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Abstracts
ISoP Annual Conference
‘The Renaissance of Pharmacovigilance’
Drug Safety

Editor: Nitin Joshi

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Aim and Scope: Drug Safety advances the rational use of pharmacotherapy by providing a programme of review articles offering guidance for safe and effective drug utilization and prescribing.
The Journal includes:
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• definitive reviews on the epidemiology, clinical features, prevention and management of adverse effects of an individual drug or drug class when given at therapeutic dosages or following overdose;
• benefit-risk assessments providing an in-depth review of adverse effects and efficacy data for a drug in a specific disease to place the benefit-risk relationship in clear perspective;
• practical reviews covering drug use in particular 'at-risk' patient groups to achieve optimal outcomes;
• concept reviews covering issues in pharmacovigilance, risk management and medication error prevention;
• original research articles will also be considered for publication.
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Drug Safety is the official journal of the International Society of Pharmacovigilance. The official representative for the Society is Dr. Hervé Le Louet from Henri Mondor Hospital, Créteil, France

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Abstract Code: ISP3427-44

Predictors of Serious Adverse Drug Reactions in Association with Complementary and Alternative Medicine in Malaysia

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Introduction: In Malaysia, Complementary and Alternative Medicines (CAM) products are easily available and increasingly used. Our spontaneous reporting system has received many reports of serious adverse events associated with the use of CAM products. Yet, little is known about factors influencing the development of serious adverse drug reactions (ADRs) due to CAM products.

Aim: To identify factors risk associated with serious ADRs due to CAM products.

Methods: All adverse reactions associated with CAM products (including CAM health supplements) submitted to the National Pharmaceutical Control Bureau (NPCB) between 2000 and 2012 were reviewed and analysed. ADRs were considered serious if the reactions led to death, hospitalisation or prolongation of hospitalisation, that were life threatening, or that caused significant disability. A multiple binary logistic regression was used to identify factors associated with serious ADRs in the reports.

Results: From a total of 43,444 reports received by NPCB, 732 (1.7%) involved CAM products. Of 732 patients, 220 (30.1%) developed serious ADRs, of which 72 died. Twelve deaths were attributed to unregistered products. Patients mainly use CAM products for health maintenance (31.8%), for the treatment or prevention of minor ailments (17.9%), for chronic illnesses (32.4%), weight loss (5.2%) and also for serious illnesses such as cancer (1.1%). Multiple binary logistic regression analysis revealed three variables (patients having concomitant diseases, ethnic group and indications of CAM use) to be predictive of the ADRs seriousness. The odds of someone with concomitant diseases experiencing serious ADR were about two-fold compared to someone without concomitant diseases (odds ratio (OR) 1.91, confidence interval (CI) 1.12–3.25). Being Chinese was associated with increased odds of experiencing serious ADRs compared to being Malaya (OR 2.35, CI 1.61–3.64). The odds of someone experiencing serious ADRs also increased if the CAM products were for chronic illnesses compared to if the products were used for health maintenance (OR 1.66, CI 1.12–2.47). The variables age, sex, and concomitant drugs were not significant predictors of serious ADRs.

Conclusions: The proportion of serious ADRs associated with CAM products was high, with several deaths. Chinese patients and those who used CAM products for chronic illness and patients with concomitant diseases were at an increased risk for developing serious ADR. The findings could be useful for planning strategies to prevent serious ADRs due to CAM products.

Abstract Code: ISP3434-42

Design and Evaluation of the Pharmacovigilance Course in Pharmacy School (Kulliyyah) in Malaysia

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Background: Deficiencies in pharmacovigilance education may contribute to low involvement and ADR underreporting among pharmacists. There is a need for Malaysian pharmacy students to be adequately trained and exposed to the challenges and the current problems in pharmacovigilance.

Objectives: To design and evaluate the new pharmacovigilance course for undergraduate pharmacy program in Malaysia and students' evaluation of the course.

Design: 3 hours face-to-face lectures and 2 hours tutorial base have been integrated in required 3-credited-hours course (research in pharmacy and pharmacoeconomics). The course designed to provide an overview of introduction to the concept of pharmacovigilance, clinical classification of adverse drug reactions, the role of the pharmacist in the reporting of adverse drug reporting, discuss the Malaysian guideline for adverse drug reporting.