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# PREVALENCE AND DETERMINANTS OF ANTIBIOTIC RELATED ADVERSE DRUG REACTIONS IN KENYA: SPONTANEOUSLY REPORTED CASES AT THE PHARMACY AND POISONS BOARD DATABASE

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**Background:** Antibiotics are useful in the treatment and prevention of many infections. Despite this, they may cause adverse drug reactions (ADRs) which could further increase the morbidity, mortality and treatment costs. The national pharmacovigilance system of the Pharmacy and Poisons board in Kenya has a database in which all actual and suspected adverse drug reactions nationally from hospitals are reported and analysed.

**Objective:** To describe the prevalence, characteristics, severity and outcome of antibiotic related adverse reactions between January 2010 and December 2015.

**Methods:** This was a retrospective cross sectional study in which all case reports of the reported antibiotic related ADRs were reviewed. Information on the patient demographics, types of antibiotics and concomitant drugs used, adverse reaction reported, the severity and outcome was abstracted and analysed using STATA version 13. Bivariate analysis and logistic regression were conducted to determine the risk factors associated with severity and outcomes of antibiotic related ADRs. Ethical approval was obtained from the Kenyatta National Hospital/ University of Nairobi Research and Ethics Committee and the Pharmacy and Poisons board.

**Results:** A total of 550 case reports were analysed. The majority of patients were female (62.3%, n=330), median age of 34 (IQR 22.0-45.0) years. The most commonly affected system was the integumentary system (60.9%, n=388), with skin rash as the most commonly reported ADR (39.7%,n=253). Cotrimoxazole contributed the majority of the adverse reactions (55.3%, n=304). Most of the reactions were mild to moderate (82.6%, n=440), leading to drug withdrawal for 79.1% (n=435). Sulphonamides and anti-TB drugs produced the most severe reactions (n=15.8%, n=84), while fatal reactions were only 1.5% (n=8). Older age was significantly associated with severity of the reported ADRs (p=0.003) while HIV status (p=0.011) and severity of the ADR (p=<0.001) were associated with poor outcomes. Causality assessment attributed 15.6% (n=86) of the ADRs to the suspected antibiotic while 56.5% (n=311) were probable.

**Conclusion:** There is a high burden of antibiotic related ADRS, most of which are skin related. HIV status and severity of the ADRs are associated with poor outcomes, and the elderly experience more severe ADRs.

**Key words:** antibiotics, adverse reaction