Data-Driven Approaches to Ensuring High Quality Recent Infection Testing

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ICAP New York
<table>
<thead>
<tr>
<th>Webinar Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recency Specimen Panel Preparation</td>
<td>August 2018</td>
</tr>
<tr>
<td>Country TRACE Updates and Introduction to the TRACE HQ Support Team</td>
<td>December 2018</td>
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<tr>
<td>Health Information Systems Solutions for TRACE Data Capture and Data Management</td>
<td>February 2019</td>
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<td>Recency in COP 2019 for Agency and ECT Leads</td>
<td>February 2019</td>
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<tr>
<td>Introducing the TRACE e-Learning Hub</td>
<td>May 2019</td>
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<tr>
<td>TRACE Recency Dashboard</td>
<td>June 2019</td>
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<tr>
<td>TRACE Continuous Quality Improvement</td>
<td>August 2019</td>
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<tr>
<td>Data-Driven Approaches to Ensuring High Quality Recent Infection Testing</td>
<td>December 2019</td>
</tr>
<tr>
<td>TRACE Data Interpretation, Use &amp; Recency Response</td>
<td>Early 2020</td>
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What is **Quality**?

- Accurate test results within a reasonable time period based on:
  - Availability of test kits & supplies
  - Condition of test kits
  - Collection and handling of specimens (type & amount)
  - Standard test procedures followed
  - Interpretation and reporting of results
## Pillars of High Quality Recency Testing

<table>
<thead>
<tr>
<th>Lab Training</th>
<th>Site Activation &amp; Monitoring</th>
<th>QC &amp; Proficiency Testing (PT)</th>
<th>Routine Data Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>• ILB Model</td>
<td>• Checklist to ensure site readiness</td>
<td>• Monthly QC</td>
<td>• Data completeness</td>
</tr>
<tr>
<td>• Hands-on using training panels (TPs)</td>
<td>• QC check before starting client testing</td>
<td>• Biannual PT</td>
<td>• QC results in aggregate</td>
</tr>
<tr>
<td>• Document training results</td>
<td>• Regular site monitoring</td>
<td>• Record &amp; review data</td>
<td>• Verification Line results</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Corrective actions as part of CQI</td>
<td>• Data plausibility</td>
</tr>
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</tbody>
</table>

**Notes:**
- CQI: Continuous Quality Improvement
- PT: Proficiency Testing
Lab Training

High Quality & Thorough Training Plan
Multi-Tiered Training Approach to Achieve Quality

**Training of Trainers**
- Trainers from HQ team & participants are lab technicians or leads
- Lectures and hands-on session is led by ILB and IP trainers
- Ratio of 1 facilitator per 6 trainees is ideal
- Prepare in-country QC and TP panels

**Customization of Training Materials**

**Cascade Training of HTS staff**
- Trainers are master trainers certified during TOT
- Participants are site level testers
- Each facilitator supervises no more than 6 trainees for hands-on
RTRI Training Components: TOT and Step-Down

• Comprehensive training package
  • Activity-based curriculum
  • Covers keys areas of quality assurance of RTRI

• Hands on practicals
  • Training (3 QC specimens) and 10 TP (5 + 5) specimens
  • Mixture of known LT, recent and negative specimens

• Certification of testers – competency assessment
  • Written (80% min), Practical (100%)

All lab training data must be captured, documented and shared with ILB.
## Training Panel Data Capture Form: Example

<table>
<thead>
<tr>
<th>Panel ID</th>
<th>Expected Results</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
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<tbody>
<tr>
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<td>LT/Pos</td>
<td>LT/Pos</td>
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<td>QC Recent</td>
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<td>Recent/Pos</td>
<td>Recent/Pos</td>
<td>Recent/Pos</td>
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<td>Recent/Pos</td>
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<td>QC Negative</td>
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<tr>
<td><strong>TOTAL Recent/Pos</strong></td>
<td>6</td>
<td>5</td>
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<td>5</td>
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<td>5</td>
<td>7</td>
<td>5</td>
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<td>5</td>
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<tr>
<td><strong>TOTAL LT/Pos</strong></td>
<td>9</td>
<td>10</td>
<td>10</td>
<td>10</td>
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<td>10</td>
<td>10</td>
<td>8</td>
<td>10</td>
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<tr>
<td><strong>TOTAL Neg</strong></td>
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</tbody>
</table>
Site Activation & Monitoring
Activation Checklist to Ensure Site Readiness for Recency Testing

• Prior to site activation
  • Ensure all players are represented
  • Inform site in advance, review checklist

• During site activation
  • Work with staff and site to define testing points for recency
  • Run QC before running 1st patient specimen to ensure kits are working and staff are proficient

• Any corrective action identified during activation and requiring follow-up should be resolved as soon as possible
## Eswatini Activation Checklist

### SOPS, Job Aids

- Adequate Supplies

### QC & Knowledge Check

<table>
<thead>
<tr>
<th></th>
<th>Knowledge Check</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>COMMENTS</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Were 3 QC panels completed for each tester and documented?</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</table>
Monitoring Checklists

Lesotho Example: Lab Component

- **Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) checklist** which includes recency
- Adopted by WHO and provides guidance on QA practices for sites offering HIV rapid and recency testing
- Covers the following areas:
  - Personnel training and certification
  - Physical Infrastructure & Safety
  - Pre-testing, Test, and Post-Test Phase
  - External Quality Assessment
  - HIV-1 Recent Infection Surveillance
Site Monitoring Findings So Far...

- Kits not stored in temperature controlled environment
- HIV RT job Aides not up to date – reflects old read time, incorrect volume for Determine; job Aides not on sight
- Timers not present or are shared between sites, limiting work flow
- Inconsistent QC testing and review
- Inappropriate use of QC, TP specimens
- Documentation disorganized, inconsistent or incomplete
- Lack of routine review of registers for completeness and accuracy
QC & Proficiency Testing
Appropriate Use of QC and TPs

**QC Panels**
- At site, once a month to verify performance of RTRI kits
- When storage temperature exceeds the manufacturer’s recommended storage conditions
- On each new lot of HIV-1 RTRI kits (NRL only)
- On each new shipment of HIV-1 RTRI kits (NRL only)

**Training Panels**
- Use the full TP (10 samples) during RTRI training
Preparing QC, TP and PT Panels

• Critical for ongoing quality control, training and proficiency

• Specimen selection for each panel is key
  • Use bulk volume, well characterised specimens
  • QC & PT specimens should be clear cut: neg, recent and LT
  • TP specimens could include specimens that are ambiguous for teaching

• QC and TP should be prepared centrally or by regional/districts labs

• PT to be prepared centrally to start

• Do not use them interchangeably!
Example on Generating Reference Results

The final interpretation (best of 3 results) will serve as the reference reading for future comparisons:

<table>
<thead>
<tr>
<th>Recency QC and Training Panel Preparation: Reference Results Form</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RTRI Results (from at least three independent runs)</strong></td>
</tr>
<tr>
<td><strong>Kit Name &amp; Lot #</strong>:</td>
</tr>
<tr>
<td><strong>Kit Expiration Date</strong>:</td>
</tr>
<tr>
<td><strong>Date Tested</strong>:</td>
</tr>
<tr>
<td><strong>Blood Bank Sample ID</strong></td>
</tr>
<tr>
<td><strong>Confirmed HIV Status</strong></td>
</tr>
<tr>
<td><strong>RTRI Interpretation (Long Term, Recent, Negative)</strong></td>
</tr>
<tr>
<td><strong>Visual 1</strong></td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>QC Long Term</td>
</tr>
<tr>
<td>QC Recent</td>
</tr>
<tr>
<td>QC Negative</td>
</tr>
<tr>
<td>TP-1</td>
</tr>
<tr>
<td>TP-2</td>
</tr>
<tr>
<td>TP-3</td>
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<td>TP-4</td>
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<td>TP-5</td>
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</tr>
<tr>
<td>TP-9</td>
</tr>
<tr>
<td>TP-10</td>
</tr>
</tbody>
</table>
Collecting QC Results

• QC results can be collected on a dedicated QC form and then electronically entered into a database or directly entered electronically onto a tablet

• Results can then be shown on the recency dashboard for review
Usage of Dried Tube Specimens (DTS) QC and Training Panel

• Similar to use of plasma QC TP and PT
• However, DTS needs to be rehydrated the day before (PBST)
  • Issues reported of failing QC, related to same day rehydration with poor elution
• DTS has few disadvantages when compared to plasma
  • Uses more tubes
  • More time required during TOT for DTS prep; mini DTS prep
    • Ensures samples selected for the QC panel preparation are correct
• DTS has some few advantages over plasma
  • Requires less volume of specimens for preparation
  • Easy transportation; no need of cool storage during transportation
  • Recommend testing within 1-2 days of receipt
Proficiency Testing (PT)

• Guidance document on starting a PT program coming soon
• Integration into routine HIV RT program if possible
• Resolve current challenges with HIV rapid testing PT program before incorporating recency
  • Characterize specimens that can be used for both
  • Use appropriate forms for each site/tester
  • Add summary results to dashboard once implemented
• Data collection either electronic or paper-based but merged into recency dashboard
• Performed by all testers, once every six months
  • Any failed PT requires immediate follow-up
Routine Data Review

Recency Dashboard
Routine Data Review: Recency Testing Quality

Review country recency data on dashboard for:

1) Data completeness
2) QC testing for site participation, testing frequency, data completion and results
3) Performance of diagnostic verification line
4) Trends of recent infections and plausibility of results

*Simulated data

https://trace-recency.org/example-dashboard/
Data Completion

Example Recency Dashboard

• Having complete data set important for analysis and impact (e.g. age, gender...)

• Incomplete data can lead to bias

• Are there any gaps? Why?

• Need additional training of testers? Counselors?

• Making process more efficient and complete
Integrating Data from Other Sources for Data Completeness

• Total Newly Diagnosed HIV+ is needed to determine recency testing uptake but is collected separately for program monitoring

• Provides information on:
  • Testing coverage
  • Testing population biases
  • Improvements needed in counseling services
  • # of repeat testers
### % RTRI Tested of Newly HIV +, by Month, August 2019 to present

<table>
<thead>
<tr>
<th>Period</th>
<th>August 2019</th>
<th>September 2019</th>
<th>October 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Newly Dx HIV+ (National Database)</td>
<td>RTRI Tested</td>
<td>% RTRI Done</td>
</tr>
<tr>
<td>13</td>
<td>11</td>
<td>84.6</td>
<td></td>
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<tr>
<td>2</td>
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<td>3</td>
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</table>
VL Monitoring Report in Power BI

- Track VL testing progress through entire testing cascade
- Requires data inputs from each step
- Tracks monthly TATs
- Table tracks specimen IDs, key dates and # days overdue
Dashboard QC Monitoring

• Monitor QC results for:
  • Kit lot performance
  • Tester performance
  • QC lot performance

• Expected QC Results : 100%

• If any failure, investigate immediately using CQI flowchart
1137 QC Panels Performed in 4 Countries as of Sept 2019

<table>
<thead>
<tr>
<th>Country</th>
<th>QC Passed</th>
<th>Recent</th>
<th>Long-Term</th>
<th>Negative</th>
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<tbody>
<tr>
<td>Country A</td>
<td>98%</td>
<td>100%</td>
<td>100%</td>
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</tr>
<tr>
<td>Country B</td>
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</tr>
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<td>Country C</td>
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<td>Country D</td>
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<td>100%</td>
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</tbody>
</table>
QC Monitoring Example

• One site reporting invalid QC
• Further inquiry found tester reading strips upside down!
• 2 of 3 QC specimens will be invalid
• Need to review client results from same locations for invalids/errors
• More training and follow-up urgently needed
CQL: Investigation of Failed QC at Testing Site

For Site/Lab Level & All Testers

*QC Pass indicates all 3 specimens QC specimens have the correct classification on the recency assay.

#QC Fail indicates any QC specimen w/ incorrect classification on the recency assay.

Perform Monthly QC Panel at Each HTS Site using Unexpired Test Kits

QC FAIL*

Is it a Tester Issue?
Repeat testing with another Tester

YES
Retrain Staff on Recency Testing Procedures Immediately

NO

Is the QC Panel Bad?
Repeat testing with Newly Thawed QC Panel if Available. If not, skip step.

YES
Discard Old QC Panel(s) and Ensure Freeze/Thaw Cycles are limited and QC Panels are Stored Properly

NO

Is the Test Kit Bad?
Repeat testing with a Different Test Kit Lot if Available. If not, skip step.

YES
Quarantine Bad Test Kit and Replace with New Test Kit

NO

Stop Testing.
Stop Recency Testing & Report to Lab/Study Manager/ILB ASAP
Performance of Diagnostic Verification Line

• Field verification of test performance using program data
• Implications about potential use of the test as part of algorithm
• Determines sensitivity of RTRI to diagnose/confirm HIV infection compared to national algorithm
• % of persons tested by RTRI with positive verification line
  • 100%?
  • Less than 100%?
  • If any “false negative”, further testing feasible?
Performance of Diagnostic Verification Line: Example TRACE Country

1028 RTRI Tested
2 RTRI Negative
0 RTRI Invalid
0 % Invalid
0 % Negative
99.8% Assay Sensitivity
RTRI Diagnostic Verification Line Sensitivity

Country A (n=2759): 100%
Country B (n=1482): 100%
Country C (n=298): 99%
Country D (n=628): 99%
Data Plausibility: Recency Results By Sex

- Which of these makes sense?
- What do we know about the country’s epidemic?
- Other data to triangulate, such as PHIA?
Are These Results Plausible?

**Key Question:** Does this make sense?
TRACE Country Data: % Recency Higher in Younger Age Groups

Does this make sense?
Many Ways to Look at Data for Plausibility

- Look at trends by month, by facility type and by name, by country map distribution, etc.
- Dashboard allows you to look at recency trends in many ways to assess plausibility and to further characterize the epidemic for a public health response.
Role of VL (RTRI vs RITA) to Improve PPV of Recency: Quality of Final Data

• **VL is added to minimize misclassification**
  • Previously diagnosed individuals (repeat testers)
  • Elite controllers
  • Individuals on ART

• **Analyze data with and without VL to assess importance of VL**
  • Recency distribution similar or different by sex, age, risk groups, geolocation?
  • Can shed light on contribution of VL
  • If picture does not differ – VL may not be needed
  • If RITA-recent distribution significantly different from RTRI-recent, then VL will remain important
Role of VL: RTRI vs RITA By Sex & Age

- Look at the changes in age distribution between RTRI and RITA results
- *Does this make sense?*
% RTRI Recent vs. RITA Recent in 2 TRACE Countries

Country A (n=155/213 w VL)

- % RTRI Recent: 14
- Reclassified: 41/155 (26%)

Country B (n=328/347 w VL)

- % RTRI Recent: 13
- Reclassified: 105/328 (32%)
Take Home Messages: Quality Counts

• Quality encompasses multiple levels from test kit quality to aggregate data review and recency data needs to be reviewed in real-time

• ILB lab training model should be used for all TOT and step-down trainings with no shortcuts. You will pay for it later!

• Site activation and regular site monitoring is critical to ensure accurate client recency results

• Regular QC testing is critical to ongoing quality monitoring and PT testing should be implemented to ensure ongoing tester competency

• Dashboard should be used for routine data review of QC results, data completeness, data plausibility and recency trends

• Collect data for all these activities and establish routine data review process with investigators
Thank You

Questions?