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Pharmacovigilance - National and International Scenario of Pharmacovigilance

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ABSTRACT

Pharmacovigilance in India was initiated the way back in 1986 is a formal adverse drug reaction (ADR) monitoring system, under supervision of the drug controller of India. World Health Organization Programme of the International Drug Monitoring in 1998 but its not successful. these National Programme the Pharmacovigilance was launched in 2005, and was renamed the Pharmacovigilance Programme of India (PvPI) in 2010.

The culture of reporting of ADRs has been achieved remarkable success, with 250 PvPI-established adverse drug monitoring centres of all over India and provision of training to healthcare professionals. spite of the achievements, several challenges are faced by the PvPI, like the monitoring of generic drugs, and disease-specific ADRs of antidiabetic, cardiovascular and antipsychotic drugs and, creating awareness, which is a continual process. At the same time, these PvPI is trying to address other challenges like counterfeit drugs, antimicrobial resistance, and surveillance during mass vaccinations and other national programmes.

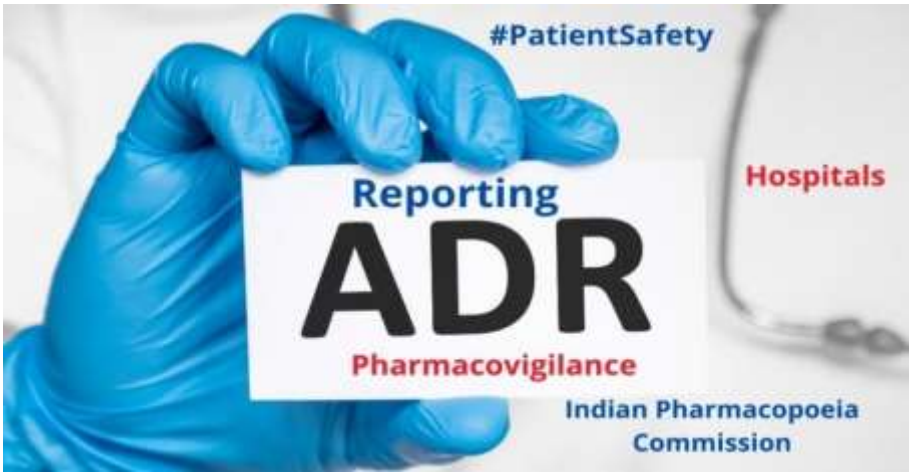
Keywords - Adverse reaction, drug, pharmacovigilance, reporting

Introduction

Pharmacovigilance has been described as "the science and activities relating to the detection, assessment, understanding and prevention of the adverse effects of drugs or any other possible drug-related problems. It is a fundamental component of effective drug regulation systems, public health programmes and clinical practice. Pharmacovigilance more than spontaneous reporting alone, and evaluation of marketed medicines is more than pharmacovigilance. The positioning of a drug usually takes place during the years following introduction, when worldwide experience has accumulated. a modest appendix of drug regulation, pharmacovigilance has become a major activity.

Pharmacovigilance, and more generally these study of the benefits and risks of the drugs, plays a major role in pharmacotherapeutic decision-making, individual, ,national or international. The addition, pharmacovigilance is the becoming a scientific discipline in its own right.

New processes, both at a regulatory and a scientific level, are being developed with the aim of strengthening pharmacovigilance. Covering the basics step-by- step, this book is perfect for beginners and is essential reading for those new to drug safety departments and pharmaceutical medicine students. In that second edition are the thoroughly revised and updated throughout and includes these new chapter of clinical aspects of pharmacovigilance.



Objectives

To Promote understanding, education and training of pharmacovigilance and effective communication to the public.

Contribute in the assessment of benefit-risk ratio, effectiveness, and risk of medicines, leading to the prevention of harm and maximization of benefits.

To Improve patient care and safety in the relation to the use of medicines and all medical interventions.

To Detect problems related to the use of the medicines and communicate findings in the timely manner.

To Improve public health and safety in relation to the use of medicines; Encourage the safe, rational, and more effective (including cost-effective) use of medicines.

Role of pharmacovigilance in PV

The Pharmacogenomics (PGx) of the combines traditional pharmaceutical sciences and biochemistry with the annotated knowledge of genes, proteins, and single nucleotide polymorphisms.

Such approaches are promise the advent of "personalized medicine"; in which the drugs and drug combinations is optimized for the individual's unique genetic makeup.

PG and PGx research remain the iterative processes and for opportunities for improvement in each of the approaches. The multiple approaches have to be combined to obtain PGx knowledge that is the value for the development of new therapeutics or for the improvement of existing therapies.

Methods

We are identified studies describing the approaches for ADR detection from social media from the Medline, Embase, and Web of Science databases, and the Google Scholar search engine. Studies that met our inclusion criteria were those are the attempted to extract ADR information posted by the users on any publicly available social media platform. categorized the studies according to different characteristics such as primary ADR detection approach, availability, and evaluation criteria.

Morbidity and mortality of ADR's

The Adverse drug reactions are ranked as the one of the top 10 causes of morbidity and mortality in the developed world **.** Adverse drug reactions represent a vast economic burden in terms of healthcare costs, contribute to a significant percentage of hospital admissions and are regarded as a major public health problem. Prior to approval, most drugs will only have been tested for short-term safety and efficacy on a limited number of carefully selected individuals . Additionally, the controlled environment of pre-marketing clinical trials bears very little resemblance of how the drug is used in larger populations.

Conclusion

Patient reporting adds the new information, perspective about the ADRs in a way otherwise unavailable. This can be contribute to the better decision-making processes in regulatory activities. These are present review identified the gaps in knowledge that should be addressed to improve the our understanding of full potential and drawbacks of patient reporting.

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