Revised Recommendations for HIV Testing in Health-Care Settings

(MMWR September 2006)

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Presentation Outline

• HIV epidemic in LAC
• Events leading up to the revised CDC HIV testing recommendations
  – Rationale for increased testing
• CDC’s recommendations, 2006
• Implications for California
  – Assembly Bill 682
• HIV reporting
• HIV Testing
• HIV Resources
The Issue

September 22, 2006 – **Routine opt-out**
HIV testing was recommended by the CDC for persons **13-64** years of age in all healthcare settings

*CDC-MMWR, September 22, 2006 / 55(RR14);1-17*
HIV Epidemic
Estimated Number of Persons Living with HIV/AIDS in LAC as of April 2007

- **Undiagnosed HIV**: 14,100 - 15,500
- **Diagnosed HIV**: 21,187 - 25,424
- **PLWA**: 21,187

*Estimates based on a range of 1:1 to 1.2:1 ratio of HIV (non-AIDS) to AIDS cases

**Estimates based on CDC’s estimate that 25% are unaware of their HIV infection (Glynn, 2005)
Average Estimated Number of Persons Living with HIV/AIDS in LAC

- Undiagnosed HIV *
- Diagnosed HIV *
- AIDS cases

25% unaware
75% aware

• Estimates from LAC HIV Epidemiology Program and CDC, as of July 1, 2006
Awareness of Serostatus Among People with HIV and Estimates of Transmission

~25% Unaware of Infection

~75% Aware of Infection

People Living with HIV

Accounting for:

~54% New Infections

~46% New Infections

New Sexual Infections

Marks, et al, AIDS 2006;20:1447-50
## Los Angeles County Department of Public Health
### HIV Epidemiology Program
### AIDS Semi-annual Surveillance Summary, July-December 2007

<table>
<thead>
<tr>
<th>World (WHO data) Cumulative Cases</th>
<th>34-46 million</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Los Angeles County</strong></td>
<td></td>
</tr>
<tr>
<td>New cases reported this period</td>
<td>777</td>
</tr>
<tr>
<td>Deaths reported this period</td>
<td>153</td>
</tr>
<tr>
<td>Cumulative cases</td>
<td>53,198</td>
</tr>
<tr>
<td>Cumulative deaths</td>
<td>30,743</td>
</tr>
<tr>
<td>Living cases</td>
<td>22,455</td>
</tr>
<tr>
<td><strong>California</strong></td>
<td></td>
</tr>
<tr>
<td>Cumulative cases</td>
<td>147,821</td>
</tr>
<tr>
<td>Cumulative deaths</td>
<td>84,532</td>
</tr>
<tr>
<td>Living cases</td>
<td>63,289</td>
</tr>
<tr>
<td><strong>United States</strong></td>
<td></td>
</tr>
<tr>
<td>Cumulative cases</td>
<td>984,155</td>
</tr>
<tr>
<td>Cumulative deaths</td>
<td>550,394</td>
</tr>
<tr>
<td>Living cases</td>
<td>433,761</td>
</tr>
</tbody>
</table>

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1 Includes all cases reported to the HIV Epidemiology Program as of December 31, 2007.  
The figures do not represent an enumeration of actual cases for this category. Rather, it is a point estimate of cases for this category that has been adjusted for reporting delay, but not adjusted for incomplete reporting.
Events Leading up to the Revised CDC HIV Testing Recommendations

Rationale for Increased Testing
History of HIV Testing

Recommendations

1981
First case reported

1983
Scientists discovered virus

1985
First HIV test FDA approved (ELISA)

1987
First Western Blot blood test kit (USPHS: HCT priority for persons at risk & seen for STDs)

1991
First drug approved (AZT)

1992
First HIV rapid test

1993
CDC: voluntary HIV counseling included hospitalized patients (outpt, ERs) & those seen in health care settings age 15-54

1994
First oral fluid test; protease inhibitors approved; drug cocktail used in tx (HAART)
History of HIV Testing Recommendations

**USPHS:** Counseling & testing of all pregnant women

**CDC:** Routine testing in high prevalence settings (>1%), risk based screening in low prevalence

- **1995:** First home and urine tests
- **1996:** First rapid test (finger prick)
- **2001:** First rapid oral fluid test
- **2002:** First rapid oral fluid test (also granted CLIA waiver)
- **2003:** Rapid finger prick test granted CLIA waiver
- **2004:** Advancing HIV Prevention initiative: voluntary routine HIV testing
- **2006:** CDC issues guidelines for routine opt-out testing in all clinical/healthcare settings (persons age 13-64)
# Source of HIV Tests and Positive Tests

<table>
<thead>
<tr>
<th>Source</th>
<th>HIV tests (%)</th>
<th>HIV+ tests (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private doctor/HMO</td>
<td>44%</td>
<td>17%</td>
</tr>
<tr>
<td>Hospital, ED, Outpatient</td>
<td>22%</td>
<td>27%</td>
</tr>
<tr>
<td>Community Clinic (Public)</td>
<td>9%</td>
<td>21%</td>
</tr>
<tr>
<td>HIV Counseling/testing</td>
<td>5%</td>
<td>9%</td>
</tr>
<tr>
<td>Correctional Facility</td>
<td>0.6%</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>0.7%</td>
<td>2%</td>
</tr>
</tbody>
</table>

*National Health Interview Survey, 2002

**Suppl. To HIV/AIDS Surveillance, 2000-2003
Rationale for Routine Testing

- 2003 [Advancing HIV Prevention (AHP)] recommendations did not have their intended effect and were not implemented
  - Only a fraction of ED STD clients screened
  - Stable number of new HIV cases since 1998
    - 2000 in LAC
  - Only 38-44% persons have tested (2002)
  - 25% still unaware of HIV status
Rationale: Reduced Effectiveness of Risk Based Screening

• Increased rates of new HIV infections in groups that do not belong to high risk groups
  – Persons <20 years
  – Women
  – Racial and ethnic minorities
  – Rural residents
  – Heterosexual men and women
Rationale: Late Testers

- Minimal decline in late testers (within 12 months of AIDS diagnosis)

1990-1992  51% positives tested <1 yr before AIDS
1993-2004  39% positives tested <1yr before AIDS
Rationale: Late Testers

- Characteristics of Late Testers
  - Younger (18-29)
  - Heterosexual
  - Less educated
  - African American or Hispanic
Rationale: Opt Out Successes

• Routine testing opt out
  – Pregnant women has reduced perinatal transmission in US <2%
  – Increases testing rates and reduces stigma associated with HIV testing
  – Patients report less anxiety about testing
Revised Recommendations
CDC Recommendation

September 22, 2006 – **Routine opt-out**
HIV testing in all healthcare settings is recommended for persons that are 13-64 years

*Routine testing* – offered like other screening tests (pap smears, mammograms etc)

*Opt out screening* – patient notified of test; test performed unless patient declines
Objectives of the Recommendations

- Increase HIV screening
- Foster early detection of HIV infection
- Identify & counsel patients with unrecognized HIV infection
- Improve linkage to HIV care/counseling
- Further reduce perinatal HIV transmission
Target Population

• Individuals seen in health-care settings only
  – ER, urgent care, inpatient units, substance abuse treatment clinics, public health & community clinics, correctional healthcare facilities

• Recommendations do not impact non-clinical settings
  – Mobile vans, community-based organizations & other non-medical care settings designed to provide anonymous or confidential HIV tests and prevention interventions
Target Population

• Persons 13-64 years

• Patients initiating TB Therapy
  (10-30% of TB patients are HIV+)

• Patients seeking STD treatment
  (60% of syphilis cases are HIV+)
  – During each new complaint
  – Suspected of behaviors to put them at risk
Repeat Screening

• High risk persons screened annually
  – IVDU and their partners
  – Exchange of sex for money or drugs
  – Sex partners of HIV positive
  – MSM / heterosexuals or their partners who have more than one partner since last HIV test
• Before initiation of new sexual relationship
Major Changes in Recommendations

- Includes non-acute healthcare settings
- Opt-out procedure
  - Patient notified; testing done unless pt. declines
  - General consent for medical services is adequate (separate HIV consent not needed)
- Annual screening for patients at risk
- Prevention & counseling not required
Changes - Pregnant Women

- HIV should be included in routine perinatal panel of tests
- True opt-out testing
- Separate written consent **not** needed
- Repeat screening during the 3rd trimester in certain cases
Testing Later in Pregnancy

- Certain jurisdictions with high incidence
- Facilities with 1 HIV infected woman/1,000
- Women known to be at risk
  - IVDU and partners, exchange for money, partners of HIV infected, women with more than one partner
- Women with symptoms of HIV
Implications for Stakeholders

- Patients
- Providers
- Payors
- Local / State / National
Implications for California Assembly Bill 682
Implications: California State

Historical Perspective

• Incorporation of consent for an HIV test into a general medical consent form. Separate written consent for HIV testing not recommended

  o CA state law previously required specific written consent for HIV testing; general consent for medical care not sufficient (except in case of a treating physician & surgeon)
  o Physicians could obtain informed consent (oral or written)

*Health & Safety (H&S) Code Section 120990*

CDHS Guidance Memo, 1/10/2007
Implications: California State

- HIV testing of people at high risk for HIV infection at least once a year
  - No current mandates on the number of times a person should be tested for HIV
  - Recommendation may be implemented as deemed appropriate by the health care provider

CDHS Guidance Memo, 1/10/2007
Implications: California State

• Prevention & counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health care settings

  o No requirements under California law for HIV prevention counseling except in two circumstances: (1) partner notification – H&S Code Section 121015; and (2) prenatal/intra-partum care of a pregnant woman – H&S Code Section 125090

  o DHS-OA funded HIV C&T sites currently require face-to-face counseling session to obtain reimbursement from OA for HIV testing

CDHS Guidance Memo, 1/10/2007
Implications: California

- *Inclusion of HIV screening in routine panel of prenatal screening tests for all pregnant women, unless patient declines (opt-out screening)*
  - CA law now aligns with this recommendation
  - Pregnant woman does not need to sign specific form agreeing to the test; form filed in patient’s medical records (which was required under previous guidance)

CDHS Guidance Memo, 1/10/2007
AB 682 (Berg, Garcia, Huffman), the California Routine HIV Screening signed 10/12/07

• Bi-Partisan Bill, sponsored by:
  – AIDS Healthcare Foundation
  – California Medical Association
  – Health Officers Association California

• Cleared the two chambers of the California Legislature in 9/07 with only a single vote against it

• Signed by Governor Schwarzenegger 10/07

• AB 682 will serve to modernize California law
• **Effective January 1, 2008**, a separate consent for HIV testing is not required.

• General consent for medical treatment is now sufficient for medical procedures including HIV testing.

• Patients must be informed about inclusion of HIV testing and can “opt out”

• **AB 682 clears obstacles for the full implementation of CDC’s new opt-out HIV testing guidelines**
Next Steps

• Administration
  – Update policies and procedures in the public and private sector

• Education and Training
  – Train public and private sector on new laws and CDC recommendations

• Care and Treatment
  – Increase capacity
  – Anticipate new types of clients
Next Steps

• Evaluation
  – Baseline and adherence to recommendations
  – Outcomes of recommendations

• Prevention
  – Acknowledge changing dynamics of HCT
  – Push alternative testing models in the non health-care settings
    • Consider emphasis on post-test counseling and reduction of pre-test counseling
Summary

- HIV screening is recommended for all patients in all health care settings after the patient is notified that testing will be performed unless the patient declines.
- Separate written consent for HIV testing should not be required.
- Prevention counseling should not be required as a part of HIV screening programs.
- Prevention counseling is strongly encouraged for persons at a high behavioral risk for HIV.
Summary contd.

- HIV test results should be provided in the same manner as results of other diagnostic and screening tests

- HIV negative results may be conveyed without direct personal contact between patient and provider
Summary contd.

• HIV positive results should be communicated confidentially through personal contact by a clinician, nurse or counselor
  – Ideally should be face-to-face
  – Neither the law nor guidelines preclude alternative means of communication
  – Phone results policy

• Efforts to normalize HIV testing in our clinics + increase capacity to evaluate and test patients for STD/HIV
HIV Test Reporting
California HIV/AIDS Reporting Laws

- 1983 AIDS added to California State list of reportable diseases and conditions
  - CA Code of Regs: Title 17, Section 2500
- 2002 California starts code-based reporting and laboratory-based reporting of HIV
- 2006 California law signed by Governor makes HIV reporting by name mandatory
  - CCR Title 17 Sections 2641.5-2543.20
  - Health and Safety Code Section 121022
California Name Based HIV Reporting System

1. Specimen to be tested (from Health Care Provider to Laboratory)

2. Lab Result (from Laboratory to Local Health Department)

3. HIV Case Report (from Health Care Provider to Local Health Department)

4. Submits unduplicated HIV cases with a completed HIV/AIDS Confidential Case Report form (to Department of Health Services, Office of AIDS)

5. Submits HIV case data after identifying information removed (to Centers for Disease Control and Prevention)
Dual Reporting System: Labs

• Laboratory Reports HIV tests to Provider & Local Health Department (HIV EPI Prgm)
  – Confirmed HIV-Antibody Tests
  – Viral Load
  – Other HIV diagnostic test

• *HIV test slip sent to lab must include: full client name, gender, DOB, provider name and address*
Dual Reporting System: Providers

- *For confirmed positive HIV test*, Provider must provide within 7 days to HIV EPI a Case Report Form, including:
  - Full client name
  - DOB
  - Address
  - *Full* Social Security Number
  - Gender
  - Race/ethnicity
  - Mode of exposure
Reporting Information

HIV Epidemiology Program

Phone 213 351-8516 / 213-351-8190

www.lapublichealth.org/hiv

600 S. Commonwealth Avenue
Suite 1920
Los Angeles, CA  90005
HIV Resources

http://www.hivla.org/search.cfm
HIV Testing
Traditional HIV Testing

1985 FDA approved HIV test
- Blood draw
- Elisa-antibody
- Small tube of blood
- Western blot confirmation
- Results in 4-10 days
- Pre-test and post-test counseling
FDA approved *CLIA-waived* rapid HIV tests available for use in the US

<table>
<thead>
<tr>
<th>Rapid HIV Test</th>
<th>Specimen Type</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OraQuick Advance Rapid</strong></td>
<td>Oral fluid</td>
<td>99.3%</td>
<td>99.8%</td>
<td>OraSure Technologies, Inc.</td>
</tr>
<tr>
<td><strong>HIV-1/2 Antibody Test</strong></td>
<td>Whole blood (fingerstick or venipuncture)</td>
<td>99.6%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td><strong>Clearview HIV 1/2 Stat-Pak</strong></td>
<td>Whole blood (fingerstick or venipuncture)</td>
<td>99.7%</td>
<td>99.9%</td>
<td>Inverness Medical Professional Diagnostics</td>
</tr>
<tr>
<td><strong>Clearview HIV 1/2 Complete</strong></td>
<td>Whole blood (fingerstick or venipuncture)</td>
<td>99.7%</td>
<td>99.9%</td>
<td>Inverness Medical Professional Diagnostics</td>
</tr>
<tr>
<td><strong>Uni-Gold Recombigen HIV</strong></td>
<td>Whole blood (fingerstick or venipuncture)</td>
<td>100%</td>
<td>99.7%</td>
<td>Trinity Biotech</td>
</tr>
</tbody>
</table>
Obtain finger stick specimen...
Collect oral fluid specimens by swabbing gums with test device
Insert device; test develops in 20 minutes
Thank You

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