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Pharmacovigilance: An Overview of Drug Safety Monitoring (*Vinitha Babuselvan et al., Pharmacovigilance: An Overview of Drug Safety Monitoring*)

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Abstract: Pharmacovigilance and drug safety are both essential for protecting patient health and making sure that the advantages of prescription drugs exceed any possible drawbacks. Pharmacovigilance plays a crucial and necessary role in clinical research. The IPC-PvPI is officially recognized as a WHO Collaborating Centre for Pharmacovigilance within Public Health Programmes and Regulatory Services. While this is a significant achievement, the PvPI still faces several challenges. These include monitoring generic drugs, biosimilars, and adverse drug reactions specific to certain diseases, such as those caused by antidiabetic, cardiovascular, and antipsychotic medications. Additionally, raising awareness about drug safety is a continuing and essential task. A drug safety issue is rarely considered fully resolved, and safety assessments remain throughout the entire lifecycle of a drug. When adverse events or harmful effects occur, particularly when they are not preceded by or followed by, it is important to report them, investigate them, and effectively convey their importance to the individuals involved in an evident and knowledgeable manner. Drug safety efforts involve thorough pre-market testing, ongoing monitoring after a drug is approved, preventing mistakes during prescription and administration, and making sure that high-quality medicines are available at healthcare facilities. Early detection and timely treatment of side effects and unusual reactions to medications are highly important. Pharmacovigilance programs collect data on both preventable and inevitable drug-related adverse effects through rigorous monitoring.

Keywords: Pharmacovigilance, Investigational Medicinal Product, Adverse Drug Events, Adverse Drug Reaction Reporting Systems, Pharmacovigilance Programme of India.

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INTRODUCTION

The World Health Organization outlines pharmacovigilance as the science and activities involved in identifying, evaluating, understanding, and preventing harmful effects or issues that may arise from the use of medicines.

In 1938, the US President Franklin Delano Roosevelt issued the Federal Food, Drug, and Cosmetic Act(FDCA), which required pharmaceutical companies to ensure the safety of the drug before being placed on the market [1].

While pharmacovigilance focuses on tracking and regulating the safety of medications after patients have started taking them, drug safety encompasses a variety of actions to ensure the safety of pharmaceutical products throughout their lifecycle. Because it assists in identifying and addressing safety issues that might not have been apparent during the initial clinical trials, pharmacovigilance is an essential part of overall medication safety efforts. The objective of the WHO Programme for International Drug Monitoring, which is a universal effort, is to identify safety issues associated with medicines and vaccines [2]. With over 180 full members and associate members, the program serves around 99 percent of the global population. The program's participating nations and regions cooperate nationally as well as globally to monitor and detect side effects of drugs and vaccines, lower patient risks, and formulate global pharmacovigilance standards and protocols.

Pharmacovigilance addresses various problems such as misuse of medications, overdoses, taking multiple drugs at the same time, interactions between drugs, increased use of traditional and natural remedies along with prescribed medicines, illegal sale of drugs online, the growing trend of self-medication, use of low-quality

medicines, medication errors, and cases where drugs fail to work as intended [3].

As the WHO Collaborating Center for International Drug Monitoring, the Uppsala Monitoring Center assists program participants in creating and expanding national medication safety monitoring systems. Members have access to a variety of resources, including data management and analytical tools and services, along with UMC's research expertise. They use this data to suggest regulations and share information about potential risks with all relevant parties [4].

Aim of Pharmacovigilance

1. Enhance patient safety and care about medication use and other medical and paramedical treatments.
2. Strengthen public safety and health concerning medication use.
3. Participate in the evaluation of the risks, benefits, harms, and efficacy of medications, promoting their safe, sensible, and more efficient (including economical) use.
4. Promote professional education, training, and general awareness of PV and efficient interaction with it.
5. PV has evolved and will continue to evolve in response to the unique requirements and unique strengths of WHO Program participants and others. Such active influence must be supported and nurtured; it is a source of vitality and creativity that has made an excessive contribution to global standards and practice [1,5].

ADR

An Adverse Drug Reaction, also known as ADR, is an unexpected and harmful reaction that occurs when a medication is taken in the usual dose, either to treat, diagnose, or prevent a medical condition.

SAE

A Serious Adverse Event (SAE) is defined as any unfavorable medical occurrence that happens during a human drug trial, regardless of the dose administered.

1. Results in death
2. Is life-threatening
3. Requires inpatient hospitalization/prolongation of hospitalization
4. Results in persistent or significant disability
5. May have caused a congenital anomaly
6. Requires intervention to prevent permanent impairment/ damage [2,3].

SUSAR

A Suspected Unexpected Serious Adverse Reaction (SUSAR) is a serious adverse event in a clinical trial that is both unexpected and suspected to be caused by the investigational medicinal product (IMP) [1].

Global Pharmacovigilance System

- WHO Programme for International Drug Monitoring (PIDM) in 1968
  Initiated by the WHO with 10 founding member countries.
- Aimed at collaborative international data sharing on ADRs.
  Established standardized reporting formats and centralized databases.
- Recommended the development of National Pharmacovigilance Centers (NPCs) in several nations.

Uppsala Monitoring Centre (UMC), Sweden –1978

- The WHO recognized the Uppsala Monitoring Centre (UMC) in Sweden as an international center for PIDM organization in 1978.
- Oversees VigiBase, the biggest ADR database in the world; offers tools like VigiFlow for managing reports and VigiLyze for detecting signals.
- Provides training, risk communication, and signal assessment assistance to nations [5].

National Development: Pharmacovigilance Programme of India (PvPI)

Recognizing the importance of drug safety in a populous and diverse country like India, the Pharmacovigilance Programme of India (PvPI) was officially launched in July 2010 by the Ministry of Health and Family Welfare.

(a) Organizational Structure:

- Indian Pharmacopoeia Commission (IPC): Functions as the National Coordination Centre (NCC).
- Central Drugs Standard Control Organization (CDSCO): National regulatory authority under the Drugs and Cosmetics Act, 1940.
- ADR Monitoring Centres (AMCs): Over 250 AMCs across India receive and analyze ADR reports from healthcare professionals and patients.

(b) Functions and Contributions:

- Reporting of Individual Case Safety Reports (ICSRs) to VigiBase.
- Causality assessment using WHO-UMC criteria.
- Dissemination of drug safety alerts, newsletters, and advisories.
- Introduction of mobile applications (ADR PvPI App) to facilitate public participation.
- PV incorporation into nursing, pharmacy, and medical education [2,6].

Challenges in Pharmacovigilance Databases

Although databases have transformed the field of pharmacovigilance, there are still several issues that need to be addressed:

- Data Quality and Accuracy – When adverse drug reaction reports are incomplete or contain errors, it can result in incorrect safety evaluations.
- Duplication of Reports – It is difficult to detect repeated entries within large sets of data.
- Interoperability Issues – Because different databases use various formats for reporting, it is challenging to combine and analyze data effectively.
- Underreporting of ADRs – A significant number of healthcare professionals and patients fail to report adverse drug reactions, which restricts the ability to thoroughly examine and understand the data [7].

Vigi-Flow (India)

Vigi-Flow is a web-based platform specifically created for maintaining Individual Case Safety Reports (ICSRs) for national centers involved with the WHO Programme for IDM. Pharmaceutical businesses and clinical research organizations can also use it to track their data. The UMC's Vigi-Flow, made in Uppsala, Sweden, is a product of the UMC and is based on the ICH E2B standard. The WHO worldwide ICSR database measure (IC value) that is stratified in various ways is called VIGIBASE, and it helps filter purposes. The device, created in 1978, has been in use for 30 years and is currently under the UMC's custody for spontaneous reporting [5,8,9].

Yellow Card Scheme (United Kingdom)

Yellow card schemes (YCS) have been used for developing spontaneous reporting systems. The system is currently among the most significant PV resources in the world. Depending on the medications and the type of adverse drug reactions, a member of the scientific team ranks the yellow cards into seven priority categories. Together, the expert team, the Panel on Safety of Medicines, and the regulatory agency, the Medicines Control Agency, monitor the YCS. The YCS designed an innovative computer application in 1991 entitled Adverse Drug Reaction Online Information Tracking, or ADROIT. Compared to other databases, ADROIT is distinct. It archives the image of the yellow card in the optical system in addition to the contents of the report [5].

European and North American Developments

- European Medicines Agency (EMA) established EudraVigilance, an electronic system to manage ADRs in the EU.
- The FDA (USA) established MedWatch (1993), a voluntary ADR reporting platform.
- The establishment of Risk Management Plans (RMPs) in the EU and Risk Evaluation and Mitigation Strategies (REMS) in the United States facilitated proactive safety measures for medication guidelines [8,10,11].

ADR Reporting Process

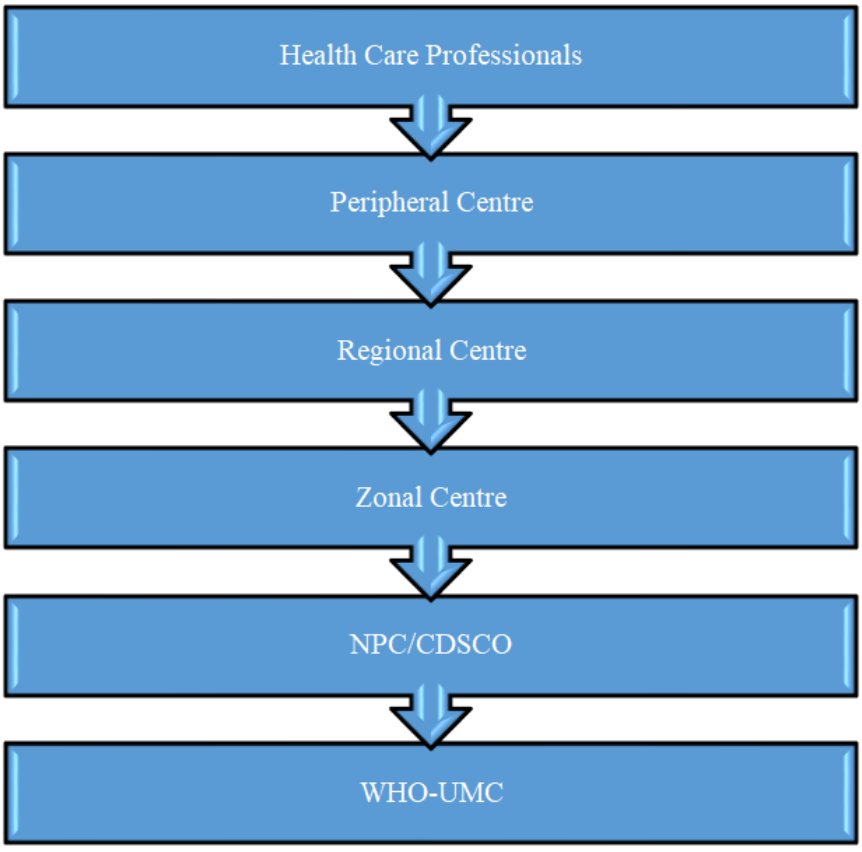

Figure 1: ADR Reporting Process

ADR Reporting Forms

- INDIA –Suspected Adverse Drug Reaction Reporting Form
- UK-Yellow Card
- AUSTRALIA- Blue Card
- US- Medwatch

ADR Reporting Apps

App Name	Region/Country	Key Features
Med Safety	Africa, Asia, Europe	Real-time reporting, multilingual support, adapted to national PV systems
Yellow Card	United Kingdom	Developed by MHRA; user-friendly interface, drug safety alerts
VigiBIP	France	High completeness scores; integrated with the national pharmacovigilance database
MedWatcher	United States	High-quality reports; supports free-text and structured data entry
ADR PvPI App	India	Developed by IPC; connects users to regional monitoring centers instantly

Table 1: ADR Reporting Apps

Future outlook

Regarding the issues and challenges encountered in developing a strong photovoltaic system in India, the following suggestions could be considered:

- Build & maintain a vigorous PV system.
- Introducing PV examinations and making PV reporting mandatory.
- High-position conversations with colorful stakeholders.
- Developing a single, national ADRs reporting form that everyone can utilize.
- Recruit qualified medical and scientific assessors for PV to boost the Medicine Controller General of India (DCGI) office.
- Creating a clinical trial and post-marketing database for SAEs, SUSARs, and ADRs for signal discovery and access to all applicable data from colorful stakeholders.
- Education and training of medical scholars, druggists, and nurses in the area of PV.
- List all new medicine suggestions by maintaining a standard database forevery pharmaceutical company.
- Uniting with PV associations to improve medicine safety throughadvancements in information technology has created new opportunities for public and transnational collaborations that can enhance postmarketing surveillance programs and increase medicine safety.
- Creating a network of PV and pharmacopeidemiologists in India [12-14].

CONCLUSION

In India, the Pharmacovigilance (PV) system has raised awareness among people about reporting adverse drug reactions (ADRs). The problem of underreporting is being addressed because of the various reporting options available, such as toll-free numbers, messages, emails, and ADR forms in local languages. Many multinational companies have begun outsourcing PV activities to India, which is helping to develop a strong PV culture. Several universities have included PV courses in their curriculum as either compulsory or elective subjects. However, the government still needs to focus on increasing awareness and improving the system. Through pharmacovigilance, we can report adverse drug events related to the effectiveness of a drug product. A drug safety associate can then investigate the case and report it to the drug regulatory authorities. Many pharmaceutical companies around the world maintain pharmacovigilance reports. India is now recognized as a hub for clinical research. Healthcare professionals, consumer groups, and hospitals should recognize that there is now a system in place to collect and analyze adverse event data. They should actively report adverse events and participate in the National Pharmacovigilance Program to help ensure that people in India receive safe drugs.

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ACRONYM:

- ADR-Adverse Drug Reaction
- ADROIT-Adverse Drug Reactions Online Information Tracking System
- AMC-ADR Monitoring Centre
- CDSCO-Central Drugs Standard Control Organization
- DCGI-Drug Controller General of India
- EMA-European Medicines Agency
- EU-European Union
- FDA-Food and Drug Administration
- FDCA-Federal Food, Drug, and Cosmetic Act
- ICSR-Individual Case Safety Report
- IMP- Investigational Medicinal Product
- IPC-Indian Pharmacopoeia Commission
- MHRA-Medicines and Healthcare products Regulatory Agency
- NCC-National Coordination Centre
- NPC-National Pharmacovigilance Centre
- PIDM-Programme for International Drug Monitoring
- PV-Pharmacovigilance
- PVPI-Pharmacovigilance Programme of India
- REMS-Risk Evaluation and Mitigation Strategy
- RMP-Risk Management Plan
- SAE-Serious Adverse Event
- SUSAR-Suspected Unexpected Serious Adverse Reaction
- UK-United Kingdom
- UMC-Uppsala Monitoring Centre
- US- United States
- WHOPIDM-World Health Organization Programme for International Drug Monitoring
- YCS-Yellow Card Scheme

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