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2079. Comparison of Recency Assays to Estimate HIV Incidence in the SIENA (eStimating hIv incidEnce amoNg Agyw) Study in Uganda

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Background. HIV-1 recent infection testing algorithms (RITAs) use recency assays to estimate population level HIV incidence rates (IRs), and are currently being employed in PrEP trials to estimate background HIV incidence rates (bHIV-IR). The SIENA study was conducted to determine the HIV incidence rate among young women in and around central and mid-western Uganda, and to assess the suitability of different recency assay platforms for use in determining bHIV-IR in future PrEP trials.

Methods. Diagnosis of HIV was confirmed by positive results on both the Alere Determine HIV-1/2 and Oraquick HIV-1/2 rapid tests. Positive samples were analyzed for recent infection using the Sedia HIV-1 Limiting Antigen Avidity Enzyme ImmunoAssay (LAg-EIA; Sedia Biosciences, Beaverton, OR) and the Sedia Asante HIV-1 Rapid Recency Assay (Asante; Sedia Biosciences). The Asante assay was performed by electronic reader (Asante-Reader) or visual read (Asante-Visual). VL was determined by COBAS TaqMan HIV-1 Test (LabCorp, Indianapolis, IN). HIV incidence was calculated based on previously determined MDRI and FRRs that were specific for the study population.

Results. Of 743 women screened, 191 were diagnosed with HIV, of whom 44 (23%) had a viral load of < 75 copies/mL. The 3 recency assays identified between 43 and 57 samples as recent and between 35 and 37 samples when the VL cutoff of < 75 copies/mL was used (Table). When no VL cutoff was used the calculated bHIV-IR was 17.9/100 person-years (PY) for the LAg-EIA, 12.8/100PY for the Asante-Reader and 20.3/100PY for the Asante-Visual. Using the VL cutoff, the calculated bHIV-IR was 11.4/100 PY with the LAg-EIA assay and 10.9/100 PY with the Asante-Reader. No MDRI or FRR for the Asante-Visual with a VL cutoff was available for calculation of the Asante-Visual HIV incidence.

Table

Assay	N (%) Called Recent	HIV Incidence/100PY (95% CI)	N (%) Called Recent with VL < 75 cutoff	HIV Incidence/100PY (95% CI)
LAg-EIA	57 (29.8)	17.9 (11.7, 27.5)	37 (19.4)	11.4 (6.61, 19.6)
Asante-Reader	47 (24.6)	12.8 (7.59, 21.4)	38 (19.9)	10.9 (5.37, 22.2)
Asante -Visual	43 (22.5)	20.3 (11.4, 36.1)	35 (18.3)	Not Done

Conclusion. When the RITA included a VL cutoff of 75 cp/mL, the LAg-EIA and Asante assays classified the number of recent and long-term infections similarly, resulting in comparable bHIV-IR results. Overall, these analyses support the use of these recency assays in the RITA to estimate the bHIV-IR in future PrEP trials. Our results demonstrate extremely high prevalence and incidence of HIV in young women in central and mid-western Uganda, highlighting the need for expanded HIV prevention options in these areas.