Abstract

BACKGROUND: The identification of populations at risk of HIV infection is a priority for trials of preventive technologies, including HIV vaccines. To quantify incidence traditionally requires laborious and expensive prospective studies. METHODS: The BED IgG-Capture enzyme immunoassay (EIA) was developed to estimate HIV-1 incidence using cross-sectional data by measuring increasing levels of HIV-specific IgG as a proportion of total IgG. To evaluate this assay, we tested 189 seroconversion samples taken at 3-monthly intervals from 15 Rwandan and 26 Zambian volunteers with known time of infection and cross-sectional specimens from 617 Kenyan and Ugandan volunteers with prevalent infection. RESULTS: The BED-EIA-estimated incidence in Uganda was unexpectedly high, at 6.1%/year [95% confidence interval (CI) 4.2-8.0] in Masaka and 6.0%/year (95% CI 4.3-7.7) in Kakira. Prospective incidence data in Masaka from the same population was 1.7%/year before and 1.4%/year after the study. Kenyan estimates were 3.5%/year in Kilifi (95% CI 2.1-4.9) and 3.4%/year in Nairobi (95% CI 1.5-5.3). From the Rwandan and Zambian data, the sensitivity of the assay was 81.2% and the specificity was 67.8%. After approximately one year, subjects misclassified as recently infected tended to have lower plasma viral loads compared with those not misclassified as recent (median copies/ml 14 773 versus 93 560; $P = 0.02$). Clinical presentation, sex and HIV subtype were not significantly associated with BED-EIA misclassification in seroconverter samples. CONCLUSION: These data suggest that this assay does not perform reliably in all populations. Further research is warranted before using this assay to estimate incidence from prevalent HIV samples.