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5th International Conference and Exhibition on

Pharmaceutical Regulatory Affairs

August 03-05, 2015   Orlando, USA

The effectiveness of the spontaneous reporting system

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Background: Spontaneous reporting systems (SRS) as the United Kingdom Yellow Card Scheme for reporting suspected adverse drug reactions (ADRs), operate in most developed and developing countries. We tested the SRS in a national cohort of multidrug-resistant tuberculosis (MDR-TB) patients in Nigeria.

Methods: Using the Nigeria Yellow Form, we collected and analyzed suspected adverse drug reactions from MDR-TB patients undergoing the eight months intensive phase treatment. These patients were treated with a standard regimen, consisting of injectable Kanamycin, Amikacin or Capreomycin and oral Cycloserine, Levofloxacin, Pyrazinamide, Prothionamide and Pyridoxine for at least eight months. Characteristics of AEs were documented and risk factors assessed.

Results: We included 460 patients 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 medical intervention and hearing aids. 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: The SRS proved effective at providing information on adverse drug reactions, which could aid post-marketing drug safety surveillance. Given its low cost, the SRS could be used in resource limited settings to detect, monitor and report ADRs, especially in public health initiatives like the anti-retroviral therapy programs.

Biography

Avong is a public health pharmacist, implementer of public health initiatives and a certified operational researcher. He holds a Bachelor of Pharmacy (BPharm) from the Ahmadu Bello University, Zaria, Nigeria and a Master of Public Health (MPH) from the University of the Western Cape, South Africa. He is also in the process of pursuing a PhD in Pharmacovigilance and Pharmaco-epidemiology. In 2009, he inspired the setting- up of the spontaneous reporting system (SRS) in two public health programs (ART and MDRTB) and supervised the collection and analysis of over 2000 individual case reports (ICRs) from these programs. He has published papers in ADRs and adherence to anti-retroviral therapy (ART). Furthermore, he has peer-reviewed many manuscripts and participated in several international researches like the START study, while contributing to the development of the current "Integrated National Guidelines for HIV Prevention Treatment and Care in Nigeria". As the head of the Pharmacy Division and Associate Director with the Institute of Human Virology, Nigeria (IHVN) – a US PEPFAR and Global Fund implementing partner with over 200,000 HIV/AIDS patients in care, he oversees the delivery of pharmaceutical care service in all the grants. He served as the liaison officer between the Martindale Pharmaceutical Limited, UK and the Federal Government of Nigeria for the importation of Narcotics for the public sector in 2003/2004. His current interest is promoting pharmacovigilance in public health programs.

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Pharmaceut Reg Affairs
ISSN: 2167-7689 PROA, an open access journal

Regulatory Affairs 2015
August 03-05, 2015

Volume 4, Issue 3

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