The Evolving Landscape of HIV Prevention and Diagnosis

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Is it okay if we just talk?
NHAS: A Call to ACT

- Reduce New HIV Infections
- Increase Access to Care and Improve Health Outcomes
- Reduce HIV-related Health Disparities and Health Inequities.
Texas HIV Treatment Cascade, 2015

- **Individuals Living with HIV at end of 2015**: 82,745
- **At Least One Visit/Lab**: 63,706 (77%)
- **Retained In Care**: 57,074 (69%)
- **Achieved Viral Suppression**: 48,632 (59%)
Almost all HIV transmissions occur *between the bars* of the HIV treatment cascade. The risk of transmission is lowest when viral load is suppressed. Transmission is most likely when people are not aware of their infection.

- Likely if have been diagnosed but aren't in care
- Even less likely if they are in care but not on ART
- Even less likely if on ART but not suppressed
- And very unlikely if viral load is suppressed
Percentage of People Living with HIV and Percentage of HIV Transmissions at Each Stage of the Care Continuum, United States and Puerto Rico, 2012.
HIV Transmissions At Each Stage Of The Care Continuum
Texas 2013

Texans with HIV
- People with undx infections: 14%
- On ARV but not suppressed: 32%
- Persons dx but not in care: 9%

Transmissions
- In care no ART: 5%
- Viral suppression: 39%
- On ARV but not suppressed: 30%
- Persons dx but not in care: 55%
What does this have to do with Testing Technology?

• Diagnosis is the first step.
• Do I know how to test?
• Am I using the best technology to detect early infection?
• Why is it important to detect early?
HIV Infection and Laboratory Markers

- HIV RNA (plasma)
- HIV p24 Ag
- IgM
- IgG

Infection Undetectable

Acute HIV Infection


A Healthy Texas
Serologic Assay Generations

• 1st generation immunoassays (IA)
  - Detects HIV antibody (Ab) IgG using viral lysates as the antigens (Ag)

• Western BLOT - 1st gen assay
2nd Gen CLIA-Waived Point-of-Care Rapid HIV Tests Detects HIV IgG Antibody

Clearview Complete

ChemBio Stat Pak

OraQuick Advance

A Healthy Texas
3rd Generation

Detects HIV 1/2 IgG and IgM Antibodies

- Siemans ADVIA Centaur - LAB
- Ortho VITROS Sei/ECIQ - LAB
- Ortho GS 1/2 +O - LAB
  - Time to results 48 – 60 minutes
- Insti
- Unigold
Antigen/Antibody Combo

- Detects HIV 1 p24 Antigen and HIV 1/2 IgG and IgM Antibodies
HIV Infection and Laboratory Markers

- **HIV RNA (plasma)**
- **HIV p24 Ag**
- **IgM**
- **IgG**

Infection Undetectable

Acute HIV Infection


A Healthy Texas
Bio Plex 2200

- Detects HIV 1/2 antibodies and p24 Antigen
- Load and run - if no detection - Negative
- Detection - runs again and will isolate what it found.
- Will tell us - HIV 1, HIV 2, p24 antigen
If BioPlex Reactive - what’s Next?
HIV 1/2 Antibody Differentiation

HIV 1/2 Geenius

HIV 1/2 Multi-Spot

A Healthy Texas
Nucleic Acid
Determine Combo Rapid HIV 1/2 Ag-Ab Test

Alere – 4th generation technology
Determine HIV 1/2 Ag/Ab

• Early Infection
  - Plasma
    • Ag not detected most Acutes (Laperche, Rosenberg, Kilembe, Duong, Conway, Faraoni)
    • Detects infection earlier than IgM-sensitive assays, not as early as Ag/Ab assays (Masciotra, JCV)
    • Detected 40 - 54% early infections (Delaney, Masciotra, Dx conference)
  - Whole Blood
    • 0% Ag sensitivity, Acutes (Lewis, AIDS)
NATs on the Horizon

Alere™ Q System

Liat™ Analyzer Roche

< 1 hour
Acute Viral Infection

- Malaise/fatigue
- Fever/chills/night sweats
- Weight loss, loss of appetite
- Sore throat
- Nausea/vomiting/diarrhea
- Swollen lymph nodes
- Aching muscles or joints
- Rash
- Rarely headache, neurologic symptoms
Clinical Syndrome of Acute HIV

40% – 90% develop symptoms of Acute HIV

→ 50% – 90% w/ symptoms seek medical care

Of those diagnosed with Acute HIV

→ 50% of patients were seen at least 3 times before diagnosis

Acute Infection: Increased Risk of Sexual Transmission of HIV

HIV RNA in Semen (Log₁₀ copies/ml)

Acute Infection: 1/30 - 1/200

Virus 75-750 times more infectious

6 wks

Asymptomatic Infection: 1/1000 - 1/10,000

HIV Progression: 1/500 - 1/2000

AIDS: 1/100 - 1/1000

Ma, J Virol 2009

Cohen & Pilcher, J Infect Dis. 2005
Prediction of the efficiency of HIV transmission according to HIV burden in the genital tract.

© 2005 by the Infectious Diseases Society of America
Acute HIV: Partner Notification

• Persons with acute HIV infection named
  - 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
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**Diagram:**
- **PrEP**
- **ARTAS**
- **Linkage!**
- **Harm Reduction**
- **Maintenance**
- **STI screen & tx**

**Steps:**
1. All persons with HIV
2. Diagnosed
3. In treatment
4. On ART
5. Viral Suppression

**Source:**
Department of State Health Services
Transitions and Change
Benefits and Challenges
Please Ponder……
How can this improve your services, the quality of care your patients receive and the overall health of your community?
Case Studies

- **17 yo male rapid test INSTI prelim +**
  - Referred to clinic for follow up testing
    - No show
  - No blood specimen to NAAT test

- **26 yo male screening Ag/Ab Combo +**
  - Geenius negative
  - NAAT +, VL 260K copies.

- **30 yo pregnant woman**
  - 3rd gen +
  - Geenius Indeterminate
  - NAAT +
Transition to Best Practices

• Current Test Technology Used
• Staff training
  - Technology
  - Specimen Collection
  - Messaging/Counseling
• Administration
• Link to Care
• Public Health Follow up
Specimen Collection

• **HIV-1/2 Ag/Ab Combo**
  – No more than 5 days cold.
  – Gold top, tiger top, spin before submit. NO DRY BLOOD SPOT.
  – Reactive samples run in duplicate.

• **Geenius HIV 1/2 Differentiation**
  – Reflex from reactive Ag/Ab Combo.
  – 25 minute average run time. Read immediately once test completed.
Why does this matter?

• Early id of infection has individual and positive public health benefits
• Laboratory testing offers the best potential for early diagnosis
• No test is perfect - limitations of tests are important to understand relay to the client.
• New technology available now and on the horizon will likely change the algorithm
Where do I fit in?

- Testing
- Education
- Promotion
- Referral AND Follow-up
- And Follow-up
- Support
- YOU MATTER!
Laboratory Testing for the Diagnosis of HIV Infection
Updated Recommendations

Laboratory Tests

In this section we provide resources for all FDA-approved diagnostic HIV tests for use in moderate and high complexity laboratories.

Laboratory Testing Guidance

- NEW! Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations
- NEW! Quick Reference: Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens
- APHL Suggested Reporting Language for the HIV Laboratory Diagnostic Testing Algorithm

FDA Approved HIV Tests

- NEW! Advantages and Disadvantages of Different Types of HIV tests
- NEW! List of Moderate Complexity Rapid HIV Tests for Laboratory Use
- NEW! List of Moderate and High Complexity HIV tests for Laboratory Use
Resources

To order materials from the DSHS Warehouse:
http://www.dshs.state.tx.us/hivstd/info/edmat.shtm

- www.aphl.org/aphlprograms/infectious/hiv/Pages/HIV-Diagnostic-Testing-Algorithm.aspx
- www.hivtestingconference.org
- www.hivforum.org/index.php?option=com_content&task=view&id=774&Itemid=92
- http://jid.oxfordjournals.org/content/202/Supplement_2/S270.full.pdf+html
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