

The Proactive Pharmacovigilance Clinical Pharmacist: Is it Specialty of its Own

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The World Health Organization (WHO) defines pharmacovigilance as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.”

The safety monitoring of pharmaceuticals is a fundamental component of daily clinical practice. Providing high eminence medical care, ongoing safety monitoring and evaluation of effectiveness are essential to the perpetual use of pharmaceuticals. Pharmacovigilance is recognized as a clinical discipline and it serves as an indicator of the standards of clinical care practiced within a country.

The clinical pharmacists have central accountability in monitoring the safety of pharmaceuticals. A key clinical responsibility of the clinical pharmacist is in the early detection of adverse drug reactions (ADRs) and other drug-related problems as well as monitoring the effectiveness of pharmaceuticals. Clinical pharmacist is actively involved in designing tools and guidelines for monitoring, detection, prevention and reporting of ADRs. Interpreting of relevant laboratory data contained in patient profile with linked data-base will enormously enrich the pharmacovigilance activity.

The clinical pharmacist, as a part of the healthcare team, is a source of both information and critical evaluation and appraisal of drug information. The clinical pharmacist's expertise is vital to the application of the safety profile of a pharmaceutical tailored to the needs of a particular patient.

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A clinical pharmacist with pharmacovigilance responsibility can be an exciting opportunity and challenging era whereby the expertise are crucial to successful implementation of clinical pharmacovigilance safety strategy. The responsibilities can be extremely versatile, providing scientific leadership, establishing and implementing the pharmacovigilance safety strategy and conveying in-depth awareness of the latest developments in the pharmacovigilance safety arena. This role identifies opportunities for improving the clinical practice of pharmacovigilance, enhancing current safety processes, leading a pro-active safety evaluation and risk management for pharmaceuticals which is extended to the post-marketing surveillance schemes.

The pharmacovigilance clinical pharmacist proactively evaluates the clinical implications of safety data from pre-clinical/clinical studies, literature and other information sources in an attempt to predict / establish the safety profile of pharmaceuticals and manage the risk to patients (risk element of the benefit/risk evaluation).

This established-role involves collaboration with experts, regulatory bodies and authorities, to promote high quality evaluation of patient and drug safety data.

The responsibilities of pharmacovigilance clinical pharmacist include utilization of safety expertise or innovations to provide safety design and support health care facilities senior management with pharmacovigilance clinical practices. This will be in addition to routine tasks of documentation, training and periodic reporting. Training and education of all healthcare professionals, patients and students is a core function to successful implementation of the pharmacovigilance services delivered by the pharmacovigilance clinical pharmacists.

There remains a question, can any person occupy such a role and responsibilities, the answer remain to be validated with evidence-based pharmacovigilance studies. In this respect the clinical pharmacist has a profound expertise and is well suited by virtue of certificates, positioning in clinical wards and drug expertise to implement a pharmacovigilance strategy and lead the initiative. The clinical pharmacist research skills are of paramount importance to this strategy. This research skill will assist and may resolve under reporting and contribute in understanding diagnosis of ADRs especially causality assessment and DDI's and others.

The clinical pharmacist can be of great asset in designing, conducting pharmacovigilance safety strategy, using electronic systems and establishing pharmacovigilance committee in the healthcare facilities.

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