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Drug Safety and Pharmacovigilance

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ABSTRACT

Pharmacovigilance (PV), also referred to as drug safety, encompasses the science and activities involved in detecting, assessing, understanding, and preventing adverse drug reactions (ADRs) and other drug-related issues. As the global consumption of pharmaceutical products continues to rise, the importance of robust pharmacovigilance systems in ensuring drug safety has become increasingly critical. This review explores the evolution of pharmacovigilance, its global regulatory framework, and the methodologies employed in monitoring drug safety. It emphasizes the contributions of healthcare professionals, patients, and regulatory authorities in reporting ADRs, alongside the incorporation of advanced technologies such as big data analytics, artificial intelligence, and social media monitoring to enhance pharmacovigilance practices. The review also addresses key challenges, including underreporting, data quality issues, and the growing complexity of new drug formulations. Looking ahead, the future of pharmacovigilance is expected to involve the adoption of more advanced signal detection techniques, enhanced patient-centered approaches, and greater international collaboration to strengthen drug safety on a global scale. This article aims to provide a comprehensive overview of pharmacovigilance and reporting requirements in several countries.

Keywords: Drug Safety, PV, ADR, AI

INTRODUCTION

Drug safety is an important cause of drug candidate attrition in the biopharmaceutical industry. These emerging biomarkers denote an expanded toolkit of minimally invasive, stable, tractable safety biomarkers for translational use, bridging findings in preclinical to clinical drug testing. The value proposition of new safety biomarkers is to improve risk-benefit assessment at all stages of drug development.

Pharmacovigilance is the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problems. Total medical cost for patients with ADRs are increased by an average of 19.86%.[3] However the lack of ability of clinicians to suspect or detect such adverse events related to drugs might lead to inappropriate management of adverse events, thus exposing the patients to additional drug hazards. To minimize the suffering of the patients from ADRs, though difficult, it is essential to establish casual relationship between the drug and the event which is the causality assessment.

Drug safety:

Drug safety, or pharmacovigilance, is the science and activity of detecting, assessing, and preventing adverse effects and other problems from medications. It is a continuous process that ensures drugs are safe for patients, encompassing the entire drug lifecycle from pre-clinical studies and clinical trials to post-market monitoring. Its goal is to ensure a positive benefit-risk balance for every medication used by the public.

IMPORTANCE OF DRUG SAFETY:

Drug safety plays a crucial and central role in modern healthcare because medicines, while essential for treating diseases, also have the potential to cause harm if not used appropriately. Ensuring the safe use of medicines is therefore fundamental to protecting

patient health, improving treatment outcomes, and maintaining trust in healthcare systems. The importance of drug safety extends across clinical practice, public health, regulatory science, pharmaceutical industry, and patient welfare.

Components of Drug Safety:

Drug safety encompasses all activities that contribute to ensuring the safety of medicines.

Some important components are;

- Clinical trials: Clinical trials are used during the development of new medicines to test their safety and efficacy to ensure they are suitable for use in humans.

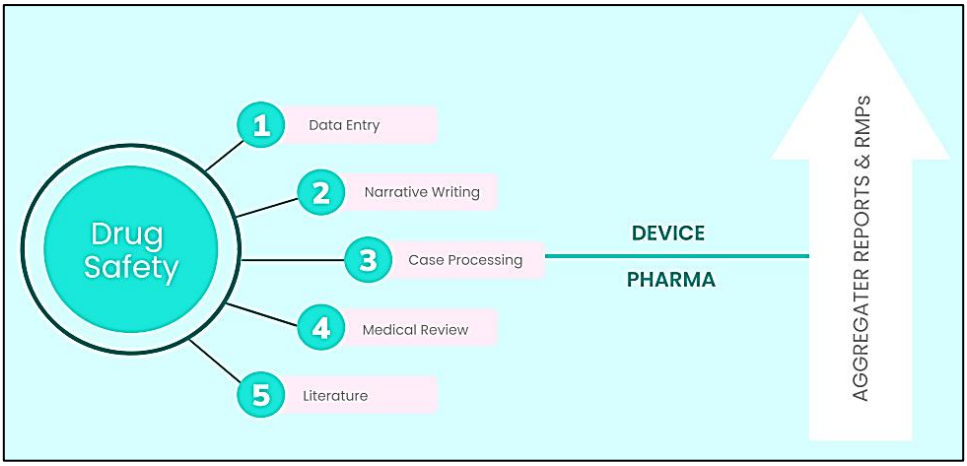
- Regulation: Regulatory agencies such as the European Medicines Agency (EMA) or the US Food and Drug Administration (FDA) review and approve medicines. They also monitor the safety of medicines already on the market.

- Pharmacovigilance: Pharmacovigilance is the monitoring of adverse drug reactions (ADRs). This involves monitoring, evaluating and reporting adverse drug reactions, both before and after medicines are launched on the market.

- Quality Assurance: Medicines are subject to strict manufacturing standards and quality controls to ensure that patient safety is not compromised by impurities or other substances.

- Risk Management: Risk management plans are in place to identify and minimise risks associated with the use of medicines.

- Training and Information: An important part of drug safety is training healthcare professionals and patients in the correct use of medicines and the recognition of adverse drug reactions. This ensures that patients and healthcare professionals are aware of the risks and benefits of new medicines and can use them safely and effectively.



Pharmacovigilance:

Pharmacovigilance is the science and activities that involve detecting, assessing, understanding, and preventing adverse effects or other drug-related problems. It is a key public health function that aims to ensure medicines are used safely and effectively by continuously monitoring their safety even after they are approved for market. This monitoring helps to identify risks, which can lead to actions such as updating product warnings, changing how a medicine is used, or, in rare cases, withdrawing it from the market.

Aims:

The aims of pharmacovigilance are

• The identification and quantification of previously un-recognized adverse drug reaction (ADR). www.wjpps.com Vol 6, Issue 1, 2017. 306 Anusha et al. World Journal of Pharmacy and Pharmaceutical Sciences.

• The identification of sub-groups of patients at particular risk of ADRs (the risk relating to dose, age, gender and underlying disease).

• The continued monitoring of a safety of a product, throughout the duration of it use, to ensure that its risks and benefits remains acceptable. This includes safety monitoring following significant newly approved indications.

ADR REPORTING:

What to Report PVPI encourages all types of suspected ADRs reporting whether they are known, unknown, serious, or non serious, frequent, or rare regardless of an established causal relationship between a drug and the reaction.

What Should be Reported:

Patient Related Details;

1.Patient details

2.Sex

3.Weight

4.Age at time of reaction or date of birth

Medicine:

1.Name (INN and brand name)

2.Strength

3.Dose, frequency

4.Dosage form

5.Route of administration

6.Indication for use

7.Duration of use

8.Batch number

Suspected Adverse Reaction:

1.Description of the reaction

2.Expectedness of the reaction

3.Date the reaction started, stopped

4.Outcomes

5.Relevant tests/ laboratory data

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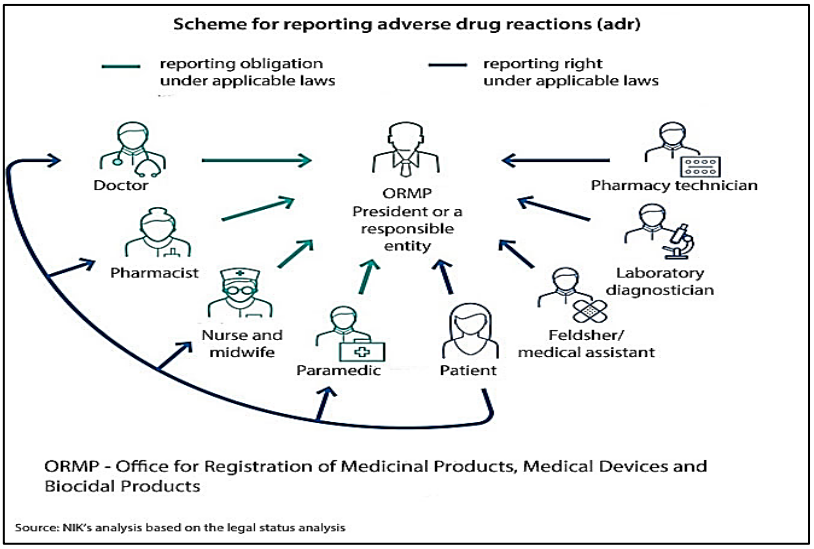
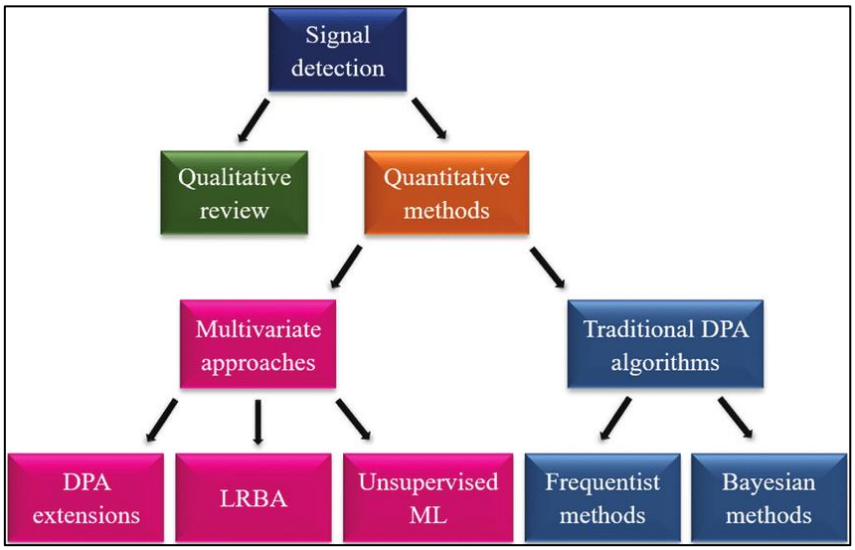


Signal detection:

Pharmacovigilance (PV) is the practice of monitoring the effects of medicines and medical devices after they have been licensed for use, in order to manage risks and keep patients safe. It aims to identify instances where the risk of using a particular drug may outweigh its potential benefits. Signal detection is an important part of the pharmacovigilance process.

Pharmacovigilance requires the collection of data on adverse drug events (ADEs). Data must then be analysed and trends evaluated to establish a drug's safety profile. In pharmacovigilance, a signal is information suggesting a previously unknown, potentially causal, association between a medicine and an adverse drug event.[1]

The Council for International Organizations of Medical Sciences (CIOMS) aims to advance public health through guidance on health research including ethics, medical product development, and safety. CIOMS Working Group VIII defines a signal as "information that arises from one or multiple sources which suggests a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events". It can be either adverse or beneficial, but must be judged to be of "sufficient likelihood to justify verificatory action".[1]



Regulatory framework:

Regulatory bodies worldwide play a central role in enforcing safety measures and guidelines that help monitor, manage, and mitigate the risks associated with pharmaceutical products. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) provides the framework for harmonizing regulatory practices, but national and

international regulatory bodies still hold the responsibility for enforcing pharmacovigilance activities within their respective jurisdictions. In this chapter, we will explore the global regulatory landscape in pharmacovigilance, focusing on key regulatory bodies like the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the World Health Organization (WHO). We will also discuss the compliance with ICH guidelines, highlighting how pharmaceutical companies and other stakeholders adhere to global pharmacovigilance standards. U.S. Food and Drug Administration (FDA) The FDA, an agency of the U.S. Department of Health and Human Services, plays a critical role in pharmacovigilance in the United States. The FDA is responsible for overseeing the safety and effectiveness of drugs, biologics, and medical devices. Its responsibilities in pharmacovigilance are governed primarily by the Federal Food.

Pharmacovigilance program in India (PvPI):

Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about the discipline. While major advancements of the discipline of pharmacovigilance-lance have taken place in Western countries, not much has been achieved in India. However, with more and more clinical trials and other clinical research activities being conducted in India, there is an immense need to understand the importance of pharmacovigilance and how it impacts the life cycle of the product. □is will enable integration of good pharmacovigilance practice in the processes and procedures to help ensure regulatory compliance and enhance clinical trial safety and post-marketing surveillance. Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services under the aegis of Ministry of Health & Family Welfare, Government of India in collaboration with Indian Pharmacopeia commission, Ghaziabad, which acts as a National Coordinating Centre (NCC), is initiating a nation-wide Pharmacovigilance program for protecting the health of the patients by assuring drug safety. center will operate under the supervision of a Steering Committee.

Relationship between drug safety and pharmacovigilance:

Drug Safety:

- Drug safety encompasses a broader concept that refers to the overall safety of pharmaceutical products, including their development, approval, manufacturing, distribution, and use.

- It involves assessing and managing the risks associated with a drug's use and ensuring that its benefits outweigh its potential harms.

- Drug safety activities include preclinical and clinical testing, risk assessment, regulatory approval processes, post-marketing surveillance, adverse event reporting, risk minimization strategies, and ongoing monitoring of drugs in the market.

- Drug safety focuses on the entire lifecycle of a drug, from its early stages of development through its availability and use by patients.

Pharmacovigilance:

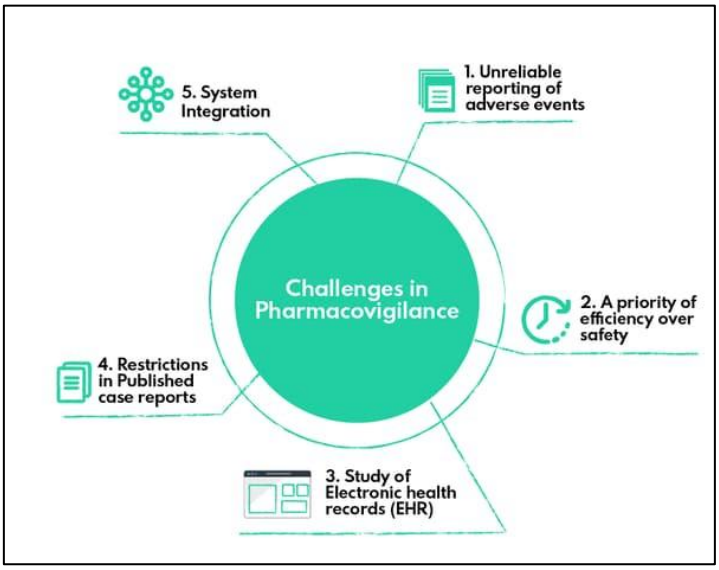
- Pharmacovigilance specifically refers to the systematic monitoring, collection, assessment, and prevention of adverse effects or any other drug-related problems associated with the use of pharmaceutical products.

- It primarily deals with the post-market surveillance of drugs, aiming to identify and understand adverse reactions that may not have been detected during clinical trials.

- Pharmacovigilance activities involve collecting and analyzing real-world data from healthcare professionals, patients, and other sources to detect patterns of adverse events and assess their potential causal relationship with the use of specific drugs.

- Pharmacovigilance aims to guarantee patient safety by quickly detecting and mitigating any unexpected or severe adverse effects that may occur after a drug's approval and availability on the market.

Challenges in Pharmacovigilance:



Future prospects for pharmacovigilance:

Pharmacovigilance has clear, well-established goals: to detect ADRs associated with the use of drugs as early as possible, and to avoid risks that may outweigh the benefits of the medication. The evolution of pharmacovigilance has been a slow and steady one.[47]From individual doctors noticing unusual effects in patients and sharing their findings with colleagues to the methods used today to monitor a drug after its release into the market, including spontaneous reports, risk management plans, prospective safety studies, and registries. The main focus of pharmacovigilance has been to detect rare ADRs while giving less attention to the common ones. Recently, however, there has been a climate of change and efforts are now being made to focus on patient-centered pharmacovigilance rather than population-based and regulation-based pharmacovigilance. A study was conducted to evaluate the different aspects of pharmacovigilance currently, and in the future.

Conclusion:

Pharmacovigilance is important for the protection of public health as it prevents, detects and assesses adverse reactions to medicinal products for human use. It encompasses whole life-cycle management of medicinal products for human use keeping safety aspect in mind. Consequently, we must stress on the necessity of the Pharmacovigilance as a continuation and completing of the analysis performed on medicines beginning from the clinical trials when the medication is administered for the first time in humans, and not only after they have been marketed. Pharmacovigilance continues to play an important role in meeting the threats posed by the ever increasing list of medicines, each of which carry an inevitable risk of unpredictable potential for harm. Whenever adverse effects and toxicity occur, especially when previously unknown, it is obligatory that these are reported, analyzed and their significance is communicated effectively to the people having knowledge to interpret the information. The harm can be reduced by ensuring that medicinal products of good quality, safety and efficacy are used rationally. In addition, the expectations and concerns about outcomes of the patient are taken into consideration when therapeutic decisions are taken. To obtain this goal and to boost a sense of trust among patients, ensure that risk in drug use are predicted, well manage and communicated to the regulatory authorities and other health care professionals.

Acknowledgement:

A drug safety and pharmacovigilance acknowledgement recognizes the collective effort in monitoring medicines for adverse effects, thanking contributors like researchers, healthcare professionals, regulatory bodies (like WHO and CDSCO in India), and even patients, for reporting issues and ensuring safe drug use through activities like adverse event monitoring (AEFI), risk assessment, and data analysis, ultimately protecting public health. It emphasizes the importance of collaboration and transparency in pharmacovigilance, highlighting efforts to improve reporting systems and share knowledge globally.

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