Opt-Out HIV Testing: Making HIV Tests Routine In the Medical Setting

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Pre-Test
The CDC recommends everyone in the U.S. between the ages of 13 and 64 test for HIV at least once because:

a. More than 25% of Americans are infected with HIV
b. Many people don’t know their HIV status and only find out when they develop serious illness as a result of HIV infection
c. Other people can avoid the HIV positive person
d. When people know they are HIV positive, they take steps to protect themselves and others
e. All of the above
f. Only b and d
g. Unsure

- More than 25% of Americans infected with HIV
- Many people don’t know their HIV status
- Other people can avoid the HIV positive person
- When people know they are HIV positive
- All of the above
- Only b and d
- Unsure
When all patients are told that they will be tested for HIV as a matter of routine, they are more likely to get tested because they don’t feel like they have been singled out as “high risk”

a. True
b. False
c. Unsure
According to CDC studies, people who know their HIV + status are responsible for 90% of new HIV infections

a. True
b. False
c. Unsure
Estimated Number of AIDS Cases, Deaths, and Persons Living with AIDS, 1985-2004, United States

Note: Data adjusted for reporting delays.
Awareness of HIV Status among Persons with HIV, United States

Number HIV infected: 1,039,000 – 1,185,000

Number unaware of their HIV infection: 252,000 - 312,000 (24%-27%)

Estimated new infections annually: 40,000

Glynn M, Rhodes P. 2005 HIV Prevention Conference
HIV Prevalence, NHANES 1999-2002

- McQuillan et al, NCHS: JAIDS April 2006
Terminology
Terminology - I

- **Diagnostic testing**: performing an HIV test based on clinical signs or symptoms
- **Screening**: performing an HIV test for all persons in a defined population
- **Targeted testing**: performing an HIV test on subpopulations of persons at higher risk based on behavioral, clinical or demographic characteristics
- **Opt-out screening**: performing an HIV test after notifying the patient that the test will be done; consent is inferred unless the patient declines
Terminology - II

- **Informed consent**: process of communication between patient and provider through which the patient can participate in choosing whether or not to undergo HIV testing.

- **HIV prevention counseling**: interactive process to assess risk, recognize risky behaviors, and develop a plan to take steps that will reduce risks.
Why Routine Testing?
Source of HIV Tests and Positive Tests

- 38% - 44% of adults age 18-64 have been tested
- 16-22 million persons 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>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
Criteria that Justify Routine Screening

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

Principles and Practice of Screening for Disease
-WHO Public Health Paper, 1968
Rapid HIV Screening in Acute Care Settings

<table>
<thead>
<tr>
<th>Study site</th>
<th>New HIV+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cook County ED, Chicago</td>
<td>2.3%</td>
</tr>
<tr>
<td>Grady ED, Atlanta</td>
<td>2.7%</td>
</tr>
<tr>
<td>Johns Hopkins ED, Baltimore</td>
<td>3.2%</td>
</tr>
<tr>
<td>King-Drew Med Center ED, Los Angeles</td>
<td>1.3%</td>
</tr>
<tr>
<td>Inpatients, Boston Medical Center</td>
<td>3.8%</td>
</tr>
<tr>
<td>Demonstration Project</td>
<td>No. tested</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>New York City</td>
<td>3,039</td>
</tr>
<tr>
<td>Bronx- Lebanon: 2 clinics, 1 ED</td>
<td></td>
</tr>
<tr>
<td>Los Angeles</td>
<td>6,909</td>
</tr>
<tr>
<td>2 clinics, 1 ED</td>
<td></td>
</tr>
<tr>
<td>Alameda County (Oakland)</td>
<td>6,283</td>
</tr>
<tr>
<td>1 ED</td>
<td></td>
</tr>
<tr>
<td>Massachusetts</td>
<td>5,994</td>
</tr>
<tr>
<td>1 outpatient, 1 inpatient, 1 clinic</td>
<td></td>
</tr>
<tr>
<td>Wisconsin</td>
<td>1,763</td>
</tr>
<tr>
<td>3 clinics</td>
<td></td>
</tr>
</tbody>
</table>

*CDC, preliminary data - Dec 2005*
Mortality and HAART Use Over Time
HIV Outpatient Study, CDC, 1994-2003

- Deaths per 100 PY
- Patients on HAART
- Deaths per 100 PY
- Year
Effect of Counseling in Conjunction with HIV testing

- Meta-analysis of 27 studies of HIV-CT:
  - HIV-positive participants reduced unprotected intercourse and increased condom use.
  - HIV-negative participants did not modify their behavior more than untested participants.

- Weinhardt et al., 1999: Am J Public Health
Opt-Out Screening

Prenatal HIV testing for pregnant women:

- RCT of 4 counseling models with opt-in consent:
  - 35% accepted testing
  - Some women felt accepting an HIV test indicated high risk behavior

- Testing offered as routine, opportunity to decline
  - 88% accepted testing
  - Significantly less anxious about testing

### Routine Opt-Out HIV Testing
### Texas STD Clinics, 1996-97

<table>
<thead>
<tr>
<th></th>
<th>Opt-In N (%)</th>
<th>Opt-Out N (%)</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>STD Visits</td>
<td>31,558</td>
<td>34,533</td>
<td>+9</td>
</tr>
<tr>
<td>Eligible Clients</td>
<td>19,184 (61)</td>
<td>23,686 (69)</td>
<td>+23</td>
</tr>
<tr>
<td>Pre-test counsel</td>
<td>15,038 (78)</td>
<td>11,466 (48)</td>
<td>-24</td>
</tr>
<tr>
<td>Tested</td>
<td>14,927 (78)</td>
<td>23,020 (97)</td>
<td>+54</td>
</tr>
<tr>
<td>Post-test counsel</td>
<td>6,014 (40)</td>
<td>4,406 (19)</td>
<td>-27</td>
</tr>
<tr>
<td>HIV-positive</td>
<td>168 (1.1)</td>
<td>268 (1.2)</td>
<td>+59</td>
</tr>
</tbody>
</table>

*Texas Department of State Health Services, 2005*
Summary of Review of Evidence

- HIV meets the criteria for screening, and effective treatment is available
- Many patients with HIV visit healthcare providers but their infection goes undetected
- People decrease their risk behaviors when they find out they are infected with HIV
- HIV screening in healthcare settings is cost-effective
- Opt-out screening increases testing rates
Awareness of Serostatus Among People with HIV and Estimates of Transmission

- Approximately 25% Unaware of Infection
- Approximately 75% Aware of Infection

People Living with HIV/AIDS: 1,039,000 - 1,185,000

Accounting for:

- Approximately 54% of New Infections
- Approximately 46% of New Infections

New Sexual Infections Each Year: ~32,000

Marks, et al. AIDS 2006;20:1447-50
Time Between First Learned of HIV+ Status and AIDS Diagnosis

Very late detection

Latex detection

Early detection

Percent

< 1 1-12 13-36 37-60 >60

Latino White Black

SHAS, HIV Epidemiology Program. LAC, 2000 - 2004 (N = 672)
Late HIV Testing is Common

• 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 years before AIDS diagnosis) were more likely to be:
  – Younger (18-29 years)
  – Heterosexual
  – Less educated
  – African American or Hispanic

* 16 States
Cost Effectiveness of Routine HIV Testing
Cost Effectiveness


“In all but the lowest-risk populations, routine, voluntary screening for HIV once every 3 to 5 years is justified on both clinical and cost-effectiveness grounds. One-time screening in the general population may also be cost-effective.”
Cost Effectiveness


“The cost-effectiveness of routine HIV screening in health care settings, even in relatively low-prevalence populations, is similar to that of commonly accepted interventions, and such programs should be expanded.”

1% HIV prevalence: $15,078 per QALY

>0.05% prevalence: <$50,000 per QALY
Cost Effectiveness

- **Prenatal HIV screening**
  - Averts ~1500 cases of neonatal HIV per year
  - Cost saving

- **HIV antibody testing of 15 million blood donations**
  - Averts ~1500 HIV infections per year
  - Costs $3,600 per QALY

- **Pooled RNA screening for HIV and HCV**
  - Averts 4 HIV and 56 HCV infections per year
  - Costs $4.3 million per QALY
Opt-Out Testing Venues

- TB clinics
- STD clinics
- Jails
- Peri-natal clinics
- Ambulatory care
- Emergency departments
HIV Testing Guidelines CDC

- Everyone aged 13-64 yrs. test at least once
- For women:
  - **Prenatal**: Routine “Opt-out” HIV test for all pregnant women
  - **Labor and delivery**: Routine rapid testing for women whose HIV status is unknown
  - **Postnatal**: Rapid testing for all infants whose mother’s HIV status is unknown

*“Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings,” MMWR Recommendations and Reports, September 22, 2006*
Opt Out Informed Consent – CDC Style*

• Patient told HIV test will be performed
• Patient given written or oral information on
  – the risks and benefits of testing,
  – the implications of HIV test results,
  – how test results will be communicated, and
  – opportunity to ask questions.
• Patients may decline test
  – Refusal documented in chart

“Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings,”
MMWR Recommendations and Reports, September 22, 2006
California HIV Laws

- Separate written consent for HIV testing no longer required, as of 01/01/08*
- Opt out testing in peri-natal care now legal. *
- HIV is reportable by name using CMR (responsibility of MD/NP/PA)

*California Health and Safety (H&S) Code Section 120990
Opt-out Informed Consent – California Style*

1) Inform patient HIV test is planned
2) Provide information about the HIV test; i.e. results
3) Tell patient that if HIV+, tx options available
   – tell patient: If negative may need to test again depending on…
4) Advise the patient of the right to decline test
5) document refusal in patient chart if no test performed

*California Health and Safety (H&S) Code Section 120990
**What to Say to Patients**

**SAMPLE SCRIPT LANGUAGE SUGGESTIONS:** *

a. “We perform routine screening for HIV on all patients and we’ll be doing that as part of your visit today.”

b. “We do this because of our desire to help keep our patients healthy and because there are excellent treatment options available for HIV.”

c. “If your test is positive we will need to do more testing but you should know there are many effective treatments for HIV.”

d. “You can decline the test and it will not affect the care you receive today.”

e. If using rapid test: “It’s a quick test and you will know the results before you leave today.”

*AETC HIV Testing Information and Resources for Clinicians*
Written Information for Patients

• Instead of all verbal communication, can use HIV testing information sheet distributed to all patients that includes the previous 5 elements

• Followed by the statement:

“We perform routine screening for HIV on all patients and we’ll be doing that as part of your visit today unless you decline the test.”
Written Informed Consent

• Continued requirements for written consent under H&S Code Section 120990(c) refer to HIV testing provided and/or processed in non-medical settings (such as OA-funded confidential HIV test sites).
Informed Consent Requirements

- Age - Patients of 12 years old and up can consent to HIV test without parental consent
- Capable of understanding process
- Testing without coercion
Test Results
Negative Result

• May be disclosed by a counselor or other designated staff
  – Persons known to be at ongoing high risk for HIV should be advised to test periodically and be offered referrals to sites where HIV counseling is part of testing
Positive Result

- Disclose in a *confidential, businesslike, yet sensitive, manner* like any other test result by a physician, NP, PA, RN, or counselor
- Referral to medical care
- 2nd sample gathered for confirmation
- Complete Confidential Morbidity Report (CMR) for confirmed HIV+
HIV+ Disclosure – The Basics

Ensure a private environment to protect patient confidentiality. Be attentive, genuine and neutral.

1. State the result in a direct, neutral tone.
   - For example: "Your rapid HIV test result is reactive."
   - Wait for patient's response before proceeding. You may need to wait for 15 to 30 seconds before speaking.
   - Explain the meaning of the reactive rapid HIV test result and need for confirmatory testing.
     - For example: "...highly likely to be infected." or "...a very good chance of being infected." and "Needs to be confirmed by a blood test"
HIV+ Disclosure – The Basics

2. Address individual needs and concerns
   A. Sources of emotional support
   B. Information about HIV infection and transmission
   C. Risk Reduction
   D. Partner Notification (to be done after confirmatory test)
   E. Medical Care

3. Make a short-term plan
   A. Ask what the patient will do after leaving your office
   B. Provide specific, appropriate, written referrals
   C. Close the session, but not the door
Brief Counseling for Negative Disclosure

- Ask how patient feels about result
- Ask if they had a recent exposure
- Suggest retesting if patient in window period or has ongoing risk
- Offer choices for risk reduction (condoms, fewer partners, different sexual activities)
- Accept patient’s choice
- Document in patient chart
CLIA Waived HIV Rapid Tests
OraQuick Advance

- Blood or oral specimen
- Store at room temperature
- Screens for HIV-1 and HIV-2
- Results read in 20-40 minutes
- Read window is 20 minutes
Stat-Pak

- Blood Specimen Only
- Store at room temperature
- Screens for HIV-1 and HIV-2
- Results read in 15-20 minutes
- Read window is 5 minutes
Uni-Gold

- Blood specimen
- Store at room temperature
- Screens for HIV-1
- Results read in 10-12 minutes
- Read window is 2 minutes
Oraquick Advance Results
Read between 20-40 minutes after started

Reactive or Preliminary +
Line at “”C”
Line at “T”

Negative Result
Line at “C”
No line at “T”
Post-Test
When all patients are told that they will be tested for HIV as a matter of routine, they are more likely to get tested because they don’t feel like they have been singled out as “high risk”

a. True
b. False
c. Unsure
According to CDC studies, people who know their HIV + status are responsible for 90% of new HIV infections

a. True
✅b. False

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For More Information

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