HIV Single Stage Testing: Integration and Maximization of Resources by Reducing Time between HIV Diagnosis and Treatment

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Objectives

- To evaluate the feasibility of conducting HIV clinical management baseline testing in addition to supplemental diagnostics on newly diagnosed individuals within the traditional pre-posttest public health visits.

- To assess the percentage of clients who return for posttest (1\textsuperscript{st} appt) and the medical provider appointment (2\textsuperscript{nd} appt) in our study population.

\textit{NOTE: This study was performed prior to the FBPHL conversion to the new HIV Diagnostic Algorithm. HIV-1 Western Blot was the primary supplemental assay.}
Rationale for Single Stage Testing

- Provides a timely baseline CD4/CD8 and HIV-1 viral load for individual clinical management and HIV surveillance purposes.

- Expedites engagement into HIV care.

- Potential to see a medical provider within 14 days of the initial HIV preliminary positive test.

- Potential to commence ART treatment in less than 30 days after the initial HIV preliminary positive test if warranted.
Methods

• Participating study sites (3) located in high-risk, high morbidity areas submitted EDTA plasma and EDTA whole blood from individuals with single or dual reactive POC rapid results.

• Individuals were informed at pretest of their preliminary positive HIV-1 results and that the confirmatory results would be available within 2 weeks.

• Based on the individual’s statement of NO previous HIV diagnosis and the POC rapid reactive result, blood specimens were processed via the Single Stage Algorithm.

• Baseline CD4 (BD FACSCount) and HIV-1 viral load (Siemens Versant HIV-1 RNA) tests were performed concurrently with a 3rd generation HIV-1/2 IA and HIV-1 Western Blot on 105 individuals, provided the preliminary positive rapid result was confirmed and specimen collection criteria was followed.
Single Staging Algorithm

POC blood rapid Prelim. Pos

POC oral/blood dual rapid Prelim. Pos

At POC draw EDTA & PPT*. If previous positive and already engaged in care draw SST.

Use overnight delivery

At Laboratory, use available databases to determine whether a new case or past positive w/ or w/o proof of care entry

New case or past positive not in care, ART naive

EDTA whole blood

Recommended: POC initiate Ryan White eligibility process to be completed at post-test counseling.

Supplemental serology: WB or Suppl. IA

CD4/CD8 baseline absolute counts

Reactive

HIV-1 viral load baseline

Past positive in care

Supplemental serology: WB or Suppl. IA

*Centrifuge PPT within 4-6 hours of collection, freeze & send frozen or on cold packs overnight priority.

EDTA whole bloods to be shipped at room temperature and must be processed for CD4/CD8 within 48 hours of collection.
RESULTS

- Of the 105 individuals with HIV-1 preliminary positive rapid results
  - 102 were confirmed positive by HIV-1 WB (3rd gen IA r/r).
  - 1 was HIV-1 WB indeterminate (gp160), HIV-1 NAAT reactive (algorithm-defined EI w/ viral load = 1,744,400 RNA copies/ml & CD4 = 294 cells/ul).
- 92 (89%) baseline HIV-1 viral loads were performed and available at posttest.
- 78 (76%) baseline CD4/CD8 absolute counts were performed and available at posttest.
- 11 specimens for viral load testing and 25 for CD4 testing were not performed due to incorrect specimen submission or QNS.
• The average percentage for return posttest counseling at ≤14 days was 44.7% (37.9%-56.5%), if posttest scheduling was expanded to ≤30 days, the average return was 75.8%. (Table 1)

• Based on the current practice, a subsequent appointment is required for the client to access a medical provider. The average percentage for non-return for the medical provider appointment was 44.6%(34.5%-50%). (Table 1)
Table 1

Time between Initial HIV Presumptive Positive HIV Result and Subsequent Posttest (1st) and Medical Provider (2nd) Appointments, Florida  n=103

<table>
<thead>
<tr>
<th></th>
<th>&lt;14 days</th>
<th>15-30 days</th>
<th>&gt;30 days</th>
<th>No return*</th>
</tr>
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<td>1st. Appt</td>
<td>44.7</td>
<td>31.1</td>
<td>10.6</td>
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<tr>
<td>2nd. Appt</td>
<td>16.5</td>
<td>13.6</td>
<td>25.3</td>
<td>44.6</td>
</tr>
</tbody>
</table>

*No Return is defined as no record of a completed appointment by the end of study (at least 8 months after the last study enrollee’s initial test).
Conclusion

• We were able to perform and report a high percentage of HIV clinical management baselines with the supplemental diagnostic results at post-test counseling.

• The collaboration between the laboratory and POC staff proved to be essential for proper specimen collection, storage and transportation.

• The decrease in the percentage of clients that returned for the medical provider (2nd appt) appointment supports the need for specific and timely clinical management test results to expedite “test-to-treat” in fewer visits.
Barriers & Future Directions

- Routine access to and procurement of EDTA and PPT blood tubes at POC.
- Continued training on proper specimen collection, storage and transporting.
- Timely verification of HIV case reports (eHARS) at the laboratory.
- Ability of POC staff to initiate Ryan White eligibility process while HIV testing is on-going and to complete the process at posttest?
- Possible use of the HIV-1 viral load as a supplemental assay?
- The addition of a baseline HIV-1 genotype?
- Clearly the new HIV-1/2 Diagnostic Algorithm will be beneficial.
- The scheduling of the medical provider appointment at or near posttest counseling? Especially with acute infections?
- Potential for Prevention & Patient Care shared funding?
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