RAPID-2-RAPID

EUGENE MARTIN, PH.D.
PROFESSOR OF PATHOLOGY & LABORATORY MEDICINE
UMDNJ - ROBERT WOOD JOHNSON MEDICAL SCHOOL

JOANNE CORBO, MT (ASCP) MBA
HIV PROGRAM MANAGER - NJ HIV

SEPTEMBER 2012
WHERE WE CAME FROM...
WHERE WE ARE...
&
WHERE WE’RE GOING!

**Principle:**
- The use of two (2) different immunoassays employing different HIV antigens to search for HIV antibodies. (Term: Orthogonal Assays)
- Evaluated in trials in NJ from 2004-Present.
- Over 100,000 have been tested in New Jersey using an RTA
- It successfully verifies a true HIV POS > 99.5% of the time!

**Practice:**
- CDC Surveillance issued guidance in November, 2011 permitting the ‘Presumptive Diagnosis’ of individuals positive by rapid screening utilizing 2 different assays.
- The designation of Presumptive Diagnosis means that additional testing CD4, viral load will affirm the diagnosis

**Consequence:**
- Now possible to diagnose, refer and count HIV screened individuals
• **Historical Review:**
• **The NJ strategy to improve outcomes**
  - Strategic Use of Rapid-Rapid Testing
  - Connecting the Screening Process to Verification AND Linkage
Why Use a Rapid Verification Process?

Disposition of Confirmed HIV + Clients

NJ Statewide Data - 2004
- **Problem**
  - Preliminary Positive clients fail to return for results (21.8%)
  - NAP succeeds ONLY 20% of the time in locating these clients
Cumulative Data – NJ Rapid-Rapid Program

<table>
<thead>
<tr>
<th>Year</th>
<th>RTA Testing Volume SINCE INCEPTION</th>
<th>Percent Refuse Western blot</th>
<th>Percent Refuse Unigold Verification</th>
<th>Percent of Prelim Positive Results not Verified by Unigold</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>108,830</td>
<td>6.8%</td>
<td>2.5%</td>
<td>4.4%</td>
</tr>
</tbody>
</table>
One Visit Scenario: Rapid-Rapid

- 74% of ‘verified’ HIV positives are linked to care on the same day

15% More than traditional rapid testing!!
OPPORTUNITIES – Where screening occurs matters!

- 62 RTA positives identified in the first six months of RTA program: 76.7% - same day appointments for treatment
- WHERE MATTERS:
  - Medical Facilities were best able to achieve and retain linkage
    - Academic medical centers (1) and FQHCs (4) identified 33 HIV positive individuals using an RTA
      - 82% received immediate appt
      - 97% were in care at six months, 1 lost to care
  - Health Departments (2) and CBOs identified 29 infections
    - 16 (55%) appts. were made on same day
    - 19 (47%) were in care at 6 months, 10 (34.4%) lost to care
  - Efforts to better connect screened, infected clients to providers is needed in non-traditional healthcare settings
Continuum of Engagement in HIV Care in the US

CDC. MMWR. 2011;60:1618-23
Significant Numbers with HIV in the US Are Not on Antiretroviral Therapy

~50% of HIV+ persons are on ART


2. Synovate Healthcare U.S. HIV Monitor Q2 2010
Washington, DC has an estimated HIV seroprevalence of 3%.

2006 Dept of Health expanded HIV testing to be included in routine care with improved clinical linkages.

From 2004 to 2006, HIV tests increased from 19,000 to 73,000.

Among newly diagnosed, median CD4 count increased 57%.

Quality Assurance is expensive.

1. The majority of specimens run for a second rapid in an RTA are run to comply with QA requirements
   - Quality Control
   - Proficiency Testing
   - Competency Assessment

2. Operators who use specimen types infrequently can be easily confused - particularly when they are under stress

3. CONCLUSION: It doesn’t make sense to make every site an RTA site
CONCEPT:
- Solve the linkage problem - by connecting the second step in screening (verification) with the first step in connecting the HIV+ client into care!

- Unfortunately... the “Devil is clearly in the details”
  - Too many models possible, so we needed to settle on a minimum number of configurations
    - Reporting issues – who gets credit?! –
      - Testing – the initial screening site
    - How to structure the process? - Use of Collaboratives – MOA

- Ambitious Goal:
  - 85% of screen positive clients are linked to care In 1-2 business days (Category C goal)
DEAR COLLEAGUES:

THANK YOU FOR JOINING US ON LAST WEEK’S HICSB QUARTERLY CALL. ATTACHED IS THE LETTER DISCUSSED DURING THE CALL REGARDING THE NEW HIV TESTING ALGORITHMS GUIDANCE ISSUED BY THE CLINICAL LABORATORY AND STANDARDS INSTITUTE (CLSI). THE LETTER AFFIRMS THAT THESE NEW ALGORITHMS MEET THE CURRENT HIV CASE DEFINITION AND PROVIDES INSTRUCTIONS FOR RECORDING A CASE DIAGNOSED USING THE NEW ALGORITHMS IN EHARS.

WE RECOGNIZE THESE NEW ALGORITHMS REPRESENT A SHIFT IN SURVEILLANCE PRACTICES. TO HELP STATES ADDRESS THESE CHANGES, HICSB IS CREATING A LIST OF FREQUENTLY ASKED QUESTIONS (FAQS). PLEASE SEND YOUR QUESTIONS TO ADRIA PROSSER AT AHP8@CDC.GOV AND CC YOUR SURVEILLANCE PROGRAM’S CDC EPIDEMIOLOGY CONSULTANT.

BEST REGARDS,

H IRENE HALL, PHD, FACE
Rapid-Rapid – 2012

Monthly Test Volume 2012

<table>
<thead>
<tr>
<th>Month</th>
<th>Total Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-16</td>
<td>1000</td>
</tr>
<tr>
<td>Mar-16</td>
<td>1500</td>
</tr>
<tr>
<td>Apr-16</td>
<td>2000</td>
</tr>
<tr>
<td>May-16</td>
<td>2500</td>
</tr>
<tr>
<td>Jun-16</td>
<td>3000</td>
</tr>
<tr>
<td>Jul-16</td>
<td>3500</td>
</tr>
<tr>
<td>Aug-16</td>
<td>4000</td>
</tr>
<tr>
<td>Sep-16</td>
<td>4500</td>
</tr>
<tr>
<td>Oct-16</td>
<td>4000</td>
</tr>
<tr>
<td>Nov-16</td>
<td>3500</td>
</tr>
<tr>
<td>Dec-16</td>
<td>3000</td>
</tr>
<tr>
<td>Jan-17</td>
<td>2500</td>
</tr>
</tbody>
</table>

YTD Tested Volume

- 23,164

- 4% Percent Refusing a second rapid
- 4.7% Percent of Prelim Positive Results not Verified by the second rapid
- 77.3% Percent UG Verified Connected to Care on Same Day
How Will the Laboratory Piece Work?

1. Until NJ HIV Procedures are changed, in writing, PLEASE DO NOT modify your existing laboratory processes!

2. The laboratory process is an RWJMS responsibility. We have statutory and regulatory responsibilities and we would ask that you direct ANY question about the handling of a laboratory matters to our attention.

3. A number of clinical sites (e.g. University Hospital, JSMC, AtlanticCare MC) have non-RWJMS Bioanalytical Laboratory Directors. Their BLD’s alone can decide to implement Rapid-Rapid Testing. We would be pleased to assist them, and will provide all procedures and validation data, but it is entirely their decision.

4. If you are a site that collects blood and sends it to PHEL for Western blot testing, PLEASE DO NOT change that process until you have a written procedure AND have been instructed to do so by Joanne or your NJ HIV liason!

5. The Collaborative Process derives from DHSTS –the issue of Patient Navigators, their responsibilities, proposed ‘Memoranda of Agreement’, and how the navigation process works is directed by DHSTS.
DRAFT PROCEDURE

FEEDBACK WELCOME!

THIS PROCEDURE HAS NOT YET BEEN APPROVED FOR USE!
Rapid –2- Rapid

R2R

SCREENING ➔ CARE
TESTING ➔ TREATMENT
Category 1

RTA SCREENING SITE IS THE TREATMENT SITE
Category 2

Non-Treatment Site with RTA
Treatment Site provides TREATMENT ONLY
Category 3

Rapid Screening Site will screen
Treatment Site will perform second rapid AND engage in care
(Example: AtlanticCare)
ALL CATEGORIES:

1. FILL OUT NJ HIV POSITIVE TRACKING FORM
   • The tracking form accompanies the Client to the Treatment Site
   • Fax HIV Positive Tracking Form to NJ HIV 732-235-9012

2. FILL OUT RAPID HIV TEST REPORT
   • The Rapid HIV Test Report accompanies Client to Treatment Site

3. REPORT ALL POSITIVE CASES TO SURVEILLANCE
   • Send Printed Copy of Eval Web Form
   • On Back of the Form you must Include:
     • Client name, ADDRESS & telephone#
CATEGORY THREE (ONLY):

1. **RESULT FROM 2\textsuperscript{ND} TEST DONE AT 2\textsuperscript{ND} SITE**
   - 2\textsuperscript{ND} site Enters Onto the NJ HIV Positive Tracking Form that the client brings with him
   - Enter Second Site Info
   - Send NJ HIV Positive Tracking Form Back to the first site

2. **1\textsuperscript{ST} SITE ENTERS 2\textsuperscript{ND} SITE INFO INTO EVAL WEB**
   - Enter 2nd Test Site ID Number in Local Field 1 in Eval Web
   - Enter 2\textsuperscript{nd} Test Site Name Local Field 2 in Eval Web
Thanks for your attention!

THE END