

Title: Drug-induced hypersensitivity reactions and their associated predictors using spontaneous reported ADRs from the Tanzania Medicines and Medical Devices Authority (TMDA) Vigflow database 2017-2018

Name: Elias M.Bukundi[2], Dr Candinda Mushiro [1], Kissa Mwamwita[3]

[1]Tanzania Field Epidemiology and Laboratory Training Programme

[2]Muhimbili University of Health and Allied Sciences, Tanzania

[3]Tanzania Medicines and Medical Device Authority

Abstract

Hypersensitivity reactions are public health problems which contribute to 10% to 20% of hospitalization. The objective of this analysis was to determine the prevalence, signal and risk factors for drug-induced hypersensitivity from spontaneous reported Adverse drug reactions (ADRs) at Tanzania medicine and medical devices Authority (TMDA) Vigflow database from January 2017 to December 2018. We conducted a secondary data analysis of 321 spontaneous reported ADRs cases. Predictors of drug-induced hypersensitivity were identified using multivariate logistics analysis. Drug-induced hypersensitivity signals were determined using the reporting odds ratio (ROR). Mapping of the geographical distribution of the reported ADRs was done using QGIS. The prevalence of drug-induced hypersensitivity was 39.6%, the independent predictors for drug-induced hypersensitivity were reports from southern highland zones (AOR =7, 95% CI = 2.1-23.8), oral route of administration (AOR =39.9, 95% CI= 3.0-529.2), reports from other health professionals (AOR=6.5, 95% CI = 1.6-26.2), age group between 15-28 years (AOR = 0.2, 95% CI =0.03-0.95), having a non-serious adverse reaction (AOR =3.9, 95% CI= 1.3-11.8) and being recovered from ADRs at the time of reporting (AOR = 4.1, 95% CI = 1.2-13.9). A signal associated with drug-hypersensitivity was detected in Isoniazid tabs, cotrimoxazole tabs, Artemether lumefantrine tabs, RHZE and antiprotozoal ATC group of drugs. Mara, Kagera, Njombe, Katavi, Simiyu, Songwe and Mtwara regions did not report any ADRs from 2017 to 2018. The prevalence of hypersensitivity reactions in the reported ADRs was quite high. More attention should be given to patients aged 15-28, those who use drug by the oral route, non-serious adverse reaction, living the Southern highland zone, those using anti TB drugs, ALU, Antibiotics and antiprotozoal drug. The analysis has highlighted the application of the case/non-case method to determine drug-associated hypersensitivity signals by regulatory authorities to identify and prevent hypersensitivity reactions and improve drug safety.

Biography

Elias M.Bukundi aged 34 years is registered Pharmacist who is who undertaking his Master's degree in Applied Epidemiology at Muhimbili University of Health and allied sciences in Tanzania. He is a region Pharmacist in Kagera Region in Tanzania. He has worked at District pharmacist for 5 years at Missenyi district council in Kagera Region, Tanzania Currently, he has completed his field placement at the TMDA for six months where he conducted data set analysis on reported ADRs at the TMDA.

Presenting author details
Full name: Elias Musa Bukundi
Session name: Biopharmaceutical Pharmacovigilance
Category: Oral
Email Id: eliasbukundi@gmail.com
Contact number: +255 764 207615