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ADVANCEMENTS IN PHARMACOVIGILANCE: SAFEGUARDING PATIENT SAFETY THROUGH GLOBAL DRUG SURVEILLANCE

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ABSTRACT

Pharmacovigilance, the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, plays a crucial role in ensuring drug safety throughout a drug's lifecycle. This article aims to explore the significance of pharmacovigilance in the pharmaceutical industry, highlighting its role in safeguarding public health, enhancing regulatory compliance, and ensuring that therapeutic products are both safe and effective. It also explores the tools and techniques employed in Pharmacovigilance, the role of healthcare professionals, and future advancements in drug safety monitoring.

Keywords: Pharmacovigilance, healthcare professionals, adverse effects, pharmaceutical industry

INTRODUCTION

Substance Post-marketing surveillance systems are crucial for tracking the incidence of adverse drug reactions (ADRs) in every nation since domestic data can inform national regulatory decisions. These initiatives could help lower the rates of in

morbidity, mortality, hospitalization, medical expenses, and liability related to adverse drug reactions. Most ADRs are frequently ignored or not reported. A structured ADR monitoring program is one way to more actively identify ADRs and so improve the standard of patient care **[1]**. There are several methods for assessing and tracking the safety of medications in clinical use are crucial for increasing public health and preventing or reducing patient harm. This means putting in place a systematic pharmacovigilance strategy in clinical practice. According to the WHO, pharmacovigilance is the science of gathering, tracking, investigating, evaluating, and assessing data from patients and healthcare professionals regarding the negative effects of pharmaceuticals, biological products, herbal remedies, and traditional medicines in order to find new information about medication-related risks and prevent patient harm **[2]**. In recent years, pharmacovigilance has become increasingly important as a science that is essential to both public health research and efficient clinical practice. The national pharmaco-vigilance centres have grown to have a major impact on drug regulatory bodies at a time when drug safety issues are becoming more and more significant in clinical practice and public health.

History

Certainly, let's delve into more detail on the key points in the history of pharmacovigilance

1. Thalidomide Tragedy (1950s-1960s): Thalidomide, originally prescribed as a sedative and antiemetic, caused severe birth defects in thousands of infants. This tragedy made it clear that systemic drug safety monitoring is essential. The fallout raised awareness of the possible risks of medications, particularly during pregnancy

2. Formation of WHO Program (1968): In response to the thalidomide incident, WHO established the international Drug Monitoring Program in 1968. By establishing a global network of pharmacovigilance centres, this program promoted cooperation in gathering and analysing of adverse drug reaction (ADR) data.

3. FDA and AERS (1970s): The FDA initiated the Adverse Event reporting system (AERS) in 1970s. AERS become a pivotal tool for collecting, managing, and analyzing data on adverse events associated with drugs, enabling the FDA to monitor and regulate drug safety in united states.

4. ICH Guidelines (1990s): The international conference on harmonization (ICH) played a crucial role in standardizing pharmacovigilance practices globally. ICH guidelines, such as E2B, provided a harmonized framework for the collection and exchange of safety data, fostering

international cooperation among regulatory authorities.

5. EU Pharmacovigilance system (2005): The European Union introduced a comprehensive pharmacovigilance system, strengthening the monitoring and supervision of medicinal products. The European medicinal agency (EMA) played a central role in coordinating safety assessments and risk management strategies.

6. Periodic safety update reports (PSURs): PSURs become a standard requirement for marketing authorization holders. These reports entail the routine reporting of safety data to regulatory bodies, guaranteeing an ongoing assessment of a drug's safety profile over the course of its life.

7. Digital Era and Signal Detection (21st century): Technological advancement in the 21st century facilitated the integration of big data and digital platforms in pharmacovigilance. An automated signal detection system improved the effectiveness of detecting possible safety issues from big datasets by employing algorithms and data mining approaches.

8. Global collaboration (present): Modern pharmacovigilance emphasizes global collaboration. Programs such as the WHO Global Individual Case Safety Reports (ICSRs) platform make it easier for nations to share information and conduct standardised reporting. Pharmaceutical corporations, regulatory bodies, medical professionals, and patients all work together to monitor and guarantee the safety of pharmaceuticals. The history is explained in **Table 1**.

Table 1: The chronological pharmacovigilance evolution with particular reference to India [3-7]

Year	Evolution
1747	First clinical trial by James Lind to prove the effect of lemon juice in treatment of scurvy.
1937	Demise of 100+ infants due to sulphanilamide toxicity.
1950	Reported aplastic anaemia due to chloramphenicol toxicity.
1961	Global catastrophe by thalidomide toxicity.
1963	Recollection of immediate action on ADRs by World Health.
1968	WHO researches for global drug monitoring on pilot scale.
1996	International standard level clinical trials introduced in India.
1997	India merged with WHO ADR monitoring program.
1998	Commencement of pharmacovigilance in India.
2002	67th National Pharmacovigilance Centre was vested in India.
2004-2005	National Pharmacovigilance Program was established in India.
2009-2010	PvPI (Pharmacovigilance Program) was commenced.
2012	Haemovigilance was started.
2015	Commencement of MvPI (Materiovigilance).

Partners in Pharmacovigilance:

In order to effectively manage medication-related difficulties, all stakeholders in pharmacovigilance must work effectively together. Everyone has an obligation to practise pharmacovigilance in order to

ensure that all medications are used safely. In addition, the Ministry of Health (MOH) or an equivalent institution in any nation needs cooperation as well as dedication from numerous pharmacovigilance partners in addition to being in charge of monitoring medication safety. A comprehensive list of these 'partners' include: -

1. Healthcare professionals: - A. Prescribers B. Nurses C. Pharmacist
2. Hospitals and academia.
3. Pharmaceutical Industry.
4. The WHO Quality Assurance and Safety (Medicines Team).
5. National Pharmacovigilance Centers (NPC).
6. Uppsala Monitoring Center (UMC).

1. Healthcare professionals:

A. Prescribers:

To ensure that a medication is prescribed, distributed, and administered to a patient, it is necessary for every individual engaged in the prescription process to have a basic knowledge of the possible adverse drug reactions (ADRs). Every medicine and treatment plan should take into account each of these variables, including the patient's unique circumstances and susceptibility to drug toxicity. Since the healthcare provider anticipates that all medications are risk-free, and the intention is to use them is to help the patient rather than harm them. They should be knowledgeable on the ADR reporting policy and processes, including instructions on how, when, and where to submit reports **[8]**.

Healthcare workers typically believe that reporting suspected ADRs is a significant part of their role as pharmacovigilance partners. In order to observe and report undesirable or unexpected ADRs, the optimal ADR management requires the participation of all healthcare personnel in both government and commercial hospitals. Spironolactone, which is contraindicated in patients with hyperkalaemia or renal impairment, is a prime example.

B. Nurses:

ADRs were not traditionally reported by nurses, however significant improvements in ADR reporting have occurred, and since nurses can now prescribe medications in some countries, such the USA and the UK, they have an obligation to record ADRs **[9-11]**.

C. Pharmacist:

A chemist is in a "cornerstone position" when it comes to dispensing medications, thus they should be cautious of any possible adverse drug reactions. In particular, the pharmacist concentrates on contributing to ADR reporting.

2. Hospital and Academia:

Collaborations between the pharmaceutical industry, academia and drug regulatory authorities has led to the development of Pharmacovigilance as a clinical discipline. academic centers of pharmacology and

pharmacy should provide a knowledge of ADRs to healthcare professionals and the public by; training, teaching and research.

3. Pharmaceutical Industry:

Every company in the pharmaceutical industry has a vital role to play in the provision and supervision of drug safety and they must inspect all drug related information, from drug development to patient use, and should also consider the assessment of the safety of the drug and monitoring system **[12]**.

4. The WHO Quality Assurance and Safety:

"To ensure the quality, safety, and efficacy of all medicines by strengthening and implementing into practice regulatory and quality assurance standards" is the primary goal of the Quality Assurance and Safety for Medicines team. Therefore, it is necessary to carry out pharmacovigilance for all associated health technologies, such as medications, vaccines, blood products, biotechnology, herbal remedies, and traditional treatments **[13]**.

5. Uppsala Monitoring Center (UMC)

Working with the WHO Collaborating centre for international drug monitoring UMC, WHO promotes Pharmacovigilance at the country level, and encourages the participation in the WHO programme for international drug monitoring. In addition, WHO still highlights the importance of collaboration and communication at local, regional and international levels, so as to ensure Pharmacovigilance delivers the necessary protection to the public **[14-16]**.

Goals of pharmacovigilance

- Optimise patient safety and care for all medical and paramedical procedures, including pharmaceutical use
- Improve public health and safety concerning the usage of medications.
- Contribute to the evaluation of the benefits, harms, effectiveness, and risks of medications; Encourage the safe, logical, and more efficient (including cost-effective) use of medications;
- Enhance clinical training, education, and an understanding of pharmacovigilance and its efficient public communication.

Need for pharmacovigilance

The development and use of medications have revolutionized healthcare, but they also introduce the potential for adverse events. While clinical trials are essential for evaluating drug efficacy and safety before market approval, they often involve limited patient populations and durations. This means that unforeseen side effects or long-term consequences may only become apparent after widespread use. Pharmacovigilance serves as a critical post-marketing surveillance system, continuously monitoring the safety of drugs throughout their lifecycle.

Table 2: Classical example of serious and unexpected adverse reactions

Medicine	Adverse reaction
Reserpine	Depression
Aminophenazone (amidopyrine)	Agranulocytosis
Practolol	Sclerosing peritonitis
Fluothane	Hepatocellular hepatitis
Chloramphenicol	Aplastic anaemia
Oral contraceptives	Thromboembolism
Statins	Rhabdomyolysis

Tools and Techniques in Pharmacovigilance:

PV is widely acknowledged as a pharmaceutical risk management technique. The process begins with the detection of a possible hazard, which is subsequently assessed and investigated before steps are taken to ultimately lower such risks. An evaluation of the procedure' effectiveness need to be the last step. The entire risk management process is iterative because of either fresh evidence or possibly inadequate measures used.

Rarely is a drug safety issue considered resolved, and the safety inquiry remains ongoing until the drug has finished its whole life cycle. The field of pharmacovigilance has evolved significantly, incorporating advanced technologies to improve the detection and monitoring of drug safety. Vigi base, Vigi lyze and Vigi flow are different tools used in PV **[17]**.

Techniques include:

- **Spontaneous Reporting Systems:** As mentioned, ADR reporting by healthcare professionals and patients forms a core part of pharmacovigilance. These systems rely on voluntary reporting to identify new or unexpected drug risks.
- **Data Mining and Signal Detection:** Statistical analysis of large healthcare databases (e.g., insurance claims, electronic health records) helps detect emerging safety concerns. Techniques like disproportionality analysis and Bayesian data mining are used to identify potential ADRs.
- **Epidemiological Studies:** Post-marketing cohort studies and case-control studies help to quantify the risk of ADRs in specific populations or compare the safety profiles of different drugs.
- **Artificial Intelligence and Machine Learning:** With the increasing amount of data generated from clinical trials, patient reports, and social media, AI and machine learning are being used to analyze vast amounts of pharmacovigilance data to predict potential risks. Artificial intelligence and machine

learning may also be useful in pharmacovigilance for:

1) Automatically entering and processing case reports,

2) Identifying clusters of adverse events that indicate symptoms of syndromes,

3) Conducting pharmaco-epidemiological studies,

4) Connecting data through probabilistic matching within datasets, and

5) Anticipating and stopping the spread of adverse events through targeted interventions.

Pharmacovigilance process:

Processes involved:

1. Collect and record ADRs
2. Causality assessment and analysis of ADRs
3. Collate and code in database
4. Compute risk benefit and suggest regulatory actions
5. Communicate for safe use of drugs among stakeholders

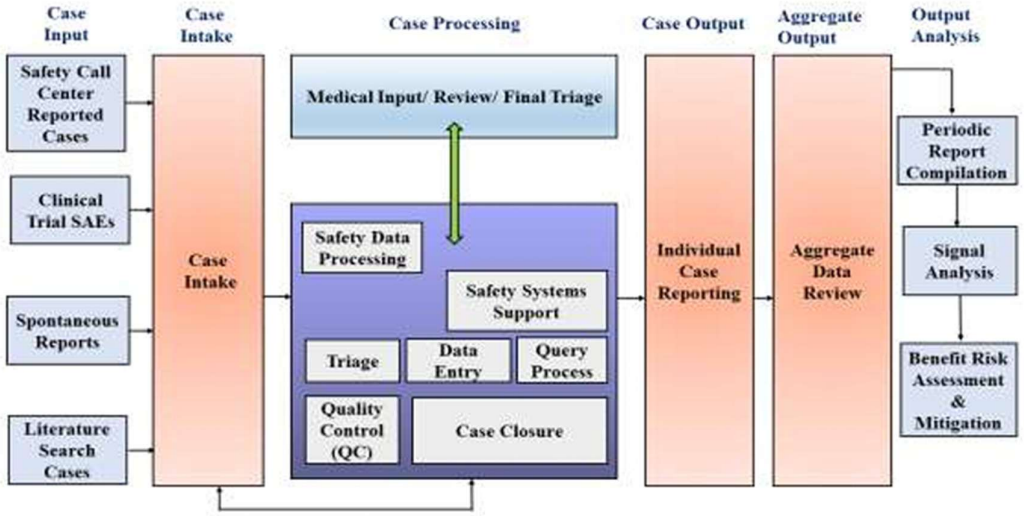

Figure 1: Activities associated with Pharmacovigilance

Role of Pharmacovigilance in ensuring safety of patients:

Following the collection of data from various sources regarding individual patient experiences of adverse drug events depicted in the **Figure 1**. The following factors need to be taken into account while analysing the data:

- Case reports of suspected adverse reactions alone are rarely sufficient to confirm that particular effect in a patient has been caused by a specific medicine.
- The fact that a suspected adverse reaction has been reported does not necessarily mean that the medicine

has caused the observed effect, as this could have also been caused by the disease being treated, a new disease the patient developed, or by another medicine that the patient is taking. Case reports need, therefore, to be assessed by an expert.

- Consider a single case report as one piece of a jigsaw puzzle, with additional information typically required to finish the picture. These comprise information from epidemiological research, clinical trials, and spontaneous case reports from all over the world.
- In addition to the exact frequency of an adverse response, the number of case reports for a certain medication or suspected adverse reaction varies according to the quantity and parameters of the medication's use, the type of reaction, and public awareness. As a result, comparing the number of case reports from various medications might give an inaccurate impression of their safety profiles.

Therefore, 'Risk Management Plans' have to be written to answer three key questions:

1. What is known or not known about the risks of the medicine?
2. What studies are needed to find out more about the risks?
3. What is needed to minimise the risks?

Risk management plans are updated throughout the life of the medicine, so over time the number of potential risks and missing information decreases. Risk minimisation can be about reducing the effects of the risk when it happens or reducing how often it happens. Different types of ADR Monitoring centre and their locations is described in **Table 3**.

Table 3: ADR Monitoring center

ADR Monitoring Centre	State
Department of pharmacology, All India Institute of Medical Science	New Delhi
Department of pharmacology, PGIMER	Chandigarh
Department of pharmacology, R.G.Kar Medical College	Kolkata
Department of Clinical Pharmacology, Lady Hardinge Medical College	Kolkata
Department of Clinical Pharmacy, JSS Medical College	Karnataka
Hospital Institute of pharmacology, Madras Medical College	Chennai

Role of Clinicians in Pharmacovigilance and Drug Safety:

The clinical pharmacist developed pharmacotherapeutic follow-up, continuously monitored the patient, maintained open lines of communication with the health team both verbally (interviews) and in writing (clinical history,

case analysis report), and made guidelines after receiving an inter consultation on SADR prepared by the hospitalisation or outpatient services physicians. The term "interconsultation" refers to a health professional's consultation with a clinical pharmacist to offer additional care for the safe and sensible use of medications in patients who are ambulatory or in hospitals.

Pharmacotherapeutic Follow-up (PF): The clinical pharmacist, in order to achieve a complete analysis of the clinical case, conducted PF to the patient: (I) Recorded health data, pharmacotherapy and other data useful for PF in appropriate formats; (II) Analyzed the case, supported by a search for evidence-based information in Dynamed, Micromedex, Drug.com, high surveillance regulatory agencies; in addition, to strengthen the pharmaceutical intervention, he performed searches under the PICO (Patient, Intervention, Comparison, Outcome) strategy to find articles related to the clinical case, using search engines: PubMed, Trip database, Scopus, Science Direct. (III) The pharmaceutical interventions were also documeneted in the patient's clinical history under the SOAP (Subjective, Objective, Assessment, Plan) modality as a response to the interconsultations.

Reporting of ADR to DIGEMID: After performing PF, clinical pharmacists acquired data on the patient's clinical evolution (therapies, analytical, diagnostic tests) that allowed SADRs to be assessed for reporting to the DIGEMID, in accordance with the provisions of NTS 123-MINSA/DIGEMID-V.01 "Technical health standard regulating pharmacovigilance and technovigilance activities for pharmaceuticals and medical devices" (RM N°539-2016-MINSA). The reports were made through e-Reporting, an On-line reporting medium of the World Health Organization-Uppsala Monitoring Center (WHO-UMC). To assess causality and severity they used the Karch and Lasagna algorithm, modified according to CENAFyT guidelines, while the type of ADR was classified according to Edwards and Aronson.

The production of clinical pharmacists was recorded in the "Health Information Sheets," where all processes related to patient care were included: Interconsultations, PF, PV. The record was made using Current Procedural Terminology (CPT) codes, according to the health sector catalog.

Artificial Intelligence in Pharmacovigilance:

The amount of healthcare data that is now available has grown significantly over the past few years and will continue to do so in the near future due to the extensive promotion of digital technologies that collect data obtained from patients. The

enormous amounts of electronic data enable the use of artificial intelligence (AI) techniques to improve pharmaceutical safety evaluation. In clinical research, information extraction—the process of extracting pertinent ideas from readily available, primarily unstructured sources utilizing text mining and natural language processing (NLP) techniques—has been becoming more and more significant. By acquiring data on adverse drug reactions (ADRs) and drug-drug interactions from a range of textual sources, text mining and natural language processing (NLP) techniques may be of great assistance in pharmacovigilance, enabling physicians and researchers monitor the safety of medications.

Pharmacovigilance may also benefit from artificial intelligence and machine learning for **[18-20]**

1) Handling case report entry and processing tasks automatically,
2) Identifying clusters of adverse events that indicate symptoms of syndromes,
3) Conducting pharmacoepidemiologic studies,
4) Connecting data by conducting probabilistic matching within datasets, and
5) Predicting and preventing adverse events using particular models based on real-world data.

Challenges in Pharmacovigilance

While pharmacovigilance systems have improved significantly, there are still challenges that need to be addressed:

- **Underreporting of ADRs:** A significant barrier to pharmacovigilance is the underreporting of ADRs by healthcare providers and patients. This can lead to incomplete safety profiles and delayed identification of risks.
- **Data Quality and Standardization:** Inconsistencies in the quality and format of reported data can hinder the analysis and comparison of ADR information.
- **Global Variability in Reporting Systems:** Different countries have different systems and regulations for pharmacovigilance. Harmonizing reporting processes globally is a challenge, especially in low- and middle-income countries.
- **Results and Impact:** As public concern over the safety of medications grows, so does public scrutiny of the behaviour of the medical community, the pharmaceutical business, and regulatory agencies. More studies on the efficiency of pharmacovigilance and its role in enhancing public perception must follow increased

accountability. The improvement of individual therapy, aiding in the identification and management of sickness brought on by medication, and generally resulting in a decrease in iatrogenic diseases must be a key focus. This information must also be made available to patients and health professionals themselves **[21]**.

Problems and suggestions

The speed, volume, and quality of ADR reporting can all be increased with PV adoption. While post-marketing surveillance is essential for detecting uncommon or chronic ADRs, pre-marketing clinical research is more suited for identifying common ADRs. Long-term monitoring data and patient studies are necessary to completely comprehend a drug's safety. PV is a helpful method for drug evaluation. Finding possible drug hazards and filling in knowledge gaps on drug safety can be facilitated by real-world data based on PV. With the ultimate goal of minimising patient damage and the financial burden on society, the most recent data will help HCPs better understand drug risks and support close patient monitoring.

The following problems still exist with respect to the implementation of PV:

Most medical staff have not received PV training, the training provided by professional courses and talents related to PV is not perfect, and the number of PV professionals in practice is insufficient.

Drug safety ultimately rests with MAHs. The difficulty for MAHs, however, is to guarantee medication quality without raising prices. In addition, the burden of PV is growing along with the number of users.

The sufficient quantity and quality of data is the basis of relevant research and necessary conditions for establishing and improving PV systems.

Important information regarding drug combinations, comorbidities, and laboratory markers for pertinent testing is lacking from public databases for certain populations. Because of this, it might be difficult to prove a link between medications and adverse occurrences.

Suggestions on how to better develop PV in special populations are as follows:

Focus on drug safety risk monitoring for special populations, set up corresponding system segments based on these populations, and establish and improve management norms and institutional systems. Different special populations should be equipped with corresponding pharmacists to review prescriptions with the goal of effectively intercepting inappropriate prescriptions and achieving early detection and resolution of any issues.

Strengthen cooperation between countries with the help of information systems to

create an efficient global pattern of PV cooperation.

In addition to mining drug safety data, PV professionals should also provide timely information to patients, the public, and HCPs to promote the safe and effective use of drugs.

The comprehensive reporting of complete medical records, excluding any identifying patient information, is highly recommended in order to improve the accuracy and analyzability of reported medical data. In order to address the persistent problem of incomplete or missing reports, a specific reward will be provided to those who submit complete medical records, thereby improving the overall quality of medical research.

By creating a collaborative drug safety law, pharmaceutical companies are forced to take proactive responsibility, and businesses that exhibit excellent PV practices for certain populations are encouraged to prolong the period of drug patent protection. This strategy puts patients' health first while encouraging the pharmaceutical industry to be more accountable and diligent.

CONCLUSION:

Pharmacovigilance is vital for ensuring ongoing drug safety after market approval. By monitoring adverse drug reactions and identifying potential risks, it helps protect public health, informs healthcare decisions, and guides regulatory actions. Through continuous surveillance, pharmacovigilance ensures that drugs remain safe and effective, ultimately safeguarding patients and enhancing the overall quality of healthcare. Pharmacovigilance is crucial for ensuring drug safety and efficacy. It enables the detection, assessment, and prevention of adverse effects, protecting public health and informing regulatory decision-making. Effective pharmacovigilance is essential for optimizing benefit-risk profiles, improving patient safety, and promoting the safe use of medications.

Conflict of Interest

The authors declare that there are no conflicts of interest regarding the publication of this review article.

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