Ensuring Patient Rights in an Era of Changing Policy: The Impact of CDC-Recommended Routine Testing

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CAPS

April 18, 2008
Old CDC HIV Testing Recommendations

• Every person in care should be screened for HIV transmission risk behavior.
• Those with a positive screen should be referred for testing for HIV.
• Those with identified risk should receive risk reduction counseling.
New(ish) Recommendations

• **Routine HIV test** for all persons age 13-64 in health care settings, not based on risk.
  – Includes STD clinics, family planning clinics, Emergency Depts, primary care clinics, etc.

• **Opt-out** HIV screening with the opportunity to ask questions and the option to decline; include HIV consent with general consent for care.

• **Prevention counseling** not required.

• **Annual repeat screening** of persons with known ongoing risk.

Revised Recommendations for HIV Testing
CDC 9/21/06
New/Revised CDC Recommendations: Repeat Screening

“At least annually for all persons at high risk of HIV infection”

WHO WOULD YOU INCLUDE?
New/Revised CDC Recommendations: Repeat Screening

• At least annually for all persons at high risk of HIV infection:
  – Injection-drug users (IDUs)
  – Sex partners of IDUs
  – Persons who exchange sex for money or drugs
  – Sex partners of HIV infected
  – Men who have sex with men (MSM)
  – Heterosexuals who themselves or their sex partners have had >1 sex partner since last HIV test

• Before new sexual relationship
Points for Clarification

• The new recommendations don’t specify RAPID TESTING, they address ROUTINIZING TESTING, whether rapid or not.

• The new/revised recommendations apply to testing in medical settings, and NOT to testing that is paid for via the California State Office of AIDS Counseling and Testing program.
Implementation Issues

• Consent Issues
  – Opt-in/Opt-out
  – Current California law and upcoming changes
  – The consent debate

• Confidentiality and chart documentation

• Performing the test in a busy clinic

• Communicating results and linking to care
Terminology

• **Informed consent**: a legal concept; defined as a communication between patient and provider resulting in an authorization to undergo HIV testing; capacity to understand testing should be assured.

• **Opt-out screening**: performing an HIV test after notifying the patient that the test will be done; consent is inferred unless the patient declines (i.e., opts out).

• **HIV prevention counseling**: interactive process to assess risk, recognize risky behaviors, and develop a plan to take steps that will reduce risks.
“Ins and Outs” of HIV Testing

- Opt-In (Linked)
  - Assessment for HIV risk done verbally.
  - Patient requests or is offered the test.
  - Explicit consent obtained, usually written.
  - Requires pre- and post-test counseling (often not done in real life).

- Opt-Out (Delinked)
  - Patient informed they will be tested for HIV along with routine blood work unless they ask not to be.
  - Counseling not required.
  - No separate consent.
Assembly Bill 682

Recent Changes to CA Law

Formal informed consent not required; prior to ordering an HIV test, a clinician must:

- Inform the patient that the test is planned
- Provide information about the test
- Inform the patient about specified treatment options and further testing needed
- Advise the patient that s/he has a right to decline the test

Passed CA Assembly September 10, 2007

To view legislation, go to www.leginfo.ca.gov/bilinfo.html and search for bill “682”
Implementation in Our Communities: East Bay

• CDC funded-State of CA African American Prevention Testing Project, Highland and Summit E.D.s
• Get Screened Oakland Campaign started 5/07
• Other???
Association Between HIV Testing Rates and Elimination of Written Consent in San Francisco

- Consent mechanism altered and streamlined at San Francisco DPH Care System
- In May 2006:
  - Conventional consent forms removed from medical settings
  - HIV antibody test added to routine lab requisition
  - Clinicians required to document in chart that patient consent was obtained
  - Patient signature was not required

Zetola et al. JAMA 2007 Mar; 297 (10): 1061-1062
Association Between HIV Testing Rates and Elimination of Written Consent in San Francisco

• Results of this structural intervention:
  – Monthly rate of HIV testing increased after this policy change, from 13.5 tests /1000 visits in June 2006 to 17.9 in December 2006
  – Mean number of positive HIV tests per month increased from 20.6 to 30.6

• Conclusion:
  – Administrative policy change simplifying consent was followed by an increase in HIV testing and increased positivity rate

Zetola et al. JAMA 2007 Mar; 297 (10): 1061-1062
Debate: Public Health Tool, or Coercive Shortcut?
Case Finding

• Many (esp. young people and women) don’t realize their risk, so don’t know to ask for testing and are not being offered testing.

• More get tested with opt-out strategy.
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

CDC/Janssen
The Undiagnosed are More Likely to Be People of Color

2003 Estimate

## 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><strong>Tested</strong></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*
Case Finding

More testing will help find who is really infected and:

– Allow prevention resources to be focused on those communities.
– Increase testing outreach to those most at risk.
## Unrecognized HIV Infection Among 1,767 MSM
(Baltimore, LA, Miami, NYC, San Francisco)

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

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

**Total**       | **1,767**     | **450 (25)**       | **217 (48)**                   |

*MMWR June 24, 2005*
Case Finding

- Universal Testing wastes resources on testing low-risk people, rather than supporting prevention and treatment for high risk people.
  
  0.05% prevalence: $50,000 per QALY

- Perpetuates history of sending resources to the “innocent victims”
  
  – MSM and IDU still at greatest risk!

Estimated Number of Adults and Adolescents Living with AIDS, by Transmission Category, 1985-2003 United States

- Male-to-male sexual contact
- Injection drug use (IDU)
- Male-to-male sexual contact and IDU
- Heterosexual contact

Year: 1985 to 2003

Note. Data adjusted for reporting delays and for estimated proportional redistribution of cases in persons initially reported without an identified risk factor.
Prevention

Testing without counseling ignores reducible risk.

- Behavioral prevention interventions *done correctly* can be effective.
- New guidelines will move emphasis from prevention to medical intervention.
- Current guidelines have not been fairly tested; insufficient resources invested to support real counseling in medical settings.

An Overview of the Effectiveness and Efficiency of HIV Prevention Programs
Curran J; *Public Health Reports*, Vol. 110, 1995
Coercive Shortcut

Prevention

Treatment

Testing
Reduction in Risk Behaviors Once Seropositive Status is Known

- Total Reduction in Unprotected Intercourse
- Percent Reduction

-53%

-68%


Slide Courtesy M. Gandhi
Medical Impact

**Individual**
- Finds people earlier in disease
  - treatment more effective

**Medical System**
- Simplifies testing and outreach by:
  - Incorporating consent in normal consent process
  - Reducing counseling requirement for people at low risk, saves time.
Mortality and HAART Use Over Time
HIV Outpatient Study, CDC, 1994-2003

-Palella et al, JAIDS 2006; 43:27.
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”)

*16 states
Medical System Impact

• Providers perceive counseling as a barrier (survey of 54 providers/10 ED’s)
  • 10% encouraged STD patients to get HIV test
  • 35% referred to outside testing

• Barriers cited: lack of follow-up (51%), believed they needed a counselor certification (45%), too time consuming (19%)
More testing “normalizes” HIV and HIV testing, reduces stigma of testing.
Opt-Out Screening and Stigma

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*

• Opt-out testing offered as routine, opportunity to decline
  - 88% accepted testing
  - *Significantly less anxious about testing*

Views on Routine HIV Testing

HIV testing should be treated just like routine screening for any other disease, and should be included as part of regular check-ups and exams.

HIV testing is different from screening for other diseases, and should require special procedures, such as written permission from the patient in order to perform the test.

Source: Kaiser Family Foundation Survey of Americans on HIV/AIDS (conducted March 24 – April 18, 2006).
ABA and ACLU:

• Violates civil rights by minimizing consent process.

• General medical consent is for care for which “risks and benefits are generally known.”
  – E.g. Genetic testing NOT covered by general consent.
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

CDC/Janssen
2005 Katrina
Audience Vote

Exceptionalism

vs.

Routinization
CPT codes: HIV Testing

- HIV Ab, confirmatory 86689 (e.g. Western Blot)
- HIV-1 Ab 86701 +/- 92
- HIV-1,2 Ab 86703 +/- 92
- HIV viral load 87534-6

Slide courtesy Dr. Steve O’Brien obriens@sutterhealth.org
# CPT codes: Office Visit

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Situation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99385</td>
<td>New patient for preventive care</td>
<td>Initial comp preventive med E&amp;M</td>
</tr>
<tr>
<td>99395</td>
<td>Existing patient for preventive care</td>
<td>periodic comp preventive med E&amp;M</td>
</tr>
<tr>
<td>36415</td>
<td>Blood draw</td>
<td>Venipuncture</td>
</tr>
<tr>
<td>99211-99215</td>
<td>Counseling for pt with pos result</td>
<td>Standard outpatient visit codes</td>
</tr>
</tbody>
</table>

Slide courtesy Dr. Steve O’Brien obriens@sutterhealth.org
ICD

- **International Classification of Diseases** is published by the World Health Organization
- ICD-10: 1992
- ICD-11: 2011

Slide courtesy Dr. Steve O’Brien obriens@sutterhealth.org
ICD codes for HIV Testing

• Diagnostic HIV Testing
  >900 ICD codes support testing
  – Infections (e.g. STD’s, OI’s)
  – Cancers (e.g. lymphoma, KS, genital)
  – Symptoms (e.g. diarrhea, weight loss)
  – Lifestyle (e.g. high risk sexual behavior)

Slide courtesy Dr. Steve O’Brien obriens@sutterhealth.org
## ICD-9 codes: Diagnosis

<table>
<thead>
<tr>
<th>Code</th>
<th>Diagnosis</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>V73.89</td>
<td>Other specified viral diseases</td>
<td>Pt seen for HIV test</td>
</tr>
<tr>
<td>V69.8</td>
<td>Problems related to lifestyle</td>
<td>Asymptomatic pt in high risk group</td>
</tr>
<tr>
<td>V65.44</td>
<td>HIV counseling</td>
<td>HIV counseling provided</td>
</tr>
<tr>
<td>V08</td>
<td>Asymptomatic HIV status</td>
<td>Asymptomatic pt given HIV+ results</td>
</tr>
<tr>
<td>042</td>
<td>HIV disease</td>
<td>Symptomatic pt given HIV+ results</td>
</tr>
<tr>
<td>V70.0</td>
<td>General medical exam</td>
<td>Patient for regular exam</td>
</tr>
</tbody>
</table>

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