

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

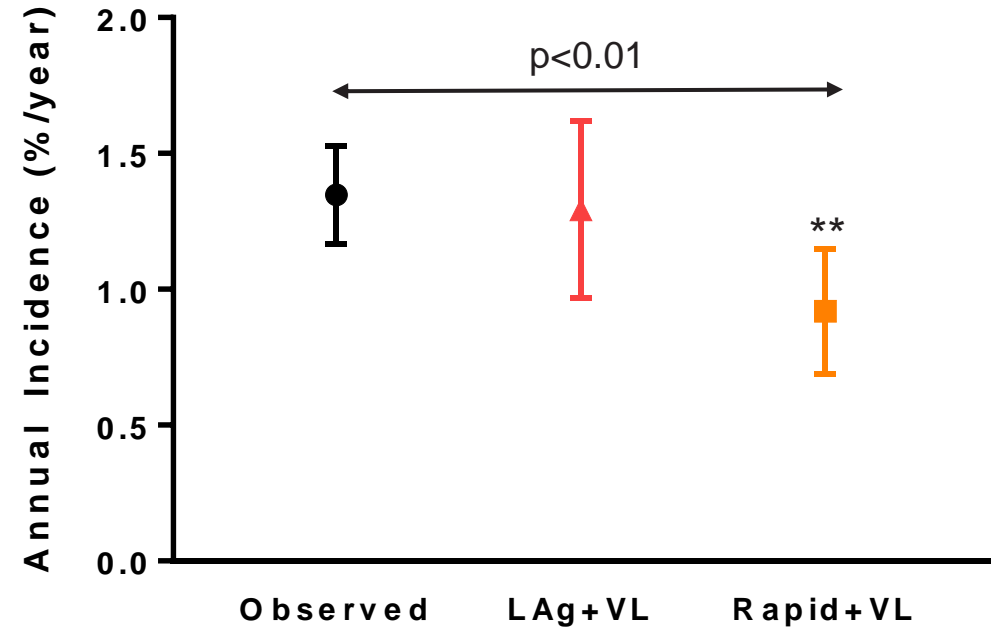
- Samples were obtained from the HPTN 071 trial for participants who had known HIV status 1 and 2 years after the start of the study (samples from Zambia and South Africa)
- 20,472 participants: 15,845 HIV- both visits; 4,406 HIV+ both visits
- 221 seroconverted between visits

| | Arm A Prevention interventions + universal ART | Arm B Prevention interventions + ART according to local guidelines | Arm C Standard of care | Overall |
|----------------|--|--|---------------------------|---------|
| # Participants | 6724 | 7534 | 6214 | 20472 |
| Zambia | 3912 | 4304 | 3658 | 11874 |
| South Africa | 2812 | 3230 | 2556 | 8598 |
| Male | 1685 | 1928 | 174 | 5335 |
| Female | 5039 | 5606 | 4472 | 15117 |
| 18-24 | 1951 | 2142 | 1775 | 5868 |
| 25+ | 4773 | 5392 | 4439 | 14604 |

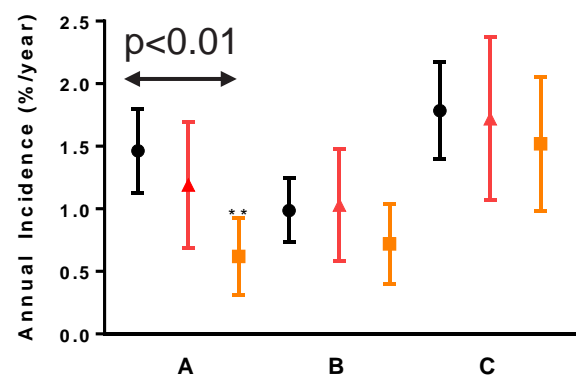
- **HIV+ samples from year 2 visit were tested with both incidence assays**
- **Asante HIV-1 Rapid Recency Assay + Viral Load (Rapid+VL)**
 - **No long-term band + viral load > 1000 → recent infection**
 - **Mean duration of recent infection = 180 days**
- **HIV-1 LAg-Avidity Enzyme Immuno Assay + Viral 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 (Kassanje, 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

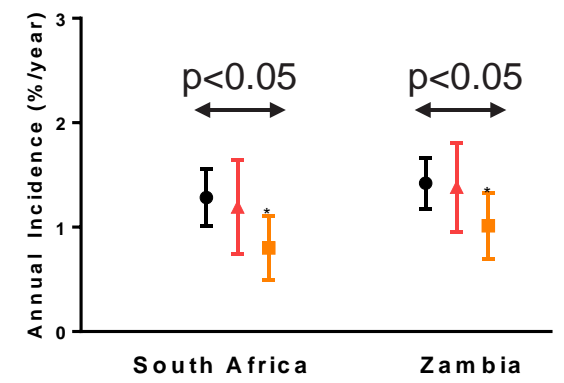
Overall Incidence Estimate



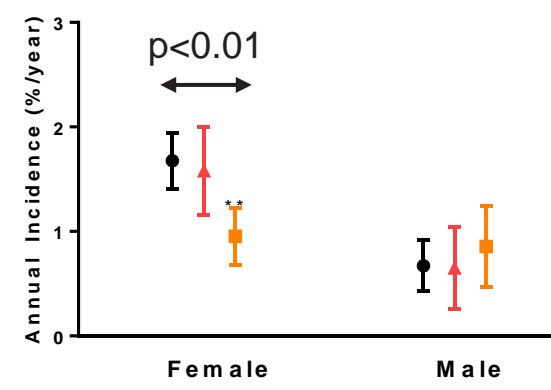
Study Arm



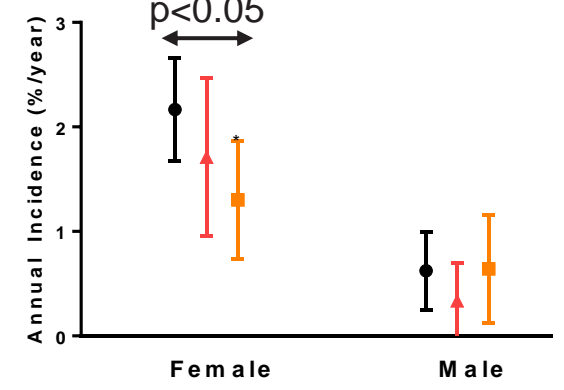
Country



Sex



Young Persons by Sex



Incidence Estimate

● Observed

▲ LAg+VL

■ Rapid+VL

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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