



***UNAIDS Reference Group on Estimates, Modelling and Projections’
statement on the use of the BED-assay for the estimation
of HIV-1 incidence for surveillance or epidemic monitoring***

On 13 December 2005, the UNAIDS Reference Group on Estimates, Modelling and Projections reviewed results of the application of the BED-assay for estimation of HIV-1 incidence in surveillance settings, and in selected validation studies. Data were presented from studies in Côte d’Ivoire, South Africa, Rwanda, Zambia, Kenya, Uganda, Ethiopia, and Thailand, and from additional laboratory validation studies.

The comparison of BED-assay derived measures of incidence with directly measured prevalence and with estimates of incidence based on different methods consistently suggests that the current BED-based method overestimates incidence. Several studies show BED-derived incidence of a third to half the prevalence. This is inconsistent with the pattern of growth of the epidemic and data about survival of people infected with HIV-1. In studies that compare different measures of incidence, BED-assay derived incidence appears 2-3 times higher than that found using other methods (e.g. HIV-1 incidence measured directly in prospective studies, or derived from prevalence surveys in young people [15-24 years old] by single year of age or modelling using the Estimation and Projection Package and Spectrum or the Asian Epidemic Model).

There is evidence that the above discrepancies arise because the BED-assay captures not only recent infections, but also late stage HIV infection (with or without antiretroviral therapy) when the levels of antibodies fall. Additionally, there may be an impact of sample storage conditions on assay results. There is evidence that assay characteristics vary by HIV-1 subtype.

Based on the above-summarised evidence, the Reference Group recommends that at present the BED-assay not be used for routine surveillance applications, neither for absolute incidence estimates, nor for monitoring trends. In addition, the BED-assay should not be applied in national surveys, and sample sizes of planned national surveys should not be increased solely for the application of the BED-assay.

The Reference Group also calls for more research on the validity of the BED assay for estimating incidence, as well as for exploring alternative laboratory assays or modelling methods. The validation of the BED-assay should go beyond seroconverter panels, and include analyses in cohorts (looking at both early and late HIV infection) with exploration of reasons for false positives and evaluation in cross sectional studies as appropriate.