Comparison of the Generic HIV Viral Load assay with the Amplicor HIV-1 monitor v1.5 and Nuclisens HIV-1 EasyQ v1.2 techniques for plasma HIV-1 RNA quantitation of non-B subtypes: the Kesho Bora preparatory study

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Abstract:

The implementation of cost effective HIV-1 RNA quantitation assays in resource-poor settings is of paramount importance for monitoring HV-1 infection. A study comparing the analytical performance of three HIV-1 RNA assays (Generic HIV Viral Load, Amplicor v1.5 and Nuclisens EasyQ v1.2) was performed on 160 plasma samples from 160 consecutive antiretroviral treatment naive HIV-1-infected pregnant women assessed for eligibility in the Kesho Bora trial aimed at prevention of mother-to-child transmission of HIV-1 in three African countries (Burkina Faso, Kenya and South Africa). Correlation and agreement of results of the three assays were assessed for plasma HIV-1 RNA quantitation in specimens harbouring mainly sub-subtype A1, subtype C, and circulating recombinant form (CRF) 02_AG and CRF06_cpx. Good degrees of correlation and agreement were observed between these HIV-1 RNA assays. However, nine (9/160, 5.6%) strains detectable with the Generic HIV Viral Load assay were not detected by either the Amplicor (n=7) or EasyQ (n=2) test. One strain (0.6%) was missed with the Generic HIV Viral Load assay. Further, concordantly positive plasma samples harbouring CRF02_AG and CRF06_cpx yielded significantly higher HIV-1 RNA concentrations when tested by Generic HIV Viral Load, as compared to Amplicor v1.5 (mean differences, +0.33 and +0.67 log(10) copies/ml; P=0.0004 and P=0.002, respectively). The Generic HIV Viral Load assay accurately quantified the majority of the non-B HIV-1 subtypes assessed in this study. Due to its low cost (approximately 10 US $/test), this assay performed with open real-time PCR instruments is now used routinely in the Kesho Bora trial and may be recommended in other African settings