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Review Article

Pharmacovigilance and its impact on drug safety

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ABSTRACT

Pharmacovigilance is the science and activities concerned with the detection, assessment, understanding, and prevention of adverse effects or any other drug related problems. Pre-marketing clinical trials provide essential information on efficacy and safety of drugs. they are limited by small sample size and short durations which makes post-marketing surveillance crucial for identifying, rare, serious and long-term adverse drug reactions. Pharmacovigilance systems rely on spontaneous reporting, active surveillance and pharmacoepidemiological studies to generate safety signals and support regulatory decision making. Effective pharmacovigilance contributes to the rational use of medicines, enhances patient safety, and improves public health outcomes through continuous monitoring of benefit-risk ratio of medicinal products. Strengthening reporting systems and increasing awareness among healthcare professionals and patients remain key to improving pharmacovigilance practices globally.

Keywords: Pharmacovigilance, Drug safety surveillance, Thalidomide crisis, Pharmacovigilance programme of India

INTRODUCTION

The practice of tracking, recognizing, and evaluating the possible dangers and advantages of pharmaceutical goods is called pharmacovigilance, or drug safety surveillance. It is crucial to guaranteeing the effectiveness and safety of medications for both patients and medical professionals.[1]

WHAT IS PHARMACOVIGILANCE IN MODERN DAY SOCIETY?

Pharmacovigilance is the process of keeping an eye on the safety of medications after they have been authorized for use. This includes identifying, evaluating, understanding, and preventing side effects or other drug-related issues.

In order to enhance patient care and public health, it is a continuous process that entails gathering, evaluating, and sharing data regarding the safety of medications.

THE HISTORY OF PHARMACOVIGILANCE

The first known records of pharmacovigilance date back to ancient Egypt, Greece, and Rome, where doctors and healers recorded the effects of various medicinal plants and chemicals. These ancient healers examined these data to identify which treatments were most effective and which had negative side effects.[2]

However, it wasn't until the 19th century that pharmacovigilance began to gain recognition as an appropriate area of research. As industrialization and pharmaceutical mass production began, the number of reported adverse drug reactions (ADRs) increased.

As a result, we set up national and international institutions to keep an eye on and research medication safety. One of the first instances of contemporary pharmacovigilance was the US's development of the therapeutic index in the 1920s. The current drug safety system was built on this index,

which was used to assess the efficacy and safety of medications.

The World Health Organization (WHO) established the global ADR monitoring program known as the WHO Collaborating Centre for International Drug Monitoring in the 1960s. This program aimed to gather and examine ADR reports from all around the world in order to identify any safety concerns and improve pharmaceutical safety.[3]

THE 1960S THALIDOMIDE CRISIS

Because thousands of babies were born with congenital deformities as a result of their mothers using the pharmaceutical thalidomide during pregnancy, this tragedy increased awareness of drug safety and led to the creation of regulatory frameworks that guarantee the safety of medications.[4]

The US Food and Drug Administration (FDA) implemented the adverse drug reaction reporting system (ADRRS) in the 1970s, requiring pharmaceutical companies to document any adverse occurrences associated with their medicines. This approach was used as a model for other countries and is currently a crucial component of the current pharmacovigilance system.

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was established in the 1990s to harmonize the regulatory requirements for drug approval across countries. One of its primary objectives is to guarantee the efficacy and safety of pharmaceuticals, and it has developed several standards and guidelines to help do this.

The European Medicines Agency (EMA) became the lead in EU drug regulation following its founding in 1995. One of its main duties is to monitor and assess the safety of pharmaceuticals, and it has implemented several programs and mechanisms to do this.

A risk management plan (RMP), a document outlining the steps pharmaceutical companies would take to assure the safe use of their medications, was first established by the FDA and the EMA in the early 2000s.

THE VIOXX SCANDAL

Another regrettable pharmacovigilance-related occurrence involves the anti-inflammatory drug Vioxx (Rofecoxib). After a study found that the drug increased the risk of heart attack and stroke, it was removed from the market in 2004. Subsequent estimates indicate that the drug caused almost 27,000 heart attacks and unanticipated cardiac deaths.

This occurrence was a major pharmacovigilance incident because it demonstrated the significance of continuous monitoring and risk-benefit analysis of pharmaceuticals even after they have been licensed and placed on the market.

As a result, the FDA's procedures for evaluating the safety of drugs and clinical trials were changed, and other COX-2 inhibitors came under more scrutiny. It also led to the creation of new pharmacovigilance rules and recommendations in the US and Europe, emphasizing the need for better post-marketing surveillance.

PROFESSIONALIZATION IN PHARMA-COVIGILANCE

The professionalization of pharmacovigilance has accelerated due to several events and advancements.[5]

Some of the key factors include increasing use of innovative technologies including the effectiveness of pharmacovigilance has increased as new technologies, such as big data analytics and electronic health records, have made it easier to gather, evaluate, and share information about drug safety.

The increase in global collaboration

The globalization of the pharmaceutical industry and the growth of international organizations like the WHO have led to an increase in cooperation between various nations and organizations to exchange best practices and knowledge on drug safety.

The increased regulatory requirements

Regulatory organizations like the US FDA and the EMA have lately implemented stricter pharmacovigilance standards, which has raised awareness of pharmaceutical safety and professionalized the industry.

All of these developments and events have contributed to improving the procedures and systems in place to keep an eye on the safety of medications as well as increasing awareness of the significance of pharmacovigilance.

HOW WILL PHARMACOVIGILANCE EVOLVE?

The ability of pharmacovigilance systems to identify and evaluate potential safety issues has greatly expanded in recent years as a result of advancements in data science and technology. For example, data mining techniques are being used to identify trends and patterns in ADR reports, and many countries have implemented automated systems for reporting ADRs. Additionally, the use of big data and artificial intelligence (AI) is expected to improve pharmacovigilance systems' ability to recognize and assess potential safety issues.[6]

In general, pharmacovigilance's history is one of adaptability and evolution. From ancient civilizations to the present, the field has developed to meet the needs of patients and healthcare professionals. It is still vital today

to ensure the efficacy and safety of pharmaceuticals, and we expect it to only improve.

WHY PHARMACOVIGILANCE IS NEEDED IN EVERY COUNTRY?

The prevalence of ADRs and other drug-related issues varies among countries (and even by region). This may be due to difference in diseases and prescription procedures, people's traditions, diet, and genetics, pharmaceutical quality and composition are influenced by the methods utilized in drug manufacture, distribution and usage of drugs, including availability, dosage, and indications, the use of traditional medicines (such as herbal therapies) that, when taken alone or in conjunction with other medications, may present some toxicological issues.

In addition to having more educational value and relevance, data from within the nation or region may promote national regulatory decision-making.

Information gathered in one nation might not apply to other regions of the world, where conditions might be different. As a result, each nation must create its own pharmacovigilance program.

PHARMACOVIGILANCE PROGRAMME OF INDIA

In collaboration with the Indian Pharmacoepia Commission (IPC), Ghaziabad, the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, under the guidance of the Ministry of Health and Family Welfare, Government of India, has launched a nationwide Pharmacovigilance Program to ensure drug safety and safeguard patient health.[7]

The Central Drugs Standard Control Organization (CDSCO) oversees the initiative, which is managed by the Indian Pharmacopeia Commission in Ghaziabad as a National Coordinating Center (NCC). The Steering Committee will oversee the center's operations.

GOAL

PVPI main objective is to protect Indian public health by ensuring that the benefits of medication use exceed the risks. In addition to informing the public and healthcare professionals about potential hazards, PvPI's goal is to gather data, analyze it, and apply the conclusions to suggest well-informed regulatory actions. Pharmacovigilance's expanded patient safety scope encompasses errors in prescription, dispensing, and administration as well as the identification of medications of inferior quality. Other pharmacovigilance issues that must be addressed include counterfeiting, antibiotic resistance, and the requirement for real-time surveillance in bulk immunizations.[8] The PvPI satisfies the WHO's minimum requirements for any working national pharmacovigilance system, which include the following

A national pharmacovigilance center with assigned personnel that works with the WHO program for international drug monitoring (the Indian Pharmacoepia Commission, Ghaziabad, under MOHFW, GOI, is the National Coordinating Center for PvPI). A national individual case safety report (ICSR) form, or ADR reporting form must be available as part of a national spontaneous reporting system. A national database or system (Vigiflow software for PvPI) is used for gathering and organizing data reports. Technical support for causality evaluation is available from a national ADR or pharmacovigilance advisory group. (the PVPI steering committee offers technical support). A well-defined plan is executed for both regular and emergency communications under PvPI, the whole country will have ADR monitoring centers (AMCs) in medical colleges as well as in the private hospitals. There are 567 AMCs till 2023 in India.

DATA FLOW

AMCs begin reporting ICSRs (ADR forms) to NCC via a Vigiflow as soon as they are registered as AMCs under PvPI. After being evaluated for data quality at NCC, these ICSRs are committed to the worldwide drug monitoring center "Uppsala Monitoring Center" in Sweden if they prove to be real. The Uppsala Monitoring Center collects data from all over the world and analyses it and report it to FDA. FDA may issue black box warning or even withdrawal of drug from market if severe adverse effects are detected. In the event that the data is incomplete or invalid, the ICSRs are returned to the relevant AMC along with any necessary comments or queries, allowing the corresponding ICSR to be completed or repaired before being sent to NCC for review once more. Additionally, CDSCO receives the data from NCC as needed (Figure 1).[9]

OBJECTIVE OF PHARMACOVIGILANCE PROGRAMME OF INDIA

The objectives of PvPI are to establish a national patient safety reporting system, to discover and evaluate fresh signals from the cases that have been reported, to evaluate the benefit-risk ratio of marketed drugs, to produce data on medication safety that is supported by evidence, to assist regulatory **bodies** in making decisions on the use of pharmaceuticals, to reduce the risk by informing different stakeholders on the safety of medication use, to become a national centre of excellence for pharmacovigilance initiatives, to collaborate with other national centers to manage data and exchange information, to assist other national pharmacovigilance centers across the world with training and consulting and to promote rational use of medicines.

How to report ADRs?

As per WHO guidelines, different case report forms are available in different countries. All of them have at least four sections which should be completed.

Patient information, adverse event, suspected medication, reporter details. The completed case report form should be sent to the national or regional ADR centre or to the manufacturer of the suspected product (Figure 2).[10]

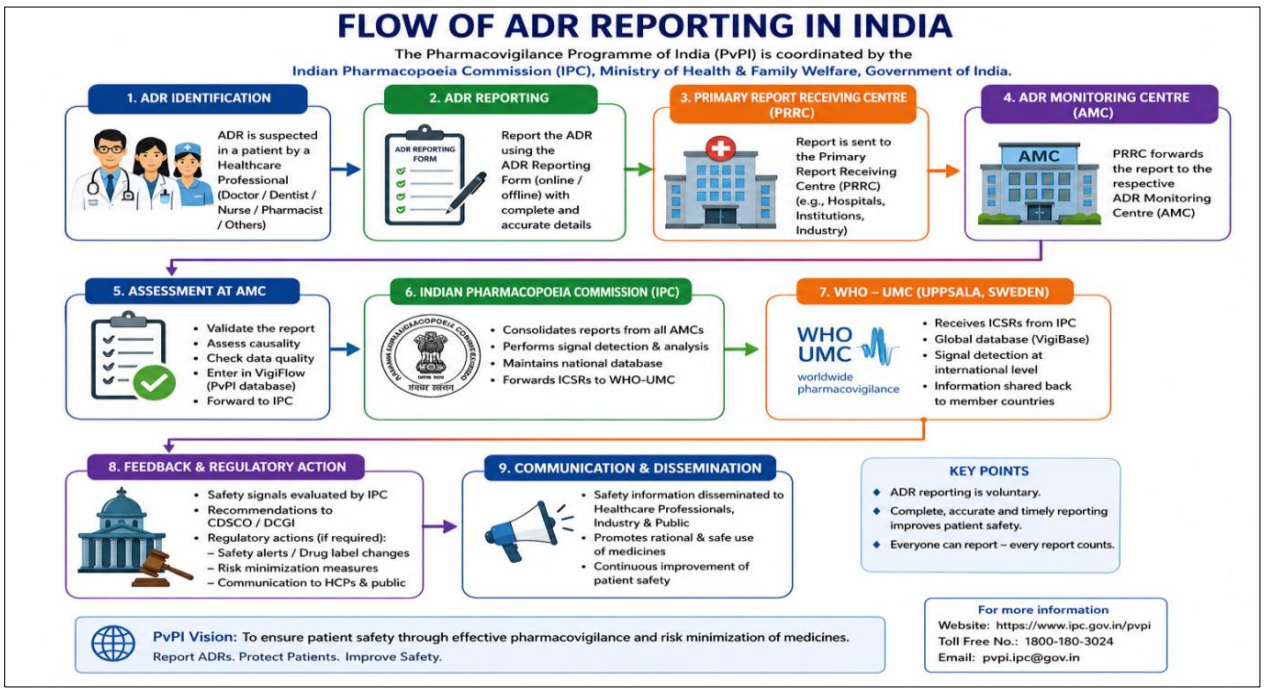

Figure 1: Flow of ADR reporting in India.

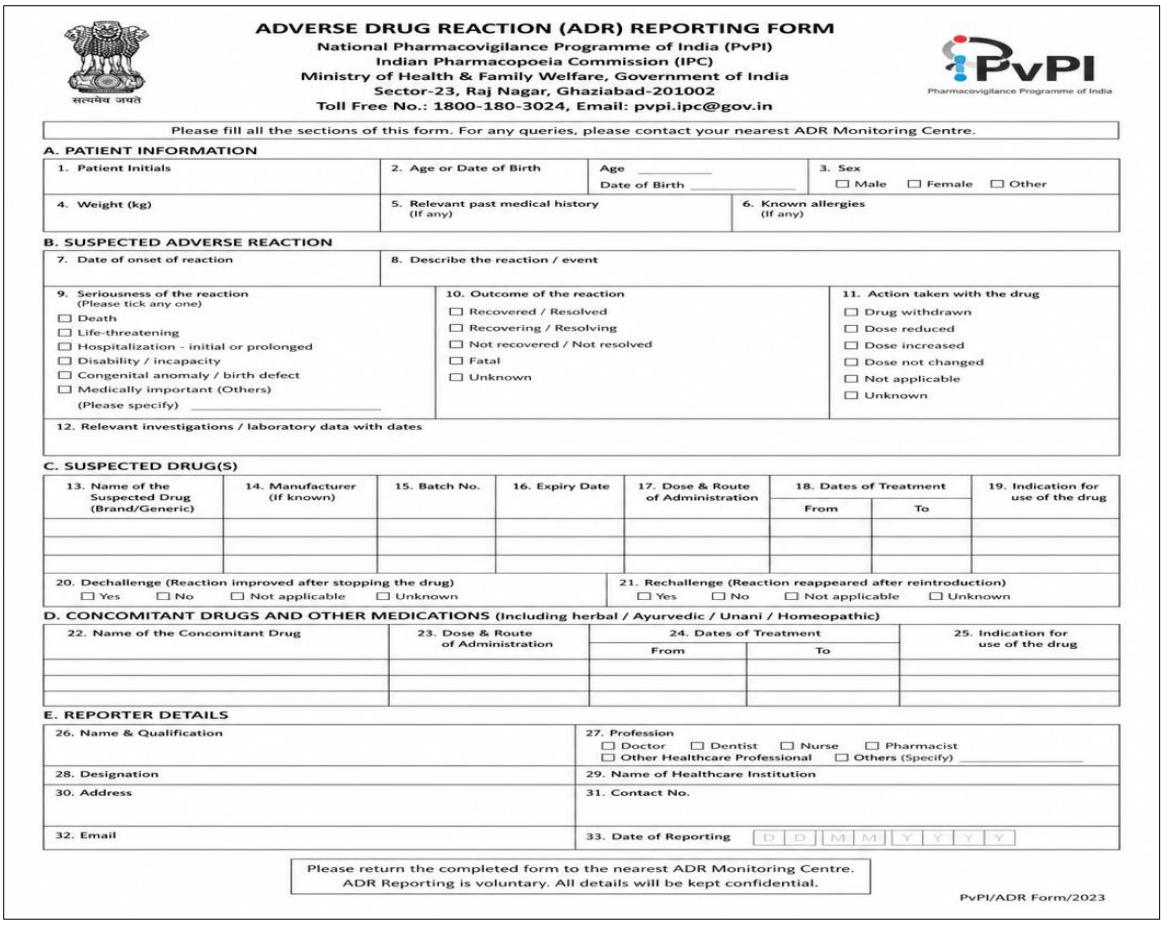

Figure 2: Suspected adverse drug reaction reporting form.

Who can report ADRs?

Healthcare workers (HCWs) (clinicians, dentists, nurses, pharmacists) as well as patients.

What to report?

All suspected drug-related adverse events, including those thought to be brought on by herbal, traditional, or alternative medicines, are encouraged to be reported by Pharmacovigilance programme of India (PvPI).[11]

The program asks for particular reports of all adverse events that may have been brought on by "drugs of current interest" and new medications, all suspected drug interactions, all reactions suspected of causing death, life-threatening, hospitalization, disability, congenital anomaly requires intervention to prevent permanent impairment or damage.

Pharmacovigilance methods

Spontaneous reporting systems

Different reporting systems have been adopted by different countries for ADRs.

In UK, there is 'Yellow Card' scheme, In India, standardized forms (ADR reporting form) are used for reporting of suspected adverse reactions to the regulatory authorities.[12]

Prescription event monitoring (PEM)

A well-known postmarketing surveillance method called Prescription event monitoring (PEM) was created to keep an eye on the general safety of recently released medications while they are applied in actual clinical settings.

Targeted clinical investigation (TCI)

Pharmacodynamic and pharmacokinetic studies can be conducted in patients and healthy volunteers to determine the risk of adverse reactions due to a particular dosing. Genetic testing can be done to determine the risk of adverse reactions.

DISCUSSION

In the past various pharmacovigilance studies has been conducted to monitor and improve drug safety. Studies range from historical system establishment (like the Yellow Card Scheme and WHO monitoring) to hospital – level ADR surveillance and modern big data analyses using global reporting systems. All these efforts aim to detect, evaluate, and prevent adverse drug effects to enhance patient safety. The current study emphasizes on the history of pharmacovigilance, what is the need of pharmacovigilance, the flow of ADR reporting in India, the importance of pharmacovigilance programme of India, and the ADR reporting procedure.

The present article highlights the critical role of pharmacovigilance in ensuring drug safety and promoting rational use of medicines. Pharmacovigilance serves as an essential component of healthcare systems by detecting, assessing, understanding, and preventing ADRs, thereby minimizing risks associated with drug therapy.[13]

The findings of this study emphasize that effective pharmacovigilance practices significantly contribute to improving patient safety and enhancing the overall quality of healthcare services.

The study demonstrates that systematic ADR monitoring and timely reporting play a crucial role in identifying previously unrecognized adverse effects and in evaluating the risk-benefit profile of medicines. This is in line with previous research that found pharmacovigilance to be a key component of post-marketing drug surveillance, enabling regulatory bodies to make evidence-based choices about drug safety.[14]

The WHO and the Indian Pharmacovigilance Program have made similar observations, highlighting the significance of spontaneous ADR reporting systems in protecting public health. According to the research, pharmacovigilance improves drug safety by identifying safety signals early, lowering avoidable adverse drug reactions, and enacting corrective regulatory measures including label changes, usage limitations, or the removal of dangerous medications. This greatly lowers the morbidity, mortality, and medical expenses related to adverse medication reactions.

Nevertheless, despite its significance, a number of issues still exist, such as the underreporting of ADRs, a lack of knowledge among medical personnel, insufficient training, and a restricted integration of pharmacovigilance procedures into standard clinical workflows. These obstacles could make ADR monitoring systems less effective. The identified defects highlight the necessity of ongoing educational initiatives, awareness campaigns, and standardized reporting systems to promote active involvement of healthcare professionals.[15]

This article's thorough analysis of the relationship between pharmacovigilance and medication safety is its strongest point. However, the completeness of safety data may be impacted by some restrictions, such as dependency on voluntary reporting systems and potential reporting bias.

Overall, the study finds that enhancing drug safety results requires boosting pharmacovigilance systems. Building a strong pharmacovigilance culture requires more cooperation between regulatory bodies, the pharmaceutical industry, and healthcare providers. To further increase the efficacy of pharmacovigilance procedures in guaranteeing

patient safety, future initiatives should concentrate on raising awareness, implementing digital reporting systems, and carrying out multicentric research.

CONCLUSION

Pharmacovigilance is crucial for patient safety since it identifies, evaluates, understands and minimizes adverse drug reactions during the course of a medication's life cycle. Pre-marketing clinical trials are insufficient to identify all risks hence post-marketing surveillance plays an important role in identification of rare and long-term adverse effects.

Effective pharmacovigilance supports rational and safe use of medicines improves treatment outcomes and reduces drug related morbidity and mortality. Pharmacovigilance data guides regulatory decisions such as label changes, risk management plans and drug withdrawal.

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