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Review Article

Pharmacovigilance: Safeguarding Patients Through Drug Safety Monitoring

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ABSTRACT

Pharmacovigilance promotes the responsible and safe use of medications. Pharmacovigilance requires the spontaneous reporting of adverse drug reactions (ADRs). ADRs are, nevertheless, significantly underreported. In developing nations, adverse medication responses have grown to be a serious issue. Pharmacovigilance knowledge could serve as the foundation for initiatives meant to increase reporting rates and lower ADRs.

INTRODUCTION

Pharmacovigilance is an important and essential part of clinical research.(1) Pharmacovigilance is the science of detecting, assessing, understanding, and preventing the harmful effects of medicines, both short-term and long-term. In simpler terms, it's all about making sure that the medicines people take are safe and effective. In India, while pharmacovigilance began back in 1998, it's still not as advanced as in Western countries. The understanding and awareness of pharmacovigilance in India is limited, and there's a need for more knowledge and focus on its importance. During clinical trials (testing of new medicines) and after a drug is available on the market (post-marketing), pharmacovigilance helps track and monitor any potential side effects or adverse reactions to ensure public safety. By integrating good pharmacovigilance practices throughout the product's life cycle, we can make sure medicines are both safe and effective. This also helps companies stay in line with regulations and improve overall patient safety.

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Even though pharmacovigilance is relatively new in India compared to other countries, it's important for the country to prioritize it to improve healthcare outcomes and build public trust in medicines(2) In 1968, the World Health Organization (WHO) started the "Programme for International Drug Monitoring," a project aimed at collecting global data on Adverse Drug Reactions (ADRs). The goal was to quickly identify any potential safety signals related to medications. The term "Pharmacovigilance" (PV) was introduced in the 1970s by a group of French scientists to describe the study of drug side effects. PV focuses on detecting, assessing, and preventing ADRs, particularly those that may appear over short or long-term use of medicines. The main purpose of PV is to monitor the risks associated with drug treatments after they are released to the market (post-marketing phase), to track known ADRs, identify new ones, and ensure the overall safety of medicines in real-world settings. The Uppsala Monitoring Centre (UMC) in Sweden manages this international program, and currently, 104 countries are part of it. However, despite India's large population and participation in the program, its contribution to the database is relatively small. This is mainly due to a lack of a strong ADR reporting system and insufficient awareness among healthcare professionals in the country. ADRs are a significant cause of illness and death in India, leading to an estimated 8% of hospital admissions, with 8-19% of patients in hospitals experiencing serious ADRs. Even when the FDA approves a new drug, its complete list of potential side effects is not always fully known because clinical trials are often limited in size and duration. These trials typically involve a small group of participants (usually fewer than 5,000), which means rare or long-term side effects may not be identified until the drug is widely used in the general population(3-10)

Adverse drug reaction

An adverse drug reaction (ADR) is when a person experiences a harmful or unpleasant effect after taking a medicine. These reactions can warn doctors about potential risks if the person continues to use the medicine. As a result, doctors may need to adjust the dose, stop the medicine, or provide treatment to manage the reaction and prevent further harm.(11) Research from the late 20th and early 21st century in the USA and UK showed that adverse drug reactions (ADRs) are common in healthcare. These reactions can lead to unexpected hospital admissions, occur while patients are in the hospital, or show up after they leave.(12-15) The rate of adverse drug reactions (ADRs) has stayed fairly consistent over time, with studies showing that around 5% to 10% of patients experience ADRs during admission, while in the hospital, or after being discharged. Despite efforts to prevent them, the number of ADRs hasn't decreased much. The way ADRs are identified can affect how often they are reported, but most ADRs aren't serious. However, these reactions can still cause harm, leading to illness or death, higher healthcare costs, and damaging the trust between doctors and patients. Certain medications are more likely to cause ADRs that lead to hospital admissions. These include drugs like antiplatelets, anticoagulants, chemotherapy drugs, immunosuppressants, diuretics, diabetes medications, and antibiotics. Fatal ADRs often happen due to bleeding, especially when blood thinners (antithrombotic/anticoagulants) are taken with anti-inflammatory drugs (NSAIDs), which can increase the risk of bleeding. (16)

Type of adverse drug reaction

type of adverse drugs reaction are main two types.i.e. More common adr include type A and type B reaction and less common adr include type C D E F(17-20)

Type A adverse reactions (ADRs) are common side effects that happen when a drug's dose is too high, making its normal effects stronger than

expected. These reactions are often linked to how the drug is processed by the body (pharmacokinetics) or how it works in the body (pharmacodynamics). Sometimes, genetic differences between people can affect how their bodies handle the drug, leading to these reactions.(21)

Type B ADRs (Adverse Drug Reactions) are rare and unpredictable reactions to a drug that depend on the individual characteristics of the patient rather than the dose of the drug. These reactions are often linked to the person's unique response to the drug, like allergies. A good example of this is a hypersensitivity (allergic) reaction to a drug.

Type A	Type B
Predictable	Unpredictable
Dose Dependent	Rarely dose dependent
High Morbidity Low Mortality	Low Morbidity High Mortality
Respond to Dose reduction	Respond to Drug withdrawal

ADRs are categorized into different types based on their characteristics:

Type A reactions are more common and predictable. They happen because of the drug's known effects and are often related to the dose. About 80% of ADRs in hospitals are of this type and they can be avoided or managed by adjusting the dose or changing the drug.

Type B reactions are rare, unusual, and not related to the dose, often due to individual patient differences.

Type C reactions are related to long-term drug use, and they depend on both the dose and time.

Type D reactions occur after a delayed time period.

Type E reactions happen when a drug is suddenly stopped.

Type F reactions are when the drug unexpectedly fails to work as intended.

Common drug classes causing ADRs in hospitals are corticosteroids, antibiotics, anticoagulants (blood thinners), cancer treatments, heart medications, painkillers (like opioids), and anti-inflammatory drugs. In children, drugs like anti-infectives, respiratory drugs, and vaccines are often the cause of ADRs.

Adverse drug reaction reporting

Studies show that women experience adverse drug reactions (ADRs) more often than men. One study found that women are 1.5 to 1.7 times more likely to have an ADR. The exact reason for this is unclear, but it could be due to differences in how men's and women's bodies process drugs, differences in immune responses, hormonal factors, or the fact that women may take more medications than men. In our study, adults who are working (the wage-earning group) were the most affected by ADRs.(22-24) Pulmonary medicine and dermatology reported a high number of adverse drug reactions (ADRs). This can be explained by the type of patients treated in these departments. The pulmonary department handles many tuberculosis patients, who require multiple medications. The combination of different drugs, the patient's health condition, and polypharmacy (using multiple medications) may contribute to these ADRs. Similarly, skin-related drug reactions are common in dermatology.(25-26) In this study, antibiotics and antitubercular drugs were the leading causes of ADRs, followed by vaccines. Ceftriaxone (antibiotic) and the pentavalent vaccine were the most common culprits.(27) Since 2018, ADR reporting completeness has improved, likely due to pharmacovigilance training through workshops and lectures. However, the lowest scores were in reporter details, aligning with Vishal R. Tandon et al. (2015). This may be due to a lack of awareness, fear of legal issues, or the busy academic schedules of postgraduate

students.(28-29) Pharmacovigilance in India has evolved over the years but still faces challenges in widespread acceptance and implementation. Despite the significant impact of Adverse Drug Reactions (ADRs) on public health, ADR reporting in India remains low. The first attempt at an ADR monitoring system in India began in 1986 but saw little progress until 1997, when India joined the WHO ADR Monitoring Programme. However, this attempt failed, leading to the launch of the National Pharmacovigilance Program for India (NPPI) in 2004, supported by WHO and the World Bank. Despite structured implementation, NPPI did not achieve the desired outcomes. To strengthen ADR monitoring, the Pharmacovigilance Programme of India (PvPI) was launched in 2010. Initially, 22 ADR Monitoring Centres (AMCs) were set up, with AIIMS New Delhi as the National Coordination Centre (NCC). In 2011, the NCC was shifted to the Indian Pharmacopoeia Commission (IPC), Ghaziabad. Currently, India has around 170 AMCs, which collect and upload ADR reports to the VigiFlow database. By 2015, around 150,000 ADR reports were generated. Despite progress, India's pharmacovigilance system lags behind developed nations due to low awareness, inadequate training, and limited knowledge among healthcare professionals. Improving education, training, and awareness can enhance ADR reporting and drug safety monitoring in India.(30-33)

Adverse drug monitoring

ADR (Adverse Drug Reaction) monitoring is a crucial process for patient safety, which includes continuous surveillance of undesirable effects suspected to be associated with medicinal products9. Some common methods utilized in ADR monitoring include case reports, cohort studies, record linkage systems, patient questionnaires, and intensive monitoring

Methods of monitoring adverse drug reactions

ADR monitoring for safety evaluation is a complicated process. Some of the commonly utilized monitoring methods are outlined below.

Case reports

The release of single case reports, or case series, of ADRs in medical literature serves as a crucial way of identifying new and severe reactions; particularly Type B reactions. Their significance is decreasing with the rise of spontaneous reporting systems. e. g. : Halothane induced hepatitis.

Cohort studies

These are forward-looking studies, which examine the outcomes of a large group of patients using a specific drug. They can also assess the rates of incidents in groups of patients utilizing the drug of interest compared to a control group. Prescription event monitoring and various record linkage systems constitute part of this prescription event monitoring. In this, prescriptions for specific drugs are recognized and tracked by requesting the prescriber to complete a simple questionnaire documenting any medical event from the patients. In this scenario, the prescriber does not need to evaluate the causality between the event and the drug. Record linkage system In this context, records from various sources such as general practice and hospital records, pharmacy records, dental records, certified cause of death, patient records, etc. are connected and examined. Such linking proves to be very beneficial when investigating the long-term impacts of drug use (e. g. , potential increased incidence of malignancy or mental retardation in individuals during their pregnancy.

Patient questionnaires

Self-administered questionnaires can be utilized for outpatients who consistently visit clinics, although they carry the possibility of recall biases. They have been instrumental in identifying numerous unforeseen adverse reactions. For

example, headaches and weakness in arms and legs attributed to metformin. They are also employed to demonstrate the absence of effects.

Intensive monitoring

These are programs based in hospitals that are intensive. In this, all patients who are admitted to a specific ward are counted in the analysis. Specially trained personnel gather the needed information from the patients and their records, including demographics, medical history, drug exposure, known side effects of the medications, any lab test results, and treatment outcomes. This approach has the ability to follow up on and investigate adverse reactions indicated by other detection systems, such as isolated case reports in medical literature. Additionally, the frequency of side effects can be investigated at a lower cost compared to a clinical trial. Essentially, intensive monitoring offers insights into relatively common and early reactions to medications utilized in hospital settings. It is not feasible to recognize delayed reactions since the patients are not hospitalized long enough for such detection. ADR monitoring represents a vital component of post-marketing surveillance, contributing to the collection of data on the safety of medications. The short-term objectives and methodologies of an ADR monitoring system vary based on the clinical environment in which it is conducted, but generally, "ADR monitoring" seeks to:

1. Encourage rational drug usage.
2. Ensure safe medicine utilization.
3. Foster safety across all medical and paramedical interventions.
4. Enhance patient care/improve public health.
5. Evaluate benefit versus harm.
6. Assess the effectiveness and risks associated with medications.

Future aspect of pharmacovigilance:

The future of pharmacovigilance in India looks promising, especially with the increasing number of clinical trials and research activities taking place in the country. There is a significant need to grasp the role of pharmacovigilance and its influence on the product life cycle. Given the current scenario, an effectively functioning pharmacovigilance system is crucial for ensuring the safe use of medications.(34-43)

CONCLUSION

Pharmacovigilance is the science of monitoring the safety of medicines to ensure they are safe and effective for people. In India, while there have been efforts to improve pharmacovigilance, challenges like low awareness and underreporting of adverse drug reactions (ADRs) still exist. The country has made progress with programs like the Pharmacovigilance Programme of India (PvPI), but more education and training are needed to enhance reporting and patient safety. As India continues to grow in clinical research, strengthening pharmacovigilance will be essential for ensuring safe medication use and building public trust.

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