The New HIV Testing Landscape: What approach is right for your health center?

Primary Care Development Corporation

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About the Primary Care Development Corporation (PCDC)

Founded in 1993, PCDC is a nonprofit organization dedicated to expanding and transforming primary care in underserved communities to **improve health outcomes, lower health costs and reduce disparities.**

- Certified as a Community Development Financial Institution (CDFI) by the U.S. Treasury
- Offices in New York City and Los Angeles County
- Three Programs:
  - Capital Investment
  - Performance Improvement
  - Policy & Advocacy
About HIP in Health Care

• PCDC's HIP in Health Care program is funded by the U.S. Centers for Disease Control and Prevention (CDC) to build the capacity of healthcare organizations to deliver HIV prevention services and strategies within clinical settings.

• We provide training and technical assistance at no cost to healthcare organizations (i.e., direct service providers) across the United States and its affiliated territories.

• In support of the National HIV/AIDS Strategy (NHAS) and CDC’s High-Impact Prevention approach, our capacity building assistance (CBA) is focused on:
  – HIV Testing
  – Prevention with Positives
  – Prevention with High-Risk Negatives
About the CPN:

• HIP in Health Care is part of the Capacity Building Provider Network (CPN)
• The CPN is a network of 22 organizations that are funded by CDC to build the capacity of the nation’s HIV prevention workforce in 3 Settings:
  – Health Departments
  – Community-Based Organizations
  – Health Care Organizations

• CPN providers provide CBA in the following areas:
  – HIV testing
  – Prevention with HIV-positive persons
  – Prevention with HIV-negative persons
  – Condom distribution
  – Organizational development & management
  – Policy

http://www.cbaproviders.org
Learning Objectives

• Increase understanding of how opt-out HIV screening can be effective in both rural and urban Louisiana primary care settings

• Increase understanding of the considerations for using rapid vs. laboratory HIV screening/testing approaches

• Increase understanding of the CDC’s recommended Laboratory HIV Testing Algorithm and the benefits of rapid linkage to care
Current State of Affairs

*H.I.V. Rates Among Gay Men Are Higher in South, Study Finds*

*New York Times, May 2016*

*More Than Half of Gay and Bisexual Men Say a Doctor Has Never Suggested H.I.V. Testing*

*New York Times, October 2015*
Diagnoses of HIV Infection among Adults and Adolescents, by Sex, 2010–2014—United States and 6 Dependent Areas

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.
Diagnoses of HIV Infection among Adults and Adolescents, by Transmission Category, 2010–2014—United States and 6 Dependent Areas

- Male-to-male sexual contact
- Heterosexual contact\(^a\)
- Injection drug use (IDU)
- Male-to-male sexual contact and IDU
- Other\(^b\)

*Note.* Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting.

\(^a\) Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.

\(^b\) Includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.
Rates of Diagnoses of HIV Infection among Adults and Adolescents, by Age at Diagnosis, 2010–2014—United States

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.
Louisiana HIV and AIDS incidence

- HIV incidence
  - Louisiana 3rd highest in US
  - New Orleans 2nd highest in US
  - Baton Rouge 4th highest in US

- AIDS incidence
  - Louisiana 3rd highest in US
  - New Orleans metro 5th highest in US
  - Baton Rouge metro 3rd highest in US

Source: 2015 LA DHH Surveillance
PLWHA in Louisiana

• 20,272 People Living with HIV and AIDS (PLWHA) in Louisiana (Q2 2015)

• 1,337 new HIV diagnoses in Louisiana in 2014

Source: LA DHH Surveillance
An ounce of prevention is worth a pound of cure.

- Benjamin Franklin

Testing as Powerful Tool to Stop HIV
Support for early detection

- 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
Knowledge of HIV Infection and Behavior

After people become aware they are HIV-positive, the prevalence of high-risk sexual behavior is reduced substantially.

Reduction in Unprotected Anal or Vaginal Intercourse with HIV-neg partners: 68%
HIV-pos Aware vs. HIV-pos Unaware

Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the U.S.
TasP

- Treatment as Prevention or TasP
- Utilizing HIV treatment, or antiretroviral therapy (ART), in individuals living with HIV to decrease risk of transmitting HIV to HIV-negative partners
- Reducing viral load to “undetectable” level significantly reduces transmission risk
- A 2011 study showed a 96% reduction in transmission of HIV to HIV-negative partners\(^1\)
- Studies have continued to support TasP as an effective HIV prevention strategy
- Rapid linkage to care remains key in TasP effectiveness

Today’s HIV Testing Landscape: Many Choices, Many Terms
DETERMINING YOUR HIV TESTING APPROACH
FIRST, A REVIEW OF THE TERMS...
What is “Opt-in” Testing?
What is “Opt-in” Testing?

Opt-in testing means testing is offered and the patient is required to actively give permission before it can occur.

Provider: Would you like an HIV test today?
Patient: No, that’s ok.
Provider: Ok.
Targeted (Opt-in) Testing

• Any screening process that is geared to meet a particular population
  – Populations identified for targeted HIV testing are considered high risk for exposure to HIV

• Targeted testing can be approached in two ways:
  – Provider initiated testing – healthcare professionals identify certain patient risks and offer HIV testing
  – Patient initiated testing – individuals who feel they may be at risk or have been exposed to HIV seek out testing
What is “Opt-out” Testing?
What is “Opt-out” Testing?

“Performing HIV screening after notifying the patient that 1) the test will be performed and 2) the patient may elect to decline or defer testing. Assent is inferred unless the patient declines testing.”

Provider: As part of our routine labs, we are going to test you for HIV today.
Patient: Ok.
Universal (opt-out) testing

- Recommended by the Centers for Disease Control and Prevention (CDC) since 2006

- Healthcare providers should test all patients between the ages of 13 and 64 years at least annually

- However, frequency of testing partially depends on clinical judgment and the individual level of risk
  - People at high risk of infection could be tested more often than once a year
  - Repeat screening of other individuals would depend on the provider's best judgment for each case
Revised HIV Testing Recommendations
CDC 2006

<table>
<thead>
<tr>
<th>Elements of HIV Testing Procedures</th>
<th>Previous CDC Recommendations “opt-in”/targeted testing</th>
<th>2006 CDC Recommendations “opt-out”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who should be tested?</td>
<td>Perceived “at-risk”, opt-in (patient asks for HIV test)</td>
<td>All ever-sexually active, age 13-64 “Opt-out” all patients tested, with right of refusal on notification</td>
</tr>
<tr>
<td>Placement of HIV Testing</td>
<td>Mostly offered during gyn/obstetric visits, symptomatic STI patients, perhaps at annual exam for all patients but uneven performance on test offered by clinicians</td>
<td>Offered to all eligible patients at every medical contact (primary medical care for any reason, ER visits). Offered at least annually to all clients as a routine part of care</td>
</tr>
<tr>
<td>Consent</td>
<td>Separate consent form often required</td>
<td>No separate consent form required, covered under general consent for receipt of care</td>
</tr>
<tr>
<td>Pre-Counseling</td>
<td>Extensive pre-counseling required, often provided by a counselor in separate setting</td>
<td>Limited pre-counseling required prior to routine performance of HIV test</td>
</tr>
<tr>
<td>Post Counseling</td>
<td>Extensive, based on test result</td>
<td>Extensive, based on test result</td>
</tr>
</tbody>
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Moore, K.M. 2009
# Targeted testing

<table>
<thead>
<tr>
<th>PROS</th>
<th>CONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximizes use of testing resources</td>
<td>Misses individuals incorrectly considered at low risk</td>
</tr>
<tr>
<td>Allows sites to focus their activities on higher risk populations</td>
<td>Misses individuals who were unaware of their risk</td>
</tr>
<tr>
<td>Yields a higher positivity rate than routine or standard testing</td>
<td>Healthcare staff have limited time and resources to conduct risk assessments in busy healthcare settings</td>
</tr>
<tr>
<td></td>
<td>Healthcare staff may not have access to specific information on the prevalence of HIV in a particular area</td>
</tr>
</tbody>
</table>
# Universal testing

<table>
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<tr>
<th>PROS</th>
<th>CONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>May reach individuals who were not accessing testing: has been shown to increase testing uptake in certain populations(^1)</td>
<td>Cost of testing all patients may be a concern</td>
</tr>
<tr>
<td>May decrease stigma or anxiety around HIV screening,(^1) may normalize testing</td>
<td>May lead to funding concerns if yielding a low incidence of positive test results</td>
</tr>
<tr>
<td>Removes potential inaccuracies in provider’s assessment of patient HIV risk</td>
<td></td>
</tr>
<tr>
<td>Represents public opinion: a majority of persons feel HIV testing should be part of the regular services and isn’t different from other tests(^2)</td>
<td></td>
</tr>
</tbody>
</table>


**Cost-effectiveness**

- Universal HIV screening has been shown to be cost-effective in clinical settings
  - Cost-effective even in situations with low HIV prevalence
  - At least as cost-effective as many other commonly recommended screening programs (such as breast and colon cancer, diabetes and hypertension)

- A study by Walensky *et al.* determined that universal inpatient screening was cost-effective even at prevalence rates up to ten times lower than recommended thresholds for universal screening (0.1% compared to 1%)

- Universal screening would increase quality of life and life expectancy of HIV-infected individuals owing to earlier identification by at least 1.5 years

Implications of Opt-out HIV Screening in Clinical Practice

• Opt-out screening strategies are **fully supported** in the 2006 CDC guidelines.
  – Applicable to most clinical settings including primary care
  – Clinicians should have policies and procedures in place to conduct opt-out screening, delivery of test results and linkage to care services
  – Most legal requirements for informed written consent have been removed or significantly diminished to facilitate guideline implementation

• Should not supplant opportunities for patient education
  – Opt-out testing doesn’t restrict counseling
  – Counseling can be beneficial for patients, including: prevention education, sexual health counseling, facilitating access to condoms and PrEP
  – Referral to outside counseling services if unavailable at clinic
Test HIV Recommendations, USPSTF

- U.S. Preventive Services Task Force (USPSTF) provides evidence-based recommendations

- USPSTF grade changes play a significant role in coverage and reimbursement for HIV testing service & form the basis for coverage of preventative services by Medicare and Medicaid

- Affordable Care Act (ACA) mandates that private insurers must cover all services given a Grade A or B by the USPSTF without cost-sharing

- Previous USPSTF recommended HIV Testing only for people at risk for HIV and pregnant women as Grade A

- Now USPSTF recommended that routine HIV screening for all adolescents and adults ages 15 through 65 as Grade A (formerly grade C)

What type of testing would work best for your setting?

- Opt-out testing?
- Targeted opt-in testing?
Testing considerations in urban and rural settings

- Opt-in testing may be important in facilities with limited testing availability
  - Essential to assess client sexual and IDU history to accurately assess testing need

- Rural communities may allow the best access to care due to distance

- Smaller communities could present stigma concern when seeking testing

- Urban areas may have a higher volume of testing facilities and offer increased confidentiality

- Urban settings may offer more specialized services for individuals who identify as LGBT

- Data on HIV incidence in rural areas may be inaccurate if individuals are traveling for testing
  - Potential for obtaining internal data to accurately assess incidence
DETERMINING YOUR HIV TESTING TECHNOLOGY
RAPID VS. LABORATORY (NON-RAPID) HIV TESTING METHODS: DOES IT REALLY MATTER??

http://kingdomauthority.org/tortoise-or-hare/
Laboratory HIV Screening Tests (non-rapid tests)

- May be best for clients who are likely to return for lab results
- Turn around time can be variable (typically less than 2 days - check with your lab)
- Easy to combine with regular blood draw at annual exam or other routine appointment, add into existing workflow
- Reflex testing allows for automatic confirmatory tests – no delivery of preliminary results
- Requires patient to return to clinic for positive test results
- Newly established diagnostic algorithm available that can detect infection earliest of available screening tests
Rapid HIV tests

- Allows preliminary HIV results to be delivered at same visit which facilitates quick linkages to care

- Appropriate for clients who may be more transient, need urgent results (occupational exposure or nPEP), or are at high risk of loss to follow-up

- Test to result time from 60 seconds to 20 minutes

- Potentially diminished sensitivity in acute infection

- Can be preformed by a variety of staff in the clinical setting

- Commonly used in non-clinical settings or non-traditional settings
3rd vs. 4th generation testing

What’s the difference?
3<sup>rd</sup> vs. 4<sup>th</sup> generation testing

- 3<sup>rd</sup> generation HIV testing looks for the presence of antibodies
  - Antibodies are the body’s immune response to the virus

- 4<sup>th</sup> generation testing looks for antibodies as well as the p24 antigen
  - Antigens are proteins from the virus

- The p24 antigen peaks during acute HIV infection

- 4<sup>th</sup> generation testing allows for detection of acute infection in laboratory testing

- 4<sup>th</sup> Generation (Ag/Ab) <strong>rapid</strong> tests may have significantly diminished sensitivity in detecting acute infection

- If presumptive acute infection consider HIV RNA testing
Window Period and HIV Infection

CDC Recommended Laboratory HIV Testing Algorithm

<table>
<thead>
<tr>
<th>Result</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1, HIV-2, and HIV p24 Ag not detected</td>
<td>Client tested NEGATIVE for HIV-1 and HIV-2</td>
</tr>
<tr>
<td>Reactive screening test (Ag/Ab), HIV-2 Antibodies detected</td>
<td>Client tested POSITIVE for HIV-2</td>
</tr>
<tr>
<td>Reactive screening test (Ag/Ab), HIV-1 Antibodies detected</td>
<td>Client tested POSITIVE for HIV-1</td>
</tr>
<tr>
<td>Reactive screening test (Ag/Ab), non-reactive/ Ab assay, with positive RNA/NAAT for HIV-1</td>
<td>Client tested POSITIVE for HIV-1, likely in the with acute HIV infection.</td>
</tr>
<tr>
<td>Reactive screening test (Ag/Ab), non-reactive Ab assay, Negative HIV-1 RNA/NAAT</td>
<td>No confirmation of antibodies, no RNA detected. Should consider HIV-2 testing.</td>
</tr>
<tr>
<td>Reactive screening test (Ag/Ab), indeterminate Ab assay, Positive HIV-1 RNA/NAAT</td>
<td>Evidence of HIV -1 antibodies, Confirmation of HIV-1 RNA. Client tested POSITIVE for HIV-1 infection</td>
</tr>
<tr>
<td>Reactive screening test (Ag/Ab), HIV-1 and HIV-2 Antibodies detected</td>
<td>Antibody evidence of infection, consider additional testing, to differentiate between HIV-1 and HIV-2 infection (RNA)</td>
</tr>
</tbody>
</table>


*Remember: If presumptive acute infection consider HIV RNA testing*
Why the Need for the New Algorithm

• Detection of Acute Infection is improved
  – High infectivity during acute infection
• Confirmation of HIV-2 infection
  – Western Blot can misclassify HIV-2 infection
• Indeterminate results
• Widely available assays
Provide a Linkage to Care!

The Most Critical Elements:

1. Assessment and education of the client
2. Referral to HIV medical provider if appropriate (outside provider)- make the appointment for the patient ASAP
3. If capable, assess for eligibility for HIV support services and assist with referral (or start paperwork)
4. Follow-up with client to ensure successful linkage and attendance at first appointment
5. Communicate with patient in the interim to check-in and provide support
6. Draw initial labs on the patient and get records to the outside provider
7. Discuss the need for partner services (testing/notification/referral)

UDS and linkage to care

• 2015 UDS (Uniform Data System) guidelines currently specify:
  – “HIV linkage to care: if patients found to be HIV positive are seen for follow-up care within 90 days of initial HIV diagnosis, then the probability of HIV-related complications and transmission of disease are reduced”

• Linkage to care is beneficial to patient and public health

• Recommendations will likely move to 30 days

• Benefits of improving linkages ahead of recommendation

• Connection with reimbursement

HIV Continuum of Care
Louisiana, 2014

70% of PLWH in care were virally suppressed

- Persons living with HIV: 18,5 (33%)
- In HIV care: 13,2 (30%)
- Retained in HIV care: 10,3 (20%)
- Viral suppression (<=200): 9,24 (0%)

Louisiana STD/HIV Program
HIV Continuum of Care
New Orleans MSA, 2014

- 100% of persons living with HIV were in care.
- 72% of those in care were retained.
- 55% of those retained had viral suppression (<=200).
- 50% of those with viral suppression were virally suppressed.

69% of PLWH in care were virally suppressed.
Linkage to care as an HIV prevention strategy!

- High rates (70%) of patients linked to care becoming undetectable
- Louisiana’s viral suppression rate is 50% among PLWH, which is 20 percent higher that the 30% national average
- Recall the 96% reduction in HIV transmission when undetectable
- HIV testing must be connected with a strong linkage to care services to be effective
- HIV testing must also be linked to good prevention services- PrEP, condom access, sexual health counseling

To review...

- HIV Screening is a powerful tool for prevention and facilitating linkage to care
- Opt-out screening is patient-centered and a standard of care
- There are many testing options, but newer technology and algorithms should be used when available (most sensitive)
  - What’s feasible for you?
  - What’s cost-effective in your practice?
- You have the power to help stop this epidemic: the first step to stopping an epidemic is identifying who is at risk and who is infected
THANK YOU!

For more information about PCDC's HIP in Health Care capacity building assistance services, contact us at:

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W:  www.pcdc.org/hipinhealthcare