Evaluation Of A Rapid Test Algorithm To Estimate HIV Incidence: HPTN 071/PopART

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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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<td># Participants</td>
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<td>6214</td>
<td>20472</td>
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</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

**Study Arm**

- **Overall Incidence Estimate**
  - p<0.01

- **Country**
  - p<0.05

- **Sex**
  - p<0.01

- **Young Persons by Sex**
  - p<0.05

**Incidence Estimate**

- Observed
- LAg+VL
- Rapid+VL
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

Conclusions
Acknowledgments

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