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A Review on Pharmacovigilance

Miss. Sakshi Chandrakant Wagh and Asst. Prof. Snehal Kadbhane
Kasturi Shikshan Sanstha's College of Pharmacy Shikrapur, Pune, India

Abstract: *Pharmacovigilance (PV), as defined by the WHO, refers to the science and activities involved in the detection, assessment, understanding, and prevention of adverse effects or other drug related problems. PV plays a crucial role in ensuring patient safety and drug efficacy. It is an integral part of the healthcare system, focusing on the assessment, monitoring, and identification of medication interactions and their impact on humans. While pharmaceutical and biotechnological treatments are designed to cure, prevent, or manage diseases, they also carry potential risks, particularly adverse drug reactions (ADRs), which can sometimes be life- threatening. Therefore, monitoring ADRs is essential throughout a drug's lifecycle, encompassing pre-marketing phases, initial drug discovery, clinical trials, and post-marketing surveillance. Adverse events recorded through PV systems are highly beneficial to public health. These systems enable efficient electronic communication with reporters and facilitate the exchange of knowledge with healthcare practitioners, making them a vital bridge between the population and public health experts. Ultimately, PV not only supports patient recovery but also helps manage or prevent illnesses effectively. Medication safety remains a collective responsibility involving the pharmaceutical industry, regulatory authorities, clinicians, and other healthcare professionals, all working together to enhance public health outcomes.*

Keywords: Pharmacovigilance , Clinical trial , Patient safety , Focusing on assessment

I. INTRODUCTION

Historical Significance of PV:

Pharmacovigilance has evolved significantly over the years, from a nascent concept to an essential component of post-marketing surveillance. The recognition of ADRs during the 20th century led to the establishment of national and international pharmacovigilance systems, aiming to safeguard public health by detecting and addressing unexpected adverse effects. Early efforts focused on collecting spontaneous ADR reports, and the collaboration between national centers and the Uppsala Monitoring Centre (UMC) played a crucial role in global drug safety monitoring.

Role in the Healthcare System:

Pharmacovigilance is a cornerstone of modern healthcare systems. It ensures that the benefits of medicines outweigh their risks in real-world settings. Through continuous monitoring, PV aims to improve patient safety by detecting ADRs that may not have been identified in clinical trials, such as rare or long-term effects. PV systems are essential for regulatory bodies, healthcare providers, and patients, providing critical data that informs decisions on drug use, labeling, and marketing.

In the healthcare ecosystem, pharmacovigilance contributes to evidence-based medicine by enabling safer therapeutic practices and fostering trust in healthcare systems. It supports healthcare providers by offering insights into the risk profiles of drugs, helping them make informed decisions in prescribing and monitoring treatments. For regulatory agencies, pharmacovigilance ensures compliance with safety standards and facilitates timely interventions, such as drug recalls or updates to product labels, to protect public health.

Pharmacovigilance also empowers patients by promoting transparency and encouraging active participation in reporting ADRs. By focusing on the detection and mitigation of risks, pharmacovigilance plays an essential role in reducing morbidity and mortality related to drug use, thereby ensuring better health outcomes. Additionally, PV strengthens public confidence in the healthcare system by demonstrating a commitment to continuous safety monitoring and improvement.

The integration of pharmacovigilance with advancements in healthcare technology, such as electronic health records (EHRs) and pharmacogenomics, further enhances its capacity to detect and address drug-related issues. As healthcare

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systems continue to evolve, the role of PV in ensuring medication safety remains critical in promoting overall patient well-being and optimizing therapeutic outcomes.

II. AIM AND OBJECTIVES

Aim of Pharmacovigilance:

- To strengthen public protection against new medications.
- To assist in the evaluation of the efficacy and risk of medicines.
- Encourage community members to communicate in a healthy manner.
- To encourage the use of medications in a sensible and safe manner.
- Drug efficacy and monitoring of drug side effects.
- Pharmacovigilance guards against adverse drug reactions.
- Improve public health and safety in connection to the use of pharmacovigilance by increasing
- public awareness, education, and clinical training. 6,3,12

Objectives of Pharmacovigilance:

- Improve patient care and safety in relation to the use of medicines and all medical interventions
- Improve public health and safety in relation to the use of medicines;
- Detect problems related to the use of medicines and communicate findings in a timely manner
- Contribute in the assessment of the benefit-risk ratio, effectiveness, and risk of medicines, leading to the prevention of harm and maximization of benefits
- Encourage the safe, rational, and more effective (including cost-effective) use of medicines
- Promote the understanding, education and training of pharmacovigilance and its effective communication to the public.

INTRODUCTION

Pharmacovigilance (PV) refers to the science and activities associated with the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) and other drug-related problems. As defined by the World Health Organization (WHO), PV plays a vital role in ensuring drug safety by identifying potential risks throughout the drug lifecycle. Initially focused on conventional medicines, PV has expanded to include not only drugs but also herbal products, vaccines, medical devices, and traditional medicines, reflecting its broadening scope in modern healthcare.

The primary goals of pharmacovigilance are to safeguard public health by minimizing the risks associated with medicinal products and ensuring a positive benefit-risk balance. This involves continuous monitoring of drugs during clinical trials and post-marketing surveillance. Advanced tools and technologies, including big data analytics, artificial intelligence, and machine learning, are increasingly being used to identify safety signals more effectively and predict adverse drug reactions.

Pharmacovigilance activities include reporting and analyzing spontaneous ADRs, conducting pharmacoepidemiological studies, and implementing risk mitigation strategies. Regulatory authorities, such as the FDA, EMA, and CDSCO, play a key role in enforcing PV guidelines, while pharmaceutical companies are required to maintain robust pharmacovigilance systems.

Methods Used in Pharmacovigilance:

Pharmacovigilance relies on various methods to assess the causality of adverse drug reactions (ADRs). These methods help determine the likelihood that a drug caused a particular adverse event, considering factors such as timing, patient history, laboratory tests, and existing knowledge of the drug. However, no single method is universally accepted as the gold standard due to the inherent complexity of ADRs. Below are some of the widely used methods:

1. Dangaumou's French Method (1977): Categorizes causality into intrinsic and extrinsic imputability using criteria like drug challenge, dechallenge, rechallenge, and clinical symptoms.
2. Kramer et al. Method: Evaluates single adverse events independently, requiring expertise for complex cases.

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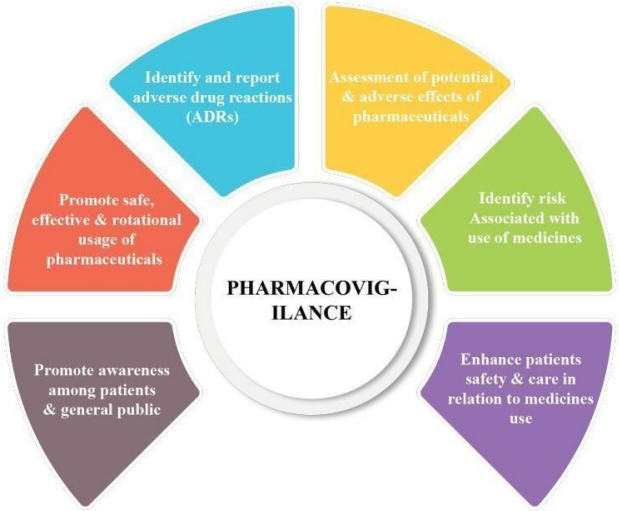
3. Naranjo et al. Method (Naranjo Scale): Uses ten yes/no questions to categorize ADR causality as definite, probable, possible, or doubtful, best for single-drug-related ADRs.
4. Balanced Assessment Method: Combines visual analogue scales (VAS) and multiple assessors for a more holistic evaluation of ADR causality.
5. Ciba-Geigy Method: A checklist of 23 questions related to medical history and adverse reactions, based on expert consensus.
6. Loupiet et al. Method: Assesses teratogenic potential by evaluating drug usage chronology and bibliographical data.
7. Roussel Uclaf Causality Assessment Method: Primarily for liver and skin disorders, especially drug-induced liver injury (DILI), with high expert agreement.
8. Australian Method: Focuses on ADR timing, lab data, and case report details, avoiding prior knowledge of the drug's profile to minimize bias.
9. Probabilistic or Bayesian Approaches: Uses epidemiological data and case-specific evidence to calculate causality, especially for complex ADRs involving multiple variables.

Need of Pharmacovigilance:

Pharmacovigilance is critical in ensuring drug safety beyond the clinical trial phase. While clinical trials are crucial in assessing a drug's safety and efficacy, they are often limited in scope and duration. The following points highlight the primary reasons why pharmacovigilance is essential:



1. Humanitarian Issue: Clinical trials can't always detect rare or long-term adverse effects, which may only appear once the drug is used by the general population.
2. Preventing Drug-Induced Harm: Pharmacovigilance detects and prevents adverse drug reactions (ADRs), ensuring treatments don't harm patients.
3. Economic Impact: ADRs increase healthcare costs, but effective pharmacovigilance helps reduce these costs by identifying risks early.
4. Encouraging Rational Drug Use: Pharmacovigilance promotes appropriate drug use, reducing misuse, overuse, and ensuring adherence to prescriptions.
5. Ethical Responsibility: Pharmacovigilance ensures that patients and healthcare providers are informed of potential drug risks, protecting patients and supporting accountability.
6. Addressing Global Drug Safety: Pharmacovigilance ensures consistent drug safety standards globally, adapting to different populations and healthcare systems.
7. Supporting Drug Development and Innovation: Pharmacovigilance provides critical safety insights, helping pharmaceutical companies develop safer and more effective drugs.

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Applications of Pharmacovigilance:

Pharmacovigilance (PV) is essential in monitoring and ensuring the safety of drugs throughout their lifecycle, from development to post-market use. It helps identify and manage risks associated with medications, improving patient safety and public health. Here are some key applications of pharmacovigilance:

1. Pharmacovigilance in Clinical Practice:

o Ensures safe drug use through continuous monitoring. o Improves healthcare quality by identifying ADRs. o Provides ongoing education and training for healthcare professionals. o Facilitates data-sharing between pharmacovigilance centers.

2. Pharmacovigilance in Disease Control:

o Essential in low-resource settings without established safety systems. o Ensures drug safety in disease programs like malaria, HIV/AIDS, and tuberculosis. o Identifies drug-induced disorders for better treatment management.

3. Pharmacovigilance in Drug Development:

o Detects early safety signals during clinical trials. o Assesses the benefit-risk balance of new drugs.
o Refines treatment protocols and ensures long-term safety monitoring.

4. Pharmacovigilance in Post-Marketing Surveillance:

o Monitors drug safety after-market launch. o Identifies ADRs not seen in trials.
o Updates drug labels and supports regulatory actions like recalls.

5. Pharmacovigilance in Global Health:

o Monitors global drug safety trends and shares data internationally.
o Ensures drug safety across diverse populations. o Supports global regulatory authorities with safety data.

6. Pharmacovigilance in Public Health Crises:

o Monitors safety of emergency-use medications during health crises.
o Helps identify adverse reactions to treatments in pandemics. o Provides rapid decision-making support and maintains public trust.

7. Pharmacovigilance in Maternal and Pediatric Health:

o Monitors drug safety for pregnant women and children. o Prevents harmful reactions in these vulnerable groups. o Ensures safe and regulated treatment use during pregnancy and early childhood.

Adverse Drug Reactions (ADRs):

Adverse drug reactions (ADRs) are harmful and unintended responses to medications that occur when used at typical therapeutic doses for the purpose of diagnosing, preventing, or treating a disease. ADRs can develop quickly or over time, and in some cases, even after the drug has been discontinued. They are common, affecting 10-25% of patients, particularly those on multiple medications. ADRs are classified into two main types:

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A. Predictable (Type-A) Reactions

• Characteristics: These reactions are expected based on the pharmacological properties of the drug.

• Nature: Typically, dose-dependent, these reactions often include side effects like toxic effects or withdrawal symptoms.

• Example: Beta-blockers can cause bradycardia (slow heart rate) as a predictable side effect.

B. Unpredictable (Type-B) Reactions

• Characteristics: These reactions occur due to individual patient characteristics and are not related to the drug's known pharmacological effects.

• Nature: Type-B reactions are less common, non-dose dependent, and can be more severe, often necessitating the discontinuation of the drug.

• Examples: Allergies to a drug, or idiosyncratic reactions such as liver damage.

ADR Reporting

Adverse Drug Reaction (ADR) Reporting is a critical component of pharmacovigilance, ensuring the safety of medicines throughout their lifecycle. It involves collaborative efforts from government agencies, regulatory bodies, pharmaceutical companies, healthcare professionals, and even patients to identify, document, and analyze ADRs effectively.

The process begins with the collection of ADR reports, which can come from various sources such as healthcare providers, patients, or literature. These reports are then triaged to prioritize cases based on severity and urgency. Data is maintained in pharmacovigilance databases, such as the WHO's Vigibase or FDA's FAERS, to ensure accessibility for analysis and compliance with regulatory requirements.

Spontaneous Reporting System

The Spontaneous Reporting System plays a key role in ADR surveillance. This system includes several important components:

1. Regionalization: ADR reports are managed at a regional level to ensure proper followup.
2. Repossession of Further Data: Additional information is obtained as necessary for further evaluation.
3. Access to Pre- and Post-Marketing Information: Helps understand how the drug performs in real-world settings.
4. Detailed Drug Utilization Data: Monitoring drug usage patterns helps detect emerging issues.
5. Standardized Evaluation: A systematic approach to assess the causality and significance of ADRs.
6. Encouragement: Efforts are made to motivate healthcare professionals and the public to report ADRs to enhance drug safety.

Benefits of ADR Monitoring

An ADR Monitoring and Reporting Program provides several key benefits:

1. Ensures Drug Safety: Offers vital information on the quality and safety of pharmaceutical products.
2. Risk Management: Helps create plans to manage and mitigate risks associated with drug use.
3. Prevention of Predictable ADRs: Helps reduce the occurrence of preventable ADRs by promoting adherence to safe medication practices.
4. Increases Awareness: Educates healthcare providers, including patients, pharmacists, and nurses, about the risks and management of ADRs.

By ensuring the continuous monitoring of drugs post-marketing, pharmacovigilance programs can improve drug safety and protect public health.

National Programme of Pharmacovigilance (NPPV):

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Before a drug is marketed to the public, clinical trials are conducted to test its safety and efficacy. However, these trials are usually performed under controlled conditions with a limited number of participants and a short duration, which may not fully capture the wide range of potential adverse drug reactions (ADRs) that may occur in the general population. Additionally, the controlled settings of clinical trials may not reflect real-world conditions where patients of different ages, health statuses, and pre-existing conditions use the medication. As a result, pharmacovigilance is crucial for monitoring the safety of medicines once they are approved for public use.

Role of Pharmacovigilance

Pharmacovigilance involves the systematic detection, assessment, and prevention of adverse drug reactions (ADRs) and adverse drug events (ADEs). The primary goals of pharmacovigilance are:

1. Ensuring the safety of medicines post-marketing:
o Identifies rare or serious side effects that were not evident during clinical trials.
2. Risk Assessment:
o Assesses the risks and benefits of medicines and provides recommendations to improve their safe use.
3. Safety Communication:
o Communicates findings to healthcare professionals and the public to enhance safe and effective medicine use.
4. Monitoring the Effectiveness of Safety Actions:
o Evaluates the success of safety measures, modifications, and recommendations made based on ADR reports and signals.

Resources for Pharmacovigilance Centers

Pharmacovigilance centers rely on specialized resources to identify, analyze, and report adverse drug reactions. Key resources include:

• Meyler's Side Effects of Drugs: A comprehensive reference on drug side effects.
• AHFS Drug Information Handbook: A drug reference tool for healthcare professionals.
• Martindale: The Complete Drug Reference: A resource that provides detailed information about drugs, including their adverse effects.
• Davies Textbook of Adverse Drug Reactions: A textbook focused on the study of ADRs.
• Physician's Desk Reference (PDR): A comprehensive reference for medications, including side effects and safety information.

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• British National Formulary: A resource providing guidance on prescribing drugs, their effects, and safety measures.
These resources help pharmacovigilance centers in detecting and evaluating adverse drug reactions.

National Pharmacovigilance Centres

National pharmacovigilance centers play a vital role in collecting, analyzing, and reporting ADRs. They work in collaboration with the Uppsala Monitoring Centre (UMC), the WHO Collaborating Centre for International Drug Monitoring. Their tasks include:

1. ADR Case Report Collection:

o Collecting reports from healthcare professionals, manufacturers, and the public to identify adverse drug reactions.

2. Signal Detection:

o Identifying potential safety concerns and emerging risks based on the ADR reports.

3. Regulatory Decision-Making:

o Taking appropriate actions such as updating drug labels, issuing warnings, or withdrawing drugs from the market when necessary based on the evidence gathered.

4. Communication and Alerts:

o Informing healthcare providers, regulatory bodies, and the public about new or emerging risks related to medicines.

5. Cooperation with WHO:

o Sharing ADR data with the World Health Organization (WHO) to monitor global drug safety and ensure coordinated actions.

Global Pharmacovigilance Collaboration

Global pharmacovigilance collaboration ensures the safety of medicines worldwide by detecting, assessing, and preventing adverse drug reactions (ADRs). Key players in this collaboration include the World Health Organization (WHO), the Uppsala Monitoring Centre (UMC), and national pharmacovigilance centers.

1. WHO and UMC Collaboration:

o WHO works with UMC, which maintains Vigibase, the world's largest ADR database. This collaboration helps in identifying safety signals from ADR reports collected globally. o Signal Detection: UMC uses tools like Vigiflow to detect potential ADR signals quickly.

2. Role of National Centers:

o National pharmacovigilance centers report ADRs and collaborate with WHO and UMC to share data, allowing for faster detection of ADRs, risk assessment, and regulatory actions (e.g., label changes or drug withdrawals).

3. International Databases:

o Databases like Vigibase and FAERS allow global data sharing, enhancing the detection and monitoring of ADRs.

4. Training and Capacity Building:

o WHO and UMC provide training and resources to improve ADR reporting and safety monitoring in countries, ensuring global consistency.

Benefits of Global Collaboration

• Improved Drug Safety: Faster identification and communication of ADRs.
• Quicker Response: Swift regulatory actions based on global ADR data.
• Harmonization: Standardized ADR reporting practices across countries.
• Enhanced Public Health: Better informed prescribing and safer medicines worldwide.

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III. REVIEW OF LITERATURE

Historical Background of Pharmacovigilance:

Author	Literature Review
JE Campbell, M Gossell-Williams,MG Lee	. Pharmacovigilance supports safe and appropriate use of drugs. Spontaneous reporting of adverse drug reactions (ADRs) is an essential component of pharmacovigilance. However, there is significant underreporting of ADRs. Adverse drug reactions have become a major problem in developing countries. Knowledge of pharmacovigilance could form the basis for interventions aimed at improving reporting rates and decreasing ADRs.
Rajkumar Soni, Vikrant Kesari	. Pharmacovigilance in India started from 1986. A formalAdverse Drug Reactions (ADR) monitoring system was initiated with 12 regional centres, each covering a population of 50 million. However, no noteworthy growth was made. Afterward in 1997, India joined the World Health Organization (WHO) and Adverse Drug Reaction (ADR) scrutinizing program based at2 Uppsala, Sweden but got fail. Hence, after 2005 WHO supported and World Bank – funded National Pharmacovigilance Programme (NPPV) of India was made operational.
Pedro inacio, Afonso Cavaco andMarja Airaksinen	Current trends in pharmacovigilance systems are veering towardspatient involvement in spontaneous reporting of adverse drug reactions (ADRs). The aim of the current systematic review was toidentify what is known and what remains unknown with respect to patient reporting to pharmacovigilance systems.
Pratik waller,Mira Harrison-woolrych	Pharmacovigilance is the science and activities relating to thedetection assessment ,understanding and prevention of adverse effect.
Christain Funk – Brentano, Joe-EileSalemb	Over the past decades , assessment of drug and safety and of theirbenefits ,adverse drug reaction is gradually becoming more common and now legal reguirement in countries.

IV. CONCLUSION

Pharmacovigilance plays a pivotal role in maintaining the safety and well-being of patients by identifying and addressing adverse drug reactions (ADRs) throughout the lifecycle of a drug. Since clinical trials often cannot detect rare ADRs, ongoing surveillance is essential for patient safety. The global healthcare system will benefit from a collective effort, where healthcare professionals view ADR reporting not as a burden but as a vital responsibility in ensuring safer drug use worldwide. This proactive approach contributes to better drug safety monitoring and improved public health outcomes.

In addition, pharmacovigilance serves as a key mechanism for public health, especially as new drugs and drug formulations continue to enter the market. The role of national pharmacovigilance centers and regulatory bodies becomes more important as they detect gaps in the safety profiles of medications. It is critical to foster awareness, train healthcare providers, and ensure continuous collaboration between regulatory agencies for the effective implementation of pharmacovigilance programs.

India, with its growing pharmaceutical production and emerging status as a clinical trial hub, faces significant challenges in establishing a robust pharmacovigilance system. Although steps have been taken toward strengthening this system, it is still in its developmental stages. To keep pace with the increasing complexity of the pharmaceutical landscape, India must continue to enhance its pharmacovigilance infrastructure. This includes improving ADR reporting, increasing public awareness, and developing advanced tools for monitoring drug safety.

As more drugs are introduced, ensuring patient safety through active pharmacovigilance is not just a regulatory obligation but a moral responsibility. By prioritizing pharmacovigilance, we can mitigate risks, protect public health, and ensure that new medications fulfill their promise of better health outcomes without unintended harm.

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