Cost-savings of viral load testing before ART second line switch in a resource limited setting

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Introduction

World Health Organization (WHO) guidelines for patients on antiretroviral therapy (ART) recommend clinical or immunologic monitoring when viral load (VL) testing is not available, and switches to second-line ART are based on WHO clinical or immunologic failure criteria [1] .

However several studies have shown that these criteria are neither sensitive nor specific and can lead to unnecessary switching of patients with suppressed viral load to second-line regimens that are more costly than first-line ART [2,3] .

Conversely , because of the low sensitivity of immunologic criteria, a significant number of patients with virological failure maybe missed, resulting in accumulation of resistance mutations and reducing future treatment options [2,3].

In an urban HIV treatment program in Kampala City, VL testing is carried out prior to ART regimen switch to confirm treatment failure following identification of immunological failure.

We sought to determine if VL testing in these patients with suspected ART treatment failure based on WHO criteria for immunologic failure. was cost-saving

Methods

We retrospectively reviewed the records of patients with immunological failure as defined by the WHO guidelines, who had VL testing prior to ART regimen switching as recommended by the existing program in 7 government-run urban clinics in Kampala, between October 2008 and October 2011.

Patients who did not meet WHO criteria for immunological failure and patients with VL tests carried out for reasons other than treatment failure were excluded.

VL testing was performed in an unsubsidized central lab facility where the cost of a VL test is $62. The cost of first-line ART averaged $14.68 per person per month and second-line ART, $35.99 per person per month at the time of the assessment.

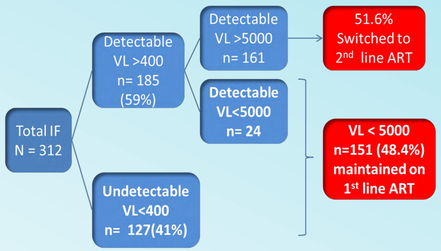
Results

312 patients were tested at 7 clinics in Kampala City, and met assessment criteria. 185 (59%) had detectable VL (>400 copies/mL) and 127(41%) had undetectable VL (< 400 copies). Of the 185 with detectable VL, 24 had <5,000 copies/ml, and did not meet WHO criteria for switching to second line ART. *(see fig 1)*

Results

161 persons whose VL were >5000 (51.6%) were switched to second-line while 151 patients with VL < 5000 (48.4%) remained on first-line therapy as indicated in figure 1.

Figure 1: Flow diagram showing VL testing outcomes among patients with immunological failure (IF), and impact on patient management



**WHO recommendation at the time was switch to 2nd line at VL>5000 copies/ml*

This proportion of detectable Vs. non detectable VL was similar across all 7 clinics as shown in graph1

The cost of targeted VL testing in patients with immunologic failure was recouped in 6.0 months when compared to the increased cost of treating patients who had immunologic failure but suppressed VL with the second line regimen as indicated in *table 1*.

Results

Graph 1: Viral load testing and outcomes by health facility

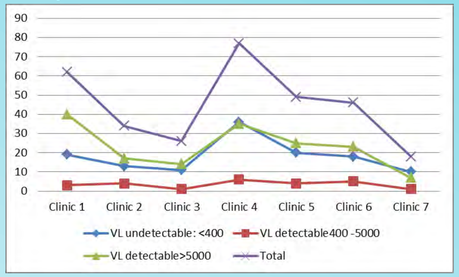


Table 1: Initial costs of each model/month

Model of care	Viral load testing carried out	No viral load testing
Costs (USD)	(312x$62) + (161x$35.99)+ (151x$14.68)	(312x$35.99)

($62x312 patients)+ (161x35.99) X + (151x14.68) X = (312x35.99) X ; where X=number of months to break even.

Conclusion

WHO criteria for immunological failure had low sensitivity for detecting virological failure, and testing with VL prior to ART regimen switch prevented the unnecessary switching to second-line ART in 48.4% of patients. This led to a recouping of the cost of VL testing in those who immunologically fail at 6.0 months. We therefore make a case for ART programs in resource limited settings to consider recommendation of targeted VL testing among patients with suspected treatment failure, given the substantially higher cost of second-line ART compared to first-line combined with the poor specificity of the WHO immunologic criteria for treatment failure.

Additionally, lack of sensitivity of immunological criteria among these patients could lead to accumulation of drug resistant virus and reduction of future treatment options in a setting where ART treatment options are considerably limited by high cost of alternative ART regimen. Studies however show that routine VL monitoring using the currently available tests is not cost effective[4].

Further evaluation is required to guide the optimum application of targeted VL testing in resource limited settings.

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