Routine HIV Testing: Implementing evidenced-based clinical change

Jonathan Pincus MD
Codman Square Health Center
Dorchester, MA
60 year old-woman with Diabetes

What does she need at her visit?
How do we incorporate HIV testing?
Criteria for Clinical Research and QI Projects

- Relevance to our community/patients
- Health Center champion
- Effect on clinical flow
- Cost
HIV Prevalence, NHANES 1999-2002

Age 18-39 years

Age 40-49 years

- McQuillan et al, NCHS: JAIDS April 2006
Awareness of Serostatus Among People with HIV and Estimates of Transmission

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

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

New Sexual Infections Each Year: ~32,000

Accounting for:

- ~54% of New Infections
- ~46% of New Infections

Marks G, et al
AIDS 2006; 20:1447
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

- Red: Late (Tested < 1 yr before AIDS dx)
- Light Blue: Early (Tested >5 yrs before AIDS dx)

Categories:
- Illness
- Self/partner at risk
- Wanted to know
- Routine check up
- Required
- Other
Advancing HIV Prevention: New Strategies for a Changing Epidemic —
United States, 2003

In several U.S. cities, recent outbreaks of primary and secondary syphilis among men who have sex with men (MSM) (1) and increases in newly diagnosed human immunodeficiency virus (HIV) infections among MSM and among heterosexuals have spurred concern that HIV incidence might be increased rapidly during the 1980s. During 1981–2001, an estimated 1.3–1.4 million persons in the United States were infected with HIV (3), and 816,149 cases of AIDS and 467,910 deaths were reported to CDC (4). During the late 1990s, after the introduction of combination antiretroviral
AHP Strategies

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
## Rapid HIV Testing in Non-Clinical Settings

<table>
<thead>
<tr>
<th>Community-based organization</th>
<th>No. Tested</th>
<th>% HIV+</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS Healthcare Foundation, L.A.</td>
<td>2,318</td>
<td>1.6%</td>
</tr>
<tr>
<td>Bienestar, L.A.</td>
<td>1,902</td>
<td>2.9%</td>
</tr>
<tr>
<td>CHAG, Detroit</td>
<td>2,011</td>
<td>1.5%</td>
</tr>
<tr>
<td>Continuum, San Francisco</td>
<td>1,772</td>
<td>1.8%</td>
</tr>
<tr>
<td><strong>HSP of Dorchester, Boston</strong></td>
<td>4,618</td>
<td>1.1%</td>
</tr>
<tr>
<td>Kansas City Free Clinic</td>
<td>1,826</td>
<td>1.1%</td>
</tr>
<tr>
<td>The Night Ministry, Chicago</td>
<td>1,867</td>
<td>1.2%</td>
</tr>
<tr>
<td><strong>Whitman Walker, Washington DC</strong></td>
<td>4,245</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

*CDC, preliminary data - Sept 2005*
CSHC HIV Testing

Annual Totals

1800
1600
1400
1200
1000
800
600
400
200
0
2003 2004 2005 2006

CDC Rapid Testing Grant

4-6 Dedicated C&T staff
Grant Funded
Heavy Administrative Burden
Low yield from non-clinical sites
Plateau Effect
• Opt-out testing
• High risk patients screened annually
• No separate consent
• No required prevention counseling
Challenges of increased HIV testing

- Ordering Test
  - Provider attitudes on testing
  - Patient attitudes on testing
  - Competing priorities/ Remembering to order test
  - Time – to discuss, to wait for results
  - Consent process
  - Language/cultural
  - Counseling

- Testing
- Results Delivery
- Follow-up
- Sustainability
Barriers to HIV Testing

Fig. 1. Venn diagram of barriers by practice setting. ACOG, American College of Obstetricians and Gynecologists; ED, emergency department; STD, sexually transmitted disease.
Barriers to HIV Testing

- Burdensome consent process
- Insufficient time
- Lack of knowledge/training
- Lack of patient acceptance
- Pretest counseling requirements
- Competing priorities
- Inadequate reimbursement
- Dealing with positive results

Implementing Routine HIV Testing: The Role of State Law

Leslie E. Wolf¹*, Alexis Donohoe², Tim Lane³

¹Program in Medical Ethics, Center for AIDS Prevention Studies, University of California at San Francisco, San Francisco, California, United States of America, ²University of San Francisco School of Law, San Francisco, California, United States of America, ³Center for AIDS Prevention Studies, University of California at San Francisco, San Francisco, California, United States of America

In September 2006, the Centers for Disease Control and Prevention (CDC) recommended routine HIV testing for all Americans aged 13–64, which would eliminate requirements for written consent and pretest counseling as previously required. However, this approach may conflict with state requirements concerning pretest counseling and informed consent for HIV testing. Our survey of state HIV testing laws demonstrates that the majority of states have HIV testing requirements that are inconsistent with the CDC’s recommendations. Moreover, states that have recently amended their laws have not eased the requirements for pretest counseling and informed consent. The reasons for the persistence of these legal requirements must be understood to effect policy changes to increase HIV testing.

Currently in the Commonwealth, Massachusetts General Laws, C. 111, § 70F requires written informed consent for HIV testing. **However, general consent for medical care containing a distinct, time-limited consent for HIV testing is sufficient.** MDPH has developed model informed consent language which facilities/practices may choose to adapt for local use (see attached language). Review of MDPH-issued patient information material regarding HIV testing is considered adequate prevention counseling and is recommended to accompany any HIV screening (see attached brochure).

**Clinical Advisory: Routine HIV Screening in Primary and Urgent Care Settings in Massachusetts, MDPH, June 24, 2009**

Q. Does the law require a time-limit on the consent?

A. **No,** the law does not. The MDPH recommends that consent expire after no more than one year.

Q. May an HIV test consent be included among other consents and legal documents at intake? For instance, may the consent for HIV testing be part of a general consent to care developed by individual sites?

A. **Yes,** the consent may be part of a general consent to care form as long as the language pertaining to the HIV test is distinct from the rest of the consent. Provided that the person consenting to the HIV test is informed about the test and understands what it is, there is nothing in 70F that prohibits health care providers from including the consent with other materials and from obtaining the consent at intake. If the consent to HIV testing is temporally separate from the test itself, the provider should let the individual know when the test is actually performed.

**Chapter 11, Section 70F, of the MGL, FAQ, MDPH June 2009**
Sample Consent Form - **HIV Testing**

My signature below indicates my consent to have my blood or a swab of my mouth tested for the presence of **HIV (the Human Immunodeficiency Virus)**.

I understand that my test results will be shared with my health care provider, and that if my health care provider diagnoses me with HIV infection or AIDS, she/he is required to submit an HIV/AIDS case report form to the Massachusetts Department of Public Health HIV/AIDS Surveillance Program.

This consent will expire one year from the date it is signed, unless I withdraw my consent in writing before this date.

_________________________________________________________
Name (please print)

_________________________________________________________
Signature

____________________
Date
My signature below indicates that:

1. I agree to be tested for HIV.
2. I have been given information about the test.
3. All of my questions about the test have been answered.
4. I understand that this consent will expire one year from the date it is signed. I understand that I may withdraw my consent at any time.
5. My decision to be tested is completely voluntary.

________________________________________
Name (please print)

________________________________________
Signature

________________________
Date
**Question:** Does a Massachusetts clinical laboratory actually have to obtain a copy of an individual’s written consent prior to performing an HIV test?

**Answer:** No. The regulation requires that the laboratory have written procedures ensuring that the physician ordering the test has obtained the required written consent and that such consent is maintained by the physician. The physician is not required to submit a copy of the actual written consent to the laboratory with the order for the test. The physician must confirm the presence of written consent on or with the order. For example, the laboratory may have a written procedure requiring that a physician’s order for an HIV test have a check off box for indicating whether the test subject provided the physician with written consent for the test. If the physician ordering the test checks the box, the laboratory may perform the test and be in compliance with the Department’s regulation.
Barriers to HIV Testing

- Burdensome consent process
- **Insufficient time**
- Lack of knowledge/training
- Lack of patient acceptance
- Pretest counseling requirements
- Competing priorities
- Inadequate reimbursement
- Dealing with positive results

Barriers to HIV Testing

- Insufficient time

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>AMC</th>
<th>MCG</th>
<th>ICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median visit Length</td>
<td>15.7</td>
<td>23.3</td>
<td>13.4</td>
<td>9.7</td>
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<tr>
<td>Median time spent on Major topic</td>
<td>5.3</td>
<td>6.7</td>
<td>4.8</td>
<td>3.2</td>
</tr>
<tr>
<td>Median time spent on Minor topic</td>
<td>1.1</td>
<td>1.4</td>
<td>0.9</td>
<td>0.7</td>
</tr>
</tbody>
</table>

AMC = academic medical center; MCG = managed care group, ICS = inner-city site

Tai-Seale M, McGuire TG, Zhang, W (2007) "Time Allocation in Primary Care Office Visits"
HSR vol 42(5), pp. 1871-1894.
Barriers to HIV Testing

- **Insufficient time**

Codman Visit Cycle Times

- Family Medicine
- Internal Medicine
- Pediatrics

60 year old-woman with Diabetes

What does she need at her visit?
How do we incorporate HIV testing?
60 year old woman with Diabetes

US Preventive Services Task Force

- 9 “A” rated recommended interventions
- 10 “B”
- 5 “C”
- 26 “I”
- 22 “D”
60 year old-woman with Diabetes

US Preventive Services Task Force

- 9 “A” rated recommended interventions
- 10 “B”
- 5 “C”
- 26 “I”
- 22 “D”

ACIP – 4 immunizations (Td, Zostavax, Influenza, Pneumococcal)

ADA – HbA1c, BP, nutrition, bariatric surgery, ASA, screening for retinopathy, nephropathy, neuropathy
60 year old-woman with Diabetes

US Preventive Services Task Force

- 9 “A” rated recommended interventions
- 10 “B”
- 5 “C”
- 26 “I”
  - Screening for substance abuse & DV, nutrition
  - Glaucoma Screening – HEDIS, GIC
- 22 “D” Interventions
  - COPD - ATS
USPSTF: HIV Screening
Grade C

The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.

Offer or provide this service only if other considerations support the offering or providing the service in an individual patient.

The USPSTF makes no recommendation for or against routinely screening for HIV adolescents and adults who are not at increased risk for HIV infection.

The USPSTF found fair evidence that screening adolescents and adults not known to be at increased risk for HIV can detect additional individuals with HIV, and good evidence that appropriately timed interventions, especially HAART, lead to improved health outcomes for some of these individuals. However, the yield of screening persons without risk factors would be low, and potential harms associated with screening have been noted (above). The USPSTF concluded that the benefit of screening adolescents and adults without risk factors for HIV is too small relative to potential harms to justify a general recommendation.
Barriers to HIV Testing

- Burdensome consent process
- Insufficient time
- Lack of knowledge/training
  - Provider training
- Lack of patient acceptance
  - Routine vs risk based
  - Expected
- Pretest counseling requirements
- Competing priorities
- Inadequate reimbursement
- Dealing with positive results

Barriers to HIV Testing

- Burdensome consent process
- Insufficient time
- Lack of knowledge/training
- Lack of patient acceptance
- Pretest counseling requirements
- Competing priorities
- Inadequate reimbursement
- Dealing with positive results

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

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GOVERNOR
TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR
JUDYANN BIRDY, MD
SECRETARY
JOHN AUERBACH
COMMISSIONER

ROUTINE HIV COUNSELING & TESTING OF PREGNANT WOMEN
CLINICAL ADVISORY UPDATE

TO: Massachusetts Prenatal Care Providers
FROM: John Auerbach, Commissioner
        Lauren Smith, MD, MPH, Medical Director
Date: June 17, 2008
Re: Routine HIV Counseling and Testing of Pregnant Women

This Massachusetts Department of Public Health (MDPH) Clinical Advisory Update is meant to provide clarification on national guidelines and outline MDPH recommendations for routine HIV counseling and testing to all women in prenatal care. In 2006, the American College of Obstetrics and Gynecology (ACOG) (www.acog.org) and the Centers for Disease Control and Prevention (CDC) (www.cdc.gov) both recommend that HIV counseling and testing be performed routinely for all pregnant women, without reference to their risk profile. This is consistent with current MDPH recommendations. The ACOG and CDC recommendations further support the elimination of informed consent for HIV counseling and testing of pregnant women, which is not consistent with Massachusetts law. In the Commonwealth, MA General Law c111, § 70F requires written informed consent for HIV testing, forming the basis for the Massachusetts opt-in system of HIV testing.
CLINICAL ADVISORY:
ROUTINE HIV SCREENING IN PRIMARY AND URGENT CARE SETTINGS IN MASSACHUSETTS

TO: Massachusetts Primary Care and Urgent Care Providers
FROM: John Auerbach, Commissioner of Public Health
Lauren Smith, MD, MPH, Medical Director
Kevin Granston, MDiv, Director, Bureau of Infectious Disease
Alfred DeMaria, MD, Medical Director, Bureau of Infectious Disease
Date: June 24, 2009
Re: Routine HIV Screening

This Massachusetts Department of Public Health (MDPH) Clinical Advisory is meant to communicate the Department’s strong support of HIV screening as a component of routine primary and urgent care in the Commonwealth. In September 2006, the Centers for Disease Control and Prevention (CDC) issued the “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings” in which the CDC recommends the routine screening of all adult and adolescent patients for HIV infection.¹
Barriers to HIV Testing

- Burdensome consent process
- Insufficient time
- Lack of knowledge/training
- Lack of patient acceptance
- Pretest counseling requirements
- Competing priorities
- Inadequate reimbursement
- Dealing with positive results

Challenges of increased HIV testing

- Ordering Test
  - Provider attitudes on testing
    - Full staff training on importance of HIV testing in our community
    - Support for dealing with positives – CM support
    - Institutional policy/initiative
  - Patient attitudes on testing
    - Routine
  - Competing priorities/ Remembering to order test
    - Engaging all staff in recommending testing: Reg. staff, MA, RN, MD/PA/NP, Phlebotomist
    - “Vital Sign” – Tobacco, MASBIRT, Influenza vaccination
  - Time – to discuss, to wait for results
    - Simplifying testing, brochures, rapid and routine testing options
  - Consent process
    - Short, concise
    - General consent issues – tracking expiration
  - Language/cultural
    - Diverse staff and staff training
  - Counseling
    - Already part of routine primary care, positives
  - DPH/CDC requirement
    - No “bubble sheets"
  - Expanding beyond primary care and urgent care e.g. Dental, BH
  - EMR changes
  - Adolescent issues
Routine HIV Testing

Implementation
Unintended consequences of quality improvement programs

- Quality of care improved (QOC) for 2 out of 3 conditions linked to incentives
- QOC declined for 2 conditions not linked to incentives
- Plateau effect
EVIDENCE REPORT AND EVIDENCE-BASED RECOMMENDATIONS:

INTERVENTIONS THAT INCREASE THE UTILIZATION OF MEDICARE-FUNDED PREVENTIVE SERVICES FOR PERSONS AGE 65 AND OLDER

PREPARED FOR: U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION
7500 Security Blvd.
Baltimore, MD 21244-1850

PREPARED BY: RAND

CONTRACT NUMBER: 500-98-0281


Interventions That Increase Use of Adult Immunization and Cancer Screening Services: A Meta-Analysis

Eric C. Steiner, MD; Kelly C. Morton, PhD; Marlies E. Heches, PhD; Margaret A. Mangione, M.A.; Rachel A. Roth, MA; Jeremy M. Grumbach, MD, PhD; Brian S. Mittleman, PhD; Lisa V. Rubenstein, MD; Laurenza Z. Rubenstein, MD; and Paul C. Shalala, J.D., PhD

Purpose: The relative effectiveness of the diverse approaches used to promote preventive care activities, such as cancer screening and adult immunizations, is unknown. Despite many high-quality published studies, practitioners and policymakers attempting to improve preventive care have little definitive information on which to base decisions. Thus, we quantitatively assessed the relative effectiveness of previously studied approaches for improving adherence to adult immunization and cancer screening guidelines.

Data Sources: MEDLINE, the Cochrane Effective Practice and Organization of Care Reviews Group register, previous systematic reviews, and the Medline Health Care Quality Improvement Project database.

Study Selection: Controlled clinical trials that assessed interventions to increase use of immunizations for influenza and pneumococcal pneumonia and screening for colorectal and cervical cancer in adults.

Data Extraction: Two reviewers independently extracted data on characteristics and outcomes from unmasked articles. Intervention components to increase use of services were described as financial incentives, mass media, organizational change, and provider feedback.

Data Synthesis: Of 552 abstracts and articles, 108 met the inclusion criteria. To assess the effect of intervention components, meta-regression models were developed for immunizations and each cancer screening service by using 81 studies with a control group. The most potent intervention types involved organizational change (the adjusted odds ratios for increased use of services from organizational change ranged from 2.47 to 17.6). Organizational change interventions included the use of separate clinics dedicated to prevention, use of a planned care visit for prevention, or designation of nonphysician staff to do specific prevention activities. The next most effective intervention components were patient financial incentives (adjusted odds ratios, 1.82 to 3.62) and patient reminders (adjusted odds ratios, 1.74 to 2.75); the adjusted odds ratios ranged from 1.29 to 1.59 for patient education and from 1.19 to 1.76 for feedback.

Conclusions: Rates of adult immunization and cancer screening are most likely to improve when a health care organization supports performance of these activities through organizational changes in staffing and clinical procedures, involving patients in self-management through patient financial incentives and reminders is also likely to positively affect performance.

For author affiliations, see end of text.
See editorial comment on pp. 701-703.

Interventions: Organizational change, standing orders, team approach, use of non-physician staff, electronic prompts, provider feedback
Influenza Vaccinations
Barriers to HIV Testing

- Burdensome consent process
- Insufficient time
- Lack of knowledge/training
- Lack of patient acceptance
- Pretest counseling requirements
- Competing priorities
- Inadequate reimbursement
  - $9-$28
  - Requested increase from lowest payor
- Dealing with positive results

Barriers to HIV Testing

- Burdensome consent process
- Insufficient time
- Lack of knowledge/training
- Lack of patient acceptance
- Pretest counseling requirements
- Competing priorities
- Inadequate reimbursement
- Dealing with positive results
  - HIV team assists with all results delivery

Challenges of increased HIV testing

- Ordering Test
- Testing
  - Rapid vs EIA
  - POC vs Lab based
  - Volume
  - Training
- Results Delivery
- Follow-up
- Sustainability
Public Health Need for Rapid HIV Tests

- High rates of non-return for test results
  - In 2000, 31% did not return for results of HIV-positive conventional tests at publicly funded sites
- Need for immediate information or referral for treatment choices
  - Perinatal settings
  - Post-exposure treatment settings
- Screening in high-volume, high-prevalence settings
## Four FDA-approved Rapid HIV Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity (95% C.I.)</th>
<th>Specificity (95% C.I.)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OraQuick Advance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- whole blood</td>
<td>99.6 (98.5 - 99.9)</td>
<td>100 (99.7-100)</td>
</tr>
<tr>
<td>- oral fluid</td>
<td>99.3 (98.4 - 99.7)</td>
<td>99.8 (99.6 - 99.9)</td>
</tr>
<tr>
<td>- plasma</td>
<td>99.6 (98.5 - 99.9)</td>
<td>99.9 (99.6 - 99.9)</td>
</tr>
<tr>
<td><strong>Uni-Gold</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Recombigen</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- whole blood</td>
<td>100 (99.5 - 100)</td>
<td>99.7 (99.0 - 100)</td>
</tr>
<tr>
<td>- serum/plasma</td>
<td>100 (99.5 - 100)</td>
<td>99.8 (99.3 - 100)</td>
</tr>
</tbody>
</table>
OraQuick Advance: Fingerstick and Whole Blood

In the past 9 months, only 1 lab based HIV test was done by fingerstick.


On June 18, this report was posted as an MMWR Early Release on the MMWR website (http://www.cdc.gov/mmwr).

The New York City Department of Health and Mental Hygiene (NYC DOHMH) operates 10 sexually transmitted disease (STD) walk-in clinics offering various free services, including confidential or anonymous testing for human immunodeficiency virus (HIV). In January 2004, the STD clinics introduced on-site rapid HIV testing of finger-stick whole-blood specimens using the OraQuick® brand test (OraSure Technologies, Bethlehem, Pennsylvania). In March 2005, the clinics replaced finger-stick whole-blood testing with oral fluid testing with the OraQuick Advance Rapid HIV-1/2 Antibody Test. The clinics use Western blot confirmatory tests on serum to confirm all whole-blood or oral fluid reactive (i.e., preliminary positive) rapid tests. In late 2005, an unexpected increase in the number of false positive oral fluid tests occurred, but the increase subsided after several months. In December 2005, while the cluster of false-positive oral fluid test results was being investigated, the NYC DOHMH increased the number of STD Control suspended oral fluid testing in the clinics for 3 weeks and replaced it with finger-stick whole-blood rapid testing, which produced no false-positive test results. On December 21, 2005, the NYC DOHMH resumed oral fluid rapid testing but also introduced the use of immediate follow-up finger-stick whole-blood testing, using a second OraQuick test, after any reactive oral fluid test result. In late 2007, another larger increase in the incidence of false-positive oral fluid rapid test results was observed. The cause for the episodic increases in false-positive oral fluid tests has not yet been determined.

NYC DOHMH has again suspended the use of oral fluid testing in STD clinics, and finger-stick whole-blood testing is the only rapid HIV test being used in this setting. These findings underscore the importance of confirming all reactive HIV tests, both from oral fluid and whole-blood specimens. In addition, the results suggest that the NYC DOHMH strategy of following up reactive oral fluid tests with an immediate finger-stick whole-blood test reduced the number of apparent false-positive oral fluid test results and might be a useful strategy in other settings and locations.
POC vs Lab

• **POC**
  - Faster
  - On-site reminder to test
  - More staff to train
  - Staff with competing activities
  - Oversight process
  - Regulatory oversight even though waived test

• **LAB**
  - Slower
  - Volume overwhelming
  - Expensive staff
  - Competing activities
  - Too many “stats”
  - Oversight easier
General POC Issues in Recent Years

- QC Issues
  - No QC run
  - Expired QC used
  - QC out of range but test run anyway
- Expired tests
- Documentation - patient identifiers, result reporting, QC.
- Oversight – multiple departments involved.
- Competency training – completing, passing
Pilot Study - POC

- MA collected specimen and ran test
- Portable clip-on timers
- MA busy with other activities and did not have enough time to run tests
- Issues with controls, reporting, documentation
Costs of Rapid Testing

- Patient Kit - $10
- Daily Control Testing Kits $10 x 3 per area
- Control Solution $35-75/month
- Staff Training
- Lab Oversight
- Clinical staff time
- Proficiency Testing
- Reimbursement $12

- $10
- 4 areas = $120/day
- $120/day x 21 weekdays = $2520, $30 x 8 weekends = 240; $2760
- $50/month
- 700 tests/month
- $2810 / 700 = $4 / test
- $10 + 4 = $14 / test + staff costs = > - $2 / test = $1400 / month
Hybrid POC Testing

MA collects the specimen and then sends the buffer vial to the lab where it is run.
HIV 1/O/2 Enhanced (EHIV)

- Multiple epitopes
- 3rd generation “sandwich” format
- Random access EIA
- FDA-approved July 2006
## Rapid vs EIA

<table>
<thead>
<tr>
<th></th>
<th>Rapid Test</th>
<th>Centaur Advia</th>
</tr>
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<tbody>
<tr>
<td>Cost</td>
<td>$12</td>
<td>$4</td>
</tr>
<tr>
<td>Sens/Spec</td>
<td>99.6/100 OQ</td>
<td>100/99.1</td>
</tr>
<tr>
<td></td>
<td>100/99.7 UG</td>
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</tr>
<tr>
<td>Time to result</td>
<td>20-60 mins</td>
<td>60 mins or &gt;</td>
</tr>
<tr>
<td>Automated</td>
<td>No*</td>
<td>Yes</td>
</tr>
<tr>
<td>POC</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Data Entry</td>
<td>Manual</td>
<td>Automated</td>
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<tr>
<td>Staff Time</td>
<td>High</td>
<td>Low</td>
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</table>
CSHC HIV Testing

Annual Totals

- 2003
- 2004
- 2005
- 2006
- 2007
- 2008
- 2009

- Annual Totals
Linkage to Care

• Preliminary + : 19
• Confirmed: 19 (100%)
• Routine 5, Walk-in 5, STD 2, Partner +, Pt request 1, Transfer/confirmation 5
• New Dx: 15
• CD4: 308 (0 – 713)

• Linkage to care:
  – In care 13 (87%) (1 moved out of state, 1 LTFU)
  – On meds: 8 (53%)
  – HIV RNA <48 : 4 (50%), 4 < 6 MONTHS ON haart vl 300
Successes

• High percentage of patients already being tested
• Consensus among stakeholders
• Provider and patient acceptance of routine testing
• Switched from C&T to T
• Established linkage to care
• Success in improving other clinical interventions – influenza vaccine, SA screening
• Lab support
• DPH and CDC support
• EMR – prompts, data reporting
Implementing Change based on Clinical Research

- Given the data, providers wanted to adopt routine testing but adding another task to the primary care visit was not feasible.
- No added work – “this will just take 2 mins”
- Clinicians not responsible for data collection
- Addressing concerns and providing support e.g. support team to deliver reactive results
Implementing Change based on Clinical Research

- Do study results/methodology apply to your setting?
  - Rapid testing may be important at an STD clinic but not so important at a CHC
- Team based approach
- It takes longer than you think
- It’s more work than you think
NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS

Clinical Issues

HIV Screening Model

In 2003, NACHC began an effort to increase HIV prevention activities whose outcomes included a new HIV testing model geared toward health centers without Ryan White funding. All tools have been tested and evaluated by health centers. Click here for additional background.

Integrating HIV Screening into Routine Primary Care: A Health Center Model: This twenty-nine-page document provides a model to move a health center to a process by which every patient 13 to 64 years of age is screened for HIV as a routine part of medical care. This model, developed with and piloted by a group of health centers, is a step-by-step approach comprised of 9 steps designed to be carried out over a period of 90 days. The model includes worksheets to track the activities to be completed for each step and references a variety of tools and forms that are listed below. These forms are ready to use or modify. Author: Cheryl Modica, RN, MPH, BSN. Source: National Association of Community Health Centers. Revision date: 10/20/2009.

Step 2 -- Routine Testing Flow Sheet: This one-page form captures and documents key information for each patient offered an HIV test through a health center's routine HIV screening process. This simple tool can be used as is or modified to meet local data collection and medical record documentation needs. Revision date: 09/13/2008.

Step 2 -- HIV Test Results Log: This one-page form records the result of each HIV test performed in a health center. This version of the tool can be used for the Uni-Gold, OraQuick and Clearview rapid HIV tests. Revision date: 10/01/2008.

Step 2 -- Control Results Log: This one-page form records the details of all internal and external test controls that are performed. This version of the tool can be used for the Uni-Gold, OraQuick and Clearview rapid HIV tests. Revision date: 10/01/2008.

Step 2 -- General Consent For Care: This one-page document is a general Consent for
• Thank You

• Philip Severin MD, Medical Director,
• Sandra Cotterell, COO,
• Jan Smith RN, Director of Clinical Operations,
• Christine Schromm, Laboratory Director,
• Michelle Bordeu, Director HIV services,
• Kevin Cranston, MA DPH, Director HIV/AIDS Bureau
• Keeta Alexander, Data Analyst
• Lemina Cisse, MA
• Carole Brignol, HIV Case Manager
• Michelle Rue, HIV Services
• Emily Cohen RN, HIV Clinical Case Manager
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>Location</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
Patients with an HIV test since 1/1/07

Percent of Patients with an HIV Test Since 1/1/07

Age

Percent

13-17
18-25
26-39
40-64
Totals

Patients seen
Aug-Sep 2008
CSHC HIV Testing

• Standard C&T
• Rapid Testing
• CDC - Advancing HIV Prevention Grant
  – Rapid Testing
  – Health Center Based Testing
  – Community Venues
• Post CDC Grant
  – C&T -> T
  – Increased primary care testing
  – Simplified consent
  – Decreased data collection
  – Rapid testing: POC and Lab based
• Routine Testing

A Rapid Review of Rapid HIV Antibody Tests

Jeffrey L. Groseclose, MD, Gale R. Burstein, MD, MPH, FAAP,
Jonathan Pincus, MD, and Bernard Brunson, MD

Introduction

Despite ongoing prevention and education efforts, an estimated 40,000 new HIV infections are acquired annually in the United States. Since the early 1980s, the estimated 1.1 million to 2.1 million persons living with HIV have approximately 200,000 to 300,000 persons who test positive [1]. Available evidence suggests that many new infections are caused by persons unaware of their HIV infection.[2-3]

HIV Testing

Many people with HIV do not get tested until late in their infection. Approximately 90% to 95% of patients with HIV infection are diagnosed within 10 years of becoming infected [4-6]. People who are unaware do not receive timely treatment that can affect their outcomes. The National Health Interview Survey found that 13.5% of persons tested in 1994 and 13.3% in 1995 did not receive their results [7], and the Centers for Disease Control and Prevention's surveillance data indicated that 2003-2011, 38% of patients who tested HIV-positive at public sector testing sites did not return to receive test results [8].

To reduce barriers to early diagnosis of HIV infection and to increase access to treatment and prevention services, the CDC announced a new initiative, "Advancing HIV Prevention: New Strategies for a Changing Epidemic" [9]. This initiative supports the expansion of rapidly testing in sites outside of provider offices and non-traditional locations for HIV testing. Additionally, it aims to maximize the importance of testing and linkage to care among individuals with high-risk behaviors, high-risk individuals, and for women during labor and delivery who have not previously been tested or in routine clinical settings.

Rapid HIV testing can play an important role in HIV prevention activities and rapid access to testing in both clinical and non-clinical settings. They can help overcome some of the barriers to early diagnosis and improve linkage to care of medical care. This paper will review the operating and performance characteristics, quality assurance and laboratory requirements, and HIV counseling implications of the currently available rapid HIV tests.
Challenges of increased HIV testing

- Ordering Test
- Testing
- Results Delivery
- Follow-up
- Sustainability
<table>
<thead>
<tr>
<th>Mode of Exposure</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSM</td>
<td>32</td>
</tr>
<tr>
<td>IDU</td>
<td>8</td>
</tr>
<tr>
<td>MSM/IDU</td>
<td>2</td>
</tr>
<tr>
<td>Het Sex</td>
<td>58</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
</tr>
<tr>
<td>Presumed Het</td>
<td>23</td>
</tr>
<tr>
<td>Unknown</td>
<td>13</td>
</tr>
</tbody>
</table>

**HIV Infection by Mode of Exposure**

Legend:
- Mattapan
- N Dorchester
- S Dorchester
- CSHC
HIV Infection by Age

![HIV Infection by Age Chart]

- Count (
- Age Groups: 0-12, 13-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50+
- Locations: Mattapan, N Dorchester, S Dorchester

Legend:
- Mattapan
- N Dorchester
- S Dorchester
Codman Square: HIV Patients by Gender

- Male: 55%
- Female: 45%
Codman Square HIV Patients: Mode of Transmission 2008

- Hetero: 76%
- MSM/Bis/Lesb: 16%
- IVDU: 6%
- Perinatal: 1%
- Blood: 1%
- Undet./Unk: 0%
- Blood transfusion: 1%

Total: 100%
Codman Square HIV Patients by Race/Ethnicity 2008

- Black/Afr-Am.: 47%
- Haitian: 26%
- Latino/a: 11%
- Sub-Saharan Afr.: 6%
- Caribbean: 4%
- Cape Verd.: 2%
- Asian: 1%
- White: 3%
- Cape Verd.: 2%
- Asian: 1%
- Sub-Saharan Afr.: 6%
- Latino/a: 11%
- Haitian: 26%
- Black/Afr-Am.: 47%