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Spontaneous reporting of adverse drug reactions: An effective strategy for post-marketing drug regulation and safety surveillance

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Background: Spontaneous reporting of adverse drug reactions is critical for the post-marketing regulation of medications. A national tool for reporting suspected adverse drug reactions in Nigeria [Pharmacovigilance Form (PVGF)] and reported wide spread adverse events (AEs) among a national cohort of multidrug-resistant tuberculosis (MDR-TB) patients in Nigeria.

Methods: Suspected adverse drug reactions from MDR-TB patients undergoing intensive phase treatment using a standard regimen consisting of injectable Kanamycin, Amikacin or Capreomycin and oral Cycloserine, Levofloxacin, Pyrazinamide, Prothionamide and Pyridoxine were collected using the PVGF and analyzed. Characteristics of AEs were documented and risk factors assessed.

Results: 460 Patients were included in the analysis: 62% were males; median age and weight were 33 years [Interquartile Range (IQR):28-42] and 51 kg (IQR: 45-59) respectively. Majority of the participants (44%) experienced AEs: Four died of AEs associated conditions. The most commonly reported AEs were gastro-intestinal (n=100), neurological (n=75), ototoxic (n=72) and psychiatric (n=60). Ototoxic and psychiatric AEs were debilitating and required intervention. Most AEs occurred after 1-2 months of therapy; some treatment centers were twice as likely to report AEs compared with others, highlighting significant inconsistencies in reporting at different treatment centers. Patients with a higher body weight had an increased risk of experiencing AEs. No differences were observed in risk of AEs between HIV-infected and uninfected patients. Age was not significantly associated with AEs.

Conclusion: A wide range of AEs were reported, indicating that the spontaneous reporting of suspected adverse drug reactions can provide information for post-marketing regulation of medications and drug safety surveillance. Safer regimens with the shortest duration are; training of health workers in monitoring and reporting AEs.

Biography

Avong Yohanna Kambai is a registered pharmacist (RPh), implementer of public health initiatives and a certified operational researcher. He holds a Master in Public Health (MPH) from the University of the Western Cape, South Africa and has certificates in drug logistics, operational research, rational drug use, biostatistics, management and leadership from the Johns Hopkins University, IPRI, Crown Agents, the Union and the World Health Organization. He is a drug manager in three international studies (START, TRUST and SAFE); first author in the Anti-retroviral Adherence and Adverse Events of MDR-TB drugs studies and co-author in several studies. His current interest is in the regulation of anti-retroviral and MDR-TB drugs through Pharmacovigilance. Recent major achievements include the setting up of the Pharmacy Division (PD) in the Institute of Human Virology, Nigeria (IHVN), serving as consultant to the Nigeria Federal Ministry of Health for the importation of narcotic drugs and wining the Johns Hopkins University scholarship in two consecutive awards. He is currently the Associate Director and head of the PD in the Institute of Human Virology, Nigeria (IHVN), where he won the long service award in 2013.

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