## Abstract

Background: Life-saving highly active anti-retroviral therapy (HAART) has been accompanied by the challenge of incident adverse drug reactions (ADRs). Locally generated data is scanty, inadequately documented, and therefore not available to inform revision of clinical protocols. Objective: To study and document the magnitude and type of ADRs associated with HAART over a 42 month period at Mbagathi District Hospital (MDH) Nairobi.

Design: A retrospective cohort study.

Setting: A high burdened HIV comprehensive care clinic based at the Mbagathi District Hospital in Nairobi, Kenya.

Subjects: HIV infected patients receiving highly active anti-retroviral therapy (HAART) Results: Adverse drug reactions associated with HAART occurred in 63% of adult study subjects. Majority (91.4%) of the ADRs experienced were medium to long term conditions, namely peripheral neuropathy in 33.3%, lipodystrophy in 32.6%, hepatic toxicity in 24.4% and lactic acidemia in 4.1 % of patients. Furthermore, occurrence of all the ADRs was associated with increasing baseline age (p<0.0001). Gender differences were found in patients with lipodystrophy (p<0.001), and lactic acidemia (p=0.047),

with a female preponderance.

Conclusion: Adverse drug reactions were experienced by 63% patients on HAART. Majority of the ADRs were those commonly associated with the medium to long term use of stavudine and nevirapine. Despite the high frequency of ADRs, patient outcomes were favourable as there were no reported deaths or hospitalisations.