New Dimensions of HIV

DIVISION OF HIV, STD, AND TB SERVICES
ANNUAL HIV COORDINATOR’S CONFERENCE

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Key Questions

1. What strategies will get more people to learn their HIV status?

2. How do we get more infected individuals into care AND encourage treatment earlier?

3. How does improved ART impact efforts to reduce transmission?
Goals this afternoon:

RWJ Program Update:
- Background
- “2011: A year of outcomes”
- “Real World Validation” Project
- New Linkage Strategies:
  - Expedited confirmation/verification (RTR: Rapid To Rapid)
- Category C: New Jersey’s Innovative Project – eRTA
A Change of Focus. Why?

1. 40% of HIV infections occur in the earliest stages of the disease
2. New 4\textsuperscript{th} generation of HIV Tests are entering the US market allowing us identify infected individuals earlier… but how early?
3. \textit{LINKAGE TO CARE} – Underpins prevention & treatment ...
4. Evolving HIV Prevention Strategies – Earlier treatment preserves immune function and improves morbidity… but by how much?
Events from HIV exposure to a reactive result

HIV Exposure

Infectiousness

Assay Reactivity (HIV-RNA/Ab)

Eclipse Phase

"Window" Period

[Time]

With thanks: M. Busch - UCSF
What does AHI have to do with pigeons?

• “AHI is a lot like pigeon eggs… you see thousands of pigeons everywhere, but how often do you actually see a pigeon egg?”

  Mike Jaker, MD – Inf. Dis. – NJMS – Fall, 2009

• … At the start of NAAT testing of pooled negative blood in Newark
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 an individual with 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
Why is this Important?
Transmission is a function of viral load!

HIV RNA in Semen (Log$_{10}$ copies/ml)

Risk of Transmission Male to Female - Blue
Reflects Genital Viral Burden – Yellow
Effect of ART – Theoretical - Red

Acute Infection
Asymptomatic Infection
HIV Progression
AIDS

(1/30 - 1/200)

(1/1000 – 1/10,000)

(1/500 - 1/2000)

(1/100 - 1/1000)

Cohen and Pilcher, JID 191:1391, 2005
Background: Linkage to Care

1. *In Care* Covers A Large Spectrum

2. Missed opportunities – Consequences
   - Additional spread of the infection
   - Additional morbidity for the patient
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.
21% Undiagnosed

31% Not linked / delayed

41% Not retained

19%-29% VL<50 c/mL

Gardner et al. Clin Infect Dis 2011;52; Marks et al. AIDS 2010;24
30 YEARS – IN SEARCH OF ‘EARLY’ ….

EVOLUTION OF HIV DIAGNOSTICS
Early Generation HIV Assays

1987
Vironostika
HIV-1 EIA

1991
Cambridge
HIV-Western blot

1992
Abbott
HIV-1/HIV-2
EIA

1994
Vironostika
Oral fluid
EIA

1985
Abbott
HIV 1 EIA

1987
April, 1987
2nd Gen. Assays
Infect. WP 42 Days

1991
Early 1990’s
3rd Gen. Assays
Infect. WP 20-25 Days

1992
Murex
SUDS

2010
4th Gen. Assay Approved USA
Infect. WP 16 Days

1985
1st Gen. Assays
Infect. WP 56 Days

1989 – PHS introduces Western blot confirmation
HIV ANTIBODY TESTING

- **Historical Driving Force:** Protection of the blood supply
  - First Generation Tests – 1985 – Viral lysate
    - **Problem:** False positives among low risk donors →
    - **Solution:** *Introduction of Western Blot Confirmation* - 1989
  - Second Generation Tests – 1987 - Recombinant proteins and synthetic peptides. Improved specificity
  - Third Generation Tests – Early 1990’s - Sandwich ELISAs use labeled antigen as conjugate. Increased sensitivity
  - Fourth Generation Tests – Antigen and Antibody together.
“2011: A YEAR OF OUTCOMES”
NJ Rapid Testing Algorithm:

- 23 sites/90,000 tested since inception
  1. > 740 HIV + IDENTIFIED
  2. << 1:200 REMOVED FROM CARE!
  3. Linkage to care increased by ~20%

- Presentations from CDC Diagnostics → AIDS 2011 (Rome)
- Two publications on RTA (2011):
  - Martin, Salaru, Paul and Cadoff: “Use of a rapid HIV testing algorithm to improve linkage to care” JCV 52S(2011) S11-S15
  - Stevinson, Martin, Marcella and Paul: “Cost effectiveness analysis of the NJ rapid testing algorithm for HIV testing in publically funded testing sites”, JCV 52S(2011) S29-S33
ORTHOGONAL

NJ RAPID TESTING ALGORITHM

Perform 1st Rapid: Oraquick OR StatPak

First rapid HIV +

PRELIMINARY POSITIVE

PERFORM 2nd Rapid – Trinity Unigold

2nd rapid HIV +

HIV Verified – Refer to Care IMMEDIATELY

GOAL: 20 MIN VERIFIED RESULT SAME DAY REFERRAL

2nd rapid HIV -

GOAL: 96 HR. DISCORDANT RESOLUTION

DISCORDANT PROCESS

Notify NJ HIV Clinicians for follow-up
White top tubes picked up -> Reference Lab

Collect Blood for HIV-1 Western blot (NJ PHEL)
White top tube for possible NAAT: spin/ freeze

NEGATIVE for HIV Antibodies

Negative for HIV Antibodies

Collect Blood for HIV-1 Western blot (NJ PHEL)
White top tube for possible NAAT: spin/ freeze

NOTIFY NJ HIV Techs pickup process and follow-up

White top tubes picked up -> Reference Lab

GOAL: 20 MIN VERIFIED RESULT SAME DAY REFERRAL

NOTIFY NJ HIV Techs pickup process and follow-up
**NJ RTA SUMMARY - 2011**

**Tested by RTA**

- **SINCE INCEPTION (DECEMBER, 2009):**
  - 7.7% Refusing Western blot
  - 1.8% Refusing Unigold Verification
  - 4.1% Prelim Positive Results not Verified by Unigold
  - 74.0% UG Verified - Connected to Care on Same Day

**Cumulative HIV +**

- **85,666** SINCE INCEPTION (DECEMBER, 2009)
- **74.0%** UG Verified - Connected to Care on Same Day
Staging an HIV Infection

**Evolving Assay Reactivity for:**

- **HIV RNA**
- **p24 Ag**
- **HIV-EIA**
- **HIV-WB**

**Exposure**


**WP** – From sufficient viremia to infect others to seroconversion (Infectious Window Period)

*With thanks: M. Busch - UCSF*
Holding on to the concept of “CONFIRMATION”

RAPID TEST ALGORITHMS AND “PRESUMPTIVE DIAGNOSIS”
Unanticipated Consequence - W blot

- People refuse confirmatory tests
  - In NJ, 7.1% of positives could not be confirmed because specimens are not collected
- Many don’t return to get their final results
  - New Jersey: 25 – 30% fail to return for a second testing-related visit.
  - Los Angeles: 35-40% fail to return
  - Other urban environments – similar story sometimes even worse
- Bottom line:
  - ONLY ~ 70% actually get their confirmed + result!!
- Impact → Linkage to Care is →
  - Delayed – Sometimes for years!
## Role of 2\textsuperscript{nd} Rapid as a Confirmatory Result

<table>
<thead>
<tr>
<th>WB Results</th>
<th>1st Rapid Positive</th>
<th>2nd Rapid Positive</th>
<th>2nd Rapid Negative</th>
<th>Notes: Percentages calculated excluding those who refused WB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total WB results</td>
<td>197</td>
<td>186</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Pct WB POS</td>
<td>95.4%</td>
<td>99.5%</td>
<td>27.3%</td>
<td></td>
</tr>
<tr>
<td>Pct WB Ind</td>
<td>0.0%</td>
<td>0.0%</td>
<td>9.1%</td>
<td></td>
</tr>
<tr>
<td>Pct WB Neg</td>
<td>4.1%</td>
<td>0.5%</td>
<td>80.0%</td>
<td></td>
</tr>
<tr>
<td>Pct Refused WB</td>
<td>7.0%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Patient’s HIV Rapid Result

- Preliminary Positive Result
- HIV antibody results confirmed by another technology: Western blot, IFA, NAAT or a second, different rapid HIV test!

Holding on to the concept of “CONFIRMATION” by use of a second rapid!
“PRESUMPTIVE DIAGNOSIS”

- When Rapid HIV Tests are used as a part of an RTA, a diagnosis can be made with a CONFIRMATORY Western blot; OR by a second (but different manufacturer’s) rapid test.

- If the diagnosis is made by a second rapid:
  - “Presumptive Diagnosis” - and requires further testing at the treatment site as a part of staging the infection.
TRADITIONAL RAPID SCREENING PROCESS

Visit 1

RAPID HIV TEST
Oragiquick or StatPack

PRELIM POS

NEGATIVE

TESTING COMPLETE

EIA/Western Blot
Drawn → PHEL
For testing

NEGATIVE

HIV POSITIVE

DISCORDANT
PROCESS

White Top
Drawn

NAAT TESTING
EIA PERFORMED
REPEAT WEEK

Visit 2

Discordant
Testing Complete

Patient, Receives Final
Results

POS

Visit 3

Risk Counseling

REFER TO CARE

SCREENING COMPLETE

NEG

SCREENING COMPLETE

FOLLOW-UP

RTA SCREENING PROCESS → PRESumptive HIV DIAGNOSIS

Visit 1

RAPID HIV TEST 1
Oragiquick or StatPack

PRELIM POS

NEGATIVE

TESTING COMPLETE

NEGATIVE

RAPID HIV TEST 2
UnGsi

PRESumptive POSITIVE

DISCORDANT
PROCESS

White Top
Drawn

NAAT TESTING
EIA PERFORMED
VSWLOT
As Needed

Visit 2

Discordant
Testing Complete

Patient, Receives Final
Result

POS

Visit 2

Risk Counseling

REFER TO CARE

SCREENING COMPLETE

NEG

SCREENING COMPLETE

FOLLOW-UP
Are We Picking Up Those MOST INFECTIOUS?

NAAT TESTING OF ANTIBODY NEGATIVE BLOOD
Screening for Acute HIV Infection in Newark, NJ

Eugene Martin1*, Debbie Mohammed2, Gratian Salaru1, Joanne Corbo1, Michael Jaker2, Joan Dragavon4, Robert Coombs4, Sindy Paul3, and Evan Cadoff1

1 UMDNJ – Robert Wood Johnson Medical School, Somerset, NJ 08873
2 UMDNJ – New Jersey Medical School
3 New Jersey State Department of Health and Senior Services, Trenton, NJ
4 University of Washington, Seattle, WA

CDC Project Support - 2009

• Use of rapid HIV in conjunction with pooled NAAT allows assessment of the burden of acute HIV infection (AHI) in a particular locale.

• Clients offered NAAT testing after rapid HIV testing. Of those accepted (~50%), specimens collected shipped to Univ. of Washington where NAAT was performed.

• 8 AHI’s identified in 6785 specimens tested. Approximately 6.9% increase in yield over AB + only
Reminder: 10 - 14 Days Ramp-Up Phase – Rapid Viral Replication

Peak viremia: $10^6$-$10^8$ gEq/mL

Ramp-up viremia
$DT = 21.5$ hrs

HIV RNA (plasma)

HIV p24 Ag

p24 Ag EIA

HIV MP-NAT

HIV ID-NAT

Viral set-point: $10^2$-$10^5$ gEq/mL

1st gen

2nd gen

3rd gen

11

16

22
# NAAT Testing of Antibody Negative Blood: Results Nationwide

<table>
<thead>
<tr>
<th>Program</th>
<th>Dates</th>
<th>Description</th>
<th>Rapid Tested</th>
<th>NAAT Tested</th>
<th>AHI</th>
<th>HIV Ab+</th>
<th>% HIV Ab+</th>
<th>% Inc in Yield</th>
<th>% Yield AHI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maryland</td>
<td>6/06-3/08</td>
<td>HIV Ab neg adults seen at two STD clinics (6/06–3/08); multiple venues 7/07-3/08</td>
<td>58925</td>
<td>7</td>
<td>1709</td>
<td>2.9%</td>
<td>0.41%</td>
<td>0.01%</td>
<td></td>
</tr>
<tr>
<td>North Carolina</td>
<td>11/02-10/03</td>
<td>HIV Ab neg persons in North Carolina seeking HIV testing at 110 publicly funded sites (n = 109,250)</td>
<td>108667</td>
<td>23</td>
<td>583</td>
<td>0.54%</td>
<td>3.95%</td>
<td>0.02%</td>
<td></td>
</tr>
<tr>
<td>Los Angeles</td>
<td>2/04-4/04</td>
<td>HIV Ab neg men seeking HIV testing at three STD clinics (n = 1712)</td>
<td>1698</td>
<td>1</td>
<td>14</td>
<td>0.82%</td>
<td>7.14%</td>
<td>0.06%</td>
<td></td>
</tr>
<tr>
<td>NEWARK, NJ</td>
<td>2/10 to 1/12</td>
<td>HIV Ab neg adults receiving testing and counseling at two high risk urban hospitals in Newark, NJ</td>
<td>12390</td>
<td>6785</td>
<td>116</td>
<td>0.94%</td>
<td>6.90%</td>
<td>0.12%</td>
<td></td>
</tr>
<tr>
<td>Seattle King County</td>
<td>9/03-1/05</td>
<td>HIV Ab neg MSM seeking HIV testing through Seattle-King County (n = 3525)</td>
<td>3439</td>
<td>5</td>
<td>81</td>
<td>2.36%</td>
<td>6.17%</td>
<td>0.15%</td>
<td></td>
</tr>
<tr>
<td>Atlanta</td>
<td>10/02-1/04</td>
<td>2202 adults receiving HIV testing and counseling at three high risk urban sites in Atlanta, Georgia</td>
<td>2136</td>
<td>4</td>
<td>66</td>
<td>3.09%</td>
<td>6.06%</td>
<td>0.19%</td>
<td></td>
</tr>
<tr>
<td>San Francisco</td>
<td>10/03-7/04</td>
<td>HIV Ab neg persons seeking HIV testing at San Francisco Municipal STD clinic (n = 3075)</td>
<td>2722</td>
<td>11</td>
<td>105</td>
<td>3.86%</td>
<td>10.48%</td>
<td>0.40%</td>
<td></td>
</tr>
</tbody>
</table>
Conclusions

• NAAT tells us we’re missing of 6-8% of those infected when we screen for antibodies!

• Those with the highest risk of infecting others are the one’s being missed!!

• The same issues with patient return and process completion occur with NAAT that occur with traditional testing!!

• **Solution:** EIA’s that pickup p24 Ag COULD pickup a substantial proportion of the same population. A POCT device could increase the pickup without losing the ability to link patients to care.
4TH GENERATION TESTS
3.5 → 4th Gen – Point-of-Care Test

### 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**
   - Add sample (50μl) to sample pad (finger stick or venipuncture)
   - Wait 1 minute

4. **Add chase buffer**

5. **Read results**
   - Control Bar
   - p24 Antigen Bar
   - Antibody Bar

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 card.
To Date: FDA Has Approved 2

4TH GEN. LAB BASED ASSAYS
FDA Approval – 4th gen. Lab Based Assays:

1. 18 June 2010 – Abbott Architect HIV Ag/Ab Combo Assay
   - First diagnostic test approved by FDA for use in children as young as 2 years of age, and pregnant women.
   - Specific for the detection of the HIV-1 p24 antigen, as well as antibodies to HIV-1 groups M and O, and as antibodies to HIV-2.

2. 22 July 2011 - GS HIV Combo Ag/Ab EIA, (Bio-Rad Laboratories)
   - Neither test distinguishes between HIV-1 p24 antigen, HIV-1 antibody, or HIV-2 antibody in a sample, but they are sensitive to the presence of p24Ag.
   - “Patients … who identify a specific risk occurring more than 4 weeks previously, should not be made to wait three months (12 weeks) before HIV testing. They should be offered a 4th generation laboratory HIV test and advised that a negative result at 4 weeks post exposure is very reassuring/highly likely to exclude HIV infection. An additional HIV test should be offered to all persons at three months (12 weeks) to definitively exclude HIV infection. Patients at lower risk may opt to wait until three months to avoid the need for HIV testing twice.
Study design

• 9150 samples at four U.S. clinical trial sites, using three kit lots. Unlinked samples were from routine testing, repositories or purchased from vendors.

Results

• GS HIV Combo Ag/Ab EIA detection in samples from individuals in two separate populations with acute HIV infection was 95.2% (20/21) and 86.4% (38/44). Sensitivity was 100% (1603/1603) in known antibody positive [HIV-1 Groups M and O, and HIV-2] samples.

• HIV-1 seroconversion panel detection improved by a range of 0–20 days compared to a 3rd generation HIV test. Specificity was 99.9% (5989/5996) in low risk, 99.9% (959/960) in high risk and 100% (100/100) in pediatric populations.
Proposed Algorithm for HIV Testing with 4th Generation Immunoassays

1. **4th Generation HIV-1/2 Immunoassay**
   - **Positive Result**
   - **Negative Result**

2. **HIV-1/HIV-2 Discriminatory Immunoassay**
   - **HIV-1 Antibody Positive – Initiate Care**
   - **HIV-2 Antibody Positive – Initiate Care**
   - **HIV-1/2 Antibody Negative**
     - **NAAT**
       - **NAAT Positive**
         - **Acute Infection – Initiate Care**
       - **NAAT Negative**
         - **Negative for HIV Infection**
QUESTION: Will Determine Combo Deliver?

- In this study presented at CROI - 2011 which tested rapid negative blood by NAT and the Determine POCT test, Determine missed 8 of 8 individuals with acute infection in Malawi.
All 7 false positive p24 Ag sera were correctly identified by the Determine Combo test as negative.

5/14 of the p24 Ag true positive sera (early seroconversion) were missed by the Determine Combo test and tested negative for both p24 Ag and antibodies.

Even though there is a 64% improvement over a third generation (Ab only) POCT, health care professionals should still be aware that the Determine HIV-1/2 Ag/Ab Combo is not as sensitive as 4th generation Lab-based EIAs in diagnosing primary HIV-1 infections!!
THE ‘REAL WORLD VALIDATION PROJECT’

• Historical:
  ▪ Alere FDA Pre-Market trials: Determine Combo in low prevalence populations - < 1%
    • Neighborhood Health Center FQHC – Plainfield
    • Henry J. Austin Health Center FQHC – Trenton
  ▪ Completed – February. FDA Submission is occurring this month.
Manufacturer’s Sensitivity & Specificity

- A manufacturer indicates in their product insert the sensitivity and specificity of their product from a relatively small population.
- Often these numbers are a bit optimistic

Our Real World Validation provides challenging samples to test these newer technologies
Questions for 4\textsuperscript{th} Gen. Assays

- How well do they pickup AHI?
- Are the issues of contamination associated with the product format?
- Do we have an unusual number of falsely positive tests? What about false negative tests?
- How well will they resolve ‘real world’ discordant specimens?
- Will a Point-of-Care test perform as well as a laboratory-based test?
Anticipated comparisons

• 3rd gen versus 4th gen assays
  ▪ Lab-based: Abbott, Biorad, Siemens,
  ▪ POCT-based: Alere

• How much of an improvement does the 4th gen assay really offer?

• Determine Combo has been called a 3 ½ gen. How well will it behave using real world specimens, we’ve collected and characterized using our RTA plus EIA/Wblot
ADMINISTRATIVE ISSUES
Administrative / Program Logistics

- Inventory Management
  - Need timely submission of monthly statistics

- New Logs
  - PEMS Site Numbers
  - Complete Name of Site, Contact Name & Number
  - Fax Pages as you complete them
  - Send all pages by the 10th of the month
  - Send Completed Forms ASAP - We Have a Report Due to the State
Administrative /Program Logistics

• Preliminary Positive Data Capture
  ▪ Need timely submission of Preliminary Positive Forms
  ▪ Make Sure You Are Using New Form
  ▪ Enter Complete Site Name
  ▪ Enter Counselor Name not Client Name
  ▪ Fax Confirmatory Result If Applicable ASAP
  ▪ Fax Client Notification and Referral To Care Info ASAP
  ▪ Need Completed Forms ASAP-We Have a Report Due to the State
Administrative/Program Logistics

• Travel Packs
  • Follow procedure For Using Travel Packs
  • For Participation in Events Requiring Travel Packs
    • Base # of test devices taken to event on:
      • Expected turn out
      • # of Counselors at event
Using the second rapid to improve patient linkage
New Initiative-Category C

CONFIRMATION AND LINKAGE
Category C: NJ’s Innovative Project

CONCEPT: Using an *enhanced*, sensitive, cost-effective, rapid testing algorithm to screen:

- 59,000 individuals annually for acute and established HIV infection in high prevalence areas; and to
- Link and retain in care at least 85% of people testing positive thereby reducing transmission.

- Expand rapid testing algorithm (RTA) to more sites based on seropositivity rates
- Introduce *eRTA* using a 4th generation test with p24 Ag detection capabilities
- Use navigators to link and retain people in care.
Category C

1. Conversion of 9 additional sites to RTA:
   - Should identify 180 HIV+ (50 more than current approach)

2. Conversion of some existing RTA sites to enhanced RTA sites (30,000 tests/annum)
   - Identify 294 HIV+ plus additional 19 AHI+

3. Sites chosen are from 10 counties with 84% of the statewide HIV+

4. Implementation of PATIENT NAVIGATORS to link/facilitate/encourage effective linkage
Expenses Associated with Rapid-Rapid

- **COSTS OF RAPID-RAPID:**
  - Training
  - Running of controls at each site
  - Proficiency testing for operators
  - Reagent supply for seldom used tests

- **PERFORMANCE BY OPERATORS**
  - Experience Matters….

- **DRIVING FORCE IN SELECTING NEW SITES:**
  - Testing volume and prevalence rate at a site
  - How to maximize the usefulness of the RTA while keeping costs in check
    - Minimize the number of sites running a second rapid and make sure sites running it are experienced.
CONSEQUENCES: License Issues – New Jersey!!

- CLIA waived HIV Testing IS NOT waived in New Jersey!
  - A testing site must be licensed
  - A licensed site is subject to periodic inspection by CLIS
  - Your Bioanalytical Laboratory Director (BLD) MUST approve ANY new testing!!
  - Just because you have been licensed to do 1 rapid HIV test, does not mean that you can add a second
  - The FDA approves tests, not test-combinations; the CDC makes recommendations for test-combinations for HIV
  - Protocols for individual tests and for test combinations must be approved by your Laboratory Director
CONSEQUENCES: License Issues – New Jersey!!

• CLIA waived HIV Testing IS NOT waived in New Jersey!
  
  ▪ If you are a non-RWJ site, we will be happy to assist you, but
  
  ▪ Take home message to RWJ and non-RWJ sites “Communicate with your Laboratory Director”
eRTA - Two Possible Pathways

• If a POCT 4\textsuperscript{th} generation assay is FDA-approved (Determine Combo Assay).
  ▪ Screen by Determine at POC site
  ▪ IF POS:
    • AHI + $\rightarrow$ Confirm by NAAT if p24 Ag only – Immediate Linkage while awaiting results
    • Non-AHI HIV+ $\rightarrow$ Confirm by Trinity UG and link
• Linkage to Care
  • Role of Patient Navigators
A PLAN FOR LOCAL COLLABORATION:

Loretta Dutton MPA, CSW- DHSTS
New Jersey
Successful Linkage to Care Plan
Rapid/Rapid HIV Testing Sites

Both Rapid Tests are Positive

Medical testing begins; assess for ART

Immediate linkage to care

If Refuses ARTAS, Education and Referrals to Prevention, RW-CM, TX, Partner SVS, etc.

If Refuses Immediate Linkage ARTAS trained counselor (1 - 5 Sessions)

HIV Testing Counselor -Linkage to Care:
• Recruit HIV Impact Populations for HIV Counseling and Testing
• Deliver ARTAS Strategy to HIV+ persons who are not yet linked to care
• Partner Services
• Ultimate goal is to link to care – ARTAS ends
• Linkage to Care – Linkage Navigator = engagement, retention, adherence, re-engagement
• F/U on those who test HIV+ and do not return for ARTAS or Care
• Navigator to collaborate with CBO for those lost to care

MOAs must be obtained between Testing Agency and Medical Care Facility

Incentives to be determined
New Jersey
Successful Linkage to Care Plan
Non-Clinical Sites

Successful Linkage to Medical Care (by Tester at Medical Site)

Immediate

Successful Linkage to Care Site for Second Rapid* Test

*Different Rapid must be used to confirm positive

First Rapid test HIV

If Refuses All Services, Referrals given for prevention, CM, TX, Partner SVS, etc.)

Immediate

If Refuses Second Rapid Test, Referred to ARTAS trained Tester – ultimate goal confirmation and linkage (1-5 Sessions)

MOAs must be obtained between CBO and Medical Care Facility

$ = Incentives to be determined

HIV Tester’s Role:
• Recruit HIV Impact Populations for HIV Counseling and Testing – refer to narrative
• Deliver A2 Strategy to persons who have a preliminary HIV+ test
• Partner Services
• Link to medical site for confirmatory testing
• F/U on those who test preliminary HIV+ and do not return for A2
Training

- Motivation Interviewing (MI) – August 1st and 2nd
- ARTAS – August 7, 8 and 9

ARTAS – Anti-Retroviral Treatment and Access to Services
Linkage and Confirmation: An evolving approach

• Concept: Site 1: Screen and identify preliminary positive
  - Accompany screen positive client to a site 2 (preferably the ‘linkage site’) where the second, different rapid can be performed by experienced operators
    - IF POS → client can be enrolled in care with the help of PATIENT NAVIGATORS
    - IF NEG → discharge
    - IF DISCORDANT → CONTACT US Cell: 732 986-3301

• Logic:
  • 99.5% will confirm and you can focus on care
  • 80% of the negative 2nd rapids will be true negatives and won’t occupy physician or nurse time

• Prelim. Pos. forms MUST be completed and returned from the initial testing site!!
CONSEQUENCES: License Issues – New Jersey!!

- Just because you have been licensed to do 2 rapid HIV tests, does not mean that you can skip the first test.
- The FDA approves tests, not test-combinations; the CDC makes recommendations for test-combinations for HIV.
- Protocols for individual tests and for test combinations must be approved by your Laboratory Director.
- Your Laboratory Director must approve use of a second test in an R-to-R agreement.
THE END