Topic: B23 Clinical trials - phase III/post-licensing

Title: Cost Effectiveness Analysis Of Routine Laboratory Or Clinically Driven Strategies For Monitoring Anti-Retroviral Therapy In Uganda And Zimbabwe (DART Trial)

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Text: **Objective:** This study compared costs and benefits of monitoring antiretroviral therapy (ART) between laboratory and clinical monitoring (LCM) and clinically driven monitoring (CDM) in HIV-infected adults enrolled in the DART trial in Uganda/Zimbabwe from the public health care sector perspective.
Methods: Individual patient data on health care resource utilisation and health outcomes of DART participants were extracted from trial records(2003-2008), and valued with primary and secondary cost estimates. We estimated total costs of first and second-line ART, CD4 tests, routine 3-monthly biochemistry/haematology tests for toxicity and extra laboratory investigations, clinic visits, concomitant medications and hospitalisations. The difference in days of survival between arms was estimated using Kaplan-Meier survival curves.
Results: 3316 (1660LCM; 1656CDM) ART-naive adults were included (65%female; median(IQR) age 37(32-42); CD4 86(31-139) cells/mm^3) and followed for mean 4.9 years. The mean total per patient costs (total US$/number of participants) over the trial period were:

ARM	1st Line Therapy	2nd Line Therapy	CD4 Monitoring	Toxicity Monitoring	Other Costs*	Total costs
	2008 US$					
LCM	$1451	$406	$175	$699	$656	$3387
CDM	$1470	$265	$0	$20	$685	$2440

[Table 1 Costs in US$ 2008]

*Other costs=clinic visits, concomitant medications, extra laboratory investigations & hospitalisations.

LCM incurred an additional cost of $947 [95% CI: 876 - 1020]. Its overall survival benefit was 41days [95% CI: -10, 88]; this translates into ICER of $8,441 per life-year gained.

Conclusions: Routine laboratory monitoring for toxicity or response to ART is a key cost driver for managing patients on ART and its costs should be weighed against its benefits in designing optimal ART roll-out programmes in Africa. Given the main DART trial results (presented in this conference), laboratory monitoring of toxicity is particularly expensive and provides no significant benefit. Cost of CD4 monitoring is lower but still substantial. Its targeted use may be cost-effective in specific situations.