NJHIV – DMHAS
Rapid HIV Testing Program
Overview
NJHIV – WHO WE ARE

• Rapid HIV testing support group
• Composed of laboratorians
  – MD, PhD, MT, RN
• Department of Pathology and Laboratory Medicine at Rutgers Robert Wood Johnson Medical School
  – Department of Psychiatry - Nina Cooperman, PsyD
    • Studies DMHAS sites to identify and eliminate barriers to HIV testing
• Built upon an existing Rutgers Robert Wood Johnson Medical School, multi-facility, point-of-care-testing program
• Develop a centralized quality assurance process
• Management by board certified Pathologists, experienced laboratory professionals, RNs and medical technologists
• Supervisory control through site coordinators
NJHIV

• Central lab oversees:
  • Regulatory and proficiency testing
  • Acquisition and validation of supplies
  • Inventory control
  • Common procedures and core policies
  • Uniform administration at all locations
  • Common training, certification of personnel, forms
  • Core communication hub: [www.njhiv1.org](http://www.njhiv1.org)
  • Quality Control Rules
  • Standardized monthly site visits
Quality Assurance Program

- Professional Oversight
- Monthly site visits by core staff
- Standardization of policies/procedures
- Proper test procedures (client and QC)
- Proficiency Testing
- Centralization of:
  - Training and operator certification
    - Proper test procedures
    - Quality control
    - Temperature monitoring
  - Regulatory requirements/licensure
  - Reagent purchase and validation
  - Inventory control
  - Technical support
  - Follow-up of discordant results
SCOPE OF THE CURRENT NJ HIV RAPID TEST SUPPORT PROGRAM

NJ HIV
New Jersey Rapid Testing

RWJ Sites: 97   Non RWJ Sites: 64

<table>
<thead>
<tr>
<th>Rapid HIV Testing NJ</th>
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</thead>
<tbody>
<tr>
<td>RWJ sites:</td>
</tr>
<tr>
<td>60 Primary</td>
</tr>
<tr>
<td>24 satellites</td>
</tr>
<tr>
<td>13 mobile</td>
</tr>
<tr>
<td>Non RWJ site:</td>
</tr>
<tr>
<td>64 sites including 12 ERS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Testing volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid-Rapid format:</td>
</tr>
<tr>
<td>YTD</td>
</tr>
<tr>
<td>From Inception</td>
</tr>
</tbody>
</table>
## Sites, laboratories and point-of-care locations supervised by the Department of Pathology at RWJ MS

**NJ HIV**
- AtlantiCare Mission Health-Atlantic County Corrections
- Atlantic City Health Department
- Bergen County Health Department
- Burlington County Health Department
- Camden AHEC
- Camden County Health Department
- Catholic Charities-Hudson & Union County Corrections
- Check-Mate
- City of Trenton
- City of Vineland
- Complete Health Care
- Cumberland County Health Department
- Dooley House
- East Orange Health Department
- Eric B. Chandler Health Center
- FamCare
- Hamilton Township STD Clinic
- HiTops Inc.
- Henry J. Austin Health Center
- Horizon Health Center
- Hunterdon County Health Department
- Hyacinth Foundation
- John Brooks Recovery (1HD)
- Jersey Shore Addiction Services (JSAS)
- Kean University
- La Casa Don Pedro
- Liberation In Truth Drop In Center
- Middlesex County Department of Health
- NAP
- Neighborhood Health Centers
- Newark Community Health Centers
- Newark STD Clinic
- NJ CRI

**NJ HIV**
- N. Hudson Community Action Corporation Health Ctrs.
- Oasis Drop In Center
- Ocean County Health Department
- Paterson Health Department
- Proceed
- Saint James Social Services
- Robert Wood Johnson Medical School
- Visiting Nurse Association of Central NJ
- Well of Hope
- William Paterson College

## Hospitals / Laboratories

- State Public Health Laboratories
- Bayshore Community Hospital
- Children’s Specialized Hospital, New Brunswick
- Children’s Specialized Hospital, Mountainside
- Robert Wood Johnson University Hospital
- Robert Wood Johnson University Hospital at Hamilton
- Southern Ocean County Hospital
- University Behavioral Healthcare, Piscataway

## Medical offices POCT

- New Brunswick/Piscataway:
  - Chandler Health Center
  - Clinical Academic Building
  - Clinical Research Center
  - Cancer Institute of New Jersey
  - Medical Education Building
  - Monument Square
  - Icon Laboratories CRC
DMHAS testing numbers

- Currently, rapid testing done at 20 sites
- 13 additional sites in process of being licensed

- Testing volume since start of DMHAS collaboration

<table>
<thead>
<tr>
<th>YEAR</th>
<th>Tests</th>
<th>Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>698</td>
<td>7</td>
</tr>
<tr>
<td>2010</td>
<td>1903</td>
<td>14</td>
</tr>
<tr>
<td>2011</td>
<td>2915</td>
<td>15</td>
</tr>
<tr>
<td>2012</td>
<td>2938</td>
<td>7</td>
</tr>
<tr>
<td>2013 (YTD)</td>
<td>1953</td>
<td>3</td>
</tr>
</tbody>
</table>
HIV EPIDEMIC IN THE US
### CDC estimates

- 1.2 million people (US) are living with HIV
- One in five (20%) are unaware of their infection
- Annual number of new US HIV infections has remained relatively stable for several years
- The new HIV infection rate is substantial →
  - About 50,000 become HIV infected each year
- **Cumulative Reported AIDS cases nationally:**

<table>
<thead>
<tr>
<th>Rank</th>
<th>State</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>New York</td>
<td>174,908</td>
</tr>
<tr>
<td>2</td>
<td>California</td>
<td>142,254</td>
</tr>
<tr>
<td>3</td>
<td>Florida</td>
<td>104,084</td>
</tr>
<tr>
<td>4</td>
<td>Texas</td>
<td>69,735</td>
</tr>
<tr>
<td>5</td>
<td>New Jersey</td>
<td>48,750</td>
</tr>
<tr>
<td>6</td>
<td>Illinois</td>
<td>33,620</td>
</tr>
<tr>
<td>7</td>
<td>Pennsylvania</td>
<td>33,417</td>
</tr>
<tr>
<td>8</td>
<td>Georgia</td>
<td>31,734</td>
</tr>
<tr>
<td>9</td>
<td>Maryland</td>
<td>30,252</td>
</tr>
<tr>
<td>10</td>
<td>Puerto Rico</td>
<td>29,511</td>
</tr>
</tbody>
</table>
New Jersey

New Jersey is a high prevalence state

- 5th in the US in cumulative reported AIDS cases,
- 3rd in cumulative reported pediatric AIDS cases,
- 1st in the proportion of women with AIDS among its cumulative reported AIDS cases.

Statewide Prevalence of Persons Living with HIV/AIDS – 2010

- Persons Living with HIV/AIDS - 36,648 Total
- Population, Estimate 7/1/10 - 8,799,593
- Prevalence Rate/100,000 pop - 416.5
Distribution of Testing Locations Tracks Prevalence

<table>
<thead>
<tr>
<th>LEGEND</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid Testing PROGRAM</td>
<td>⏰</td>
</tr>
<tr>
<td>COMMUNITY BASED ORG. (CBO)</td>
<td>⋄</td>
</tr>
<tr>
<td>MEDICAL CTR. ER</td>
<td>★</td>
</tr>
<tr>
<td>MOBILE VAN</td>
<td>★☆</td>
</tr>
<tr>
<td>PRISONS</td>
<td>▲</td>
</tr>
</tbody>
</table>
HIV AND IVDU
HIV cases among IVDU

- Historically (1995-2000), up to 41% of HIV cases in New Jersey were among IVDU.
- In the past 2-3 years only 8% of reported HIV cases were from IVDU.
Diagnoses of HIV Infection among Adults and Adolescents, by Transmission Category, 2006–2009—40 States and 5 U.S. Dependent Areas

- Male-to-male sexual contact
- Heterosexual contact
- Injection drug use (IDU)
- Male-to-male sexual contact and IDU
- Other

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing risk-factor information, but not for incomplete reporting.

*a Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.

*b Includes hemophilia, blood transfusion, and risk factor not reported or not identified.
New York City IVDU study

- 1990s >30% seropositivity
- 2000s 5-6% seropositivity
- Most cases are old
- New cases < 1% per year
- incidence parallels Herpes Virus infection
- incidence does not parallel Hep C Virus infection

• IVDU population engages in high-risk sexual activity
Importance of early detection

• Early treatment may delay clinical disease
• Treatment prolongs survival-HAART
• ½ of transmission is from someone infected within the prior 6 months
• Risk reduction counseling does work
• Treatment reduces perinatal transmission
• High risk behaviors put others at risk
• High risk behaviors include high risk sexual behaviors
• Evidence from HIV Prevention that much of the transmission among drug addicts is of a sexual nature (NY)
AHI – Acute HIV Infection

- 70-80% symptomatic, 3-12 weeks after exposure
- Surge in viral RNA copies to >1 million
  - Recently we had one 10 million copies!!
- CD4 count drop to 300-400 w/ rebound
- Recovery in 7-14 days
- Because individuals with AHI are highly infectious, have engaged in high risk behaviors, and are often unaware of their status, they contribute substantially to the spread of HIV.
- Although AHI is short (typically 3-4 weeks), studies have consistently shown that 40-50% of new HIV transmissions are caused by onward transmission from individuals within 6 months of AHI.

SYMPTOMS - ACUTE HIV INFECTION
- Rash &/or fever(s), possibly in combination with:
  - Malaise
  - Loss of Appetite
  - Weight loss
  - Sore Throat
  - Mouth Sores
  - Joint Pain
  - Muscle Pain
  - Swollen lymph nodes
  - Diarrhea
  - Fatigue
  - Night sweats
  - Nausea/vomiting
  - Headache
  - Genital Sores
• Routine HIV testing for adolescents and adults in health-care settings
• Test everybody unless specifically denied
• Screen for HIV regardless of prevalence (as effective in very low prevalence as in high prevalence areas).
• **High-risk individuals at least annually, recommended every 6 months**
• **Drug users are by definition high-risk**
  – Addiction treatment centers
  – Methadone programs
  – Needle exchange programs
  – …strange advantage – patients keep returning to the center, so counseling, linkage to care or additional tests can be performed
HIV Testing Recommendations for Substance Abuse Treatment Providers

• **Recommend OPT-OUT testing to your clients, if possible**
  - More effective strategy than risk-based testing only

• **Test EVERYONE at your agency, unless specifically denied**
  - Request information on why client denies testing and document it

• **Drug users are by definition HIGH-RISK**
  - High-risk individuals should be tested every six (6) months
Overview of HIV Testing

- 1980s - T-cell assays
- 1985 – HIV Antibody testing
- 1987 – HIV Western Blot criteria
- 1996 – Oral mucosal transudate testing- OraSure
- 2003 – Rapid testing (blood and then oral transudate)
- Current: Rapid 3rd gen assays and laboratory 4th gen assays with available nucleic acid amplification testing (NAAT)
- Current: Rapid 4th gen assays with both antibody and antigen p24 testing (Determine, FDA approved)
- Future: Rapid CD4/CD8 assays and rapid viral load assays
HIV Infection

Symptoms

Antibody by 1st gen EIA

Antibody by Western Blot

Antibody by 3rd gen EIA

Antigen

RNA / NAAT

Acute Infection
Weeks after infection

Silent Infection
5-10 years

AIDS
1-3 years
HIV Tests have come a long way.

Sequence of Assay Reactivity Plasma

Data indicates APTIMA reactivity is ~9-11 days after infection

Rapid Testing

- Currently in New Jersey
  - Rapid HIV tests, several
  - FDA approved
  - CLIA-waived complexity

- OraQuick HIV 1/2 (OraSure Technologies)
- StatPack (Clearview HIV 1/2, Alere)
- Unigold (Trinity Biotech)
- Insti
- Multispot (BioRad) moderate complexity
- Determine, moderate complexity (for now)
Test on site vs. Refer for testing

• Results available during intake session
• Takes probably less time to perform testing than to follow-up and obtain outside HIV results
CONCEPT: “In care” encompasses relationships that vary in consistency and durability and change over time.

TERMS: linkage to care, engagement/retention, and re-engagement in care and re-entry to care - reflect degrees of relationship within the ‘care system’.

SOMETIMES A FOCUS ON DIAGNOSTIC PERFORMANCE MISSES THE FUNDAMENTAL ISSUE: BRINGING THOSE NOT IN CARE INTO CARE AND KEEPING THEM THERE.
Determine® HIV-1/2 Ag/Ab Combo Whole Blood Procedure

(Refer to package inserts for assay procedures) (Refer to the other side for Serum/Plasma procedure)

1. Remove tests
2. Remove cover
3. Add sample

Wait 1 minute

Add 60 µl to sample pad (finger stick or venipuncture)

Note: Removal of the test units should start from the right side of the test card to preserve the lot number which appears on the left side of the cord.

4. Add chase buffer

Wait 20 minutes

Add one drop of chase buffer

5. Read results

- \(+\) p24 Antigen Bar
- \(+\) Antibody Bar
- \(-\) Control Bar
- Invalid
NJ HIV MOBILE COUNSELOR

Person who would travel from a central office location to your sites to perform all activities related to rapid HIV testing

Expectation to increase the number of HIV tests performed

Costs supported by DMHAS through NJHIV and RWJ Medical School
Mobile HIV Counselor/Tester

NJHIV

- Certified HIV counselor by DHSS/DHSTS
- Trained HIV tester by NJHIV
- Trained phlebotomist
- Based in Somerset, NJ licensed facility
  - No need to license individual sites
  - Reports to NJHIV and State DMHAS
  - Compiles statistical data for reporting
- Maintains inventory
- Quality assurance program/ quality control
- Proficiency requirements compliance
- Reporting requirements
- Bioanalytical Laboratory Director - oversees the program and can assist the site with discordant or unexpected results
  - Mobile counselor will collect blood samples if required to resolve discordant testing. No additional personnel required from the site
Study finds first evidence that PrEP can reduce HIV risk among people who inject drugs
*Lancet*, June 12, 2013

- Pre-Exposure Prophylaxis (PrEP)
- reduced the risk of HIV acquisition among people who inject drugs by 49 percent
- “This is a significant step forward for HIV prevention. We now know that PrEP can work for all populations at increased risk for HIV,” said Jonathan Mermin, M.D., director of CDC’s Division of HIV/AIDS Prevention. “Injection drug use accounts for a substantial portion of the HIV epidemic around the world, and we are hopeful that PrEP can play a role in reducing the continued toll of HIV infection in this population.”
- PrEP complements other available tools, including access to new sterile needles and syringes and regular HIV testing

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• CDC recommends that PreExposure Prophylaxis (PrEP) be considered as one of several prevention options for persons at very high risk for HIV acquisition through the injection of illicit drugs

• In all populations, PrEP use
  – is *contraindicated* in persons with unknown or positive HIV status
  – should be targeted to adults at very high risk for HIV acquisition
  – should be delivered as part of a *comprehensive set of prevention services*
  – should be accompanied by *quarterly* monitoring of HIV status, pregnancy status, side effects, medication adherence, and risk behaviors
NJHIV Rapid HIV Testing Program

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- Lisa May
- Karen Williams

**NJ DMHAS**
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- Mollie Greene

Site coordinators and counselors throughout New Jersey