



PHARMACOVIGILANCE ON PUBLIC HEALTH AND PATIENT SAFETY

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ABSTRACT

Ensuring patient safety is a critical aspect of releasing newly developed drugs or those already established in the market. With its significant contribution to public health, pharmacovigilance is one of the most important scientific disciplines worldwide. The World Health Organization (WHO) defines pharmacovigilance as "the science and activities aimed at detecting, assessing, understanding, and preventing adverse effects or any other drug-related problem." The implementation of pharmacovigilance activities is crucial to promote and safeguard public health globally. By reducing the significant burden of morbidity, mortality, and associated healthcare costs, adverse reactions to medicines can be prevented. In fact, pharmacovigilance is of utmost importance, as it can save lives. For instance, adverse drug reactions are responsible for about 197 thousand deaths annually and cost society 79 billion euros in the European Union (EU).

KEYWORDS : Patient safety, Pharmacovigilance, Adverse effects, public health, Drug-related problems

Introduction:

Pharmacovigilance is a crucial aspect of ensuring patient safety for both newly developed drugs and those already established in the market. It is a science and set of activities that aim to detect, assess, understand, and prevent adverse effects or any other medicine-related problem. Pharmacovigilance is necessary for all stages of the drug production, distribution, and use process, including indications, dose, availability, genetics, diet, and traditions of the people. It is also concerned with pharmaceutical quality and composition, including active and inactive ingredients. [1]

The primary goal of pharmacovigilance is to monitor, review, evaluate, and communicate information on the safety of pharmaceutical products. It is the process and science of monitoring the safety of medicines and taking action to reduce the risk and increase the benefits of medicines. It is a key public health function used to detect, assess, understand, and prevent the adverse effects of medication. [1]

The major components of pharmacovigilance systems include data collection, which can be passive, active, or mandatory, data analysis, and reporting. The safety of medicines for patients, the quality of the products, the prevention of harm due to drugs in the market, and the knowledge of drug efficacy are some of the critical concepts of pharmacovigilance.

Data collection is a key component of pharmacovigilance systems. It involves gathering information about adverse drug reactions (ADRs) and other drug-related problems through various means such as voluntary reporting by healthcare professionals and patients, electronic health records, and clinical trials. Data collection can be passive, where information is submitted voluntarily, or active, where information is actively sought out through methods such as surveys or audits. Mandatory reporting is a requirement in some countries. Once the data is collected, it is analyzed to identify potential safety signals or patterns of ADRs. Analysis can involve statistical methods, data mining, and signal detection. This helps to identify new or previously unrecognized risks associated with drugs and assess their potential impact on patient safety. Finally, the results of the analysis are reported to regulatory agencies, healthcare professionals, and the public. Reporting helps to inform decision-making and improve the overall safety of drugs. It is important to ensure that data is reported accurately and in a timely manner to enable prompt action to be taken to address any safety concerns. [1], [2]

Pharmacovigilance is a critical aspect of ensuring the safety and efficacy of medicines in the Indian population. The objectives of pharmacovigilance are multifaceted and involve various stakeholders. One of the primary objectives of pharmacovigilance is to monitor Adverse Drug Reactions (ADRs) in the Indian population. ADRs are unintended and harmful reactions that occur due to the use of a drug or a medical product. It is crucial to monitor ADRs to ensure that the benefits of the drug outweigh the risks. [2]

Another objective of pharmacovigilance is to monitor the benefit-risk profile of medicines. This involves assessing the benefits and risks associated with the use of a drug, which helps in determining its overall efficacy and safety. Monitoring the benefit-risk profile is important as it allows for the identification of potential issues with the drug and facilitates the implementation of necessary measures to ensure its safe use.

Pharmacovigilance also plays a crucial role in supporting the Central Drugs Standard Control Organization (CDSCO) in formulating safety-related regulatory decisions for medicines. The CDSCO is the national regulatory body for Indian pharmaceuticals and medical devices. Pharmacovigilance data is essential for the CDSCO to make informed decisions about the approval, post-marketing surveillance, and recall of medicines.

Finally, communicating pharmacovigilance findings with all key stakeholders is another important objective of pharmacovigilance. This includes healthcare professionals, patients, regulators, and the general public. Effective communication ensures that all stakeholders are aware of the risks associated with the use of a particular drug and allows for the implementation of necessary measures to reduce the risks and ensure patient safety. [2]

Pharmacovigilance has fundamental goals that are crucial in ensuring the safety and effectiveness of medicines. Firstly, it aims to identify drug-related problems early by monitoring adverse drug reactions (ADRs) and other interactions that were previously unrecognized. This enables the timely reporting of resulting outcomes, which is essential in preventing harm to patients.

Secondly, pharmacovigilance seeks to detect changes in the incidence of known adverse reactions. By doing so, it can alert regulatory authorities and healthcare professionals of emerging risks, leading to more effective risk management strategies.

Thirdly, pharmacovigilance carefully monitors and assesses the benefit, harm, side-effects, efficacy, and risks of commercialized medicines. This helps in reducing the risks and increasing the benefits of medicines during their lifecycle. By promoting the rational and effective use of several drugs, it ensures that patients receive optimal therapy with minimum adverse effects.

Fourthly, pharmacovigilance aims to strengthen patient care and safety. It ensures that healthcare professionals are aware of the latest information on drug safety and that patients receive the best possible care. By safeguarding public health, it promotes trust in the healthcare system.

In summary, pharmacovigilance plays a critical role in monitoring the safety and effectiveness of medicines. Its fundamental goals of early identification of drug-related problems, detection of changes in adverse reactions, careful monitoring and assessment of benefits and risks, promotion of rational drug use, and strengthening patient care and safety ensure that patients receive the best possible therapy with minimum harm.

Pharmacovigilance recognizes the importance of educating and informing the public, healthcare professionals, and other stakeholders about drug safety issues. By promoting education and knowledge, pharmacovigilance can raise awareness and enhance understanding about the risks and benefits associated with pharmaceutical products. This can lead to better decision-making by healthcare providers, patients, and regulators, ultimately improving patient care and safety. [3]

In addition, accurate and timely communication of pharmacovigilance findings is essential for promoting public health. It involves disseminating information about drug safety issues, such as ADRs and other drug-related problems, to key stakeholders, including regulatory agencies, healthcare providers, and patients. By providing accessible and understandable information, pharmacovigilance can empower patients to make informed decisions about their healthcare and help healthcare providers to provide better care to their patients. Ultimately, the promotion of education, knowledge, accurate information, and clinical training in the field of drug safety is a critical component of pharmacovigilance's efforts to safeguard public health. [3]

Medicines play a vital role in healthcare and ensuring their safety and quality is crucial. From the early stages of clinical trials, drugs undergo rigorous testing and analysis to assess their effects. However, it is equally important to continue monitoring the effects of medicines during and after they are released on the market to ensure their safety and effectiveness. This is where pharmacovigilance comes in. Pharmacovigilance aims to promote patient care and safety by monitoring the effects of medicines, contributing to the assessment of their benefit, harm, effectiveness, and risk, and encouraging safe, rational, and effective use of drugs. It is a critical aspect of drug regulation and helps identify potential risks associated with the use of medicines, allowing for timely intervention and preventing adverse reactions. Therefore, pharmacovigilance is a crucial element in ensuring public health and patient safety. [3]

Public Health & ADR Reporting:

To achieve the goal of improving public health, national regulators and international organizations must take steps to empower healthcare professionals and the public to report more adverse drug reactions (ADRs). Programs like the FDA MedWatch in the USA and MHRA Yellow Card scheme in the UK have been established to allow healthcare professionals and patients to report adverse reactions of different types of

medicines and devices into a central consolidated database. However, public awareness of such schemes is limited, and wider exposure and knowledge of them is vital if the trend of underreporting is to be addressed. Moreover, data collection from non-traditional sources, such as social media, must be better integrated into the ADR reporting process. [1], [3]

It is essential for all stakeholders - patients, pharmaceutical, biotech and medical device companies, regulators, and technology organizations - to work together to meet the challenges and ensure that, as far as the safety of medicines and devices is concerned, improving public health remains paramount. By adopting a collaborative approach, it is possible to address the issues faced by pharmacovigilance systems and develop effective solutions that can safeguard public health.

Patient Safety in Pharmacovigilance

Pharmacovigilance is a crucial component of drug development and commercialization, ensuring that medicines are safe for patients to use. It involves the collection, analysis, monitoring, and prevention of adverse effects related to drugs and therapies, with the ultimate goal of protecting public health. Strict regulations are in place to ensure patient safety, and pharmacovigilance is responsible for ensuring that these regulations are followed throughout the drug's life cycle.

Pharmacovigilance is a continuous process that extends beyond clinical trials and continues throughout the drug's commercial life. It involves monitoring the effectiveness and risks of a drug in real-world scenarios, such as after it has been released to the market. The information gathered through pharmacovigilance helps healthcare professionals make informed decisions about the use of medicines, ensuring that patients receive safe and effective treatments. Pharmacovigilance is, therefore, a critical function within the life science industry. It enables drug developers and manufacturers to identify and manage risks associated with their products, and it ensures that patients can use medicines with confidence, knowing that their safety has been carefully monitored and assessed. Overall, pharmacovigilance is a vital component of public health and a cornerstone of the pharmaceutical industry's commitment to patient safety. [2], [3], [4]

Patient safety and continuous vigilance

Drug safety, also known as pharmacovigilance, plays a critical role in ensuring the safety and wellbeing of patients throughout the entire drug development lifecycle. From the initial clinical trials to post-market surveillance, drug safety professionals continuously monitor drugs for potential side effects and adverse events that may impact patient health.

One of the key responsibilities of drug safety professionals is to collect, analyze, and report adverse drug reactions (ADRs) to regulatory authorities. This is done through a variety of mechanisms, such as patient and healthcare professional reporting, medical literature review, and analysis of clinical trial data. These reports allow regulators to make informed decisions about the safety and efficacy of drugs on the market, as well as take any necessary actions to protect patient health. The focus of drug safety is exclusively on ensuring patient safety and minimizing harm. While other departments within pharmaceutical companies may focus on improving patient outcomes, drug safety professionals have a unique responsibility to ensure that drugs are used safely and effectively. This sharp focus on patient safety is critical to maintaining public trust in the pharmaceutical industry and ensuring that patients can benefit from the therapeutic advances made in medicine. [2], [3], [4]

Importance of Pharmacovigilance to Patients:

Pharmacovigilance plays a crucial role in ensuring the safety and efficacy of medicines. The need for safety monitoring has arisen due to unfortunate incidents in the past where drugs have caused harm to patients. One of the most significant examples is the thalidomide disaster in the 1960s, which resulted in thousands of babies being born with congenital malformations. Another example is the use of diethylstilbestrol (DES) to prevent miscarriages, which was later found to have harmful effects on the offspring of women who took the drug. In addition, there have been cases of deaths caused by anesthesia, highlighting the importance of monitoring adverse effects. These incidents have led to the development of pharmacovigilance systems, which aim to detect, assess, understand, and prevent adverse effects of medications. By implementing pharmacovigilance measures, we can prevent similar incidents in the future and ensure that patients receive safe and effective treatment.

Safety management plan in pharmacovigilance

A Safety Management Plan (SMP) is a systematic and structured approach to identify, evaluate, manage, and communicate risks associated with a drug or therapeutic product. The SMP is an essential component of a comprehensive pharmacovigilance program, and it is required by regulatory authorities worldwide. The SMP aims to ensure the ongoing safety of a drug or therapeutic product throughout its entire life cycle, from clinical trials to post-marketing surveillance.

The SMP outlines the procedures and processes for identifying, assessing, and managing potential safety risks associated with the drug or therapeutic product. It includes the collection and analysis of safety data from various sources, such as clinical trials, post-marketing surveillance, spontaneous reports, and scientific literature. The SMP also establishes the roles and responsibilities of individuals involved in the pharmacovigilance program, such as the drug manufacturer, marketing authorization holder, and regulatory authorities.

The SMP includes a risk management plan that outlines the actions and measures to be taken to manage identified safety risks associated with the drug or therapeutic product. These measures may include changes in labeling, dosing, or contraindications, as well as the implementation of additional risk mitigation measures. The SMP also includes a plan for communicating safety information to healthcare professionals, patients, and regulatory authorities.

In summary, the SMP is a critical tool for ensuring the ongoing safety of a drug or therapeutic product. It provides a framework for identifying and managing potential safety risks associated with the drug, and it outlines the procedures and processes for collecting and analyzing safety data. The SMP also establishes the roles and responsibilities of individuals involved in the pharmacovigilance program and outlines the risk management plan and communication plan for managing identified safety risks. [2], [3], [4]

Conclusion:

Pharmacovigilance plays a crucial role in the continuous monitoring of drug safety by collecting and analyzing spontaneous adverse drug reaction reports. Through clinical assessment and judgment, the impact of adverse reactions on the overall safety profile of the drug can be evaluated. It is essential for healthcare professionals, including physicians, nurses, and pharmacists, as well as patients, to report all adverse drug reactions promptly. Regulatory authorities can then take necessary actions, including banning drugs worldwide, and ensuring that they are not available in India.

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