Revised Recommendations for HIV Screening of Adults, Adolescents, and Pregnant Women in Health Care Settings

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The findings and conclusions in this presentation are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.
Presentation Outline

- Epidemiologic background
- The case for increased HIV testing
- Current testing
- Current recommendations and their effects
- Considerations for revising recommendations
  - Adults and adolescents
  - Pregnant women
- Summary
Estimated Number of AIDS Cases, Deaths, and Persons Living with AIDS, 1985-2004, United States

No. of cases and deaths (in thousands)

Prevalence (in thousands)

Year of diagnosis or death

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number HIV infected</td>
<td>1,039,000 ÷ 1,185,000</td>
</tr>
<tr>
<td>Number unaware of their HIV infection</td>
<td>252,000 - 312,000 (24% - 27%)</td>
</tr>
<tr>
<td>Estimated new infections annually</td>
<td>40,000</td>
</tr>
</tbody>
</table>

Glynn M, Rhodes P. 2005 HIV Prevention Conference
HIV/AIDS Diagnoses among Adults and Adolescents, by Transmission Category – 33 States, 2001-2004

Males (n = 112,000)

- MSM/IDU: 61%
- IDU: 16%
- Heterosexual: 17%
- Other: 5%

Females (n = 45,000)

- IDU: 76%
- Heterosexual: 21%
- Other: 3%

MMWR, Nov 18, 2005
Estimated Annual Rate of HIV/AIDS Diagnoses, by Sex and Race/Ethnicity — 33 States, 2004

CDC. HIV/AIDS Surveillance Report, 2004
Estimated Number of Perinatally Acquired AIDS Cases, by Year of Diagnosis, 1985-2004 United States

- PACTG 076 & USPHS ZDV Recs
- CDC HIV screening Recs

~ 95% reduction
The Case for Increased HIV Testing
Mortality and HAART Use Over Time
HIV Outpatient Study, CDC, 1994-2003

Deaths per 100 PY

Patients on HAART

Deaths per 100 PY

Year


0 0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9

Patients on HAART

0 0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9
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.
Awareness of Serostatus Among People with HIV and Estimates of Transmission

~25% Unaware of Infection

~75% Aware of Infection

Accounting for:

People Living with HIV/AIDS: ~1,050,000

New Infections Each Year: ~40,000
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

MMWR June 27, 2003
*16 states
Reasons for testing: late versus early testers

Supplement to HIV/AIDS Surveillance, 2000-2003

- Late (Tested < 1 yr before AIDS dx)
- Early (Tested >5 yrs before AIDS dx)

Bar chart showing reasons for testing: late versus early testers.
Lessons from Kenya

Six types of HIV testing:

1. VCT: initiated by a client
2. Routine: initiated by HCW
3. Diagnostic: requested by HCW as part of w/u
4. Required: without consent (military, immigration)
5. Blood and tissue donation
6. Formedical research
Lessons from Kenya

Consent with six types of HIV testing:
1. VCT: Consent implicit in seeking test; verbal
2. Routine: Inform client, opt-out, option to decline
3. Diagnostic: consent implicit, inform patient, opt-out, option to decline
4. Required: Inform; no consent
5. Blood and tissue donation: Inform; no consent
6. Medical research: Special provisions
Lessons from Kenya

Five principles:

1. Provide information about HIV
2. Must know they are being tested
3. Opportunity to decline
4. Must be offered their test results
5. Access to treatment
Current Testing
Terminology - I

- **Diagnostic testing**: HIV testing based on clinical signs or symptoms
- **Screening**: HIV testing for all persons in a defined population
- **Targeted testing**: offering testing to subgroups at higher risk based on behavioral, clinical, or demographic characteristics
- **Opt-out testing**: HIV testing after notifying the patient that the test will be done; consent is inferred unless the patient declines
**Inform ed 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.
### 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**
Current Recommendations and their Effects
Current Recommendations

Recommendations for HIV Testing Services for Inpatients and Outpatients in Acute-Care Hospital Settings

and

Technical Guidance on HIV Counseling

Revised Guidelines for HIV Counseling, Testing, and Referral

and

Revised Recommendations for HIV Screening of Pregnant Women

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
Atlanta, Georgia 30333
Four priorities:

1. Make voluntary HIV testing a routine part of medical care

2. Implement new models for diagnosing HIV infections outside medical settings

3. Prevent new infections by working with persons diagnosed with HIV and their partners

4. Further decrease perinatal HIV transmission
Existing CDC Recommendations
Adults and Adolescents

- Routinely recommend HIV screening in settings with high HIV prevalence (≥ 1%)

Are Recommendations Having Their Intended Effect?

Advance Data
From Vital and Health Statistics
Number 340 ● March 18, 2004

National Hospital Ambulatory Medical Care Survey:
2002 Emergency Department Summary
by Linda F. McCaig, M.P.H., and Catharine W. Burt, Ed.D., Division of Health Care Statistics
### Recommendations Are Not Having Their Intended Effect in Acute Care Settings

EDs account for 10% of all ambulatory care visits

<table>
<thead>
<tr>
<th></th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED visits</td>
<td>108 million</td>
<td>107 million</td>
<td>110 million</td>
</tr>
<tr>
<td>Age 15-64</td>
<td>68.3 million</td>
<td>69.4 million</td>
<td>69.6 million</td>
</tr>
<tr>
<td>HIV serology</td>
<td>215,000</td>
<td>201,000</td>
<td>163,000</td>
</tr>
</tbody>
</table>
# 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 Medical 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
Lessons Learned

- Difficult to obtain written consent and provide counseling, yet still screen the large numbers of patients in acute care settings.

- Sustainability will depend on streamlined systems, additional staff, or both.
Existing CDC Recommendations
Adults and Adolescents

- Routinely recommend HIV screening in settings with high HIV prevalence (>1%)
- Targeted testing based on risk assessment
Paradox No. 1

- We cannot rely on risk-based screening
- We cannot eliminate risk-based screening
### Criteria for Targeted Screening among STD Clinic Patients

<table>
<thead>
<tr>
<th>Risk factors in patients or partners</th>
<th>% of Patients Tested</th>
<th>% of HIV+ Patients Identified</th>
<th>HIV Prevalence Among Patients Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10%</td>
<td>39%</td>
<td>7.5%</td>
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- Sex Transm Dis, 1998
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<td>39%</td>
<td>7.5%</td>
</tr>
<tr>
<td>Risk factors, all patients ( \geq 30 ) yrs</td>
<td>40%</td>
<td>79%</td>
<td>3.8%</td>
</tr>
</tbody>
</table>

- *Sex Transm Dis, 1998*
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<th>HIV Prevalence Among Patients Tested</th>
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<td>Risk factors in patients or partners</td>
<td>10%</td>
<td>39%</td>
<td>7.5%</td>
</tr>
<tr>
<td>Risk factors, all patients ≥ 30 yrs</td>
<td>40%</td>
<td>79%</td>
<td>3.8%</td>
</tr>
<tr>
<td>Risk factors, pts. ≥ 30, black males</td>
<td>70%</td>
<td>92%</td>
<td>2.5%</td>
</tr>
</tbody>
</table>

*Sex Transm Dis, 1998*
<table>
<thead>
<tr>
<th>Criteria for Targeted Screening among STD Clinic Patients</th>
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<th>% of HIV+ Patients Identified</th>
<th>HIV Prevalence Among Patients Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk factors in patients or partners</td>
<td>10%</td>
<td>39%</td>
<td>7.5%</td>
</tr>
<tr>
<td>Risk factors, all patients 2 30 yrs</td>
<td>40%</td>
<td>79%</td>
<td>3.8%</td>
</tr>
<tr>
<td>Risk factors, pts. 2 30, black males</td>
<td>70%</td>
<td>92%</td>
<td>2.5%</td>
</tr>
<tr>
<td>All patients</td>
<td>100%</td>
<td>100%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

- Sex Transm Dis, 1998
Existing CDC Recommendations
Pregnant Women

- Routine, voluntary HIV testing as a part of prenatal care, as early as possible, for all pregnant women
- Simplified pretest counseling
- Flexible consent process
- HIV rapid testing and treatment during labor and delivery for women without prenatal testing
- Re-screening in third trimester for select, high-risk women
Existing CDC Recommendations
Adults and Adolescents

- Routinely recommend HIV screening in settings with high HIV prevalence (>1%)
- Targeted testing based on risk assessment
- Annual testing for sexually active MSM
### HIV Prevalence and Proportion of Unrecognized HIV Infection Among 1,767 MSM, by Age Group and Race/Ethnicity

**NHBS, Baltimore, LA, Miami, NYC, San Francisco**

<table>
<thead>
<tr>
<th>Age Group (yrs)</th>
<th>Total Tested</th>
<th>HIV Prevalence No.</th>
<th>HIV Prevalence %</th>
<th>Unrecognized HIV Infection No.</th>
<th>Unrecognized HIV Infection %</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-24</td>
<td>410</td>
<td>57</td>
<td>(14)</td>
<td>45</td>
<td>(79)</td>
</tr>
<tr>
<td>25-29</td>
<td>303</td>
<td>53</td>
<td>(17)</td>
<td>37</td>
<td>(70)</td>
</tr>
<tr>
<td>30-39</td>
<td>585</td>
<td>171</td>
<td>(29)</td>
<td>83</td>
<td>(49)</td>
</tr>
<tr>
<td>40-49</td>
<td>367</td>
<td>137</td>
<td>(37)</td>
<td>41</td>
<td>(30)</td>
</tr>
<tr>
<td>≥ 50</td>
<td>102</td>
<td>32</td>
<td>(31)</td>
<td>11</td>
<td>(34)</td>
</tr>
</tbody>
</table>

**Race/Ethnicity**

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Total Tested</th>
<th>HIV Prevalence No.</th>
<th>HIV Prevalence %</th>
<th>Unrecognized HIV Infection No.</th>
<th>Unrecognized HIV Infection %</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>616</td>
<td>127</td>
<td>(21)</td>
<td>23</td>
<td>(18)</td>
</tr>
<tr>
<td>Black</td>
<td>444</td>
<td>206</td>
<td>(46)</td>
<td>139</td>
<td>(67)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>466</td>
<td>80</td>
<td>(17)</td>
<td>38</td>
<td>(48)</td>
</tr>
<tr>
<td>Multiracial</td>
<td>86</td>
<td>16</td>
<td>(19)</td>
<td>8</td>
<td>(50)</td>
</tr>
<tr>
<td>Other</td>
<td>139</td>
<td>18</td>
<td>(13)</td>
<td>9</td>
<td>(50)</td>
</tr>
</tbody>
</table>

**Total**

|                  | 1,767 | 450 | (25) | 217 | (48) |
Paradox No. 2

- Measures put into place that were intended to protect patients from stigma and coercion may now increase stigma or discourage access to beneficial testing and services.
Opt-Out Consent

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
1996-2005
Targeted Opt-In Testing
Prior to 1996

- Clients with high risk behaviors (e.g., MSM, IDU, genital ulcer disease)
- Clients requesting an HIV test
- Separate consent form required
Background: Focus Groups

- Pre-test counseling identified as a deterrent to HIV testing
- Many clients thought they were tested routinely and assumed they were HIV negative after their STD clinic visit
- Focus group participants strongly recommended making routine HIV testing part of STD screening
Sec. 81.105. Informed Consent.

(a) Except as otherwise provided by law, a person may not perform a test designed to identify HIV antibody without first obtaining the informed consent of the person to be tested.
Sec. 81.106. General Consent.

(a) A person who has signed a general consent form for the performance of medical tests is not required to also sign a specific consent form relating to medical tests to determine HIV infection that will be performed on the person during the time in which the general consent form is in effect.
Evaluation Objective

Evaluate major changes in the implementation of routine, opt-out HIV testing in STD clinics:

- Change in eligibility, from "targeted" to "routine"

- Change in consent, from
  - "opt-in" (separate consent solicited) to
  - "opt-out" (HIV test included as one of regular screening tests, unless it is refused.)
Methods

- 6-month evaluation periods before and after implementing opt-out at 6 STD programs: Amarillo, Austin, Dallas, Fort Worth, Houston, Lubbock

- Each site recorded data on:
  - Utilization of HIV testing, prevention counseling
  - Number of new HIV infections identified
  - Partner elicitation, counseling, and HIV testing
DALLAS COUNTY
HEALTH & HUMAN SERVICES
S. T. D. CLINIC
(SEXUALLY TRANSMITTED DISEASE)

ALL PATIENTS SEEN IN THIS CLINIC WILL BE TESTED FOR:

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

<table>
<thead>
<tr>
<th></th>
<th>Opt-In</th>
<th>Opt-Out</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>

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Texas Department of State Health Services, 2005
Evaluation Summary

- HIV testing increased 54% (attendance increased 9%)
- HIV-positive clients identified increased 60%
- Number of HIV-positive clients successfully referred to early intervention programs increased 89%
- Number of new HIV-positive partners increased 200%
- Demographics did not change
- Risk profile did not change
- HIV-negative STD clients receiving prevention counseling decreased
Eligible STD Clients
Percent Tested for HIV, 1997 - 2005

Semi-annual Period

STD Clients HIV Tested (Goal 95%)
Eligible STD Clients
Percent Positive, 1997-2005

Semi-annual Period
Eligible STD Clients
Percent Prevention Counselled, 1997 - 2005

Semi-annual Period

97-1 97-2 98-1 98-2 99-1 99-2 00-1 00-2 01-1 01-2 02-1 02-2 03-1 03-2 04-1 04-2 05-1

- 54%
- 56%
- 52%
- 46%
- 50%
- 47%
- 44%
- 45%
- 44%
- 49%
- 52%
- 49%
- 51%
Conclusions: 1997-2005

- HIV testing rates remain high (average, 92%)
- The proportion of clients who test HIV-positive remains stable (average, 0.8%)
- Approximately half of persons tested with opt-out consent (average, 48%) accept prevention counseling
- This compares favorably to the percentage of STD clients who accepted participation in the Project RESPECT study of prevention counseling (43%)
Make Voluntary HIV Testing a Routine Part of Medical Care
Considerations for Revising Recommendations
The CDC guidelines are a carefully crafted attempt to simultaneously increase the numbers of individuals who know their HIV status while maintaining the historical emphasis on extensive pretest counseling and consent procedures—an attempt to balance the historical commitment to voluntarism and prevention with an increased focus on identification.

It remains to be seen whether this carefully constructed compromise will endure.

Phillips, Bayer, Chen, JAIDS 2003
Rationale for Revising Recommendations

- Many HIV-infected persons access health care but are not tested for HIV until symptomatic
- Effective treatment available
- Awareness of HIV infection leads to substantial reductions in high-risk sexual behavior
- The need for pre-test counseling is decreased due to high levels of knowledge about HIV
- Great deal of experience with HIV testing, including rapid tests
- Inconclusive evidence about prevention benefits from typical counseling for persons who test negative
The Case for HIV Screening in Medical Care Settings
Criteria that Justify Routine Screening

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

Principles and Practice of Screening for Disease
WHO Public Health Paper, 1968
Newborn Screening Results, 1994

Newborn screening, 1994
- 3.7 million infants screened, twice

<table>
<thead>
<tr>
<th>Condition</th>
<th>Cases</th>
<th>Incidence</th>
<th>PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>PKU</td>
<td>289</td>
<td>1:13,050</td>
<td>2.65%</td>
</tr>
<tr>
<td>Galactosemia</td>
<td>54</td>
<td>1:62,8000</td>
<td>0.57%</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>1203</td>
<td>1:3,300</td>
<td>1.77%</td>
</tr>
<tr>
<td>Adrenal Hyperplasia</td>
<td>51</td>
<td>1:25,100</td>
<td>0.53%</td>
</tr>
</tbody>
</table>

Arch Pediatr Adolesc Med, 2000
Example: Chlamydia Screening

- First recognized as a major cause of STDs in 1970s (Schachter, 1975)
- Screening tests (other than culture) became available in the 1980s – 1990s
- Screening criteria developed based upon results of pilot screening programs
- Like HIV: Primary, community (e.g., school) and health care provider prevention strategies
Recommendations for Prevention and Management of Chlamydia Trachomatis Infections, 1993

Health care provider strategies:

- Recognize and manage associated conditions
  - MPC, PID, urethral syndrome, urethritis
- Implement screening
  - Sexually active women < 20 years of age
  - Women 20-24 who meet either criteria or women > 24 years who meet both:
    - Inconsistent use of barrier contraception
    - New or more than one sex partner in the past 3 months
Cost Effectiveness


- Routine inpatient HIV screening programs are not only cost-effective, but would likely remain so at a prevalence of undiagnosed infection 10 times lower than recommended thresholds.

  - 1% HIV prevalence: $35,400 per QALY
  - 0.1% HIV prevalence: $64,500 per QALY

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. Ø

1% HIV prevalence: $15,078 per QALY
> 0.05% prevalence: < $50,000 per QALY
**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."

(CDC)
Process for Revising Recommendations

- HIV Prevention Leadership Summit, San Francisco, August 2005
- Community consultation, Atlanta, September 2005
- Peer review of "HIV Screening Recommendations for Adults, Adolescents, and Pregnant Women in Health Care Settings," Atlanta, November 2005
- Public comment on revised draft, March 2005
Proposed Revisions
Adults and Adolescents - 1

- Routine, voluntary HIV screening for all persons 13-64 in health care settings, not based on risk or prevalence
- Repeat HIV screening of persons with known risk at least annually
- Opt-out HIV testing with the opportunity to ask questions and the option to decline; include HIV consent with general consent for care
  - Communication of test results
- Prevention counseling in conjunctions with HIV screening in health care settings is not required
Proposed Revisions
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, corrections

- Provide clinical HIV care or establish reliable referral to qualified providers
State and local regulations should be reviewed and revised as needed.

- Low prevalence settings: consider "sunset" provision
  - Initiate screening
  - If HIV prevalence shown to be < 0.1%, continued screening may be unwarranted.
Proposed Revisions

Pregnant Women

- Universal opt-out HIV screening
  - Include HIV in panel of prenatal screening tests
  - Consent for prenatal care includes HIV testing
  - Notification and option to decline

- Second test in 3rd trimester for pregnant women:
  - Known to be at risk for HIV
  - In key jurisdictions
  - In high HIV prevalence healthcare facilities

- Opt-out rapid testing for women with undocumented HIV status in L&D
  - Initiate ARV prophylaxis on basis of rapid test result

- Opt-out newborn testing if mother’s status unknown
Remaining Issues

- Who will pay?
  - Reimbursement as for other screening
  - Public funding
- Assuring access to care
- Continuing work to reduce stigma
There is an urgent need to increase the proportion of persons who are aware of their HIV-infection status.

Expanded, routine, voluntary, opt-out screening in health care settings is needed.

Such screening is cost-effective.

In 2006, CDC will issue revised recommendations for HIV testing of adults, adolescents and pregnant women in health care settings.
Investigation of Reports of Excessive False-positive Oral Fluid Rapid HIV Tests

Bernard Branson\textsuperscript{1}, Laura Weisolowski\textsuperscript{1}, Kevin Delaney\textsuperscript{1}, Mauushum Imavinkurve\textsuperscript{2}, Teri Dowling\textsuperscript{3}, Duncan Mackellar\textsuperscript{1}

\textsuperscript{1}Centers for Disease Control and Prevention
\textsuperscript{2}New York City Dept of Health and Mental Hygiene
\textsuperscript{3}San Francisco Dept of Public Health
Background

- Oraquick Rapid HIV-1 Antibody Test
  - Approved for use with whole blood November 2002
  - CLIA-waived February 2003
  - Approved for use with oral fluid March 2004
  - Approved for HIV-2 detection and name changed to OraQuick Advance June 2004

- CDC initiated post-marketing surveillance in 2003
Background

Press reports of false-positive oral fluid tests:

- SF Clinics Getting High False-Positive Rate on Oral HIV Test - San Francisco Chronicle 12/10/05
- False Positives from HIV Test - New York Times 12/11/05
- Facility Halts Use of Oral HIV Test - Los Angeles Times 12/16/05
- More Sites Drop Oral HIV Test - Los Angeles Times 12/20/05
Sources of Data

- 4 prospective studies with parallel testing of whole blood & oral fluid OraQuick, EIA, & Western blot, 2000 - 05

- CDC post-marketing surveillance, 368 sites in 14 states and 3 cities August 04 - June 05

- Outlier analysis, 41 sites in 3 states Sept - Nov 05

- Recent testing data, NYC STD clinics, Dec 05 - Jan 06
# Combined Results: 4 Prospective Studies

<table>
<thead>
<tr>
<th></th>
<th>Reference Negative</th>
<th>False Positive</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>OralQuick</td>
<td>12,010</td>
<td>12</td>
<td>99.9%</td>
</tr>
<tr>
<td>Whole blood</td>
<td>12,010</td>
<td>54</td>
<td>99.6%</td>
</tr>
<tr>
<td>OralFluid</td>
<td>12,010</td>
<td>35</td>
<td>99.7%</td>
</tr>
<tr>
<td>Serum EIA</td>
<td>12,010</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


## Individual Study Results

<table>
<thead>
<tr>
<th></th>
<th>Reference Negative</th>
<th>False Positive</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Los Angeles</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole blood</td>
<td></td>
<td>4</td>
<td>99.9% (99.8-</td>
</tr>
<tr>
<td>Oral fluid</td>
<td></td>
<td>21</td>
<td>99.6% (99.4-99.7)</td>
</tr>
<tr>
<td>EIA</td>
<td></td>
<td>23</td>
<td>99.6% (99.4-99.7)</td>
</tr>
<tr>
<td><strong>M IRIAD</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole blood</td>
<td>2</td>
<td></td>
<td>99.9% (99.8-</td>
</tr>
<tr>
<td>Oral fluid</td>
<td>5</td>
<td></td>
<td>99.6% (99.4-99.8)</td>
</tr>
<tr>
<td>EIA</td>
<td>7</td>
<td></td>
<td>99.6% (99.4-99.7)</td>
</tr>
</tbody>
</table>
### Individual Study Results

<table>
<thead>
<tr>
<th>Reference</th>
<th>False Positive</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Negative</strong></td>
<td><strong>Positive</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Phoenix</strong></td>
<td>2,000</td>
<td>3</td>
</tr>
<tr>
<td>Whole blood</td>
<td>5</td>
<td>100% (99.9-</td>
</tr>
<tr>
<td>Oral fluid</td>
<td>0</td>
<td>100.0)</td>
</tr>
<tr>
<td>EIA</td>
<td>2</td>
<td>99.9% (99.6-</td>
</tr>
<tr>
<td><strong>Minnesota</strong></td>
<td>2,405</td>
<td>23</td>
</tr>
<tr>
<td>Whole blood</td>
<td>5</td>
<td>99.8% (99.5-99.9)</td>
</tr>
<tr>
<td>Oral fluid</td>
<td>0</td>
<td>100.0)</td>
</tr>
<tr>
<td>EIA</td>
<td>0</td>
<td>100.0)</td>
</tr>
</tbody>
</table>
Minnesota Cluster, Oral Fluid False Positives - 2004

- March 2002 ÷ March 2004:
  7 false positives, 2017 tests (Specificity 99.7%)

- April 2004 ÷ August 2004:
  16 false positives, 407 tests (Specificity 96.1%)

- Follow-up study, Feb-May 2005, 9 sites in 3 states:
  0 false positives, 2,314 tests (Specificity 100%)
  Case-control study could not proceed
Postmarketing Surveillance: Aug 2004 - June 2005

Median seropositivity and specificity for 17 project areas,
368 testing sites

<table>
<thead>
<tr>
<th></th>
<th>Seropositivity</th>
<th>Observed Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median % (range)</td>
<td>Median % (range)</td>
</tr>
<tr>
<td>Whole blood</td>
<td>0.83 (0.08 - 2.60)</td>
<td>99.98 (99.73 - 100)</td>
</tr>
<tr>
<td>(n= 135,724)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral fluid</td>
<td>1.00 (0 - 4.02)</td>
<td>99.89 (99.44 - 100)</td>
</tr>
<tr>
<td>(n= 26,066)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Outlier Analysis, 41 Sites in 3 Jurisdictions:
False-positive Oral Fluid tests, Sept-Nov 2005

Sites (by region):
- New York City
- New Jersey
- San Francisco
New York City: Sept † Nov 2005

<table>
<thead>
<tr>
<th>Sites</th>
<th># tests</th>
<th># false pos</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sept</td>
<td>1662</td>
<td>4</td>
<td>99.8%</td>
</tr>
<tr>
<td>Oct</td>
<td>1762</td>
<td>10</td>
<td>99.4%</td>
</tr>
<tr>
<td>Nov</td>
<td>1581</td>
<td>32</td>
<td>98.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sites</th>
<th># tests</th>
<th># false pos</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sept</td>
<td>2316</td>
<td>2</td>
<td>99.9%</td>
</tr>
<tr>
<td>Oct</td>
<td>2279</td>
<td>1</td>
<td>99.9%</td>
</tr>
<tr>
<td>Nov</td>
<td>2164</td>
<td>3</td>
<td>99.9%</td>
</tr>
</tbody>
</table>
## New York City STD Clinics

<table>
<thead>
<tr>
<th>Month</th>
<th># False Positive</th>
<th># of Tests</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>August</td>
<td>4</td>
<td>3400</td>
<td>99.88</td>
</tr>
<tr>
<td>September</td>
<td>7</td>
<td>3960</td>
<td>99.82</td>
</tr>
<tr>
<td>October</td>
<td>12</td>
<td>4038</td>
<td>99.65</td>
</tr>
<tr>
<td>November</td>
<td>37</td>
<td>3735</td>
<td>98.97</td>
</tr>
<tr>
<td>12/6-21/05</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>January</td>
<td>27</td>
<td>4192</td>
<td>99.35</td>
</tr>
<tr>
<td>February</td>
<td>14</td>
<td>3779</td>
<td>99.63</td>
</tr>
<tr>
<td>Total</td>
<td>101</td>
<td>23,104</td>
<td>99.56</td>
</tr>
</tbody>
</table>

Fingerstick testing only
Counseling Message:
Both rapid tests we ran today were preliminary positive. It is likely that you have HIV. To make absolutely sure, we are going to draw blood and send it to our lab so they can run confirmatory testing. The results of those tests will be ready in 1 week. In the meantime, you should assume that you are infected with HIV, and take all necessary precautions to protect your partners.

Counseling Message:
Although the oral rapid test we ran today was preliminary positive, the fingerstick test was negative. Because the fingerstick test is a more accurate test, it's likely that you don't have HIV. In order to know for sure, we need to draw blood and send it to our lab for confirmation. The results of those tests will be ready in 1 week. In the meantime, you should assume that you may be infected with HIV, and take all necessary precautions to protect your partners.
## Positive Oral Fluid Tests with Reflex to Finger-stick, New York City STD Clinics

<table>
<thead>
<tr>
<th>Oral Fluid</th>
<th>Finger-Stick</th>
<th>Western blot</th>
</tr>
</thead>
<tbody>
<tr>
<td>127 reactive</td>
<td>64 reactive</td>
<td>64 positive</td>
</tr>
<tr>
<td>17 no result</td>
<td>17 positive</td>
<td></td>
</tr>
<tr>
<td>46 negative</td>
<td>45 negative</td>
<td>1 positive</td>
</tr>
</tbody>
</table>

December 22, 2005 ⏰ February 28, 2006
Conclusions

- OraQuick specificity is slightly lower with oral fluid than with whole blood, but well above FDA's minimum threshold (98%) with both specimen types.

- Excess false-positives at 3 sites appear to be related to unidentified site- or host-specific factors.

- Finger-stick test after reactive oral fluid test may reduce the number of persons who receive false positive results, but confirmatory testing is still required.