

Adverse Drug Reactions Reported to a National HIV & Tuberculosis Health Care Worker Hotline in South Africa: Description and Prospective Follow-Up of Reports.

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Abstract

INTRODUCTION:

The National HIV & Tuberculosis Health Care Worker (HCW) Hotline provides advice on the management of suspected adverse drug reactions (ADRs). We describe suspected ADRs reported to the hotline by HCWs, concordance with advice, and patient outcomes.

METHODS:

We reviewed suspected ADRs in HIV-infected patients, patients taking antiretrovirals and patients taking anti-tuberculosis therapy reported from May 2013 to October 2014. We performed causality assessment using the World Health Organization Uppsala Monitoring Centre (WHO-UMC) criteria. We included suspected ADRs categorized as certain, probable or possible in further analysis.

RESULTS:

We received 772 ADR reports, of which 87/772 (11.3 %) were classified as certain, 176/772 (22.8 %) as probable, 361/772 (46.8 %) as possible, and 148/772 (19.2 %) as unlikely or unassessable. The most frequent ADRs were rash, drug-induced liver injury (DILI) and kidney injury, comprising 110/624 (17.6 %), 87/624 (13.9 %), and 77/624 (12.3 %), respectively. The ADR was severe in 27.3 % of rashes, 36.4 % of kidney injury reports and 88.5 % of DILI reports. Most frequently implicated drugs, either alone or in combination with other potentially causative drugs, were efavirenz (rashes), efavirenz and anti-tuberculosis drugs (DILI) and tenofovir (kidney injury). In 383 cases with HCW follow-up, 254 (66.3 %) improved, 9 (2.3 %) had complete resolution, 32 (8.4 %) remained unchanged, 6 (1.6 %) deteriorated, 10 (2.6 %) died and 72 (18.8 %) had unknown outcome. Advice provided was followed in 93.2 % of these cases. Of 223 ADRs with preventability data, 40 (17.9 %) were preventable.

CONCLUSION:

Queries about rashes, DILIs and kidney injuries were common. Detection and management of these ADRs should be included in HCW training. In cases with follow-up, concordance with advice was high, and HCWs reported improvement in the majority.

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