EVALUATION OF A RAPID TEST ALGORITHM TO ESTIMATE HIV INCIDENCE: HPTN071/PopART

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Disclosure: None
Purpose and Methods

Purpose
• To evaluate the performance of the Sedia Asante HIV-1 Rapid Recency Assay (Rapid assay) for estimating population level incidence
• To compare the performance of the Rapid assay to the Sedia HIV-1 LAg-Avidity Enzyme Immuno Assay (LAg assay)

Study Methods
• Samples were obtained from the HPTN 071 trial for participants who had known HIV status 1 and 2 years after the start of the study (samples from Zambia and South Africa)
• 20,472 participants: 15,845 HIV- both visits; 4,406 HIV+ both visits
• 221 seroconverted between visits

<table>
<thead>
<tr>
<th></th>
<th>Arm A Prevention interventions + universal ART</th>
<th>Arm B Prevention interventions + ART according to local guidelines</th>
<th>Arm C Standard of care</th>
<th>Overall</th>
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</thead>
<tbody>
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<td># Participants</td>
<td>6724</td>
<td>7534</td>
<td>6214</td>
<td>20472</td>
</tr>
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<td>4773</td>
<td>5392</td>
<td>4439</td>
<td>14604</td>
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</tbody>
</table>
Methods

• HIV+ samples from year 2 visit were tested with both incidence assays

• Asante HIV-1 Rapid Recency Assay + Viral Load (Rapid+VL)
  • No long-term band + viral load > 1000 → recent infection
  • Mean duration of recent infection = 180 days

• HIV-1 LAg-Avidity Enzyme Immuno Assay + Viral Load (LAg+VL)
  • Normalized optical density <1.5 + viral load >1000 → recent infection
  • Mean duration of recent infection = 130 days

• Incidence estimates were calculated with the ABIE v3 incidence calculator by CEPHIA (Kassanjee, et al. ARHR 2014; 30:45-49)

• Sub-analyses were performed by country, study arm, sex, and young persons by sex (age 24 & under)
Results

Overall Incidence Estimate

Annual Incidence (%/year)

- Observed
- LAg+VL
- Rapid+VL

P<0.01

Study Arm

Country

Annual Incidence (%/year)

South Africa
Zambia

Sex

Young Persons by Sex

Incidence Estimate

- Observed
- LAg+VL
- Rapid+VL

P<0.01

P<0.05
Conclusions

The Rapid+VL algorithm underestimated HIV incidence in a large population-based cohort from South Africa and Zambia

- This algorithm was less accurate for estimating incidence compared to the LAg+VL algorithm

Possible explanations:

- The mean duration of recent infection (180 days) suggested by the manufacturer may be too long
- The Rapid assay is not accurately detecting recent infections

Additional studies are needed to determine the correct MDRI for the Rapid+VL algorithm
Acknowledgments

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