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The role of the clinical trials pharmacist in reporting of adverse drug reactions

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The reporting of adverse drug reactions is an important element of pharmacovigilance. Drug safety data collection and recording and reporting of adverse reactions are essential to the clinical trial protocol and their importance is strongly emphasized. However, sponsors of clinical trials have somewhat neglected the involvement of the clinical trials pharmacist on adverse drug reaction reporting. In Australia, the spontaneous reporting of adverse drug reactions to the Advisory Committee on the Safety of Medicines (ACSOM), Therapeutic Goods Administration (TGA) by health professionals or the pharmaceutical industry is analogous to the voluntary reporting to the Adverse Event Reporting System (AERS) under the FDA. Pharmacists play a major role in reporting of adverse drug reactions in Australia and the mean level of contribution by pharmacists in adverse drug reaction reporting between 2004 and 2008 was 23.3%. At the Royal Melbourne Hospital in 2011, 54% of adverse drug reactions were reported by pharmacists compared to 28% by doctors, 14% by radiology staff and 4% by nurses. The clinical trials pharmacist has an in-depth knowledge of pharmacotherapy of the study drugs in addition to the knowledge of a broad range of drugs and clinical therapeutics. They can thus contribute to improved pharmacovigilance by being actively involved in adverse drug reaction reporting in clinical trials as well as detecting other drug-related problems such as drug interactions with over-the-counter medications, conventional and alternative drugs. The role of the clinical trials pharmacist can be expanded beyond drug management, record keeping and participant education to pharmacovigilance including adverse drug reaction reporting.

Biography

Eugenia Hong and Emma Michael are senior pharmacists in charge of clinical trials pharmacy at the Royal Melbourne Hospital, Australia. They lead clinical trials pharmacy which provides a comprehensive clinical research service including protocol review, assistance in protocol development, investigational drug management, preparation and dispensing, drug information, patient randomization, emergency 24-hour services and educating clinical trial participants and staff on clinical trials medications for over 300 studies conducted at RMH. Eugenia Hong is a committee member of The Society of Hospital Pharmacists of Australia and Emma Michael is a member of the Human Research Ethics Committee of Melbourne Health.

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