IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 2, Issue 5, June 2022
Impact Factor: 6.252

A Review on Adverse Drug Reaction in Pharmacovigilance

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Abstract: *Pharmacovigilance is a practice aimed to monitor drug safety in real life conditions and capture adverse drug events during the post marketing phase of drug's life cycle. But under reporting of adverse reactions is a major cause of concern and a threat to the pharmacovigilance systems. The present article looks into the major obstacles affecting the spontaneous reporting of adverse drug reactions (ADRs) in India and the possible solutions. As per available scientific literature, the major impediments to ADR reporting are inadequate knowledge and awareness among health professionals, clinicians' perceptions towards reporting, problems with establishing reporting systems in hospitals and insufficient training to recognize ADRs. Measures to improve the situation include greater involvement of nurses, pharmacists as well as consumers in the reporting of ADRs, making the process simpler and faster through electronic means, introducing educational interventions and training programs for health care providers and spreading awareness about the reporting system amongst caregivers and receivers alike. Providing a momentum to the pharmacovigilance system and ensuring a robust reporting process is a challenge but proper planning, feasible solutions and focussed efforts can help bring about the change ensuring patient safety - the ultimate goal of pharmacovigilance.*

Keywords: Adverse drug reactions; spontaneous reporting; under reporting

I. INTRODUCTION

Drugs have changed the way in which diseases are treated. Despite all the advantages of pharmacotherapy, adverse reactions are a recognized hazard of drug therapy. Adverse drug reactions (ADRs) are a common, frequently preventable cause of illness, disability and death. An ADR may be defined as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product".

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".

One of the first pieces of evidence of the establishment of a system to monitor drug safety was the committee set up by the Lancet to report on mortalities resulting from anaesthesia in Britain and its colonies. The formation of the committee was in reaction to the 1848 death of a 15-year old girl who had undergone chloroform anaesthesia for the removal of an ingrown toenail.

II. MORBIDITY AND MORTALITY OF ADRs

Adverse drug reactions are ranked as one of the top 10 causes of morbidity and mortality in the developed world. Adverse drug reactions are documented in the USA to claim 100 000 to 218 000 lives annually and are the third leading cause of death after heart disease and cancer (14–16). However, the burden of the problem may actually be underestimated, as in many instances, ADRs are not suspected, thereby leading to under-reporting (17, 18). 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 (19–22). In the USA, the costs resulting from drug-related problems in the ambulatory care setting was estimated to exceed US$177 billion annually (15).

These estimates are significant when compared with the health-related cost in the USA of other major diseases such as diabetes ($174 billion in 2007), obesity ($147 billon in 2009) and cardiovascular diseases [$503 billion in 2010] (23–25).

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Prior to approval, most drugs will only have been tested for short-term safety and efficacy on a limited number of carefully selected individuals (26). In some cases, as few as 500 subjects and seldom more than 5000 will have received the drug prior to its release (27). In order to identify an ADR that occurs in 1 in 10 000 patients, at least 30 000 patients need to be treated with the drug (2). Consequently, the limited numbers of persons involved in pre-marketing clinical trials do not facilitate good estimation of the ADR profile of a drug. Additionally, the controlled environment of pre-marketing clinical trials bears very little resemblance of how the drug is used in larger populations. It is after release, when the drug is used in more patients having a variety of concurrent diseases and who may be taking other drugs, that limitations to its use become evident.

Classification of adverse drug reactions

- Type A reactions – sometimes referred to as augmented reactions – which are 'dose-dependent' and predictable on the basis of the pharmacology of the drug.
- Type B reactions – bizarre reactions – which are idiosyncratic and not predictable on the basis of the pharmacology.

III. METHODS OF QUANTIFYING ADRs

A number of methods have been used to quantify the frequency of ADRs. They include spontaneous ADR reporting, ecological studies and analyses of medical claims databases, prescription-event monitoring which collects all drug-related events that occur while patients are receiving selected monitored medications, and meta-analyses (38–41). No single method is capable of covering all the requirements for the efficient collection of ADR data and therefore a multiplicity of methods is needed (42).

Spontaneous reporting is the most common method used in pharmacovigilance and the best one to generate signals on new or rare ADRs (43). This reporting scheme has contributed significantly to successful post-marketing drug safety surveillance and can be regarded as the cornerstone of pharmacovigilance (44). There are numerous limitations of the scheme, including the poor quality of submitted reports, difficulty in calculating rates because of incomplete numerator (adverse events) data along with inaccurate denominators (number of prescriptions) and limited ability to determine causality (13, 45). However, the main limitation is under-reporting (26, 43, 45–48).

In a review of 37 studies from 12 countries, undertaken to estimate the extent of under-reporting of ADRs to spontaneous reporting systems, Hazell and Shakir (49) reported a median under-reporting rate of 94% across these studies. Perez-Garcia and Figueras (50), in a study of physicians and pharmacists in Venezuela, reported poor knowledge of the voluntary ADR reporting system in that country. They concluded that study of the actual knowledge of pharmacovigilance could form the basis for specifically designed interventions aimed at overcoming misconceptions and improving reporting rates.

In Jamaica, ADR reports are made to the regulatory authority, the Standards and Regulation Division, Ministry of Health. The standardized ADR reporting form is the “PharmWatch” form (51). A study of the knowledge and attitude of healthcare professionals toward pharmacovigilance and ADR reporting identified training as a significant factor in the improvement of the reporting of ADRs (52). Subsequently, a workshop that could i) facilitate training in the sensitization of healthcare professionals to the importance of pharmacovigilance and ii) effect an improvement in ADR reporting through understanding the importance of the “Pharm Watch” pharmacovigilance programme was designed.

3.1 Method of ADR Reporting

Pharmacovigilance and methods of Adverse Drug Reactions reporting Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India Dr. Lokendra Sharma Professor, Department of Pharmacology & Coordinator, ADR Monitoring Centre, SMS, Medical College, Jaipur.

Pharmacovigilance in India Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India

National Pharmacovigilance Programme 02-Jan-2018 Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India

Adverse Drug Reaction (ADR) A response to a drug which is Noxious and Unintended occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function. (WHO, 1972) Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India

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WHY ADR Reporting ? ADRs are among the leading causes of death in many countries (World Health Organization, 2008) Account for 5% of all hospital admissions in India. Source: http://www.ncbi.nlm.nih.gov/pmc/ articles/PMC3795320/ Constitutes a significant economic burden on the patient and government Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India

Benefits of ADR Reporting

Assess the safety of drug therapies, especially recently approved drugs. Provides updated drug safety information to health care professionals and other stakeholders Measuring the economic impact of ADR prevention as manifested through reduced hospitalization, optimal and economical drug use, and minimized organizational liability Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India

- Regulatory action on the basis of ADR reports to ensure patient's safety
- Upgrading package insert
- Marketing Authorization Recall (withdrawal)
- Batch recall based on clustering of ADR
- Changes in classification, e.g. o From over the counter to prescription only medicines.

Special prescription o Restricted prescription Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India

ADR Reporting Procedure ¬ Who can report ¬ What to report ¬ How to report ¬ Whom to report ¬ Where to report Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India

LIndian Pharmacopoeia Commission, Pharmacovigilance Programme of India Who can report? All healthcare professionals (Clinicians, Dentist, Pharmacist, Nurses, Physician, Physiotherapist etc) • All non- healthcare professionals including consumers/ patients etc can report ADRs.

What to Report ? All types of suspected adverse reactions

- Known or unknown,
- Serious or non-serious and
- Frequent or rare ¬ Reactions from all types of pharmaceutical products
- Allopathy,
- Ayurvedic
- Vaccines,
- Medical devices etc.

Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India Health Care Professionals Consumer NCC-PvPI Ghaziabad AMCs Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India Industry Who can report? How to report ?and whom to report?

A reporter can also report ADR Via Helpline number launched in October 2013 1800 -180- 3024 (Monday to Friday 9:00AM to 5:30 PM) Toll free-Helpline Number Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India

Android Application ADR Reporting App. can be downloaded from Google play store (free to download) Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India ADR-PvPI is the indigenously developed Mobile App for all healthcare professionals and consumers to report adverse drug reactions

Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India Worldwide Reporting Forms CIOMS for US MED-WATCH FOR UK

ADR Reporting form for Healthacare Professionals Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India Suspected Adverse Drug Reaction Reporting Form For Health Care Professionals This form is divided into four sections: A. Patient Information B. Suspected Adverse Reaction C. Suspected Medication(s) D. Reporter Details Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India

A. Patient Information Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India A. Patient Information

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1. Patient Initials _____
2. Age at time of event or date of birth _____
3. M □ F □ Other □ _____
4. Weight _____ Kgs
5. B. Suspected Adverse Reaction B. Suspected Adverse Reaction
6. Date of reaction started (dd/mm/yyyy)
7. Date of recovery (dd/mm/yyyy)
8. Describe reaction or problem Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India
9. C. Suspected Medications Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India C. Suspected medication(s) S.N o
10. Name (Brand /Generic) Manufacturer (If known) Batc h No./ Lot no. Exp. Date (if known) Dose used Route used Frequency (OD, BD, etc.) Therapy dates Indication Causality assessment Date started Date stopped..
11. Suspected Medications Action taken- Mark the appropriate option for the action taken with respect to Suspected drug. Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India S.No. as per C
12. Action Taken (Please Tick) Drug withdrawn Dose increased Dose reduced Dose not changed Not applicable Unknown.
13. Suspected Medications Rechallenge/ Reintroduction - The point at which a drug is again given to a patient after its previous withdrawal. Mark the appropriate option whether the suspected drug reintroduced & reaction occurred or not or effect unknown. Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India
14. Reaction reappeared after reintroduction (Please Tick) S.No. Yes No Effect Unknown Dose (If reintroduced)
15. Concomitant medications Concomitant medical product (s) information given in the following tabs. Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India
16. Concomitant medical product including self medication and herbal remedies with therapy dates (exclude those used to treat reaction) S.No. Name (Brand /Generic) Dose used Route used Frequency (OD, BD, etc.) Therapy dates Indication Date started Date stopped

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