JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

Review paper on Pharmacovigilance and Adverse Drug Reactions : Their Management

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ABSTRACT

➢ Pharmacovigilance, or PV, is the process of continuously monitoring pharmaceuticals once they are put on the market in order to evaluate and enhance their safety profile. Increasing the number of adverse drug reactions (ADRs) that are spontaneously reported is the primary goal in order to collect a wide range of data. The World Health Organization (WHO) defined pharmacovigilance as the science and set of procedures concerning the identification, assessment, comprehension, and rejection of negative effects or problems associated with various drugs in nursing. A clinical test may involve an analysis study involving human subjects in order to address particular health questions. Carefully carried out clinical trials are the fastest and safest methods because they help individuals receive treatments that work and because they improve health. Pharmacovigilance, which provides information on the negative effects that the drug-using population typically experiences, is acknowledged to be essential to the sensible use of pharmaceuticals. Adverse drug reactions (ADRs) are becoming more and more common, and various methods, including scientific and administrative research, indepth observation, impromptu reporting, and information studies, are being developed with the goal of enhancing pharmacovigilance. Because assessment procedures contain some subjective judgements, integrator reliability is frequently low. In summary, there is Apresently no well recognized mechanism for assessing casualties from ADRs.

➢ **KEYWORDS** :- Pharmacovigilance; adverse drug reaction; signal detection ; spontaneous reporting; risk management; Pharmacovigilance system.

❖ **Literature Review** :

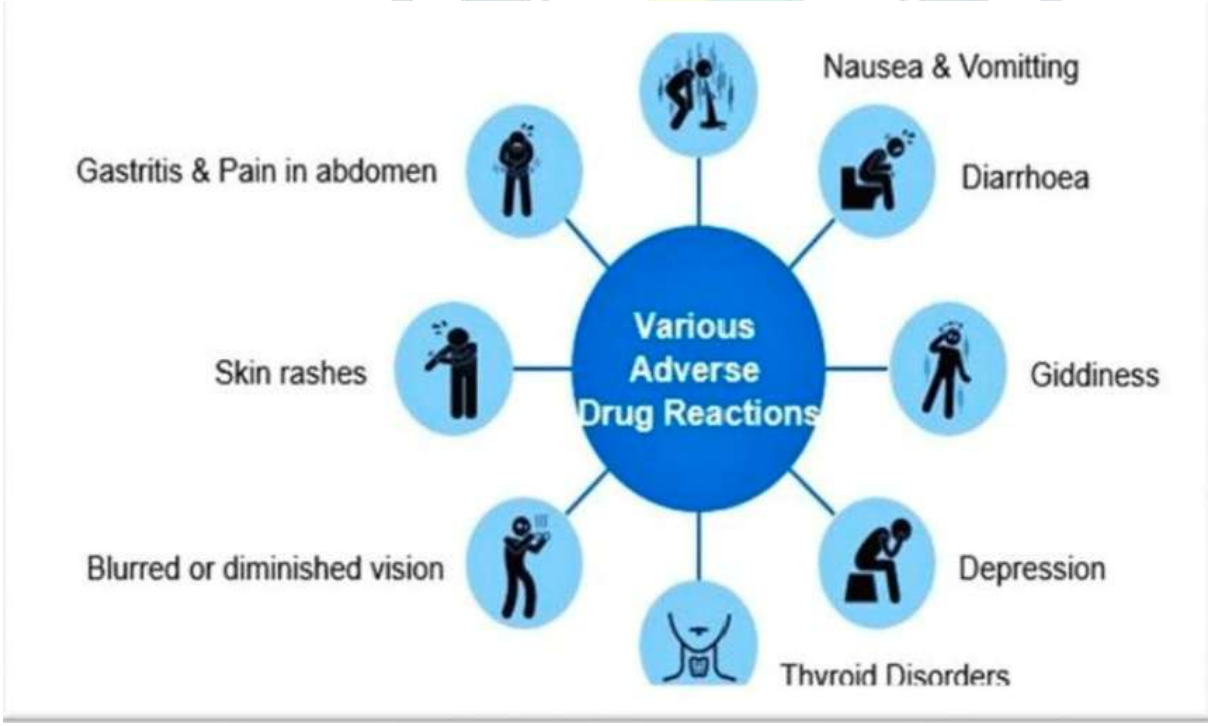
Year	*Name of author*	Country	*Duration of study*	*Studies (reference)*
2025	Amy bobbins, Miranda davis	UK	3 years	Safty and effectiveness of the anti-amyloids monoclonal antibody drug lecanemab for early alzheimer disease: the Pharmacovigilance Perspective
2021	Tamine salehi, *Naiemeh seyedfatemi*	Iran	2 Years	Nurses knowledge, attitudes and practice in relation to pharmacovigilance and advers drug reaction
2024	Rohit Vishwakarma,vishal rai	India	*1 years*	A review paper of pharmacovigilance : an overview
2024	*Suraj hanumant kore*	India	*6 Month*	A reviw on pharmacovigilance and its importance
2024	*Nikhil kharde*	India	*1 Month*	A review on advers drug reaction and its type with their management

DRUG	EFFECTS
Tetracycline	Poor absorption of tetracyclines
Amino glycosides	Hearing problem, Kidney problem
Anti diabetic	Lower blood sugar
Warfarine	Increase risk of bleeding
Phenytoin	CNS and respiratory depression.
Barbiturates	Muscle weakness, Reduced consciousness.
Lithium	Hypothermia
Alprazalon	CNS depression
Diazepam	Sedation
Methotrexate	Bone marrow suppression
Benzodiazepines	Sedation and Respiratory suppression
Ethanol	Additive CNS effect, death
Prednisone	Edema
Theophyllines	Insomnia, seizure, restlessness
Miconazole	Severe hypoglycemia
Warfarine	Haemorrhage

❑ INTRODUCTION :-

➢ An undesired side effect of a medication that happens during routine therapeutic use is known as an adverse durg response (ADR). In healthcare facilities, adverse drug reaction happen practically every day. They can negatively impact a patient's quality of life and frequently result in significant morbidity and mortality. Finding the patient demographics most at risk, the medications most at frequently to blame, and the possible causes of adverse drug reaction have all received a lot of study. A growing number of medications on the market, an older population, and an increasing trend in polypharmacy are all factors that contribute to adverse drug reaction (ADRs) globally.

It must pass a number of tests to guarantee its efficacy and safety before it can be sold commercially. ButThe following are some of the limitations of clinical trials: Strict inclusion and exclusion standards restrict their application to a very limited group of patients; specific demographics like children, expectant mothers, and the elderly are not examined during the trials; and additional elements that contribute to drug reactions, including genetic, environmental, and drug-drug interactions, maynot examined in the course of the clinical trials.



➢ Little is known about a drug's safety in clinical settings once it is marketed because only roughly 1500 patients are likely to have used it. Drug safety evaluation should therefore be regarded as a crucial component of routine clinical practice since Clinical acumen is frequently required for detection and diagnosis.

❑ History of Pharmacovigilance :-

➢ The thalidomide disaster of the 1960s became a turning point in the evolution of drug safety, driving international efforts to monitor and regulate medicines more effectively. Earlier, a Lancet article published in 1893 on chloroform-related deaths had already raised awareness about drug safety concerns. Subsequent reforms, such as the amendments to the U.S. FDA Act in 1906 and 1962, were introduced following tragedies linked to sulphanilamide elixir and thalidomide, respectively. The United Kingdom's Medicines Act of 1968 and the establishment of the World Health Organization's Program for International Drug Monitoring in the same year further reinforced global pharmacovigilance initiatives.

❖ Chronological Development of Pharmacovigilance

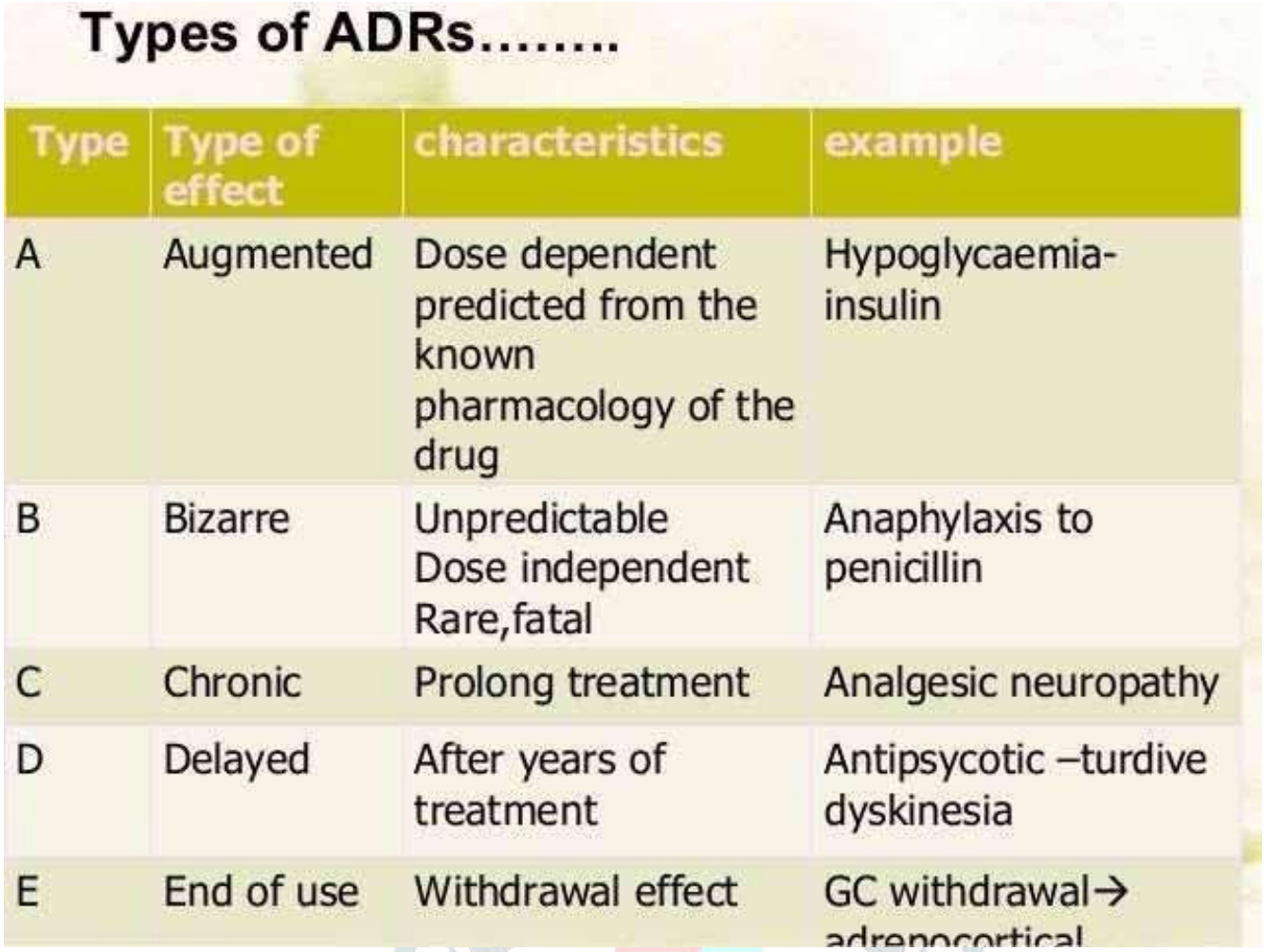
Year	Development
1747	James Lind conducted the first recorded clinical trial, proving lemon juice's effectiveness in preventing scurvy.
1947	Over 100 children died due to sulphanilamide toxicity.
1950	Chloramphenicol was found to cause aplastic anaemia.
1961	The global thalidomide tragedy highlighted severe drug toxicity issues.
1963	The 16th World Health Assembly emphasized the urgent need for action on Adverse Drug Reactions (ADRs).
1968	WHO launched a pilot project for international drug monitoring.
1996	Internationally standardized clinical trials began in India.
1997	India joined the WHO Adverse Drug Reaction Monitoring Program.
1998	The practice of pharmacovigilance formally began in India.
2002	The 67th National Pharmacovigilance Centre was set up in India.
2004–05	India launched its National Pharmacovigilance Program.
2005	Structured clinical trials were successfully implemented in India.
2009–10	The Pharmacovigilance Programme of India (PvPI) was officially initiated.

❑ Adverse Drug Reaction (ADR)

➢ An Adverse Drug Reaction (ADR) is a harmful or unintended response to a medication that occurs at normal doses used for prevention, diagnosis, or treatment of disease. It is different from overdose, misuse, or medication errors.

❑ Objectives of Studying ADRs :-

1. Ensure patient safety by detecting and preventing harmful effects.
2. Improve therapeutic outcomes through safer drug use.
3. Identify risk factors associated with specific patients or drugs.
4. Support regulatory decisions for drug approval, labeling, or withdrawal.
5. Enhance rational drug use and public health policies.



Types of ADRs.....

Type	Type of effect	characteristics	example
A	Augmented	Dose dependent predicted from the known pharmacology of the drug	Hypoglycaemia-insulin
B	Bizarre	Unpredictable Dose independent Rare,fatal	Anaphylaxis to penicillin
C	Chronic	Prolong treatment	Analgesic neuropathy
D	Delayed	After years of treatment	Antipsycotic –turdive dyskinesia
E	End of use	Withdrawal effect	GC withdrawal→ adrenocortical

❑ **A system for spontaneous reporting :-**

1. The process of regionalization
2. Returning additional data
3. Availability of all crucial pre- and post-marketing data
4. Comprehensive information on drug use.
5. Standardized Assessment of Significance and Causation
6. Motivation

❑ **ADR documentation :-**

➢ The global pharmacovigilance curriculum encourages all suspected drug-related adverse events to be reported. ought to be described. It looks into reports of the following: (A) Any negative impact that is suspected or has happened by newly developed medications and medications currently in use (B) Records of different medications that result in adverse drug reactions, such as Congenital abnormalities, hospitalization, disability, death, and life-threatening conditions.

Organ system	**Example**
Toxicity	Isoniazide Ethanol Aminglycosides, Rifampicin, Pyrazinamide, Ethanol
Ocular toxicity	Isoniazide, Rifampicin, Vincristin, Haloperidol, Thiazide
Gastrointestinal toxicity	Doxycilline, Sulphonamides, Gold uretics, Paramino salicylic acid
Dermatological toxicity	Parazosin, Resorpine, Haloperidoside, Anti-tuburourar drugs vincristin

❑ **ADR monitoring's benefits :-**

1. It provides information on pharmaceutical products' safety and quality.

2. It starts plans for risk management.

3. It helps measure adherence to ADRs and prevents predictable negative effects.

4. It informs patients, pharmacists, and nurses about the negative effects of medications and develops knowledge of ADRs. ADR monitoring's primary goal is to reveal the caliber and frequency of ADRs as well as to determine the risk factors that may contribute to the negative reactions. [10]

❑ **India's Pharmacovigilance :-**

➢ India boasts 15,000 hospitals with 6,24,000 beds and more than half a million qualified physicians. It is the world's fourth-largest pharmaceutical manufacturer. It is becoming a significant trial center in thethe world. In our nation, a lot of new drugs are introduced. Consequently, an active pharmacovigilance program is required. system in place to safeguard the populace against the possible harm that some of thesenovel medications. The Central Drugs Standard Control Organization is well aware of how big the task is (CDSCO). has started a highly participatory and organized national pharmacovigilance program.

❑ **Technological Advancements in Pharmacovigilance**

1. Artificial Intelligence (AI) & Machine Learning (ML):

Algorithms help detect adverse drug reactions (ADRs) from large datasets.

ML models can predict potential safety signals earlier than traditional methods.

Used for automating case processing and literature monitoring.

2. Big Data Analytics:

Integration of data from electronic health records (EHRs), social media, and clinical trials.

Helps identify rare or delayed adverse drug events.

Enhances real-world evidence generation.

3. Natural Language Processing (NLP):

Extracts safety-related information from unstructured sources such as medical notes, emails, and reports.

Improves accuracy in identifying ADRs in multiple languages and formats.

4. Blockchain Technology:

Provides secure, transparent, and tamper-proof data sharing across stakeholders (pharma companies, regulators, healthcare providers).

Strengthens traceability and integrity of pharmacovigilance data.

5. Cloud Computing:

Enables global collaboration and real-time access to pharmacovigilance databases.

Facilitates scalability, faster data processing, and integration of multiple sources.

6. Mobile Applications & Digital Reporting Tools:

Empower patients and healthcare professionals to report ADRs easily.

Increases participation in post-marketing surveillance.

7. Data Mining & Signal Detection Tools:

Automated systems such as VigiBase, FAERS, and EudraVigilance use data mining for early signal detection.

Reduces manual workload and improves risk assessment.

8. Internet of Things (IoT) & Wearable Devices:

Continuous monitoring of patients' vital signs.

Real-time data transmission for early detection of drug-related adverse events.

❑ Aims of pharmacovigilance:

1.Improve patient care and safety:

To protect patients by identifying and mitigating risks associated with medicines.

2.Enhance public health:

To safeguard the public's health by ensuring that the benefits of a medicine significantly outweigh its risks.

3.Promote rational and effective use of medicines:

To provide information that supports the safe, rational, and effective use of drugs by both patients and healthcare professionals.

4.Assess benefit-risk ratio:

To continually evaluate the benefit, harm, effectiveness, and risk of medicines throughout their lifecycle.

5.Detect and communicate problems:

To identify problems related to medicine use, such as adverse drug reactions, and communicate these findings to relevant stakeholders in a timely manner.

6.Prevent harm:

To prevent harm from medicines by identifying potential issues and taking appropriate action.

❑ ADR MANAGEMENT

1. Recognition and Tracking

Careful Evaluation: Medical professionals should

carry out comprehensive evaluations to find possible

ADRs, especially in the early stages of treatment

as well as following dosage adjustments.

Using scales: The Naranjo Scale is one useful tool.

scertain the probability that an ADR is connected to a drug.

2.Modification of Therapy

Modification of Dosage: If an adverse drug reaction (ADR) is suspected, think about changing the dosage or moving to a different drug with a better safety record.

Drug Discontinuation: In extreme circumstances, stopping the offending substance right away might be required.

3.Assistance with Care

Symptomatic Treatment: Offer remedies to reduce the symptoms brought on by ADRs, including Antiemetics or antihistamines for allergic reactions for nausea.

Monitoring: Vigilant observation might be necessary for patients who are having serious adverse drug reactions to make sure safety and deal with issues.

4.Multidisciplinary Approach

Teamwork: Involve nurses, pharmacists, and additional medical specialists to evaluate and effectively handle ADRs. An interdisciplinary method can improve patient safety and care.

5. Monitoring

Even if a well-established or causal relationship is unclear, it is the duty of all medical professionals to notify their peers about clinically significant adverse drug reactions they observe outside of official surveillance systems.

A national center that is in charge of providing general information about drugs and taking regulatory action should receive information about what has happened and how the diagnosis was made. This data is sent to the WHO global database by national centers.The WHO Collaborating Centre for International Drug Monitoring (the Uppsala) analyzes this global data.

6. **Strategy to improve drug safety**

Avoiding functional groups in chemicals that are well known to result in toxicity when designing drugs For instance, phenols, epoxides, aromatic amines,

The creation of medications that are metabolically inert to prevent metabolic processes and stop the development of harmful metabolites, such as vigabatrin and Gabapentin Creation of appropriate in vivo and in vitro systems to clarify the function of transient, potentially harmful In the pathophysiology of idiosyncratic poisoning.

The use of in vitro systems has increased. For example, cell lines expressing enzymes that break down drugs, in order to forecast the possibility of harmful drug interactions and Different metabolic pathways Premarketing research on high-risk patients phase of drug development to determine pharmacokinetic as well as pharmacodynamic elements that affect vulnerability to toxicity from drugs.

❑ FUTURE DEVELOPMENTS :-

- The WHO monitoring program's efforts in A detailed description of Uppsala can be found elsewhere. The program additionally aids the European Research Group for Pharmacovigilance, which has permitted drug safety experts and regulators from various European nations in the future to organize coordinated drug-safety activities.
- These kinds of initiatives could lead to much more rational advancement and analysis of medication safety signals all over the world.
- Understanding the human genome will enable us to forecast vulnerability to a growing number of illnesses, including those brought on by drugs, will also improve. recognized as we learn more about genetic impacts on the pharmacokinetics of drugs Pharmacodynamics: phenotyping is already used, and using genotyping to forecast certain drug-related issues metabolism of drugs.
- Additional advancements in genomics will enable us to create tests that predict how drugs will work, encompassing negative drug reactions, preserving the potential for more precise therapy customization to the person.
- As we gather more and more data regarding drug reactions, we must not overlook the alarming fact that roughly 50% of drug-related harm resulting from potentially preventable adverse drug interactions responses.

❑ Role of health-care professional :-

- Health-care professional , including physicins, pharmacist, nurses, play a crucial role in pharamacovigilance. The are responsible for identifing and reporting ADRs, educating patients, and ensuring that benefits of medication out weight it's. Continous education and training in pharmacovigilance practices are essentially for health care professionals to inhance their ability to manage ADRs effectively.

❑ CONCLUSION :-

The significance of negative drug reactions is frequently undervalued.

They are prevalent, have the potential to be fatal, and prohibitively costly.

By lessening the burden of drug toxicity, the actions listed in the box above are crucial for increasing the benefit to risk ratio of drug treatment.

Due to the vast array of medications that are available, the

Toxicological symptoms can vary and impact any organ system.

In actuality, negative responses have replaced Tuberculosis and syphilis are excellent mimics of other illnesses.

It is probable that the toxicity pattern will shift with the launch of novel biotechnology goods.

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