualified providers

**Revised CDC Guidelines for
HIV testing in Non-Medical
Care Settings**

In Development

Opportunity

- Over 1,000,000 people in the United States are living with HIV
 - 40,000 new cases each year
 - 250,000 – 300,000 of persons living with HIV are unaware they are infected
 - 1/4 of persons who test HIV-positive (with standard testing) fail to return to receive results
- 40% of persons diagnosed with HIV receive an AIDS diagnosis within one year
- Drug abuse continues to be major transmission vector, via injection and sexual risk behaviors

Many HIV-infected persons are not aware

- Many newly-diagnosed may not even suspect that they are HIV infected.
 - CDC's 2004-2005 National HIV Behavioral Surveillance study surveyed and tested 2,261 men who have sex with men in Baltimore, Los Angeles, Miami, New York City, and San Francisco. Almost half (48%) of the 450 men who tested positive were unaware of their HIV infection (Sifakis, Flynn, Metsch et al., 2005).
 - Data from a pooled cross-sectional analysis of the 2000-2005 National Health Interview Survey showed that less than one-fourth of respondents who reported engaging in HIV risk behaviors in the past year reported having an HIV test in that period (Ostermann, Kumar, Pence, & Whetten, 2007).

Late HIV Testing is Common

Supplement to HIV/AIDS Surveillance, 2000-2003

- Among 4,127 persons with AIDS*, 45% were first diagnosed HIV-positive within 12 months of AIDS diagnosis (“late testers”)
- Late testers, compared to those tested early (>5 yrs before AIDS diagnosis) were more likely to be:
 - Younger (18-29 yrs)
 - Heterosexual
 - Less educated
 - African American or Hispanic

Benefits of HIV Testing

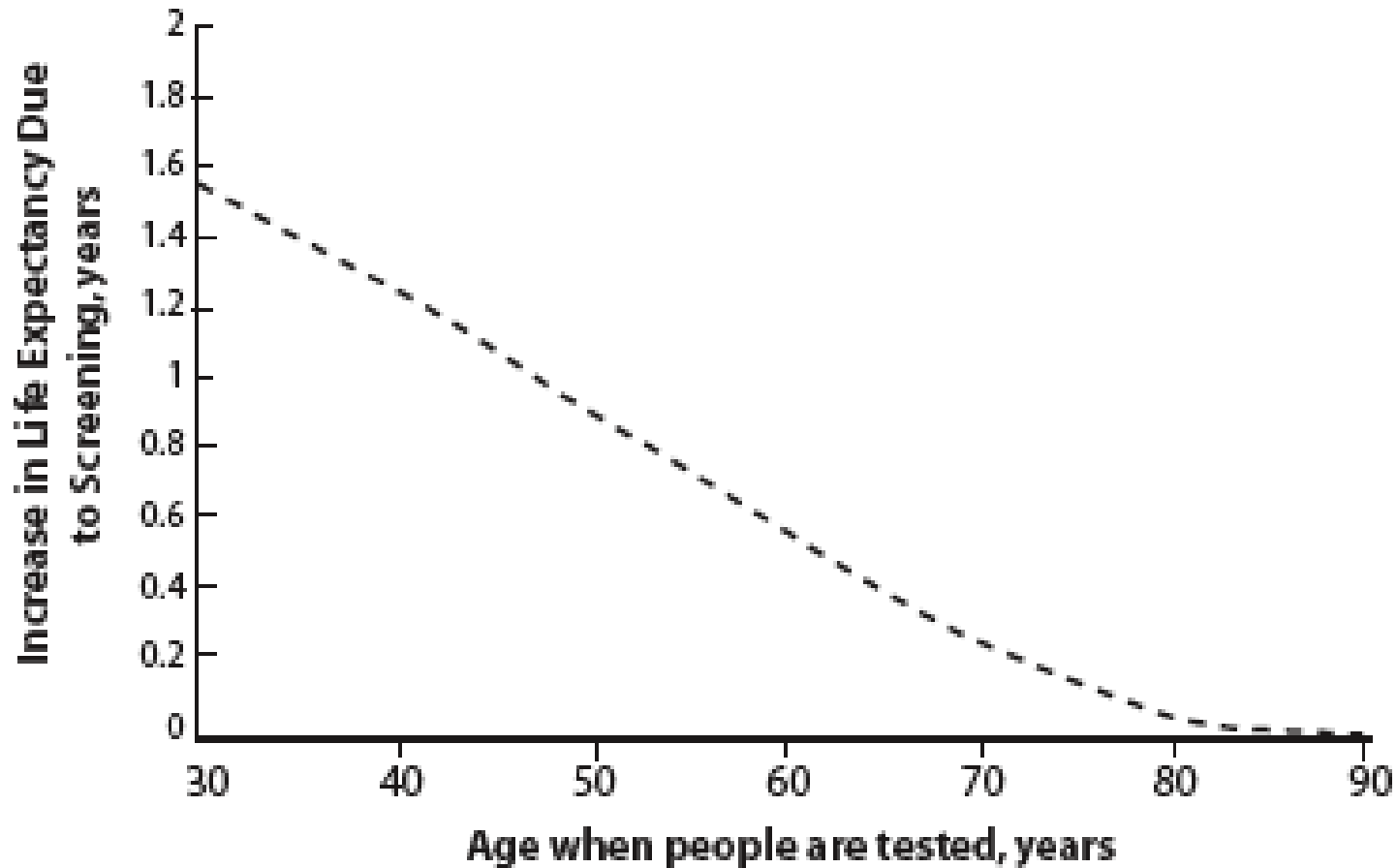
- Decreases spread of HIV: an HIV diagnosis is associated with reduction in high risk sexual and injection behaviors
- Improves survival: Linkage to care and treatment

Knowledge of Serostatus Reduces Risk Behavior

- Majority of persons who learn that they are HIV+ will reduce their risk behaviors
- Majority of new HIV infections in U.S. stem from persons who are unaware of their HIV status
- Among HIV-negative cohorts, counseling interventions based on behavioral theory have led to reduced STD incidence and reduced risk behaviors associated with the acquisition of HIV

Colfax et al., 2002; AIDS
Marks et al., 2005, 2006; AIDS
Kamb et al., 1998, JAMA
NIMH Multisite, 1998, Science

Study Predicts Routine Voluntary HIV Testing Would Extend Survival



HIV Testing and Other Routine Tests: Cost-Effectiveness Compared

Test	\$/QALY* Gained
HIV test: All inpatients†	38,600
HIV test every 5 years: People at high risk (3% prevalence)†	50,000
HIV test one time (1% prevalence)‡ - Individual benefit only	41,736
- Including benefit to others	15,078
HIV test one time: U.S. general population (0.1% prevalence)†	113,000
Breast cancer test: Annual mammogram, age 50-69§	57,500
Colon cancer test: FOBT + SIG every 5 years, age 50-85§	57,700
Type 2 diabetes test: Fasting blood glucose, age >25§	70,000
Hypertension testing§	48,000

FOBT indicates fecal occult blood test; SIG, sigmoidoscopy.

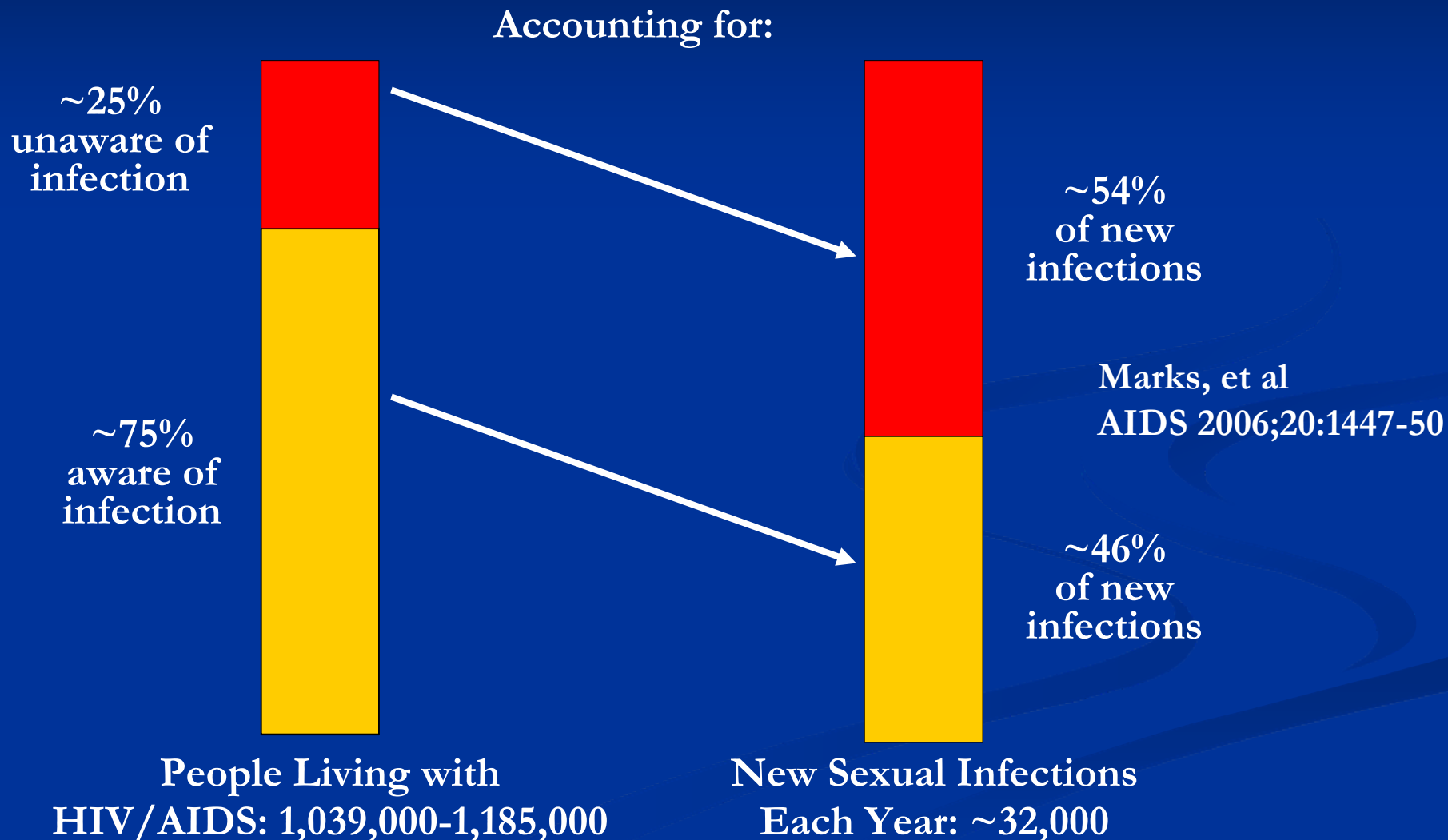
*In quality-adjusted life years (QALYs), which account for both longevity and health-related quality of life.

†Paltiel et al. (2005); ‡Sanders et al. (2005);

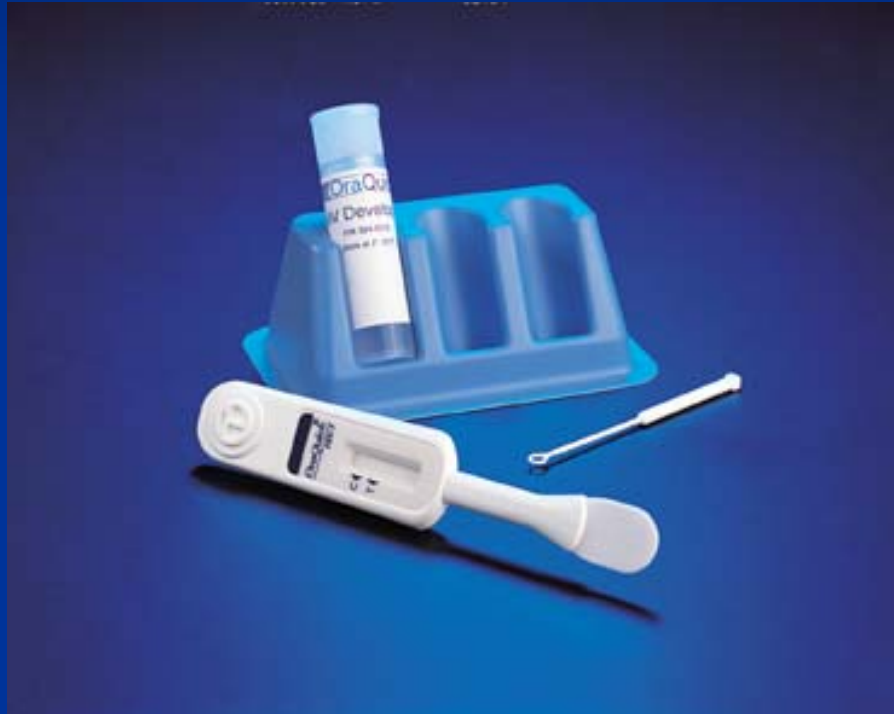
§Adapted from personal communication, Sanders and Paltiel, 2005.

NIDA Notes Vol. 20 (3), 2005.

Awareness of serostatus among people with HIV and estimates of transmission



HIV Rapid Test



- FDA approved
- Only requires blood from a finger stick or oral fluid from a swab
- Results in 20 minutes
- Does not require laboratory facilities and can be done by drug counselors

Understanding HIV Test Results

- Traditional HIV testing can yield three results
 - Positive
 - Negative
 - Inconclusive
 - Test cannot determine HIV infection
- Rapid HIV testing can yield three results
 - Reactive (Preliminary Positive – not a diagnosis)
 - Non-reactive (Negative)
 - Invalid
 - Problem with the device or sample

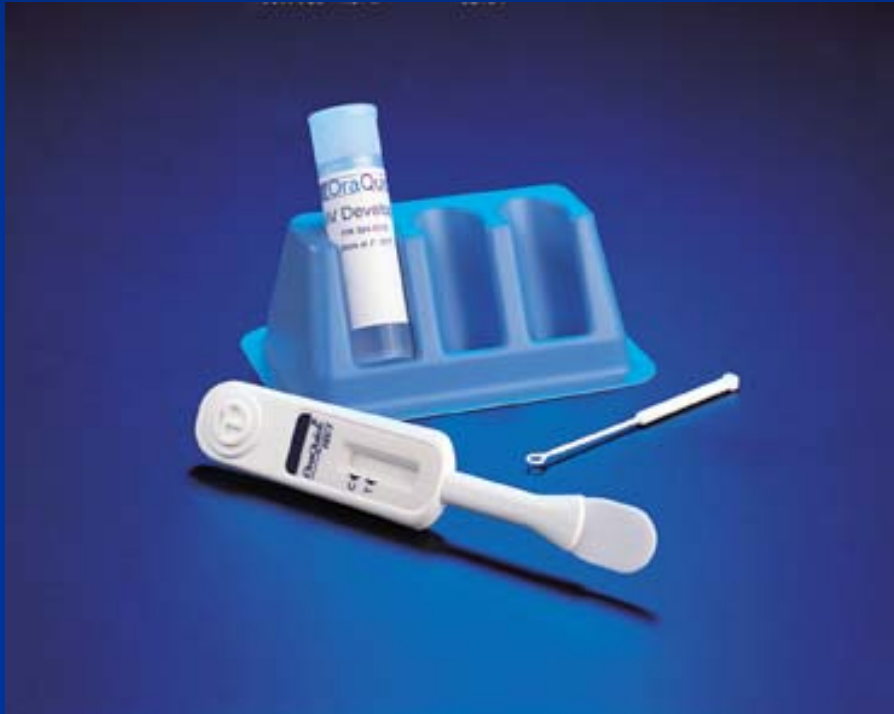
Test Accuracy

	OraQuick ADVANCE Blood	OraQuick ADVANCE Oral Fluid	Uni- Gold	Reveal	Multispot
Specificity	100%	99.8%	99.7%	99.1%	99.9%
Sensitivity	99.6%	99.3%	100%	99.8%	100%

Confirmatory Testing

- Still requires follow-up blood draw or oral fluid
- Takes 1 – 2 weeks to get results
- Studies are currently evaluating using a second rapid test as confirmatory testing

HIV Rapid Test



- A meta analysis of 17 studies with over 20, 000 clients showed
 - Rapid testing clients (compared with traditional testing clients) were 2X as likely to receive test results
 - Rate of false-positive test results was < 1 percent
- Studies have also showed that HIV+s in rapid testing trials more likely to be linked to HIV care

Kendrick et al., 2005 JAIDS

Hutchinson et al., 2006 AIDS

Counseling in the rapid testing era

- All new persons who test positive receive counseling
- Unclear effect on HIV-negatives
 - What is the effect of counseling on persons' decision to get HIV tested?
 - Does testing reduce risk behaviors among HIV-negatives?
 - Do we triage high-risk persons for counseling?

What are the benefits of counseling?

- Project RESPECT: Evidence-based counseling that demonstrated significant reduction of STD incidence
 - Brief, client-centered, individually administered 2 - session counseling intervention that has been conducted on mass basis in STD clinics
- Multiple counseling studies demonstrate reductions in self-reported risk behavior of around 25%

Project RESPECT:

Counseling reduces STI incidence



RESPECT updated

- RESPECT-2:
 - Adapted RESPECT in rapid testing era
 - 2-visit, 2-session RESPECT vs. rapid RESPECT
- More persons in rapid arm received results
- Overall no difference in STIs between arms
 - Higher incidence among men
 - Higher incidence among MSM

Drug abuse treatment as an opportune venue for offering HIV testing

- Many facilities have the capacity and organizational linkages to refer HIV+ clients to medical providers.
- Drug abuse treatment programs serve a distinctive population facing high HIV risks.
- National Institute on Drug Abuse (NIDA), in its *Principles of Drug Addiction Treatment*, states that drug tx programs should assess clients for HIV infection and for other infectious diseases, and should provide counseling to address behavioral risks.

Barriers to Counseling & Testing in Drug Abuse Treatment

- Drug treatment programs may lack resources, financial incentives, or expertise to routinely and effectively provide these services.
- Counseling and testing may provide an uneasy fit with drug treatment program's core mission or with the practice philosophies of their key staff.
- For example, a free standing outpatient treatment program that serves populations deemed at low risk may place a low priority on HIV counseling and testing services.
- The impact of these barriers largely unknown.

The Case for Drug Abuse Treatment....

- Fewer than 1/3 of U.S. drug treatment programs offer HIV testing and counseling *
- Less than 1/2 of CTN community treatment programs made HIV testing available either in the CTP, through referral or outsourced **

SAMSHA, 2004 *

Brown et al. JSAT, 2006, AJP, 2007 **

**Is there a need to offer
HIV testing in drug
abuse treatment?**

Pollack & D'Aunno Analysis

Unpublished Results

- 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

Unpublished Results

	1995 (wave 4) [95% CI] (N=568)	2000 (wave 5) [95% CI] (N=501)	2005 (wave 6) [95% CI] (N=500)
Percentage of clients who receive <i>off-site</i> HIV tests	10.3% [7.6, 13.0]	7.4% [4.6, 10.2]	9.1% [4.4, 13.8]
Percentage of clients who receive <i>on-site</i> HIV tests	16.5 [12.2, 20.8]	14.2 [10.4, 17.8]	13.8 [10.3, 17.3]
Percentage of units, weighted by caseload, which provide at least some <i>on-site</i> HIV testing.	34.9 [28.2, 41.6]	42.6 [32.1, 53.1]	41.2 [32.0, 50.3]

Need for Scientific Studies

- CDC new guidelines for offering HIV testing in health care settings represent recommendations without attached dollars
- CDC and new guidelines are moving away from HIV counseling at the time of testing
- Guidelines for non-medical care recommendations for HIV testing are underway
- Scientific study is needed to evaluate the effectiveness of offering HIV rapid testing + counseling in drug treatment programs
 - Effect on getting people to receive their HIV test results
 - Effect on sexual risk behaviors

David Holtgrave: *Costs and Consequences of the New CDC Testing Guidelines*
(June, 2007; www.plosmedicine.org)

- Article questions costs and consequences of new CDC guidelines regarding routine HIV testing without risk reduction counseling (compared with a more targeted counseling and testing strategy)
- Uses scenario and cost-effectiveness analysis
- Concludes that abandoning counseling would have real public health consequences in terms of HIV infections that could have been averted

David Holtgrave: *Costs and Consequences of the New CDC Testing Guidelines*
(June, 2007; www.plosmedicine.org)

- Editor's note says that Holtgrave's article

“has a major limitation in that it tried to predict what might happen in the future – it did not study the actual impact of the two different types of testing on a group of people.”

Previous Research

- Speilberg et al. (JAIDS, 2005)
 - Study of 7,014 participants in needle exchange site and two bath houses
 - Offered participants choice of traditional T & C, rapid testing and standard counseling, oral fluid testing and standard counseling, and traditional testing with choice of written materials or standard counseling
 - Results suggest that participants prefer oral fluid test and written pre-test materials compared to traditional counseling and testing
 - Very low testing acceptance rates (8.7% - 19.5% in needle exchange)

Previous Research

- Anaya et al. (IGIM, 2008)
 - Study of 251 participants in 2 VA sites in Southern California
 - RCT to evaluate models to increase rates of HIV testing and receipt of results
 - Traditional Counseling/Testing
 - Nurse-Initiated Screening, Traditional Counseling/Testing
 - Nurse-Initiated Screening, Streamlined Counseling, Rapid Testing

Anaya et al. (JGIM, 2008)

- Results showed that nurse-initiated, streamlined counseling, rapid testing model worked best
 - Participants in this group were 5x as likely to receive HIV test results compared to those who received traditional testing/counseling
- There were no significant differences in reported sexual risk behavior and knowledge (secondary outcomes)

CTN 0032

NIDA Funded National Drug
Abuse Treatment
Clinical Trials Network

Research Questions

Among persons who attend substance abuse treatment and report being HIV negative or not knowing their status...

(1) What is the more effective testing strategy to ensure they get HIV tested and receive their results?

(2) What is the more effective testing strategy to decrease their risk behaviors?

Three Testing Strategies to be evaluated in 3 arm RCT

- Offer on-site HIV rapid testing (via oral fluid) with brief participant-tailored prevention counseling
- Offer on-site HIV rapid testing (via oral fluid) with information only
- Offer referral for HIV testing in the community

Persons who test HIV-positive

- Extensive and close follow-up for persons who test HIV+
 - Post-test counseling is provided
 - Evidence-based brief case management will be offered for persons who are not linked to care
(Gardner, Metsch et al., AIDS, 2005)

Overview of Proposed Methods

- Participant-Level Randomization
- 1,272 drug treatment clients will be enrolled at 12 CTPs in the U.S.
- Sites that are currently offering on-site testing would be excluded
- All types of treatment programs are eligible

Participant Eligibility

- 18 years and older
- Report being HIV-negative/unknown status
- Report no HIV test with receipt of results in past 12 months
- Able and willing to sign informed consent
- Able to provide locator information
- Willing to sign a release that will allow us to abstract HIV testing records and medical records for persons who test positive

Study Outcomes and Assessment

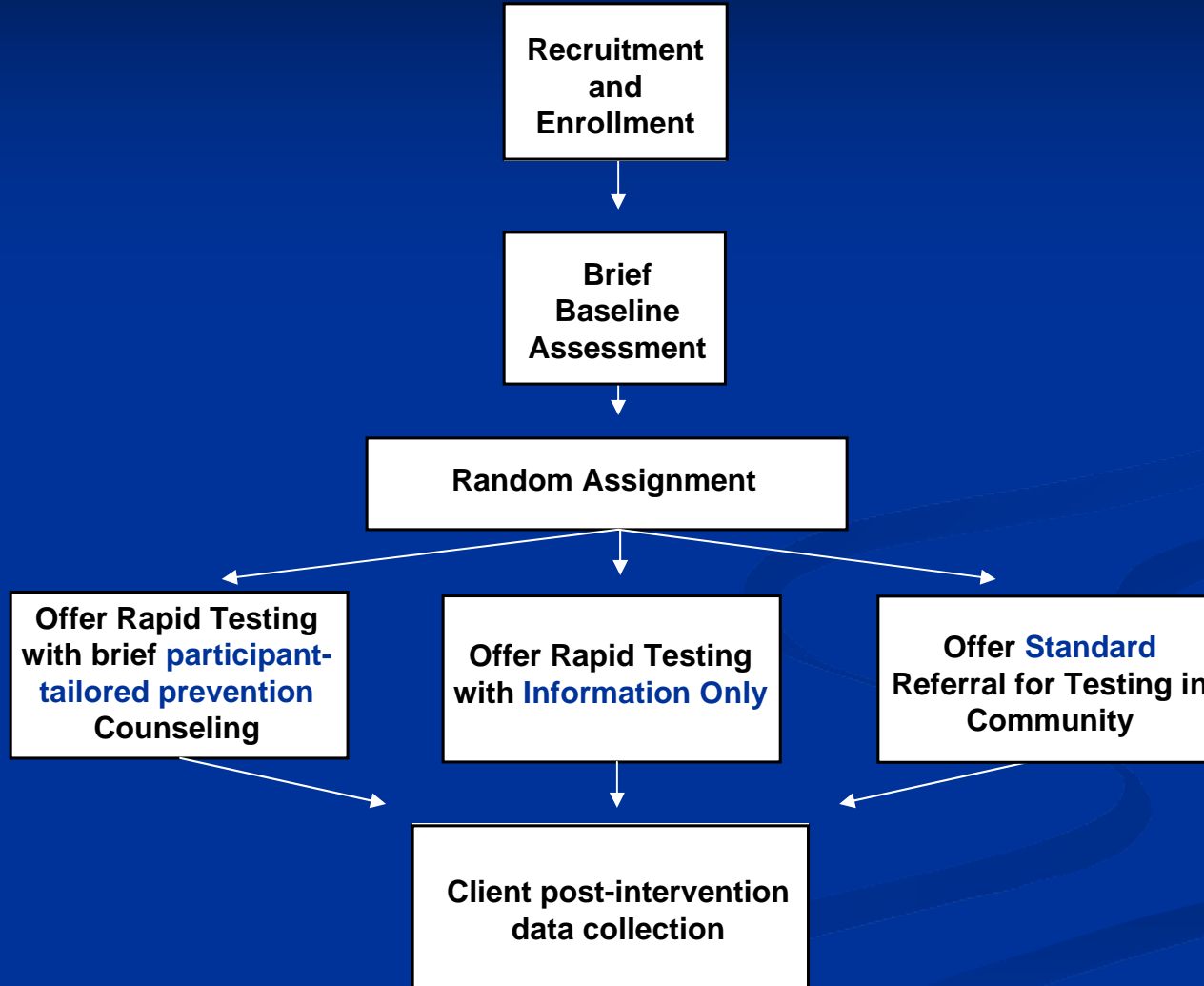
Two Primary Outcomes:

- Self-reported receipt of HIV test results at one month follow-up
- Self-reported sexual risk behavior at 1 month and 6 month follow-up

Data collected on Web-Based ACASI (Audio Computer Assisted Self Interview) and **Electronic Data Collection Form (eCRF)**

Strong Emphasis on Intervention Fidelity and Quality Assurance

Overview of Study Design



Cost Study

- Led by Bruce Schackman, Ph.D. at Cornell U.
- Submitting supplement to NIDA Health Services Research Branch
- Supplemental Research proposes to:
 - Document costs of three intervention strategies
 - Conduct preliminary modeling of cost-effectiveness of on-site testing (with and without counseling) in drug treatment setting using CEPAC modeling.

*We hope to begin randomizing
participants in Fall, 2008*