

## Routine HIV Testing: Lessons Learned

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## DISCLOSURE STATEMENT

I have no real or perceived vested interests that relate to this presentation nor do I have any relationships with pharmaceutical companies, biomedical device manufacturers, and/or other corporations whose products or services are related to pertinent therapeutic areas.



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## Objectives

- To review the 2006 CDC recommendations for HIV screening
- To review the appropriate testing for HIV in patients based on their age and clinical presentation
- To discuss a few articles in the Literature that have addressed implementation of routine HIV testing



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## Polling Question

- My profession is best described as:
  - 1. Prescriber (physician, NP, PA)
  - 2. Nursing
  - 3. Health Education / Nutrition
  - 4. Social Work / Case Management
  - 5. Administrator
  - 6. Dental professional
  - 7. Pharmacist
  - 8. Other



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## Polling Question

- My familiarity level with the 2006 CDC Recommendations for HIV Screening is:
  - 1. Extensive
  - 2. Moderate
  - 3. Slight
  - 4. Non-existent



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## Polling Question

- My ability to decide the appropriate test to order to detect HIV infection in clinical settings is:
  - 1. High
  - 2. Moderate
  - 3. Low
  - 4. Non-existent



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## 2006 CDC Recommendations for HIV Screening Testing



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## HIV Serologic Screening Recommended

- Persons between 13 and 64 years of age routinely offered at entry to care
- Persons with STD's
- Persons with tuberculosis



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## HIV Serologic Screening Recommended

- Women considering conception and pregnancy
- All pregnant women
- Women in delivery with undocumented HIV status
- Infants born to mothers of undocumented HIV status



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## HIV Diagnostic Testing

- Signs or symptoms of HIV infection
- Patients at high risk for HIV based on risk assessment, offered yearly



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## “Opt-Out Testing”

- Oral or written information given at time of testing at an appropriate health literacy level for the patient
  - Explaining what HIV infection is
  - Describing ways to prevent transmission
  - Meaning of positive and negative results
- Testing is voluntary and never coerced and prior knowledge is still needed. Patient then given the opportunity to decline testing
  - If refuses, explore reasons. Offer at subsequent visits.
  - Document refusal in patient record
- General consent for medical care is sufficient for HIV testing



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## Giving results

- Negative test results
  - Can be conveyed without personal direct contact
  - High risk patients should be encouraged to get retested in future
- Positive results
  - Conveyed in private setting in person
  - Assure confidentiality. Do NOT use family members as translators
  - Discuss partner notification
  - Document in patient record
  - Refer for care



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## Case

- 18 year old woman presents to the local STD clinic for evaluation for a vaginal discharge. She has no history of STIs but does report two prior episodes of vaginal yeast infections. Evaluation of her discharge is consistent with gonorrhea.



## Polling Question

- If you wanted to screen this young woman for chronic HIV infection (>3 months), which test is the most appropriate to order:
  - 1. HIV cDNA PCR
  - 2. HIV ELISA
  - 3. HIV RNA PCR
  - 4. HIV Western Blot
  - 5. p24 Antigen



## Answer to Polling Question

- If you wanted to screen this young woman for chronic HIV infection (>3 months), which test is the most appropriate to order:
  - 1. HIV cDNA PCR
  - 2. **HIV ELISA**
  - 3. HIV RNA PCR
  - 4. HIV Western Blot
  - 5. p24 Antigen



## Polling Question

- After the ELISA is positive, which test is used to confirm HIV infection:
  - 1. HIV cDNA PCR
  - 2. HIV RNA PCR
  - 3. HIV Western Blot
  - 4. p24 Antigen
  - 5. Repeat HIV ELISA



## Answer to Polling Question

- After the ELISA is positive, which test is used to confirm HIV infection:
  - 1. HIV cDNA PCR
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  - 3. **HIV Western Blot**
  - 4. p24 Antigen
  - 5. Repeat HIV ELISA



## Enzyme-Linked ImmunoSorbent Assay (ELISA) HIV Enzyme Immunoassay (EIA)

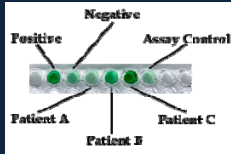
- 1) Apply a sample of HIV antigens
- 2) Apply patient's serum containing antibodies
- 3) Apply second antibody (anti-human immunoglobulins)
- 4) Apply a color changing substrate



Positive ELISA      Negative ELISA



## ELISA - EIA



Positive Control	Negative Control	Patient A	Patient B	Patient C	Assay Control
1.689	0.153	0.055	0.412	1.999	0.123



## Structure of HIV

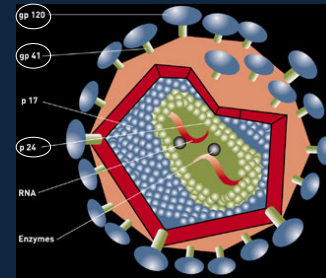
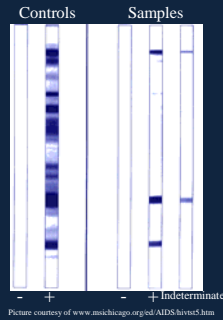


Illustration from SCIENCE & TECHNOLOGY  
August 27, 2001 Volume 79, Number 35 CENEAR 79 35 pp. 37-44



## Western Blot

- Procedure continues similar to ELISA
- Results are read
  - If no viral bands are present, the result is negative
  - If less than the required number of viral bands (p24, gp41, gp120/160) are detected, the result is indeterminate



## Interpreting HIV Serology

- HIV Positive = + ELISA AND + Western Blot
- HIV Indeterminate = + ELISA AND 1-2 bands on WB

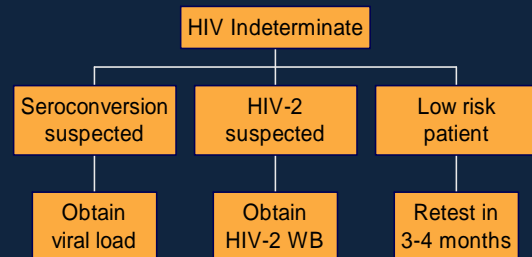


## Explanations for HIV Indeterminate

- Early infection, seroconverting
- Advanced infection with decreased p24 antibodies
- Cross-reactive antibodies or auto-antibodies from CVD, autoimmune process, or malignancy
- HIV-2 infection; O clade HIV-1
- Experimental HIV vaccine recipient
- Late pregnancy

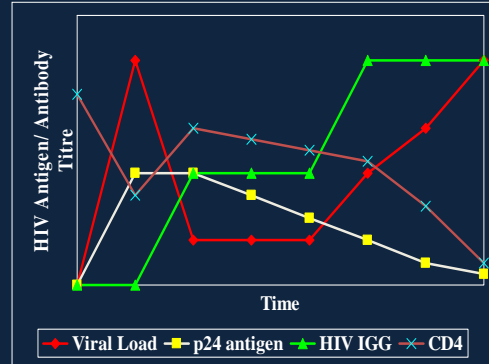


## Interpreting HIV Serology



## Case

- The young lady's initial ELISA is negative. She returns to your office a year later with complaints of weight loss and fatigue and a sore throat. She has had a new sexual partner over the past three months and they stopped using condoms about two weeks ago.



## Acute Retroviral Syndrome

- Primary HIV infection
- Often overlooked
- 50 - 90% experience some symptoms
- Symptoms occur 1-3 weeks after exposure
- Seroconvert 6-12 weeks after exposure



## Acute Retroviral Syndrome-Symptoms

- Fever (96%)
- Lymphadenopathy (74%)
- Pharyngitis (70%)
- Rash (70%)
- Myalgia/arthralgia (54%)
- Headache
- Diarrhea
- Nausea and vomiting
- Hepatosplenomegaly
- Weight loss
- Thrush
- Neurologic symptoms



## Rapid Testing

- Currently six rapid tests are available in the US
  - OraQuick® Rapid HIV-1/2 Antibody Test\*
  - Reveal™ Rapid HIV-1 Antibody Test
  - Uni-Gold Recombigen® HIV Test\*
  - Multispot HIV-1/HIV-2 Rapid Test
  - HIV 1 / 2 Stat Pak\*
  - Sure Check HIV 1 / 2 Assay\*
- All are interpreted visually
- \* CLIA-waived



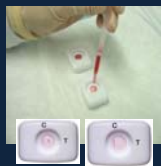
Uni-Gold Recombigen



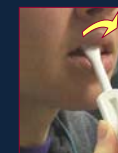
Multispot HIV-1/HIV-2



Clearview Complete HIV 1/2



Reveal G3



OraQuick Advance



Clearview HIV 1/2 Stat Pak



## Interpreting Rapid Test Results

### For a laboratory test:

*Sensitivity:* Probability test=positive if patient=positive

*Specificity:* Probability test=negative if patient=negative

### Predictive value:

PPV is Probability patient=positive if test=positive

NPV is Probability patient=negative if test=negative



Example: Test 1,000 persons  
Test Specificity = 99.6% (4/1000)

HIV prevalence = 5%

True positive: 50      False positive: 4

Positive predictive value:  $50/54 = 93\%$



Example: Test 1,000 persons  
Test Specificity = 99.6% (4/1000)

HIV prevalence = 10%

True positive: 100      False positive: 4  
Positive predictive value:  $100/104 = 96\%$

HIV prevalence = 0.2%

True positive: 2      False positive: 4

Positive predictive value:  $2/8 = 25\%$



## Case

- The young lady becomes pregnant and returns to your office at 24 weeks. She is found to be HIV+ at this time on HIV ELISA and Western Blot.



## Polling Question

- If you wanted to test the infant at 2 weeks after delivery for HIV infection, which is the best test to order?
  - 1. HIV cDNA PCR
  - 2. HIV ELISA
  - 3. HIV RNA PCR
  - 4. HIV Western Blot
  - 5. p24 Antigen



## Answer to Polling Question

- If you wanted to test the infant at 2 weeks after delivery for HIV infection, which is the best test to order?
  - 1. **HIV cDNA PCR**
  - 2. HIV ELISA
  - 3. HIV RNA PCR
  - 4. HIV Western Blot
  - 5. p24 Antigen



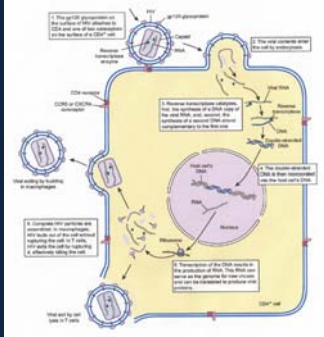


Illustration borrowed from <http://www.txtwriter.com/Backgrounders/Aids/HIVLifeCycle.gif>



## HIV Testing in Infancy

- Recommended testing schedule for cDNA PCR
  - (Within first 48 hours)
    - Do NOT use umbilical cord blood
  - 2-3 weeks
  - 4-8 weeks
  - 4-6 months
- Positive test – repeat as soon as possible on a second blood sample



## HIV Testing in Infancy

- Other tests:
  - HIV ELISA / Western blot
    - Up to 18 months or longer would be testing for maternal antibodies
  - p24 Antigen
    - Less sensitive
    - False positives in first month of life
  - HIV RNA PCR
    - Neg test NOT exclusionary in patients < 18 months of age
    - Can have false positives at low levels
    - Lower sensitivity during first 2 months of life than cDNA



## HIV Testing in the Toddler

- If a child had perinatal testing that was negative:
  - HIV ELISA / Western Blot are then ordered at 12-18 months of age
  - Can also be considered negative if 2 blood samples obtained at least one month apart after 6 months of age are negative



## Lessons Learned



## Barriers to Implementation of Routine HIV Screening

- Cost of testing and inadequate re-imburement
- Acceptance by patients
- Consent process complexity
- Comfort of personnel with testing
- Language
- Lack of knowledge / training
- Competing priorities
- Time
- Administrative concerns
  - Risk management
- Reliability of assay in low prevalence areas



## Barrier reported: Cost

- Estimated cost of \$50,000 - \$64,000 per quality-adjusted life-year in areas where prevalence is 0.05-0.1%.
- Similar in cost to Pap smears and screening colonoscopies



## Cost effectiveness

- Comparison of three intervention models for HIV counseling and testing:
  - Model A – traditional testing and counseling
  - Model B – nurse-initiated routine with traditional testing and counseling
  - Model C – nurse-initiated routine rapid HIV testing and streamlined counseling
- Results: When benefit of decreased transmission included, Model C was \$10,660/QALY versus \$48,650

Sanders GA et al. Cost-effectiveness of strategies to improve HIV testing and receipt of results: economic analysis of a randomized controlled trial. J Gen Intern Med 2010, e-pub 03-04-10.



## Polling Question

- Which population has the highest acceptance of routine HIV testing?
  - 1. Obstetrics
  - 2. In-patient hospitalized
  - 3. Outpatient primary care
  - 4. Adolescent clinics
  - 5. Emergency room



## Answer to Polling Question

- Which population has the highest acceptance of routine HIV testing?
  - 1. **Obstetrics**
  - 2. In-patient hospitalized
  - 3. Outpatient primary care
  - 4. Adolescent clinics
  - 5. Emergency room



## Acceptance of testing

- In OB wards and ERs
  - 33-86% acceptance
  - Less likely to accept
    - Non-English speaking
    - Older age
    - Higher level of education
    - Asian race
    - White race



## L & D – Declination of Rapid Testing

- MIRIAD Study
- 102 decliners versus 478 acceptors interviewed
- Decliners: more likely to
  - Have had prenatal care
  - Be Hispanic ethnicity
  - Have a high school education

Tan KR et al. Matern Child Health J, epub 1-10-10.



## Howard University Experience

- First hospital-wide HIV testing protocol – October 2006
- Rapid testing throughout the hospital using the OraSure OraQuick Advance test
- Report of the first 8 months

• Scott VF et al. Transactions of the American Clinical and Climatological Association, Vol 120, 2009



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## HUH Experience

- 9817 patients offered testing
  - 5642 consented
  - 90% black
  - Mean age 40.7 years
  - 55% female
  - Preliminary positive in 139
    - Seroprevalence 2.46%
    - 98% black
    - 63% male
    - Peak age range 40-54



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## HUH Experience

- Problems encountered
  - Obtaining confirmatory testing
    - Only 39 of first 130 had confirmatory testing
    - Reasons: homelessness, patient denial and avoidance, demographic misinformation
  - More than 40% of those approached consented to testing
    - Recommended public media campaign before beginning routine testing to improve consenting



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## Community Health Centers

- Cunningham CO et al. Routine opt-out HIV testing in an urban community health center. AIDS Patient Care and STDs 2009; 23: 619-623
- Myers JJ et al. Routine rapid HIV screening in six community health centers serving populations at risk. J Gen Intern Med 2009 Dec; 24(12): 1269-74.



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## CHCs - Cunningham

- 7/07 to 3/08
- Physician or designated HIV tester approached patients presenting for a primary care visit
- Patients told they “would be tested unless they declined testing.”
- ELISA via venipuncture
- 300 patients approached – 35% agreed to testing – no new cases found



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## CHCs - Cunningham

- Reasons for declining testing
  - Perceived low risk 54.4%
  - Previous HIV testing self-reported 45.1%
- Accepting testing
  - Younger
  - Hispanic
  - Having another blood draw



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## CHCs - Cunningham

- Questioned efficacy of routine HIV testing in primary care settings
- Suggested testing be offered when another blood draw was needed
- Rapid testing offers may increase acceptance
- Concerns expressed about “testing fatigue” in low prevalence areas (< 0.1%)



## CHCs - Myers

- Compared frequency of testing before and after routine screening was in place
- NC, SC, MS
- 3000 patients tested in year prior to protocol,
- 10,769 of 16,148 tested after protocol in place (13 months)
  - 39 rapid tests preliminary positive
  - 17 newly detected infections
  - Younger, African American, and Hispanic patients more likely to receive testing



## CHCs - Myers

- Persons offered testing
  - Men under 18 less likely to be offered testing
  - Latinos less likely to be offered testing than whites
  - African Americans more likely to be offered testing
  - Compared to uninsured patients, those with Medicaid or Medicare less likely to be offered testing and private insured patients were more likely to be offered testing



## CHCs - Myers

- Persons accepting testing
  - Over 55 years old less likely
  - 18 to 34 years old most likely to accept
  - Non-Caucasian patients more likely to accept testing, especially Hispanic (OR 2.72 for males, 2.18 for females)
  - Privately insured slightly less likely to get tested (OR 0.82)



## VA Setting

- 4 focus groups with patients (n=28) and 2 with primary care providers (n=13) at 2 geographically diverse VA medical centers
  - HIV Testing Should Be Routine
    - Patients and providers concurred
    - Should be equated with other chronic diseases
    - Important to know for one’s own health as well as for public health reasons
  - Decrease of HIV stigma
    - Routine testing decreases stigma
    - Fears about confidentiality and disruption of patient-provider relationship
- Bokhour BG et al. Barriers and facilitators to routine HIV testing in VA primary care. J Gen Intern Med 2009; 24(10): 1109-14.



## VA Setting

- Barriers to HIV Testing
  - Signing consent forms was anxiety-producing, intimidating, and hard to understand
  - Pre-test counseling
    - Leads to HIV exceptionalism
    - Wished to talk in depth about HIV only if positive
  - Patients expressed wait time to results as a barrier
  - Wish to be *asked* to be tested instead of *told*
  - Informing patients that 21% of HIV+ people do not know their status helps them decide to get tested



## VA Setting

- 6 R's for routine testing
  - **Raise** the topic of HIV testing
  - **Reassure** the patient that this is not based on clinical signs
  - Provide **Rationale** that 21% of people do not know they are infected
  - **Respond** to any questions
  - **Request** permission to order the test
  - Tell patient when to expect the **Results**



## VA Setting

- Survey of recent testing experiences via My HealtheVet, a website allowing registered veterans to access personal health info.
- "Health screening" survey done 2008-2009
- Random 4% of users sampled; responses ranged from 31,237 to 33,074
- 9% reported offering (91% acceptance) of an HIV test in past 12 months (83% cholesterol, 65% blood sugar, 19% HCV).
- "Very likely" acceptance in 73% for HIV, 79% for HCV, 75% for cholesterol, and 75% for blood sugar

Valdiserri RO et al. Need to improve routine HIV testing of US veterans in care: results of an internet survey. J Commun Health, epub 2-10-10.



## Emergency Rooms

- GWU ED in DC 2/7/2007 to 10/1/2007
- 1560 rapid tests in adults seen for non-HIV related presenting symptoms
  - 13 (0.008%) positive OraQuick Advance
  - 100% confirmation by Western blot

Brown J et al. Another look at emergency department HIV screening in practice: no need to revise expectations. AIDS Research and Therapy 2010; 7: 1-6



## Emergency room

- Provider attitudes and barriers
- 21 item survey given (Boston) before implementation of routine HIV testing in ED and given again re-administered 6 months into the program
- 108/146 providers completed both surveys
  - 55% supportive of routine testing in EDs
  - 38% willing to offer most or all of the time
  - Most common cited barriers: inadequate time (62%), inadequate resources (60%), and concerns about provision of follow-up care (59%)

Arbelaez C et al. Emergency provider attitudes and barriers to universal HIV testing in the emergency department. J Emerg Med 2009, epub



## Routine testing acceptance

- Very well accepted in OB units
- Good acceptance in ERs and among adolescents
- Less acceptance among older patients, white or Asian patients, and those with higher education levels
- Consider using the 6 R's: Raise, reassure, rationale, respond, request, results



## Polling question

- As compared to how I felt before the presentation, my ability to order the appropriate HIV test is:
  - 1. much improved
  - 2. a little improved
  - 3. not improved
  - 4. worsened – I am more confused now



## Polling Question

- As compared to my ability to identify some barriers to routine testing acceptance before the presentation, I now am:
  - 1. Much more confident
  - 2. A little more confident
  - 3. No change
  - 4. I just woke up or joined the talk 5 minutes ago and have no idea what this question is about.



## Thank you

What questions do you have?

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