

## Abstract

### Background:

Using highly active antiretroviral therapy (HAART) as the core preference for management of people infected with Human Immune deficiency virus (HIV) is associated with decreased mortality and morbidity. However with HAART there come a considerable number of adverse drug reactions which are not monitored and reported in many settings. ADR reporting is a critical tool in pharmacovigilance. Its success however, depends on collaborative and motivated healthcare providers. Under reporting of adverse drug reactions (ADRs) by healthcare providers is a prevalent or common problem. The current study was undertaken to assess the pharmacovigilance among ART healthcare providers in Mulago HIV clinic through evaluating the common ADRs and their causes, then assessing their monitoring and reporting by evaluating the knowledge, attitude, and practices (KAP) regarding ADR reporting among healthcare providers at Mulago HIV clinic, to get an insight into the causes of under reporting of ADRs

### Method:

This study was a questionnaire-based study conducted in Mulago HIV clinic. It included all ART healthcare providers (32) and a random selection of 386 patients on HAART between 2006 and 2013 in search of common HAART associated Adverse Drug effects (ADRs) and their causes, then assessing their monitoring and reporting by the healthcare providers in the clinic. The prevalence of ADRs defined as the proportion of the study population with ADRs was determined and stratified by age, sex, education level, HAART regimen, reporting and counseling on foods to take with the ART regimen, medical charts were reviewed to validate the patient responses and reasons of the treatment modifications, interruptions or switches. To assess ADR reporting, ART healthcare providers (32) were issued with a pretested questionnaire comprising of 51 questions (operation of the current ADR reporting system 13; knowledge 8; Attitudes 18; Practice 4; and ADRmanagement process 8). Microsoft Excel worksheet (Microsoft Office 2007) and STATA 12 were used for statistical analysis.

### Results:

Ninety three (24.09%) of the 386 patients on HAART reported ADRs. Among those who reported ADRs, 27.96% were on AZT-3TC-NVP, 20.24% on AZT-3TC-EFV, 16.13% on TDF-3TC-NVP, 16.13% on TDF-3TC-EFV and 19.35% on other regimens. Skin reactions were the most common ADRs and presented 23.28% of all ADRs. AZT containing regimens were responsible for 47.96% (OR = 54.64, 95% CI 19.61-152.26,  $p < 0.00$ ) and 46.37% of all ADRs were reported in patients that had been previously taking regimens containing D4T.

Among ART healthcare providers the total mean score of the knowledge of the respondents on ADRs was 7.05 (70.5%), ADR reporting was deemed as important by 96.68% of the respondents; predominantly for improving patient safety (59.38%) and the need to measure the incidence of ADRs (15.63%). A greater part of the respondents 68.75% stated that they would be keen on reporting all ADRs.

However, 78.13% of the 32 ART healthcare staff in ISS clinic reported that there is no ADR reporting system in the clinic; 81.25% reported that there is no focal person responsible for handling ADRs in the clinic; 78.13% reported that there was no system in place for analysis of ADRs after they have been recorded in patient files. 81.25% reported that ADR reports are produced rarely and 90.63% reported that there were challenges faced in the current ADR reporting system deterring them from reporting ADRs. The reasons cited for this were lack of a clearly documented ADR reporting system (12.5%), no specific ADR database (15.63%), lack of specific ADR reporting forms (9.38%), no ADR focal person (12.5%) and lack of frequent trainings (3.13%). The suggested approaches for enhancing reporting were CMEs (14.46%), training staff to report ADRs, establishing a focal person (9.64%), and implementing an ADR reporting system (7.23%) among others.

### **Conclusion and recommendations:**

HAART-associated ADRs are common in Mulago HIV Clinic and the Healthcare providers are informed or aware of the ADRs and the significance of their reporting. However, under-reporting and lack of knowledge about the reporting system are clearly apparent or noticeable.

Establishing or setting up awareness about ADR reporting and devising methods to make it easy and convenient may support in enhancing spontaneous reporting. This could be done through: Educational interventions, acknowledgment, feedback to all healthcare reporters about the ADRs reported by them, and offering them support through a pharmacist on reporting and managing of ADRs.