Advances in HIV and HCV Testing: Opportunities for Health Department Prevention and Linkage Programs

March 9, 2017
## HIV Test Volume by Type, 2006 – 2014

Selected Health Departments (N=34)

<table>
<thead>
<tr>
<th>Year</th>
<th>Conventional</th>
<th>Rapid</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>1,211,099</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>1,308,366</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>1,522,130</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>1,947,529</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td></td>
<td>2,256,147</td>
</tr>
<tr>
<td>2013</td>
<td></td>
<td>2,131,497</td>
</tr>
<tr>
<td>2014</td>
<td></td>
<td>2,034,580</td>
</tr>
</tbody>
</table>
HIV Test Volume by Specimen Type, 2005-2014, Subset of PHLs (n=41)
Laboratory-Based Testing Practices (N=52)

HIV

- 32 SPHL conduct Ab/Ag
- 14 SPHL conduct NAT*

*All states have access to HIV NAT

HCV

- Providers required to use public health laboratory
  - 29
  - 56%
- Providers required to use commercial or clinical laboratories
  - 3
  - 6%
- Other
  - 6
  - 11%
- 22 SPHL conduct Ab

*All states have access to HIV NAT

Sources:
APHL 2014 HIV Diagnostics Survey
Integrating HCV Testing (N=52)

2014 Volume of HCV Tests: 147,047

- Provided in selected settings/venues in which HIV testing provided: 30 (58%)
- Provided in all settings/venues in which HIV testing provided: 9 (17%)
- Plan to support HCV testing within 12 months: 4 (8%)
- No plans to support HCV testing: 6 (11%)
- Other: 3 (6%)

Opportunities

- Facilitate access and utilization
  - Population considerations, preferences
  - Provider capacity
  - Public health infrastructure and resources
  - Programmatic/policy priorities

- Sustainability, improvement, and expansion
  - Early identification of HIV infection
  - Identification of HCV infection
  - Linkage to care and treatment
  - Integration of HIV and HCV services
  - Strengthen surveillance
Laboratory Diagnostics of HIV and HCV

Mark Pandori
Director, Alameda County Department of Public Health Laboratory
Associate Clinical Professor, Laboratory Medicine
UCSF
Goals:

• Describe the methods / technologies for screening and confirmation

• Discuss the Importance and Diagnosis of **Acute HIV**

• Describe the current HIV Lab Testing Algorithm

• Describe HCV testing options and Algorithm

• Indicate how labs might integrate HCV and HIV testing
HIV Screening Tests
Screening tests:

- **Laboratory based antibody tests**
  --called: “immunoassays” or often “IA”

- **Point-of-Care, “rapid” tests**: examples: OraQuick, Stat-Pak, Alere Determine
HIV IA: The First Generation Tests

• Don’t detect antibody to all HIV-1 strains, or HIV-2 reliably

• Only IgG detected

• Still on the market:

• One is FDA approved for oral fluid testing; and dried blood spots (Avioq HIV-1)
HIV EIA: *Third* Generation

- IgM and IgG detection
- Detects Group O, Detects HIV-2 antibodies
- Shorter Window Periods
“4th Generation” EIA: Antigen-Antibody Combo testing

• FDA Approved in June, 2010

• Detects virus and/or antibody simultaneously

• Detects “antigen” of virus, not RNA

• Shorter Window period
“4th Generation” EIA: Antigen-Antibody Combo testing

- Examples:
Lab Based Serology/Screening Assays

Bio-Rad GS HIV Combo Ag/Ab
~ 3-4 hours

Abbott Architect Ag/Ab Combo Assay**
~30 mins

ADVIA Centaur® HIV Ag/Ab Combo**  #
~ 1 hour

BioPlex® 2200 HIV Ag-Ab ** #
~ 1 hour

Slide courtesy of M. Owen
BioPlex 2200 HIV Ag-Ab

- Bio-Rad Bioplex platform
- Detects and differentiates HIV-1 antigen and HIV-1 and HIV-2 antibody
- Sensitivity for HIV-1 p24 antigen: 5.2 pg/ml
BioPlex 2200 HIV Ag-Ab

- Abbott Architect sensitivity for p24: 18.39 pg/ml

- BioPlex may be more sensitive for Ag detection by a factor of ~3.5x.

- Translate to window period enhancement?
Supplemental Testing

Aka “Confirmation” testing
Confirmation / Supplemental Tests

- tests that confirm a positive screening test result

- Currently, all confirmation is laboratory-based
Multispot HIV-1/2 Differentiation test

Off the market, December 2016…
Geenius HIV-1/2 Differentiation test

-A “rapid western blot”...

-High specificity

Detected antibodies to: gp140, gp36 (HIV-2); and gp41, p24, pg160, p31 (HIV-1)
TMA (Transcription-mediated amplification) The only RNA test with an FDA claim for diagnostic use:

- **GenProbe Aptima**
  - Qualitative
  - Manual only
  - Sensitivity ~30 RNA copies/ml
Where these tests sit in the window period
HIV Testing and the “Window Period”

Infection event

Day 0

Virus Detectable

Day 11

IgM Detectable

Day 22

Virus becomes detectable

16

IgG Detectable

Day 36

Antibody becomes detectable

Lab-based 3rd gen Ab Test

Lab-based 1st gen Ab Test

4th Gen. IA
HIV Testing and the “Window Period”

- Infection event
- Virus Detectable
- IgM Detectable
- IgG Detectable
- Antibody becomes detectable
- Virus becomes detectable

- 16th day

- Lab-based 3rd gen Ab Test
- 4th Gen. IA
- Lab-based 1st gen Ab Test

Supplemental Testing

- Day 0
- Day 11
- Day 22
- Day 36
Rapid (Point of Care) testing options
Point-of-care, “Rapid” HIV testing

- Rapid Tests, also known as “point of care” tests are considered waived in terms of complexity by CLIA

- Tests are routinely done outside of lab; positive results must go to a lab for confirmation

---Some Labs are using rapid tests as their screening test (random access nature)
Rapid testing options (in U.S.):
OraQuick Rapid test

- Swab the gums or:
- “loop” of blood (5 ul)
- 20 minutes to result
Clearview Stat-pak

• Similar sensitivity and functionality to OraQuick

• Can only use blood / plasma
Uni-Gold Rapid Test (an IgG & IgM-sensitive rapid test)

- 50 ul of blood
- Detects antibodies to HIV-1 and 2
- 10 minutes
Biolytical Insti

- Fast (60 seconds development time)
- Detects IgG and IgM
Alere Determine HIV Ab/Ag test

Test in just 3 easy steps

1. **Prepare Test**
   Tear one strip from the right and remove cover.

2. **Add Sample**
   Add sample of whole blood, wait 1 minute and add chase buffer. Also compatible with serum and plasma. Read full instructions prior to running test.

3. **Read Results**
   Read the results – for both the HIV-1 p24 antigen (Ag) and HIV-1/2 antibodies (Ab) – in just 20 minutes.
   The control line should appear for all results. If it does not appear, the results are invalid.

<table>
<thead>
<tr>
<th>Line</th>
<th>Positive</th>
<th>Negative</th>
<th>Invalid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>[ ] [ ]</td>
<td>[ ] [ ]</td>
<td>[ ] [ ]</td>
</tr>
<tr>
<td>Ag</td>
<td>[ ] [ ]</td>
<td>[ ] [ ]</td>
<td>[ ] [ ]</td>
</tr>
<tr>
<td>Ab</td>
<td>[ ] [ ]</td>
<td>[ ] [ ]</td>
<td>[ ] [ ]</td>
</tr>
</tbody>
</table>

Result key

20 min
HIV Testing and the “Window Period”

- Lab 4th Gen. IA
- Lab-based 3rd gen Ab Test
- Lab-based 1st gen Ab Test

Supplemental Testing

- Infection event
- Virus detectable: Day 0
- IgM detectable: Day 11
- IgG detectable: Day 22
- Antibody becomes detectable: Day 36
- Virus becomes detectable: Day 16
HIV Testing and the “Window Period”

- **Infection event**
- **Virus Detectable**
- **IgM Detectable**
- **Antibody becomes detectable**
- **Virus becomes detectable**
- **Lab-based 3rd gen Ab Test**
- **Lab 4th Gen. IA**
- **Rapid IgG screens**

**Timeline:**
- **Day 0**
- **Day 11**
- **Day 22**
- **Day 36**
HIV Testing and the “Window Period”

- **Virus Detectable**
  - **Day 11**

- **IgM Detectable**
  - **Day 22**

- **Antibody becomes detectable**
  - **Day 36**

- **Lab 4th Gen. IA**

- **Lab-based 3rd gen Ab Test**
  - **Virus becomes detectable**

- **Rapid IgM-capable**

- **Rapid IgG screens**
  - **Antibody becomes detectable**
Watch the Gap!

- There is a window period gap between Lab Screening tests and Confirmation tests.
- There is a gap between many rapid tests and Confirmation Tests.
- This means there can be discordance between screens and confirmation in cases of recent infection.
Importance of Recent / Acute HIV Diagnostics
What is meant by “acute”

- Definitions vary: all agree it refers to “recent HIV infection”

- For diagnostics, a refined definition would be “pre-seroconversion”

- This would be the approximate 3-6 week period before antibody development
• **After infection:** Virus replicates “unchecked”-- becomes detectable by RNA ~ day 10-12; load becomes very high; **correlates with load in semen; may be a viral prodrome associated**

• After ~ 3 weeks **antibody** develops, becomes detectable
Risk of Sexual Transmission of HIV

Risk of Transmission Reflects Genital Viral Burden

HIV Testing and the “Window Period”

- **Virus becomes detectable**: Day 11
- **IgM Detectable**: Day 22
- **Antibody becomes detectable**: Day 36
- **Lab-based Ab Test**
- **Rapid, POC test**
HIV Testing and the “Window Period”

- **Viral RNA**: Virus becomes detectable
- **Lab-based Ab Test**: Antibody becomes detectable
- **Rapid, POC test**

- **Infection event**
  - **Day 0**: Infection event
  - **Day 11**: Virus detectable
  - **Day 22**: IgM detectable
  - **Day 36**: IgG detectable
Direct Detection of Virus

RNA detection
Current NAT Technology

Hologic Aptima HIV-1 Qualitative NAT

Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1*

Abbott RealTime m2000*

* Quantitative NAT, not FDA approved for diagnosis but can be ordered by physicians

Roche cobas® 6800*

Slide courtesy of M. Owen
Current APHL/CDC Guidelines for testing
Recommended Laboratory Algorithm

HIV-1/2 antigen/antibody combination immunoassay

- (+) → Negative for HIV-1 and HIV-2 antibodies and p24 Ag
- (-)

HIV-1/HIV-2 antibody differentiation immunoassay

- HIV-1 (+) HIV-2 (-)
  - HIV-1 antibodies detected
- HIV-1 (-) HIV-2 (+)
  - HIV-2 antibodies detected
- HIV-1 (+) HIV-2 (+)
  - HIV antibodies detected
- HIV-1 (-) or indeterminate HIV-2 (-)
  - HIV-1 NAT
    - (+) indicates reactive test result
    - (-) indicates nonreactive test result
    - NAT: nucleic acid test
    - HIV-1 NAT (+)
      - Acute HIV-1 infection
    - HIV-1 NAT (-)
      - Negative for HIV-1
Benefits of the Current Algorithm

- Sensitive for recent infection
- Can discriminate between infection HIV-1 and HIV-2
- Can say whether someone is acute or not
- More rapid turnaround time
- Less work on the supplemental testing end
Issues with the Current algorithm
Issues

- It will rely on singular products, for a while (Geenius issues)
- Dealing with discordants: RNA?
- Still No HIV-2 RNA test
HCV Infection

• HCV RNA detectable in 1-2 weeks
• Antibodies to HCV are detectable 6-8 weeks post infection, can take several months
  – >97% of infected persons have detectable HCV antibody 6 months after exposure
• If infection resolves on its own
  – RNA will be undetectable
  – Antibodies will persist
• If infection becomes chronic
  – RNA will be detectable >6mo after onset
HCV Laboratory Markers

http://www.hepatitisc.uw.edu/go/screening-diagnosis/acute-diagnosis/core-concept/all
Recommended Testing Sequence

- Begin with a FDA-approved immunoassay to test for HCV antibodies in blood
  - This may be an instrument-based immunoassay or a rapid test

- Currently, only one FDA-approved rapid test
  - CLIA-waived for whole blood collected by fingerstick or venipuncture
Recommended Testing Sequence

• If antibody test (lab or rapid) is positive:

Perform an HCV RNA test
(laboratory based)
Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

1. HCV antibody
   - Nonreactive
     - No HCV antibody detected
     - STOP*
   - Reactive
     - HCV RNA
       - Not Detected
         - No current HCV infection
         - Additional testing as appropriate†
       - Detected
         - Current HCV infection
         - Link to care

* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

# FDA Approved HCV Antibody Tests

<table>
<thead>
<tr>
<th>Assay</th>
<th>Manufacturer</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott HCV EIA 2.0</td>
<td>Abbott</td>
<td>Laboratory Based Manual</td>
</tr>
<tr>
<td>Advia CENTAUR HCV</td>
<td>Siemens</td>
<td>Laboratory Based Automated</td>
</tr>
<tr>
<td>ARCHITECT Anti-HCV</td>
<td>Abbott</td>
<td>Laboratory Based Automated</td>
</tr>
<tr>
<td>AxSYM Anti-HCV</td>
<td>Abbott</td>
<td>Laboratory Based Automated</td>
</tr>
<tr>
<td>OraQuick HCV Rapid Antibody Test</td>
<td>OraSure</td>
<td>Rapid Test Manual</td>
</tr>
<tr>
<td>Ortho HCV Version 3.0 EIA</td>
<td>Ortho</td>
<td>Laboratory Based Manual</td>
</tr>
<tr>
<td>VITROS Anti-HCV</td>
<td>Ortho</td>
<td>Laboratory Based Automated</td>
</tr>
</tbody>
</table>

# FDA Approved HCV RNA Tests

<table>
<thead>
<tr>
<th>Qualitative Diagnostics</th>
<th>Test Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>VERSANT HCV RNA Assay</td>
<td>Siemens</td>
<td></td>
</tr>
<tr>
<td>AMPLICOR HCV Test, v2.0</td>
<td>Roche</td>
<td></td>
</tr>
<tr>
<td>APTIMA HCV RNA Qualitative Assay</td>
<td>Hologic</td>
<td></td>
</tr>
<tr>
<td>COBAS AmpliPrep/ COBAS Taqman HCV Test v2.0</td>
<td>Roche</td>
<td></td>
</tr>
<tr>
<td>COBAS HCV for COBAS 6800/8800</td>
<td>Roche</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dual-Claim Management</th>
<th>Test Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott RealTime HCV</td>
<td>Abbott</td>
<td></td>
</tr>
<tr>
<td>VERSANT HCV RNA 3.0 bDNA</td>
<td>Siemens</td>
<td></td>
</tr>
</tbody>
</table>

Modified from APHL’s “Testing For Hepatitis C Viral Infections: Frequently Asked Questions”
HCV Tests on the Horizon

- HCV Core Ag
- More HCV NATs with Dual Claim (Diagnostic and Quantitative)
- Cepheid HCV Assay
Testing Integration-POC Screening Test considerations

• HIV
  – Multiple tests available
    • Blood
    • Oral Fluid
  – High sensitivity and specificity for established infections
  – Decreased sensitivity for early infections

• HCV
  – OraQuickHCV Rapid Antibody Test
    • Fingerstick or venous whole blood

Slide courtesy of M. Owen
HCV and HIV antibody testing Integration: some options on the market

- **AdviaCentaur**
  - HCV, HIV1/O/2 Enhanced (EHIV), HIV Ag/Ab Combo (CHIV), Syphilis

- **Abbott Architect**
  - Anti-HCV, HIV Ag/Ab Combo

- **Ortho Vitros**
  - Anti-HCV, Anti-HIV 1+2

*Slide courtesy of M. Owen*
Testing Integration-NAAT (RNA)

- **Abbott Molecular**
  - RealTimeCT/NG, RealTimeHCV*, RealTimeHIV-1*

- **Hologic**
  - AptimaCombo 2 assay for CT/NG#, Aptima HCV RNA assay, Aptima HIV-1 RNA qualitative assay, Aptima HIV-1 RNA Quant (Panther)

- **Roche**
  - COBAS® AmpliPrep/COBAS® TaqMan®, HIV-1 Test, v2.0, HCV Test*, HBV Test, v2.0*
  - cobas® 4800 System
    - CT/NG Test, HPV Test, HSV 1 and 2 Test
Summary:

• The new HIV algorithm allows for programs and laboratories to play to the strength of new technology: detect recent infection

• There are many opportunities for labs to integrate their HIV and HCV testing operationally / technologically
Thank You for your Attention

"Cherish the planet": picture drawn by a child at the HIV Prevention Department in St. Petersburg
Program Challenges & Opportunities

Carolyn Wester, MD, MPH
Medical Director, HIV/STD/Viral Hepatitis
Tennessee Department of Health
Outline: HIV & HCV Testing in TN

❖ HIV Testing
  • Background
  • Progress
  • Challenges & Opportunities

❖ HCV Testing
  • Background
  • Progress
  • Challenges & Opportunities
HIV Testing in Tennessee

(Case rates calculated per 100,000 population)
TN HIV Continuum of Care: 2010 Status vs. 2015 Goals

- Diagnosed: 100%
- Linked: 64% (TN Goal 2015), 80% (TN 2010)
- Retained: 64%
- Achieved Viral Suppression: 51% (TN Goal 2015), 35% (TN 2010)

Tennessee eHARS, internal resource
## Tennessee’s HIV/AIDS Strategy Progress Report

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Increase Access to Care &amp; Improve Health Outcomes Among Persons Living with HIV Infection</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase Linkage to HIV Medical Care ≤ 3 Months of Diagnosis</td>
<td>64%</td>
<td>76%</td>
<td>≥ 80%</td>
<td></td>
</tr>
<tr>
<td>Increase Retention in HIV Medical Care</td>
<td>29%</td>
<td>53%</td>
<td>≥ 64%</td>
<td></td>
</tr>
<tr>
<td>Increase Viral Suppression</td>
<td>35%</td>
<td>52%</td>
<td>≥ 51%</td>
<td></td>
</tr>
<tr>
<td><strong>Reduce HIV-Related Disparities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase Viral Suppression Among <strong>MSM</strong> by 20%</td>
<td>39%</td>
<td>56%</td>
<td>≥ 47%</td>
<td>✔️</td>
</tr>
<tr>
<td>Increase Viral Suppression Among <strong>Blacks/AA’s</strong> by 20%</td>
<td>31%</td>
<td>50%</td>
<td>≥ 37%</td>
<td>✔️</td>
</tr>
<tr>
<td>Increase Viral Suppression Among <strong>Hispanics</strong> by 20%</td>
<td>30%</td>
<td>43%</td>
<td>≥ 36%</td>
<td>✔️</td>
</tr>
<tr>
<td>Increase Viral Suppression Among <strong>25 – 34 year olds</strong> by 20%</td>
<td>28%</td>
<td>45%</td>
<td>≥ 34%</td>
<td>✔️</td>
</tr>
</tbody>
</table>

Tennessee eHARS, internal resource
TN’s 4\textsuperscript{th} Gen HIV Testing: Progress


<table>
<thead>
<tr>
<th>Test Description</th>
<th># Clients</th>
</tr>
</thead>
<tbody>
<tr>
<td># Clients undergoing 4\textsuperscript{th} generation HIV-1/2 immunoassay</td>
<td>178,174</td>
</tr>
<tr>
<td># clients negative for HIV-1 &amp; HIV-2 Abs and p24 Ag</td>
<td>176,214</td>
</tr>
<tr>
<td># clients positive for HIV-1 and HIV-2 Abs or p24 Ag</td>
<td>1,960 (1.1%)</td>
</tr>
<tr>
<td>Of clients undergoing HIV-1/HIV-1 Ab differentiation assay</td>
<td></td>
</tr>
<tr>
<td># clients with only HIV-1 Abs detected</td>
<td>1,774 (90.5%)</td>
</tr>
<tr>
<td># clients with only HIV-2 Abs detected</td>
<td>2 (0.1%)</td>
</tr>
<tr>
<td># clients with both HIV-1 &amp; HIV-2 Abs detected</td>
<td>0</td>
</tr>
<tr>
<td># clients testing negative or indeterminate for HIV-1 or HIV-2 Abs</td>
<td>184 (9.4%)</td>
</tr>
<tr>
<td>Of the clients undergoing HIV-1 RNA Testing</td>
<td></td>
</tr>
<tr>
<td># clients with HIV-1 RNA detected</td>
<td>26 (14.1%) (0.01% of all samples)</td>
</tr>
<tr>
<td># clients without HIV-1 RNA detected</td>
<td>158 (85.9%)</td>
</tr>
</tbody>
</table>
4th Gen HIV Testing: Lessons Learned

• Of samples going to Step 2
  • ~90% were confirmed positive
  • 2 cases of HIV-2 detected

• Of samples going for RNA testing
  • ~90% were negative
  • ~10% were determined to be acutely infected

• 26 acute HIV infections identified
  • 22 AHI’s linked to care
    o 1 (4.5%) determined to be chronically infected (perinatal)
    o 2 (9.1%) determined to be HIV negative (undetectable VL followed by negative results on repeat screening)

• Considering utility of quantitative vs. qualitative HIV-1 RNA for Step 3
## HIV Testing: Community Based Organizations (TDH, 2016)

<table>
<thead>
<tr>
<th>Program / Site</th>
<th>Tests Conducted</th>
<th>Total Positivity</th>
<th>Newly Diagnosed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Core Prevention (Cat A)</td>
<td>3,532</td>
<td>133 (3.8%)</td>
<td>77 (2.2%)</td>
</tr>
<tr>
<td>Expanded Testing (Cat B)</td>
<td>39,382</td>
<td>150 (0.38%)</td>
<td>55 (0.14%)</td>
</tr>
<tr>
<td><strong>Non-Clinical</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Core Prevention (Cat A)</td>
<td>2,024</td>
<td>14 (0.7%)</td>
<td>13 (0.6%)</td>
</tr>
<tr>
<td>Expanded Testing (Cat B)</td>
<td>2,442</td>
<td>25 (1.02%)</td>
<td>22 (0.90%)</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>47,380</td>
<td>322 (0.7%)</td>
<td>167 (0.4%)</td>
</tr>
</tbody>
</table>
Pause / Summarize (HIV)

❖ Progress... (2015 compared to 2010)
  • Implementation of 4th generation HIV testing (state lab)
  • New HIV Diagnoses ↓ by 17%
  • Late stage HIV diagnosis ↓ by 9%
  • HIV-deaths ↓ by 20%

❖ Challenges
  • Disparities persist (younger, R/E minorities, PWID)
  • High impact strategies focus on disproportionately affected populations; yet lack of testing in low prevalence, high-risk settings

❖ HIV Vulnerability among PWID
  • “PWID are at increased risk for HIV, HCV, HBV, and other negative health outcomes. In 2014, 9% of HIV diagnoses were among PWID. Although substantial progress has been made in reducing HIV infections among PWID, recent changes in drug use could challenge this success.”

Wejnert C et al, MMWR, 2016
Hepatitis C
## Reported Cases of Acute HCV in Tennessee

<table>
<thead>
<tr>
<th></th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>US</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>case rate</td>
<td>0.3</td>
<td>0.4</td>
<td>0.6</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>cases</td>
<td>850</td>
<td>1,229</td>
<td>1,778</td>
<td>2,138</td>
<td>2,194</td>
</tr>
<tr>
<td><strong>TN</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>case rate</td>
<td>0.7</td>
<td>1.3</td>
<td>2.0</td>
<td>1.5</td>
<td>1.9</td>
</tr>
<tr>
<td>cases</td>
<td>46</td>
<td>83</td>
<td>129</td>
<td>98</td>
<td>123</td>
</tr>
<tr>
<td>rank</td>
<td>4&lt;sup&gt;th&lt;/sup&gt;</td>
<td>4&lt;sup&gt;th&lt;/sup&gt;</td>
<td>4&lt;sup&gt;th&lt;/sup&gt;</td>
<td>6&lt;sup&gt;th&lt;/sup&gt;</td>
<td>5&lt;sup&gt;th&lt;/sup&gt;</td>
</tr>
</tbody>
</table>


* per 100,000 population
The Syndemic of HCV & Opioid Abuse
(< 30 year olds in 4 Appalachian States)

Zibbell AE et al, MMWR, 2015
Intersection of Epidemics

Opioid Abuse

Hepatitis C

HIV
CDC’s HIV Risk Vulnerability Assessment: TN Profile, County-Level


Van Handel MM et al, JAIDS, 2016

Newly Diagnosed HIV Cases

Acute HCV Cases

Tennessee NBS, accessed February 10, 2017
Note: County Data Unavailable for n=19 HCV Cases
Tennessee eHARS, internal source
Natural Breaks/Manual, 5 Classes
Strengthening Prevention & Treatment Along the Spectrum of TN’s HCV Continuum of “Cure”

U.S. HCV "Continuum of Cure"  
(Holmberg et al, NEJM, 2013)

<table>
<thead>
<tr>
<th>Stage</th>
<th>Engagement in HCV Care &amp; Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infected (3.2 mill)</td>
<td>100%</td>
</tr>
<tr>
<td>Detected (1.6 mill)</td>
<td>50%</td>
</tr>
<tr>
<td>Confirmed (750 K)</td>
<td>23%</td>
</tr>
<tr>
<td>Treated (360 K)</td>
<td>11%</td>
</tr>
<tr>
<td>Cured (200 K)</td>
<td>6%</td>
</tr>
</tbody>
</table>

Surveillance & Education

Navigation

Case Management

Prevention

Prevention
Tennessee’s HCV Continuum of “Cure” Activities

❖ **Prevention**
  - Community & Provider Education
  - Hepatitis B Vaccination Program (jails)
  - Syringe Exchange, Opioid Substitution Therapy, PrEP

❖ **Surveillance / Outbreak Investigation**
  - Augment HCV lab reporting & case investigation
  - Build capacity (centrally & regionally) – planning, detection, response
  - Data-to-Care

❖ **TDH Laboratory Capacity**
  - **HCV Testing** (Ab with reflex to HCV RNA)
  - GHOST surveillance (Global Hepatitis Outbreak Surveillance Technology)

❖ **Partnerships**
  - HDs, CBOs, Corrections, MHSA, Community Providers, Academic Institutions

❖ **Pilots**
  - HCV Testing, HCV Treatment, Expanded HBV Vaccination
Community Based Organization (CBO)  
HCV Testing Project

- **Rapid Antibody test kits are provided to those CBO’s serving at risk populations**
  - History of IV or intranasal drug use
  - Known to be HIV (+)
  - Sexual partner known to be HCV (+)
  - History of incarceration > 24 hrs
  - History of non-professional tattoos or piercing
  - Any known other risk factors

- **Reporting Requirements**
  - Monthly report (all tests conducted)
  - Line-item report (HCV Ab (+) individuals only)
CBO HCV Testing: Monthly Report (All Tests Conducted)

<table>
<thead>
<tr>
<th>Monthly Data Report - ALL Hepatitis C Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total # of Tests Done</td>
</tr>
<tr>
<td>-----------------------</td>
</tr>
<tr>
<td>Jan-17</td>
</tr>
<tr>
<td>Feb-17</td>
</tr>
<tr>
<td>Mar-17</td>
</tr>
</tbody>
</table>
# CBO HCV Testing: Report for Positives

**CBO HCV Ab Testing Form**

**Tennessee Department of Health**

---

### INSTRUCTIONS: Fax for Positives Only

This form is to be completed by Community Based Organization’s (CBO’s) for all individuals tested using TDH-supplied rapid HCV test kits. For individuals testing positive: Completed forms must be submitted within one week of test date via secure fax or email to Shannon De Pont in the Viral Hepatitis Program. Shannon De Pont, phone: 615-532-8518, fax: 615-741-3691, email: shannon.depont@tn.gov

---

### AGENCY INFORMATION:

| Agency Name: |  
| --- | --- |
| Agency Phone Number: |  
| Name of Person Conducting Testing: |  

---

### PATIENT INFORMATION:

- **HCV Antibody collection date (MM/DD/YY):**
- **Patient Name:**
- **Patient Address:**
- **City:**
- **State:**
- **Zip code:**
- **Phone:**
- **DOB (MM/DD/YY):**
- **Gender:**
- **Ethnicity:**

| Race: |  
| --- | --- |
| Black/African American | American Indian/Alaska Native | Asian | Native Hawaiian/Pacific Islander | White |

- **Has the patient been previously tested for HCV?**
  - Yes
  - No
  - IF YES, what was the result?  
    - Positive
    - Negative
    - Unknown

- **Has the patient been vaccinated for HAV?**
  - Yes
  - No
  - IF YES, did they complete the 2-dose series?  
    - Yes
    - No

- **Has the patient been vaccinated for HBV?**
  - Yes
  - No
  - IF YES, did they complete the 3-dose series?  
    - Yes
    - No

---

### HCV TESTING SETTING:

- **Facility Name:**
- **Type of Facility:** (Check all that apply)
  - Correctional Facility
  - Substance Abuse Treatment Facility
  - Agency Walk-In
  - Other, specify:

---

### REASON FOR TESTING:

- **Born from 1945 through 1965**
- **History of incarceration > 24 hours**
- **History of injection drug use (ever)**
- **HIV positive**
- **History of illicit intranasal drug use (ever)**
- **History of STD or multiple sex partners**
- **History of tattoo or body piercing**
- **Sexual contact with HCV positive individual**
- **Other, specify:**
- **No Identified Risks**

---

### HCV TESTING RESULTS / LINKAGE TO CARE:

- **HCV Ab test result:**
  - Positive
  - Negative

- **Patient informed of HCV Ab result?**
  - Yes
  - No
## CBO HCV Testing: Results

*(TDH, 2016)*

<table>
<thead>
<tr>
<th>Site</th>
<th>Tests Conducted</th>
<th>Antibody Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>East TN</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 CBOs</td>
<td>958</td>
<td>350 (36.5%)</td>
</tr>
<tr>
<td><strong>Middle TN</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 CBO</td>
<td>773</td>
<td>310 (40.1%)</td>
</tr>
<tr>
<td><strong>West TN</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 CBOs</td>
<td>429</td>
<td>63 (14.7%)</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>2,160</td>
<td>723 (33.5%)</td>
</tr>
</tbody>
</table>
Health Department (HD) HCV Testing

- **State Laboratory (Nashville)**
  - HCV Ab with reflex to RNA

- **Supplemental funding / Epi Aid (Jun – Oct 2016)**
  - Pilot in 3 metropolitan HDs in Eastern TN
  - Primarily STD & FP clinics
  - Basic risk factor assessment at time of sample collection
  - Developed protocols
    - Specimen transport, pre- & post-test messaging, referral info
  - Additional analyses
    - Nested case-control: drug use behaviors among PWID, by HCV Ab status
    - GHOST pilot (Global Hepatitis Outbreak and Surveillance Technology)
HCV Testing:
Health Department Pilot Study / Epi Aid

- From June 1–October 31, 2016:
  4,753 Patients were tested for HCV
### HCV Testing: HD Pilot Results

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total n (%)</th>
<th>HCV Ab (+) n (%)</th>
<th>HCV Ab (-) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>4,753</td>
<td>397 (8.4)</td>
<td>4,356 (91.6)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (years, range)</td>
<td>31.0 (10–79)</td>
<td>37.3 (14–71)</td>
<td>30.4 (10–79)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1892 (39.8)</td>
<td>204 (10.8)</td>
<td>1688 (89.2)</td>
</tr>
<tr>
<td>Female</td>
<td>2861 (60.2)</td>
<td>193 (6.7)</td>
<td>2668 (93.3)</td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White, Non-Hispanic</td>
<td>2291 (48.2)</td>
<td>339 (14.8)</td>
<td>1952 (85.2)</td>
</tr>
<tr>
<td>Black, Non-Hispanic</td>
<td>1652 (34.8)</td>
<td>48 (2.9)</td>
<td>1604 (97.1)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>753 (15.8)</td>
<td>5 (0.7)</td>
<td>748 (99.3)</td>
</tr>
<tr>
<td><strong>Testing facility type</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STD Clinic</td>
<td>3381 (71.1)</td>
<td>331 (9.8)</td>
<td>3050 (90.2)</td>
</tr>
<tr>
<td>FP Clinic</td>
<td>1337 (28.1)</td>
<td>46 (3.4)</td>
<td>1291 (96.6)</td>
</tr>
<tr>
<td><strong>Risk Factor</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection Drug Use</td>
<td>425 (8.9)</td>
<td>276 (69.5)</td>
<td>149 (3.4)</td>
</tr>
<tr>
<td>Intranasal Drug Use</td>
<td>967 (20.3)</td>
<td>295 (74.3)</td>
<td>672 (15.4)</td>
</tr>
<tr>
<td>Incarceration</td>
<td>1309 (27.5)</td>
<td>303 (76.3)</td>
<td>1006 (23.1)</td>
</tr>
<tr>
<td>Tattoo / Piercing</td>
<td>1092 (23.0)</td>
<td>188 (47.4)</td>
<td>904 (20.7)</td>
</tr>
<tr>
<td>No Risk Factors</td>
<td>2598 (54.7)</td>
<td>39 (9.8)</td>
<td>2559 (58.7)</td>
</tr>
</tbody>
</table>
HCV Testing: HD Pilot Results (cont’d)

- 4,753 persons tested for HCV
  - 8.4% Ab positive
    - 74.1% RNA positive

- Risk Factors among population tested
  - ~10% injection drug use
  - ~20% intranasal drug use
  - ~25% incarceration

- Females 11-50 yo represented 58% of persons tested
  - 6.3% Ab (+)
    - 5 were pregnant at the time of testing
HCV Testing: Moving Forward

- **Statewide Health Department Roll-Out (Apr 2017)**
  - Health Department Clinics (STD, Primary Care, FP)
  - Risk factor questions embedded into lab order entry screen
  - Protocols / training materials
    - Statewide nursing protocol
    - Training manual
    - Specimen collection & transport instructions
  - Working with academic partners to build HCV treatment capacity within rural areas
  - Developing Provider Directories (HIV, HCV, MHSA)
Health Departments: HCV Testing Indications
(TDH Nursing Protocol)

One time test for all patients:
- Born from 1945 to 1965
- Identified as high risk
- Seeking evaluation and/or treatment for STIs
- Requesting HCV testing or counseling

Repeat testing (> 12 months apart) for persons with ongoing risk factors, including:
- Injection drug use (even once)
- Illicit intranasal drug use (even once)
- History of incarceration over 24 hours
- Receipt of an unregulated tattoos
- High-risk sexual behaviors
  - Multiple sex partners, unprotected sex, or sex with an HCV (+) person or a PWID
Health Department HCV Testing: Routine Risk Factor Questions

- Born from 1945-1965?
- Ever Injected Drugs?
- Ever snorted illicit drugs?
- Ever had a non-professional tattoo?
- Ever incarcerated for >24 hours?
- Blood transfusion or organ transplant before 1992?
- Contact with someone who has/had HCV?
  - No -- No Contact Reported
  - Yes –
    - Drug Use Partner
    - Sexual Contact
    - Household Contact
    - Other Contact
- Is the Patient Pregnant? Y/N
HCV Testing: Challenges & Opportunities

• **Opportunities**
  - Integration of services within HD
    - Testing (HIV, STD, HCV – including reflex to RNA)
    - Clinical services (immunizations, family planning)
  - Referral for additional services
    - Prevention (SSPs, PrEP, OD Prevention)
    - Treatment (HIV, HCV, MHSA)

• **Challenges**
  - Funding
    - Testing
      - Laboratory-based and rapid testing, staff
    - Clinical personnel
      - Conduct testing, basic messaging
      - Follow-up HCV positives (case investigation, prevention services & LTC)
      - Follow-up PWID, regardless of HCV status (prevention services & LTC)
Acknowledgements

- TDH
  - Viral Hepatitis & HIV Prevention Teams
  - State Laboratory
- TDH/CDC Epi Aid Team
- Community Based Partners
- Local HDs throughout TN
- TN CFAR
- NASTAD / APHL
Questions

You can ask questions by typing them into the chat box or virtually raising your hand so we can unmute your line.

If you are joining via phone only, you can raise your hand to ask a question by pressing *9.
Contact Us

Alyssa Kitlas
Manager, Hepatitis
akitlas@NASTAD.org

NASTAD
444 North Capitol Street NW, Suite 339
Washington, DC 20001
Phone: (202) 434.8090
Fax: (202) 434.8092
www.NASTAD.org

LinkedIn | Facebook | Twitter | YouTube | Instagram
Thank You!