HIV Screening in 2015: Where Are We Now?

Bernard M. Branson, M.D.
Scientific Affairs LLC
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Disclosures
Dr. Branson has received consulting fees from:
- Chembio Diagnostic Systems Inc.
- Gilead Sciences FOCUS Program

Topic Outline
- Burden of HIV disease and rationale for screening
- Testing considerations:
  - Updated HIV Testing Recommendations
  - POC versus laboratory
  - Acute HIV infection
- Facilitators and barriers for routine screening

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

Persons with HIV and Awareness of HIV Status, United States - 2012

Number living with HIV: 1,201,100
Number unaware of their HIV infection: 168,300 (14%)
Estimated new infections annually: 47,500

What percentage of persons with HIV in California are unaware of their infection?

- 1. 25%
- 2. 14%
- 3. 11%
- 4. 5%
- 5. Not sure

- CDC, HIV Surveillance Supplemental Report, 2014
Persons with HIV and Awareness of HIV Status, California- 2012

- CDC, MMWR June 26, 2015

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
5. Treatment must be accessible

Rationale for Expanded Screening

Why Screen in Healthcare Settings?

Estimated Number of Adults and Adolescents Living with HIV Infection and Percent Undiagnosed – United States, 1985 - 2011

- CDC, HIV Counseling and Testing at CDC-Supported Sites, 1989 - 2012

Positive HIV Tests, 1989-2012 CDC Funded Testing Sites

- CDC, HIV Counseling and Testing at CDC-Supported Sites, 1989 - 2012
HIV Screening in 2015

The majority of CDC-funded HIV tests are conducted in:

1. HIV counseling and testing sites
2. Health-care settings
3. Community-based organizations
4. STD clinics

CDC-funded HIV tests, 2013

<table>
<thead>
<tr>
<th>Health care settings</th>
<th>HIV Tests</th>
<th>New HIV Diagnoses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary care clinic</td>
<td>659,306</td>
<td>2,178 (0.3%)</td>
</tr>
<tr>
<td>STD clinic</td>
<td>621,010</td>
<td>4,766 (0.8%)</td>
</tr>
<tr>
<td>Emergency</td>
<td>363,064</td>
<td>1,075 (0.3%)</td>
</tr>
<tr>
<td>Correctional facility</td>
<td>254,719</td>
<td>841 (0.3%)</td>
</tr>
<tr>
<td>Non-Health care</td>
<td>855,195</td>
<td>6,607 (0.8%)</td>
</tr>
</tbody>
</table>

- CDC, MMWR June 26, 2015
HIV Screening in 2015

1. The Medical Rationale

- Treatment for HIV is Effective.
- Treatment is recommended for all patients with HIV, regardless of CD4 count
  - March 2012 – DHHS Treatment Guidelines

2. ART Stops HIV Transmission

Prevention of HIV-1 Infection with Early Antiretroviral Therapy


HPTN 052: HIV Transmissions

1,763 sero-discordant couples (97% heterosexual)
118 HIV transmissions
- Cohen M et al, NEJM 2011

3. The Business Case

How Much Does It Cost?

How much does an HIV test cost?

0% 1. $10
2. $25
3. $50
4. $100
5. I have no idea
3. The Business Case

How Much Does It Cost?

It Depends.

<table>
<thead>
<tr>
<th>Test</th>
<th>Submitted Charges</th>
<th>Plan Allowance</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Antibody</td>
<td>$127</td>
<td>$11.02</td>
</tr>
<tr>
<td>HCV Antibody</td>
<td>$150</td>
<td>$19.42</td>
</tr>
</tbody>
</table>

Rapid Test Costs

- Cost per Rapid test:¹
  - With counseling: Average $56 (range $40-$75)
  - With information only: Average $23 (range $18-$28)

Reimbursement for HIV antibody test:

<table>
<thead>
<tr>
<th>Test</th>
<th>CPT</th>
<th>CMS Fee</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Antibody test</td>
<td>86703</td>
<td>$19.43</td>
<td>1</td>
</tr>
</tbody>
</table>

1°Metsch et al, AWARE study, JAMA 2013

Laboratory: Median Costs Per Specimen

<table>
<thead>
<tr>
<th>Test</th>
<th>Medium Volume (3)</th>
<th>High Volume (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV (-)</td>
<td>HIV (+)</td>
<td>HIV (-)</td>
</tr>
<tr>
<td>3G Advia, Bio-Rad, Vitros</td>
<td>7.04</td>
<td>17.88</td>
</tr>
<tr>
<td>4G Architect, Bio-Rad</td>
<td>9.08</td>
<td>26.44</td>
</tr>
</tbody>
</table>

What tests to use?

- Oral fluid rapid test
- Finger-stick blood rapid test
- Laboratory 4th gen Antigen/Antibody test
- Laboratory test, not sure which one

Evolution of HIV Tests: “Five” Generations
HIV Screening in 2015

Evolution of HIV Tests

1st generation: whole viral lysate, detects IgG antibody

2nd generation: synthetic peptides, detects IgG antibody

3rd generation: detects IgM and IgG antibody
Chemiluminescence Immunoassay

Random Access Multiplatform analyzers for HIV testing

Evolution of HIV Tests
- 1st generation: whole viral lysate, detects IgG antibody
- 2nd generation: synthetic peptides, detects IgG antibody
- 3rd generation: detect IgM and IgG antibody
- 4th generation: detects IgM, IgG antibodies, p24 antigen

“5th generation” HIV Ag/Ab Combo Assay
- Beads conjugated to
  - HIV-1 Group M (gp160) and O antigens
  - HIV-2 gp36 antigen
  - Monoclonal p24 antibody
- Distinguishes between
  - HIV-1 antibodies
  - HIV-2 antibodies
  - p24 antigen

Abbott Architect Ag/Ab Combo
Bio-Rad Ag/Ab Combo
Determine Combo Ag/Ab Rapid Test
Siemens Advia Centaur CHIV
BioPlex 2200 HIV Ag-Ab

STAT sample requests without pausing
Results in <60 minutes

On-board Refrigeration of Multiple Different Assays

Random Access Multiplatform analyzers for HIV testing
HIV Screening in 2015

APTIMA Qualitative HIV-1 RNA Assay
- Aid to HIV-1 diagnosis
- Diagnosis of acute HIV-1 infection in antibody-negative persons
- Confirmation of HIV-1 infection in antibody-positive persons when it is reactive
- FDA-approved July 2006

Nucleic Acid Test (NAT) for Diagnosis: Qualitative vs Viral Load
- APTIMA HIV-1 qualitative RNA assay is the only NAT FDA-approved for diagnosis
- Under FDA and CLIA regulations, clinicians can order HIV-1 RNA viral load tests, but labs cannot use them as a reflex part of the algorithm

APTIMA HIV-1 qualitative RNA assay is the only NAT FDA-approved for diagnosis

Relative Seroconversion Sensitivity
- 26 seroconverters were analyzed with 14 tests
- 17 seroconverters with WB positive used for cumulative frequency analysis

Sequence of Test Positivity Relative to WB (plasma)
166 specimens, 17 seroconverters - 50% Positive Cumulative Frequency

HIV Infection and Laboratory Markers

Relative Seroconversion Sensitivity

Sequence of Test Positivity Relative to WB (plasma)

HIV RNA (plasma)
HIV p24 Ag
IgM
IgG

Days before WB positive


Days before WB positive


Luo et al., J Clin Virol 2013

Laboratory Testing for the Diagnosis of HIV Infection
Updated Recommendations
Published Sept 27, 2014


Luo et al., J Clin Virol 2013
**HIV Screening in 2015**

**4th generation HIV-1/2 immunoassay**

- Positive for HIV-1 and HIV-2 antibodies
- Positive for p24 Ag
- HIV-1 (+) HIV-2 (-) HIV antibodies detected
- HIV-1 (-) HIV-2 (+) HIV-2 antibodies detected
- HIV-1 (+) HIV-2 (+) HIV antibodies detected
- HIV-1 (-) HIV-2 (-) NAT
- Acute HIV-1 infection
- Negative for HIV-1

**HIV-2 Infection**

- HIV-2 Remains uncommon in U.S., but
  - Does not respond to NNRTIs, some PIs (first line therapy)
  - Undetectable by HIV-1 viral load tests

- Misclassification by HIV-1 Western blot:
  - 54/58 (93%) HIV-2 patients tested had positive HIV-1 WB (NYC)
  - 97/163 (60%) HIV-2 cases reported had positive HIV-1 WB (CDC)

- HIV-2 often diagnosed after immunologic deterioration in patient with negative viral load

1. Torian et al, Clinical Infectious Disease 2010
2. MMWR, July 2011

**HIV-1/HIV-2 Differentiation Assay:**

- Multispot HIV-1/HIV-2 Rapid Test
  - CLIA moderate complexity with serum, plasma
  - Perform test in 15 minutes
  - FDA-approved for use in algorithm March 28, 2013

**FDA-approved HIV-1/HIV-2 Antibody Differentiation Assay**

- Geenius HIV-1/2 Supplemental Assay
  - FDA-approved October 2014

**Dual Path Platform Technology**

- Conjugate
- Specimen
HIV Screening in 2015

The Geenius™ HIV-1/2 Lines

HIV-1 & HIV-2 Associated Lines

Add 5 µL serum/plasma
Or 15 µL whole blood

Add
2 drops buffer
Wait 5-7 minutes

Add
5 drops buffer
To buffer well.

Wait min 15-20 min (max 30 min) for results

Insert test cassette in reader for automated interpretation
HIV Screening in 2015

Sequence of Test Positivity Relative to WB (plasma)

166 specimens, 17 seroconverters - 50% Positive Cumulative Frequency


Acute HIV: Clinical Syndrome

- 40-90% develop symptoms of Acute HIV
- 50%-90% with symptoms seek medical care
- Of those diagnosed with Acute HIV, 50% of patients seen at least 3 times before diagnosis

- Kahn et al., NEJM 1998
- Weintrob et al., Arch Int Med 2003

Clinical Manifestations

101 seroconverters, HIVNET cohort

<table>
<thead>
<tr>
<th>Symptom</th>
<th>1995-98</th>
<th>Median Duration Days (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any symptom</td>
<td>85%</td>
<td>9 (5-29)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>56%</td>
<td>5 (4-10)</td>
</tr>
<tr>
<td>Fever</td>
<td>55%</td>
<td>5 (4-10)</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>43%</td>
<td>7 (5-10)</td>
</tr>
<tr>
<td>Lymphadenopathy</td>
<td>36%</td>
<td>7 (4-14)</td>
</tr>
<tr>
<td>Rash</td>
<td>16%</td>
<td>8 (6-14)</td>
</tr>
</tbody>
</table>

- Celum et al., JID 2001

Why Is Acute HIV Important?

Increased Risk of Sexual Transmission of HIV

Virus 75-750 times more infectious

Cohen MS, et al., J Infect Dis. 2005
HIV Screening in 2015

Acute HIV: Partner Notification

- Persons with acute HIV infection
  - 2.5 times as many sex partners
  - 1.9 times as many partners newly diagnosed with HIV
  ... as did persons with new diagnosis of established HIV infection

Moore et al, JAIDS 2009

HIV-1 Transmission, by Stage of Infection and Behavior Pattern

<table>
<thead>
<tr>
<th>Infection Stage</th>
<th>Transmission Hazard per Person-year</th>
<th>Mean Duration, Years (%)</th>
<th>No. (%) New Transmissions, by Sexual Behavior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td>2.76</td>
<td>0.24 (2%)</td>
<td>Serial Monogamy: Random Mixing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute: 0.10 (9%) 0.67 (31%)</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>0.106</td>
<td>8.38 (82%)</td>
<td></td>
</tr>
<tr>
<td>AIDS</td>
<td>0.760</td>
<td>0.75 (16%)</td>
<td></td>
</tr>
</tbody>
</table>

Hollingsworth et al, JID 2008

Role of Acute HIV Infection in Spread of HIV

- Cohen et al, NEJM 2011

Acute Infections in MSM detected by RNA only

- 0.3% of 14,005 frequently tested MSM in Seattle STD clinic; 20% of all HIV infections detected
- Stokler et al, Clin Infect Dis 2009

- 26 (74%) of 35 AHI cases detected in LA at MSM clinic; 25% of all HIV infections detected
- Patel et al, Archives Int Med 2010

- 0.08% of 21,425 STD clinic patients in New York City; 9% of all HIV infections detected; 94% were MSM

Phoenix ED Screening July 2011 through February 2013

- 4th gen screening of patients who had blood drawn
  - 15% of patients declined testing
  - 13,014 patients tested
  - 37 (0.3%) new HIV infections
    - 12 (32.4%) had Acute HIV Infection (antibody negative)

- Median viral load:
  - Patients with acute infections: 3.6 million
  - Patients with established infections: 27,000

It's not only about 4th generation...

- 3rd generation laboratory testing, 2 screening programs in Dallas/Ft. Worth hospital EDs
  - 238 repeatedly reactive EIA, Western blot negative or indeterminate, sent for NAT testing
  - 26 (10.9%) positive = acute HIV infection: IgM antibody detected, IgG tests (WB) negative
RNA vs. 4th Generation Ag/Ab Assay

- RNA+ 3rd gen-negative specimens detected by 4th generation EIA:
  - 38 of 46 (83%) – Australia*
  - 10 of 14 (71%) – CDC AHI study**
  - 51 of 61 (84%) – CDC panel***
  - 4 days after RNA – 9 seroconversion panels***

* Cunningham P, HIV Diagnostics Conf 2007
** Patel P, CROI 2009
*** Owen M, CROI 2009

Pooled NAAT - 9550 High-Risk MSM, Vancouver

<table>
<thead>
<tr>
<th></th>
<th>Siemens 3rd gen</th>
<th>Siemens 4th gen</th>
<th>Architect 4th gen</th>
<th>NAT</th>
<th>WB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute HIV</td>
<td>Reactive</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Non-reactive</td>
<td>6</td>
<td>4</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Indeterminate</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>0%</td>
<td>33.3%</td>
<td>66.7%</td>
<td>100%</td>
<td>4</td>
</tr>
</tbody>
</table>

Early HIV: Reactive          9 9 9 9 9 9 9 9 9 9
Non-reactive      0 0 0 0 0 0 0 0 0 0
Indeterminate     0 0 0 0 0 0 0 0 0 0
Sensitivity 100% 100% 100% 100% 100%

Established HIV
Reactive          n n n n n n
Non-reactive      0 0 0 0 0 0
Indeterminate     0 0 0 0 0 0
Sensitivity 100% 100% 100% 100% 100%

**Krajden et al, J Clin Virol 2015**

The largest number of new HIV infections are being transmitted by:

- Persons with acute HIV infection.
- Persons unaware of their HIV infection.
- Persons with diagnosed HIV who are not in care.
- Persons with HIV who are in medical care.
Estimated U.S. HIV transmissions, 2009

<table>
<thead>
<tr>
<th>Persons who are</th>
<th>% of total</th>
<th>Transmissions per 100 person-years</th>
<th>% of new transmissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undiagnosed</td>
<td>18%</td>
<td>6.6</td>
<td>30%</td>
</tr>
<tr>
<td>Diagnosed, not in care</td>
<td>45%</td>
<td>5.3</td>
<td>61%</td>
</tr>
<tr>
<td>In care, not on ART</td>
<td>4%</td>
<td>2.6</td>
<td>3%</td>
</tr>
<tr>
<td>On ART, not virally suppressed</td>
<td>7%</td>
<td>1.8</td>
<td>3%</td>
</tr>
<tr>
<td>On ART, virally suppressed</td>
<td>25%</td>
<td>0.4</td>
<td>2.5%</td>
</tr>
</tbody>
</table>

- Skarbinski et al, JAMA Int Med 2015

NC Acute HIV Infection Program, 2002-2013

- 358 acute HIV infection cases
  - 932 partners named
  - 218 partners were HIV-infected
    - 162 (74%) previously diagnosed
    - 11 (5%) new acute HIV infection
    - 45 (21%) newly diagnosed established HIV infection
  - Limitation: For 184 (51%) of index cases, no HIV-infected partner was identified


California Requirements – Facilitators

- 2007: written consent, pre-test counseling barriers removed
- 2012: HIV testing confirmed as an “essential health benefit.”
- 2014: Law requires offer of an opt-out HIV test whenever blood is drawn at a primary care visit

Sustainability of Screening: Facilitators and Barriers

Covered California Health Plans, 2014-2015

- 10 plans surveyed; 5 (50%) responded

<table>
<thead>
<tr>
<th>Health Insurance Companies</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the HIV** require providers to ask new enrollees about their HIV status?</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Does the HIV require providers to take sexual history for new enrollees?</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Does the plan ask providers to offer an HIV screening test to each new enrollee?</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Do you rely on Electronic Medical Records to make your Initial Health Assessment?</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

**HIV = Initial Health Assessment


California Providers, 4 Counties, 2014-2015

- 60 (19%) of 320 providers responded to survey

<table>
<thead>
<tr>
<th>Routine HIV Screening</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of responses</td>
<td>100%</td>
</tr>
<tr>
<td>Always/most times</td>
<td>32%</td>
</tr>
<tr>
<td>Sometimes</td>
<td>35%</td>
</tr>
<tr>
<td>Rarely/never</td>
<td>33%</td>
</tr>
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**Facilitators and Barriers to Sustainability**

1. Electronic Health Record modifications

- Through a controlled and collaborative process, the authors integrated custom documentation elements specific to HIV screening into the triage/intake process, implemented and utilized clinical decision support tools to guide clinicians in each step of the process, and used electronic data collection and reporting to drive new screening protocols that led to a significant increase in overall HIV testing rates.

**Using a configurable EMR and decision support tools to promote process integration for routine HIV screening in the emergency department**

Robert McGuire1, Eric More2

*Journal of American Medical Informatics Association, September 2015*

**Abstract**

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**Maricopa Integrated Health Services HIV Screening Program**

- 4th gen HIV testing of ED patients who:
  - have blood drawn as part of care visit
  - were not tested in previous year
  - not known to be HIV-positive
  - not in custody or unable to consent
  - do not decline
HIV Screening in 2015

MIHS HIV Screening Program, 2011 - 2014

EMR Analytics, July 2011 – June 2014

Total encounters 130,761
Tested 33,683
Private insurance 1,468 (4%)
Medicaid 10,068 (30%)
Medicare 2,105 (6%)
No insurance 19,386 (58%)

Not tested 97,078
Tested in previous year 26,713 (28%)
No labs drawn 21,156 (22%)
Declined 19,943 (21%)
Did not decline, but not tested 9,947 (10%)
Age > 64 years 7,883 (7%)
In custody 6,745 (7%)
Unable to consent 4,076 (4%)
Self-reported HIV-positive 2,119 (2%)

Facilitators and Barriers to Sustainability

1. Electronic Health Record modifications
2. POC vs routine laboratory testing

Results: Application to ED

Proportion of ED patients >= 13 with known HIV status

As Routine As It Gets: Five Years of Routine HIV Screening in two Houston Emergency Centers

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Facilitators and Barriers to Sustainability
HIV Screening in 2015

**Routine Universal Screening for HIV (RUSH) Program:**

- Patients 16 and older requiring blood draw for other reasons will receive HIV test unless they opt out.
- Patients are informed at registration and are given the opt-out form along with other registration forms.
- The program was designed to have minimum impact on the process of patient care in the busy emergency departments:
  - Standard HIV blood test done on rapid basis • 2 hour turn around time
  - Service Linkage Workers stationed at each IC deliver positive results, provide counseling, and link to care within 90 days.
- Over 250,000 HIV tests in the two EC’s between 2009 and 2013, 3,946 of which positive (1.5%), including 757 new diagnoses (0.29%).

**Gilead HIV FOCUS Program (Frontlines of Communities in the U.S.)**

- Public-private partnerships in 18 cities, expanding to 45 cities; adding HCV screening.
- Promotes routine, sustainable screening.
- Since 2010:
  - 2 million HIV tests
  - >15,000 HIV-positive tests
  - 245 acute HIV infections

**Four pillars of routine screening**

- Systemic policy change at leadership levels.
- Testing integrated into normal clinic flow as a routine aspect of typical care.
- Electronic medical record modification to identify persons in need of testing, prompt providers.
- Training, feedback, and quality improvement.

**Example: Urban Health Plan, NYC**

<table>
<thead>
<tr>
<th></th>
<th>Risk-based, POC 2010</th>
<th>Routine, Laboratory Jan 2011 – Sept 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients tested</td>
<td>3,358 (8%)</td>
<td>32,534 (56%)</td>
</tr>
<tr>
<td>HIV-positive</td>
<td>19 (0.57%)</td>
<td>148 (0.45%)</td>
</tr>
<tr>
<td>- Newly diagnosed</td>
<td>3 (16%)</td>
<td>43 (29%)</td>
</tr>
</tbody>
</table>

- None of 148 HIV-positive patients receiving HIV care; 120 successfully initiated care.
- UHP continues HIV screening after FOCUS support ended.

- MMWR June 27, 2014

**Scalability: Rapid Test vs Laboratory Testing**

Case Study, NYC hospital

**2015 National Summit on HCV and HIV Diagnosis, Prevention and Access to Care**

June 4-6, 2015

http://www.hivforum.org/projects/2015-national-summit

Michael Menchine1,2, Kathleen Jacobson1, Chun Nok Lam1, Ira Shulman1, Sanjay Arora1,2

1USC Keck School of Medicine, Los Angeles, CA; 2USC Schaeffer Center for Health Policy and Economics, Los Angeles, CA

Results

- # HIV tests increases
  - 8,983 → 22,593
- # New HIV diagnoses increased
  - 36 (0.4%) → 115 (0.5%)
- Acute HIV Identified
  - 0 → 14 cases
  - 12.2% of new diagnoses
  - 12/14 (86%) attended ≥ 1 outpatient HIV follow up

Background

- 2006 CDC → non-targeted HIV screening in Eds
- 2011 → 'R/O HIV at the LAC+USC ED' - POC
- 2013 → 4th gen HIV testing (Ag/Ab) - Lab

Acute HIV Infection and Sero-Conversion: Why You Should Screen for HIV and Why You Should Keep Doing it

Siavash Pasalar1, Nancy P. Miertschin1, Monisha Arya2, Charles E. Stager3, Shkelzen Hoxhaj2, and Thomas P. Giordano2

1Harris Health System, Houston, TX; 2Baylor College of Medicine, Houston, TX; 3Pacific AIDS Education and Training Center

- We would like to thank City of Houston Department of Health and Human Services and Harris County Public Health and Environmental Services for assistance with data.
- Our routine HIV testing program and its evaluation has been supported in part by grants from the CDC, Texas Department of State Health Services, Baylor UT Houston CFAR, and the Gilead HIV FOCUS program.

LRADATORY DRIVEN EXPEDITED HIV SCREENING AND CONFIRMATION AT AN URBAN EMERGENCY DEPARTMENT IN WASHINGTON, DC

TAMMEY J. NAAB, MD

DIRECTOR LABORATORY, HOWARD UNIVERSITY HOSPITAL
ASSOCIATE PROFESSOR OF PATHOLOGY
HOWARD UNIVERSITY COLLEGE OF MEDICINE

15,996 patients screened in one year with FOCUS, identifying 127 positives

PRE-FOCUS

YEAR 1

PRE-FOCUS

YEAR 1

147% increase

Routine screening realized

Routine screening realized

1,000
2,000
3,000
4,000
5,000
6,000
7,000
8,000
9,000
10,000

ED
ATS
INPATIENT

1,000
2,000
3,000
4,000
5,000
6,000
7,000
8,000
9,000
10,000

Identifying Acute HIV Infections
in the Emergency Room:
Benefits of Fourth Generation
HIV Testing

Michael Menchine1,2, Kathleen Jacobson1, Chun Nok Lam1, Ira Shulman1, Sanjay Arora1,2

1USC Keck School of Medicine, Los Angeles, CA; 2USC Schaeffer Center for Health Policy and Economics, Los Angeles, CA

Results

- # HIV tests increases
  - 8,983 → 22,593
- # New HIV diagnoses increased
  - 36 (0.4%) → 115 (0.5%)
- Acute HIV Identified
  - 0 → 14 cases
  - 12.2% of new diagnoses
  - 12/14 (86%) attended ≥ 1 outpatient HIV follow up

Background

- 2006 CDC → non-targeted HIV screening in Eds
- 2011 → 'R/O HIV at the LAC+USC ED' - POC
- 2013 → 4th gen HIV testing (Ag/Ab) - Lab

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HIV Screening in 2015

Bernard M. Branson M.D.
HIV Screening in 2015

Why Repeat Testing?

- Among 1184 new diagnoses made between August 2008 and May 2015, 132 (11.1%) had a prior negative HIV test in our system.
- The median time between the last negative test and new diagnosis was 354 days.
- 8 of these patients were diagnosed during their acute infection phase (including 6 diagnosed with the new algorithm).

Observations

- HIV testing in Lab vs POC:
  - Allows high volume routine screening
  - Increased number of tests and positive tests
  - Allows diagnosis of acute HIV infection
  - Results available during same visit
  - Facilitates reimbursement
- POC testing
  - Suitable when blood not otherwise drawn

Facilitators and Barriers to Sustainability

1. Electronic Health Record modifications
2. POC vs Laboratory testing
3. Billing and reimbursement

Assessing Billing Practices For Routine HIV & HCV Tests In Philadelphia’s Clinical Settings

Tina J. Penrose, RN, MSN, MPH
PA/MidAtlantic AIDS Education & Training Center
Health Federation of Philadelphia
6/5/15

Billing & Sustainability Assessment

- Assessed pertinent billing practices, reimbursement models, and programmatic information
- HIV (n=9) and HCV (n=2) testing sites included:
  - Inpatient (n=2)
  - Emergency department (n=2)
  - Ambulatory care (n=7)
- Provided intensive individualized technical assistance to complete assessment tools

Results

| Sites Reporting Consistent Coding, Charge Capture, & Billing |
|-------------|------|--------|
| Inpatient  | 100% |
| ED         | 50%  |
| Ambulatory Care | 83% |

Reimbursement Findings

- All setting types received bundled payments for clinical services
- Ambulatory care settings reported potential for fee-for-service reimbursement
- Remittance for point-of-care HIV tests often “covered under capitation”
- Sites reported fewer denials and less departmental expenditures for laboratory-based tests
Facilitators and Barriers to Sustainability

1. Electronic Health Record modifications
2. POC vs Laboratory testing
3. Billing and reimbursement
4. Re-engagement in care

US Continuum of Care, 2011

Expanded Hospital ED Testing: Opportunities for Re-engagement
HPTN 065,  2011-2013

<table>
<thead>
<tr>
<th>Year</th>
<th>Bronx, New York (n=9)</th>
<th>Washington D.C. (n=7)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive HIV Tests</td>
<td>New Diagnoses</td>
</tr>
<tr>
<td>2011</td>
<td>153</td>
<td>119 (78%)</td>
</tr>
<tr>
<td>2012</td>
<td>122</td>
<td>86 (71%)</td>
</tr>
<tr>
<td>2013</td>
<td>133</td>
<td>72 (54%)</td>
</tr>
</tbody>
</table>

Benefits of a Routine Opt-Out HIV Testing and Linkage to Care Program for Previously Diagnosed Patients in Publicly Funded Emergency Departments in Houston, TX

- Previously-diagnosed patients = 0.39% of all HIV tests in routine ED testing program
- Compared outcomes for patients with HIV diagnosis at least 1 year prior to ED visit, before and after introduction of routine screening program

Outcomes among previously-diagnosed patients before and after a screening-era ED visit

Summary

- HIV screening is recommended annually for persons at high risk and at least once in health care settings for all adults ages 15-64.
- Antibody tests are negative during the highly infectious acute HIV infection stage.
- Laboratory testing facilitates routine screening.
- Routine screening facilitates re-engagement in care.
- HIV screening is not yet routine – but it can be.