Comparison of Assays Used in the Serological Testing Algorithm for Recent HIV Seroconversion (STARHS) in an STI Clinic Population and a Proposed Algorithm to Improve the Accuracy of Identification of Recent HIV Infection (RHI)

Abstract Category:	New HIV Diagnostic Technologies Including Those That Are Not FDA Approved
Primary Author:	Gary Murphy
Affiliation:	Health Protection Agency Centre for Infections
Co-Authors:	Elaine McKinney, Luciana Rubinstein, Martin Fisher, David Pao, Gillian Dean, Denis McElborough, David Muir, Miranda Cowan, Sarah Fidler, John Parry

OBJECTIVE

To compare the ability of 3 assays to distinguish recent from long-standing HIV infection and to investigate the use of an algorithm to improve specificity.

METHODS

Anti-HIV-1 positive specimens from 89 newly diagnosed individuals attending a STI clinic, 34 specimens from patients with documented long-standing HIV infection (without AIDS and treatment naive) and a further 80 sequential specimens from 19 patients receiving HAART were tested using the Vironostika 'detuned'; Calypte BED; and AxSYM HIV avidity STARHS assays. RHI was inferred if: detuned SOD <1.0, BED ODn <0.8 or avidity index <80%.

RESULTS

Of the newly diagnosed infections: 31 (35%) specimens were identified by all 3 assays as from an RHI. 'BED' categorized the greatest proportion of infections as an RHI (48%), compared to detuned (43%) and avidity (39%). The detuned was the only assay that did not uniquely categories an infection as a RHI. BED identified 6 specimens that did not give a result consistent with RHI by either alternate, while avidity identified 3. Of the 34 specimens from those with a long-standing infection the detuned misclassified three as RHI, BED two, and avidity one (this one was also misclassified in the other two assays). Following therapy for 2 years no further specimens were misclassified by the avidity assay as from patients with RHI, but one patient intermittently breached the threshold for RHI in the BED assay and 3 were consistently misclassified by the detuned assay.

CONCLUSIONS

Assays for RHI show good correlation despite differences in their sensitivities and specificities. Our data suggests the avidity assay has a shorter window period than 'detuned' or 'BED' and is less likely to misclassify long-standing infection due to factors such as undisclosed anti-retroviral therapy. However, its current format is not suited for use 'in the field', thus an algorithm whereby specimens identified as recent by 'detuned' or 'BED' are subsequently tested centrally in the avidity assay may improve accuracy and confirm RHI in patients closer to their date of infection than by using 'BED' or 'detuned' alone.