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

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ABSTRACT

Introduction: Hypersensitivity is an important public health problem which causes morbidity and mortality in the health care system. 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) data on Vigflow database at Tanzania Medicines and Medical Device Authority (TMDA) from January 2017 to December 2018.

Methodology: The study involved secondary data analysis of 321 spontaneous reported ADRs cases from the TMDA vigflow database. Predictors of drug-induced hypersensitivity were identified using multivariate logistic regression analysis. Signals associated with drug-hypersensitivity were detected using data mining algorithms. Reporting odds ratio (ROR) and its 95% confidence interval (CI) are presented. Mapping of the geographical distribution of the reported ADRs was done using geographical information system (QGIS) whereby percentage for each region were presented in the map.

Results: The proportion of drug-induced hypersensitivity was 39.6%. Independent predictors for drug-induced hypersensitivity were reports from southern highland zones (AOR =7, 95% CI = 2,08-23.81), oral route of administration (AOR =39.9, 95% CI= 3.01-529.15), reports from other health professional (AOR = 6.5,95% CI = 1.61-26.20), 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% CL= 1.28-11.81) and being recovered from ADRs at the time of reporting (AOR = 4.1, 95% CI = 1.19-13.97) A signal associated with drug-hypersensitivity was detected in Isoniazid tabs, cotrimoxazole tabs, Artemether lumefantrine tabs, RHZE and antiprotozoal ATC group of drugs. Mara region, Kagera region, Njombe region, Katavi region, Simiyu region, Songwe region and Mtwara region did not report any ADRs from 2017 to 2018.

Conclusion/Recommendations: 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 medicines by oral route, non-serious adverse reaction, living the Southern highland zone, those using anti TB drugs, ALU, Antibiotics and antiprotozoal drug so as to minimize the risk of drug-induced hypersensitivity ADRs. Monitoring of drug hypersensitivity reactions should be strengthened through conducting drug safety evaluations, and benefit-risk assessments, so as to increase patient's safety and protect public health.

Keywords: Hypersensitivity reactions, Reporting odds ratio (ROR), Signals, Tanzania Medicines and Medical Devices (TMDA), Vigflow database, Adverse Drug Reactions (ADRs)