HIV Testing Strategies in TLC-Plus

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Division of HIV/AIDS Prevention
National Center for Viral Hepatitis, HIV, STD, and TB Prevention
Persons with HIV and Awareness of HIV Status, United States - 2006

Number HIV infected 1,106,400

Number unaware of their HIV infection 232,700 (21%)

Estimated new infections annually 56,000

Campsmith M et al, MMWR October 2008
HIV Prevalence, NHANES 1999-2002

Household-based National Probability Sample

Prevalence of HIV Antibody, %

- National Health and Nutrition Examination Survey
  McQuillan et al, JAIDS April 2006
### Screening: HIV vs Cervical Cancer

<table>
<thead>
<tr>
<th></th>
<th>HIV</th>
<th>Cervical CA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual new cases</td>
<td>56,300</td>
<td>11,270</td>
</tr>
<tr>
<td>Deaths</td>
<td>15,564</td>
<td>4,070</td>
</tr>
</tbody>
</table>
### Source of HIV Tests and Positive Tests

- 40% of adults age 18-64 have been tested
- 18 million adults age 18-64 tested annually in U.S.

<table>
<thead>
<tr>
<th>Source</th>
<th>HIV tests (%)</th>
<th>HIV+ tests (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private doctor/HMO</td>
<td>53%</td>
<td>17%</td>
</tr>
<tr>
<td>Hospital, ED, Outpatient</td>
<td>18%</td>
<td>27%</td>
</tr>
<tr>
<td>Community clinic (public)</td>
<td>5%</td>
<td>21%</td>
</tr>
<tr>
<td>HIV counseling/testing</td>
<td>5%</td>
<td>9%</td>
</tr>
<tr>
<td>Correctional facility</td>
<td>0.4%</td>
<td>5%</td>
</tr>
<tr>
<td>STD clinic</td>
<td>0.1%</td>
<td>6%</td>
</tr>
<tr>
<td>Drug treatment clinic</td>
<td>0.4%</td>
<td>2%</td>
</tr>
</tbody>
</table>

*National Health Interview Survey, 2006
**Suppl. to HIV/AIDS surveillance, 2000-2003
**Late HIV Testing Remains Common**

<table>
<thead>
<tr>
<th>Year of HIV Dx</th>
<th>Number of Dx</th>
<th>AIDS in 1 year</th>
<th>AIDS in 3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996</td>
<td>18,016</td>
<td>43.2</td>
<td>49.1</td>
</tr>
<tr>
<td>1997</td>
<td>16,882</td>
<td>41.5</td>
<td>47.1</td>
</tr>
<tr>
<td>1998</td>
<td>15,429</td>
<td>41.6</td>
<td>47.4</td>
</tr>
<tr>
<td>1999</td>
<td>23,295</td>
<td>40.6</td>
<td>46.9</td>
</tr>
<tr>
<td>2000</td>
<td>28,842</td>
<td>39.5</td>
<td>46.0</td>
</tr>
<tr>
<td>2001</td>
<td>38,818</td>
<td>36.4</td>
<td>43.8</td>
</tr>
<tr>
<td>2002</td>
<td>36,244</td>
<td>36.7</td>
<td>44.4</td>
</tr>
<tr>
<td>2003</td>
<td>33,826</td>
<td>37.7</td>
<td>44.5</td>
</tr>
<tr>
<td>2004</td>
<td>35,645</td>
<td>37.6</td>
<td>--</td>
</tr>
<tr>
<td>2005</td>
<td>34,424</td>
<td>36.4</td>
<td>--</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>281,421</strong></td>
<td><strong>38.3</strong></td>
<td><strong>45.0</strong></td>
</tr>
</tbody>
</table>

- MMWR June 26, 2009
Rationale for Expanded HIV Screening
1. Treatment Is Effective

Mortality and HAART Use Over Time
HIV Outpatient Study, CDC, 1994-2003
Per-Person Survival Gains with Various Disease Interventions

- Chemotherapy
- Adjuvant chemotherapy
- Acute MI
- BMT
- OI Proph
- ART

- Non-small-cell lung cancer
- Node + breast cancer
- Coronary artery disease
- Relapsed non-Hodgkins lymphoma
- AIDS

- Walensky et al. JID, 2006
## Lifetime Per-Person Costs by Initial CD4 Count

<table>
<thead>
<tr>
<th>Initial CD4 Count</th>
<th>Life Expectancy</th>
<th>Lifetime Medical Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;500</td>
<td>24.4 years</td>
<td>$230,044</td>
</tr>
<tr>
<td>200-499</td>
<td>15.4</td>
<td>$195,318</td>
</tr>
<tr>
<td>&lt;199</td>
<td>8.5</td>
<td>$192,325</td>
</tr>
</tbody>
</table>

_Hutchinson et al, JAIDS 2006_
Incidence of Hospitalizations among 7,155 HIV-Infected Patients, 1994-2005

HIV Outpatients Study
- Buchacz et al, AIDS 2008
Patient Outcomes, HIV Result at Admission vs Testing as Inpatient

<table>
<thead>
<tr>
<th></th>
<th>Rapid Test in ED N= 48</th>
<th>Conventional Test in Hospital N=55</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean length of stay, days</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>ICU stay</td>
<td>5 (10%)</td>
<td>17 (31%)</td>
</tr>
<tr>
<td>Intubation required</td>
<td>1 (2%)</td>
<td>6 (11%)</td>
</tr>
<tr>
<td>Discharged before HIV test result</td>
<td>0</td>
<td>9 (16%)</td>
</tr>
</tbody>
</table>

- Lubelchek et al, Arch Int Med 2005
Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings
Revised Recommendations - 2006

- 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

- Separate, signed consent should not be required

- Prevention counseling in conjunction with HIV screening in health care settings should not be required
Professional Association Endorsement

American College of Obstetricians Gynecologists (Aug 08)
- American College of Physicians (Jan 09)
- HIV Medicine Association (Jan 09)
- American College of Emergency Physicians
- American Academy of Pediatrics
- American Medical Association
- National Medical Association
- American Academy of HIV Medicine
Models of HIV Testing
Rapid HIV Tests
Uni-Gold Recombigen

Multispot HIV-1/HIV-2

OraQuick Advance

Clearview Complete HIV 1/2

Clearview HIV ½ Stat Pak
Rapid HIV Testing in the ED

- OraQuick testing since Jan 03
  - 62% accept HIV testing
  - 98% receive test results
  - 3,305 patients screened
  - 83 (2.5%) new HIV positive
  - 80% entered HIV care (median 18 days)

- HIV tests ordered by ED providers increased from 5 to 29 per month

- Lyss et al, JAIDS 2007
Characteristics, Rapid Test Positive Patients Identified in ED Screening

N = 83

No previous test 47 (57%)
Risk factors
   MSM 30 (34%)
   IDU 8 (10%)
   High risk hetero partner 3 (4%)
   No identified risk 42 (51%)

- Lyss et al, JAIDS 2007
### Screening vs Provider Referral: Chicago

<table>
<thead>
<tr>
<th>Category</th>
<th>Routine Screening</th>
<th>Provider Referral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligible</td>
<td>4849</td>
<td>436</td>
</tr>
<tr>
<td>Accepted</td>
<td>2824 (58%)</td>
<td>414 (95%)</td>
</tr>
<tr>
<td>HIV-infected</td>
<td>35 (1.2%)</td>
<td>48 (11.6%)</td>
</tr>
<tr>
<td>Admitted</td>
<td>19 (54%)</td>
<td>34 (71%)</td>
</tr>
<tr>
<td>CD$_4$ &lt;200</td>
<td>14 (45%)</td>
<td>37 (82%)</td>
</tr>
<tr>
<td>% of total</td>
<td>35 (42%)</td>
<td>48 (58%)</td>
</tr>
</tbody>
</table>
CDC’s ED Demonstration Projects

- Los Angeles, New York: Exogenous staff
  - Counselors offered and performed rapid test
  - Provided pre- and post-test counseling

- Oakland: Indigenous staff
  - Triage nurse offered test
  - ED staff (usually nurses) performed rapid test, disclosed test results

- MMWR, June 2007
## CDC’s ED Demonstration Projects

<table>
<thead>
<tr>
<th></th>
<th>Los Angeles</th>
<th>New York</th>
<th>Oakland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>47,736</td>
<td>72,948</td>
<td>65,731</td>
</tr>
<tr>
<td>Offered testing</td>
<td>1,742 (4%)</td>
<td>1,543 (2%)</td>
<td>31,342 (48%)</td>
</tr>
<tr>
<td>Accepted</td>
<td>1,713 (98%)</td>
<td>1,296 (84%)</td>
<td>16,547 (52%)</td>
</tr>
<tr>
<td>Tested</td>
<td>1,709 (100%)</td>
<td>1,288 (84%)</td>
<td>6,368 (39%)</td>
</tr>
<tr>
<td>HIV-positive</td>
<td>13 (0.8%)</td>
<td>19 (1.5%)</td>
<td>65 (1%)</td>
</tr>
</tbody>
</table>
Highland Hospital ED Testing Overview

- Feasibility study
  - Rapid HIV screening in ED and urgent care
  - Routinely offer HIV testing to all eligible patients at triage
  - Existing staff perform test
  - Streamlined testing and counseling protocol
Negative Test Results

- Disclosed by nurse at bedside
- Negative handout provided

NEGATIVE HIV TEST

Your test result was negative.

There are two things you need to do:
- First, we need to make sure your test result is truly negative
- Second, we need to teach you how to stay healthy and HIV negative

Are your test results correct?
To know if your test results are correct, you need to ask yourself 2 questions:

1. Did you have sex (vaginal, oral, or anal) without a condom, even just once, in the last 3 months?
   - YES
   - NO

2. Have you shared needles in the last 3 months?
   - YES
   - NO

If you answered YES to either of these questions, you need another test in 3-6 months!

Why do I need to be retested?
The HIV test you just had does not look for the HIV virus itself. It looks for the cells in your body that fight HIV. These are called antibodies, and the body starts making them in reaction to the HIV virus. It can take your body up to 6 months to make these cells. So, if you had an exposure in the last 3-6 months, you could be HIV positive and today’s test result could be wrong! You will need another test in 3-6 months.

If you answered NO to both questions, you are not infected with HIV.
Your next step is planning how you will stay healthy and HIV negative.

Your plan to stay healthy:
A negative HIV test does not protect you from HIV in the future — you can still get this disease and you need to protect yourself.

How can I protect myself (and others) from HIV?
HIV is spread through four fluids — blood, semen (cum), vaginal fluids, and breast milk. To prevent HIV, don’t let another person’s fluids get inside your body. You can also get HIV from sharing needles when shooting up drugs.

Follow these rules to stay HIV negative:
- The surest way is to not have sex (vaginal, anal, or oral).
- If you do have sex, always use a latex or polyurethane condom.
- Never reuse a condom — always open a new one.
- Never share needles for drug use, tattooing, or body piercings.
- Never share items that could become contaminated with blood.

How can I tell if someone has HIV?
You can’t. Most people with HIV look and feel healthy. They may not even know that they have it. Act as if everyone has HIV. If you want to be sure, ask your partner to get tested for HIV.
Preliminary Positive Results

- Physicians
  - Disclose
  - Counsel
    - HIV Counselors serve as back-up
  - Link to care

- Preliminary Positive Packet
George Washington University Hospital

- Opt-out screening in ED Sept - Dec 2006
  - Additional staff; OraQuick rapid test

- 4,187 patients offered screening
  - 2,486 (60%) accepted
  - 26 (1.1%) HIV-positive

- 680 patients completed satisfaction surveys
  - 70% who accepted HIV test
  - 30% who declined

- Brown et al, JAIDS 2007
George Washington University Hospital
Washington, DC

- Opt-out screening in ED Sept - Dec 2006
  - 7,034 persons offered screening
  - 3,922 (56%) accepted
  - 41 (1%) HIV-positive

- 519 patients completed satisfaction surveys
  - 70% who accepted HIV test
  - 30% who declined

- Brown et al, Public Health Reports 2008
What do the patients think?

“The ED is a good place to perform HIV testing”

- Brown et al, Public Health Reports 2008
What do the patients think?

Would you recommend to a friend to get an HIV test if they went to the ED?

- Brown et al, Public Health Reports 2008
San Francisco General Hospital 2006-2007

- Unigold rapid test in lab
- Increased testing rates in both inpatients and outpatients
- Mean number of positive tests increased from 21 to 31 per month
Routine, Opt-Out HIV Screening: An Integrated Model in Houston

Marlene McNeese-Ward
Houston Department of Health and Human Services

Year Three Update
Houston’s Proposal

• Routine, opt-out HIV screening in Emergency Departments
  – Ben Taub General Hospital (Level I)
  – LBJ General Hospital (Level III)
  – Memorial-Hermann Hospital (Level I)

• Routine, opt-out HIV/STD screening in community health clinics
  – Federally Qualified Health Centers (FQHC)
  – Two Legacy Community Health Services locations (Lyons and Westheimer)
  – Also syphilis, HBV, and HCV testing
Testing Technology

• These emergency centers use conventional HIV venipuncture testing rather than rapid HIV testing technology. However, the hospitals are able to deliver a “rapid result” without a rapid test.
  – To make as routine as possible and implementing as few changes to process as possible
  – Increased batching of EIA and WB at hospital locations

• The use of rapid testing was piloted in Memorial Hermann
  – They opted for conventional testing after the pilot due to stat laboratory constraints
The ADVIA® Centaur™ Random Access HIV 1/O/2 Enhanced (EHIV)

FDA-approved July 2006
On-board Refrigeration of 30 Different Assays
STAT sample requests without pausing
Results in ~60 minutes
Ortho VITROS ECI/ECiQ

FDA-approved March 2008
Abbott Architect 4th Generation Combo Ag/Ab Assay

- Detects p24 antigen and HIV antibody
- Time to result: 29 minutes
- 100 results/hour
- FDA-approved
  June 22, 2010
Screening Process

• **HCHD – BTGH** (Aug 4, 2008)
  – 24/7 testing in the Emergency Department
  – Driven by nursing staff
  – Only those receiving phlebotomy for other reasons

• **HCHD – LBJ** (March 2009)
  – 24/7 testing in the Emergency Department
  – Driven by nursing staff
  – Only those receiving phlebotomy for other reasons

• **Memorial-Hermann** (June 2008)
  – 24/7 testing in the Emergency Department
  – Driven by nursing staff
  – Will do phlebotomy just for this screening test
# Actual YTD Year Three Testing

<table>
<thead>
<tr>
<th>AGENCY</th>
<th>TESTS</th>
<th>NEW (+)S</th>
<th>PRE (+)S</th>
<th>+ RATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCHD-BTGH</td>
<td>34928</td>
<td>132</td>
<td>415</td>
<td>1.57%</td>
</tr>
<tr>
<td>HCHD-LBJ</td>
<td>17302</td>
<td>99</td>
<td>118</td>
<td>1.25%</td>
</tr>
<tr>
<td>LEGACY 215</td>
<td>1,875</td>
<td>26</td>
<td>21</td>
<td>1.23%</td>
</tr>
<tr>
<td>LEGACY LYONS</td>
<td>1,249</td>
<td>16</td>
<td>11</td>
<td>2.16%</td>
</tr>
<tr>
<td>MEM-HER – TMC</td>
<td>12,813</td>
<td>118</td>
<td>145</td>
<td>2.05%</td>
</tr>
<tr>
<td>MEM-HER – SW</td>
<td>4850</td>
<td>95</td>
<td>23</td>
<td>2.43%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>73,017</strong></td>
<td><strong>486</strong></td>
<td><strong>809</strong></td>
<td><strong>1.77%</strong></td>
</tr>
</tbody>
</table>

Realizing a 7.59% opt-out rate
Lessons Learned

• Integrated, routine, voluntary, opt-out screenings in health care settings is needed

• Such screening can be cost effective
  – No need to utilize rapid test devices in order to deliver a “rapid result”

• Successful implementation will require training, training, and more training

• Buy-in should be elicited from all levels of clinical and administrative operations

• Sustainability will depend upon streamlined systems, appropriate technology use for the setting, and changes to staffing plans or operating orders.
Expanded HIV Testing Initiative: New York Health and Hospitals Corporation

- Largest municipal health-care delivery system in the U.S. for New York City residents
- 4,934,000 annual visits
- 19,000 patients with HIV infection in care
- Signed informed consent for HIV testing
The Initiative was designed to increase:

- The number of unique patients who know their HIV status
- The proportion of infected patients entering care early
- The proportion of patients retained in care
Number of Unique Patients Tested Before and After the HIV Testing Expansion Initiative

FY06 to FY08 Outpatient, Inpatient and ED (Source: Facility Reports)

NOTE: HIV Testing Expansion Initiative began with pilot testing in ED in FY05
Prevalence is Highest in the IP Areas

Chart showing the prevalence rates from Jul-05 to Jan-08 for OP Prev, IP Prev, and ED Prev.
How HHC Expanded Testing

- Built upon an action **consensus** and establishment of **testing targets**
- Facilities decided how best to expand testing
  - Each facility had to:
    - Have a **Plan** in place to expand HIV testing
    - **Expand** to 3 venues - IP, OP, ED
    - **Monitor** progress against targets
    - Use rapid HIV test or not
HIV Testing Achievement

- From FY06 through FY09 over 500,000 individuals tested for HIV while holding the number of prenatal patients tested relatively constant.
- Over 3,000 individuals newly diagnosed* for HIV. On average 67% of newly diagnosed are linked to care at an HHC facility within the month of diagnosis.

*New diagnosis based on patient self-report and review of facility medical record
Percent of Patients with a Concurrent AIDS Diagnosis

- FY06: 32.3%
- FY07: 21.2%
- FY08: 21.8%
VAMC-DC Inpatient Testing

- November 2007 – March 2009
  - Written consent with pre-test counseling

- Testing weekdays on 2 medical wards and mental health ward
  - Whole blood specimens from medical inpatients tested in lab with rapid test
  - Oral fluid test after weekly group HIV education session for mental health ward

-Siegel et al JAIDS 2010
### VAMC-DC Inpatient Testing

<table>
<thead>
<tr>
<th></th>
<th>Medical</th>
<th>Mental Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligible</td>
<td>3027</td>
<td>440</td>
</tr>
<tr>
<td>Tested</td>
<td>611 (20%)</td>
<td>227 (48%)</td>
</tr>
<tr>
<td>HIV+</td>
<td>7 (1%)</td>
<td>3 (1.4%)</td>
</tr>
<tr>
<td>new HIV+</td>
<td>6</td>
<td>1</td>
</tr>
</tbody>
</table>

- Among 3,504 patients not approached for routine testing, HIV test was ordered for 133 (3.8%)  
  
  - Siegel et al JAIDS 2010
CDC Expanded HIV Testing Initiative
Percentage of Tests and New HIV+ Tests by Venue, Oct 2007 through Sept 2009
CDC’s Expanded HIV Testing Initiative
### Estimated Number of New HIV-Positives, by Selected Outcome


<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Clinical Settings</th>
<th>Nonclinical settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>New HIV-positives</td>
<td>10,520</td>
<td>8,732</td>
<td>1,788</td>
</tr>
<tr>
<td>New HIV+ receiving test results</td>
<td>86%</td>
<td>89%</td>
<td>73%</td>
</tr>
<tr>
<td>New HIV+ linked to medical care</td>
<td>75%</td>
<td>77%</td>
<td>66%</td>
</tr>
</tbody>
</table>

Data Source: Year-1 APR and Year-2 APR
Expanded Testing in Hospitals

- Possible with rapid or conventional tests

- Acceptance rates: 25% – 90% range

- Testing inpatient admissions: least explored

- Institutions need to develop policies and practices specific to their settings