Journal Article

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Pharmacoepidemiology and Drug Safety

Journal tags:
- antiretroviral treatment [1], Namibia [2], adverse drug reaction [3], pharmacovigilance [4], HIV & AIDS [5], SIAPS [6]

Link:
Sentinel site active surveillance of safety of first-line antiretroviral medicines in Namibia [7]

Abstract

**Purpose:** Active surveillance pharmacovigilance systems better estimate the burden of adverse events (AEs) and can generate useful information on risk factors of AEs for more effective medicine use, especially in conjunction with introduction of new medicines and/or changes in treatment guidelines. This project aimed to implement an active surveillance pilot program for first-line antiretroviral therapy (ART) at sentinel sites in Namibia.

**Methods:** Sentinel sites were outpatient ART clinics at the Windhoek Central Hospital and Katutura Intermediate Hospital. An active surveillance data collection form was developed and placed into patient charts. HIV+ adults naïve to ART were enrolled. Physicians recorded ART and health information during each follow-up visit, including presence or absence of AEs.

**Results:** A total of 413 patients were included from August 2012 to April 2013. Average age was 37±years; 51% of patients were at WHO clinical stage 1; and mean baseline CD4 count was 216. The most common ART regimen was tenofovir/lamivudine/nevirapine. Presence or absence of AEs was recorded in active surveillance forms for 94% of first follow-up visits. In total, 66 patients experienced 119 AEs of any severity. Incidence of experiencing at least one AE was 33/100 person-years. Most common AEs were rash and abdominal pain. On active surveillance forms, demographic variables were missing in 14% of patients, and follow-up
visits were recorded for 82% of patients.

**Conclusions:** Completeness of AE recording on active surveillance forms was high. With improved logistical considerations, such as incorporation of active surveillance forms into medical records, long-term active surveillance programs could be successful.

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