Review Article

Incidence of Adverse Drug Reactions in Hospitalized Patients – A Comprehensive Review

B.Akshitha[1], G.Vaishnavi[1], B. Harshitha[1], K. Jyothsna[1], V.Mahender*[2], K.Purnachander[3]
1. Department of Pharmacy Practice, Jyothishmati Institute of Pharmaceutical Sciences, Karimnagar, Telangana, India.
2. Professor, Jyothishmati Institute of Pharmaceutical Sciences, Karimnagar, Telangana, India.
3. Professor & HOD of Pharmacy Practice, Jyothishmati Institute of Pharmaceutical Sciences, Karimnagar, Telangana, India.
***Corresponding author's E-mail:** mahi.kirru@gmail.com

Received: 15-08-2025; **Revised:** 22-11-2025; **Accepted:** 30-11-2025; **Published online:** 20-12-2025.

ABSTRACT

Pharmacovigilance, the science and activities related to detection, assessment, understanding and prevention of adverse effects or any other drug- related problems, is intrinsically linked to effective information management. Pharmacovigilance supports safe and appropriate use of drugs spontaneous reporting of adverse drug reactions is an essential component of pharmacovigilance. However, there is significant underreporting of adverse drug reactions. Adverse drug reactions have become a major problem in developing countries. Knowledge of pharmacovigilance could form the basis for interventions aimed at improving reporting rates and decreasing adverse drug reactions.

Keywords: Adverse reaction, drug, Pharmacovigilance, side effects.

INTRODUCTION

Pharmacovigilance (PV) is the science and activity of monitoring medicine safety, focusing on detecting, assessing, understanding, and preventing adverse drug reactions (ADRs) and any other drug-related problems after a medicine is on the market, ensuring drugs remain safe and effective for widespread public use, involving patients, healthcare providers, manufacturers, and regulators.

Objectives of the Pharmacovigilance are as follows:

1. Safety Monitoring:

Continuous safety monitoring involves the ongoing assessment of drugs after they have been approved for public use. This objective ensures that any adverse effects not observed during clinical trials can be identified and addressed promptly. Through systematic data collection from various sources, pharmacovigilance helps maintain an up-to-date understanding of a drug's safety profile.[1,2]

2. Adverse Event Detection:

The detection of adverse drug reactions (ADRs) is a fundamental goal of pharmacovigilance. ADRs can occur in any population, often revealing risks that may not have been apparent in pre-market clinical trials. By analyzing reports from healthcare providers, patients, and other stakeholders, pharmacovigilance systems can uncover patterns and trends in ADR occurrences, facilitating timely interventions.[1]

3. Risk Assessment:

Risk assessment involves evaluating the potential risks associated with a drug's use, including the severity and frequency of ADRs. This objective helps determine the overall benefit-risk balance, which is critical for informed decision-making by healthcare providers. Risk assessments may lead to changes in drug labeling, prescribing guidelines, or even drug withdrawal if risks are deemed unacceptable.[1]

4. Signal Detection:

Signal detection refers to identifying indications that a drug may be causing an unexpected safety issue. This process relies on statistical methods and data mining techniques to analyze large datasets for unusual Compliance By recognizing safety signals early, pharmacovigilance can prompt further investigation and lead to timely regulatory actions or safety communications.[1]

5. Regulatory Compliance:

Ensuring regulatory compliance means adhering to established national and international guidelines regarding drug safety monitoring. Regulatory bodies like the WHO, FDA, and EMA set forth requirements for report safety and managing adverse events. Compliance is essential for maintaining public trust and ensuring that safety information is shared appropriately among stakeholders.[1]

6. Public Health Protection:

The overarching goal of pharmacovigilance is to protect public health. By identifying and mitigating risks associated with drug use, pharmacovigilance contributes to patient safety and quality of care. This objective involves disseminating important safety information to healthcare providers and patients to help them make informed decisions about medication use.[1]

7. Communication and Education:

Effective communication of drug safety information is vital for pharmacovigilance. This includes potential healthcare professionals about recognizing and reporting ADRs, as well as informing patients about potential risks associated with

their medications. Clear and timely communication can enhance awareness and facilitate better safety practices in clinical settings.[1]

8. Promotion of Safe Use:

Promoting the safe and effective use of medications is a key objective that involves developing guidelines and recommendations based on safety data. This includes risk management strategies, such as Risk Evaluation and Mitigation Strategies (REMS), to ensure that drugs are used appropriately and that patients are monitored for adverse effects.[3]

9. Research and Development:

Pharmacovigilance plays an essential role in informing drug development processes. Safety data gathered post marketing can influence clinical trial design, including the identification of specific populations at risk and the evaluation of long-term effects. Incorporating real-world evidence into the drug development pipeline can lead to safer therapeutic options.[3]

10. Stakeholder Collaboration:

Fostering collaboration among various stakeholders—regulatory agencies, healthcare providers, pharmaceutical companies, and patients—is crucial for effective pharmacovigilance. By sharing data and insights, these groups can work together to enhance safety monitoring efforts, address emerging safety concerns, and improve patient outcomes. This collaborative approach can lead to a more comprehensive understanding of drug safety across different contexts.[4]

The World Health Organization (WHO) defines an adverse drug reaction as reaction to a drug which is harmful and unintentional and which occurs at doses usually used in man for prophylaxis, identification or treatment of the disease or for the alteration of physiological function. It is well known that ADR is one of the major causes of the hospitalization, and each drug has probable adverse effects as well as interaction with other substances. The risk of ADR is governed by several factors such as dose and frequency of administration, genetic and pharmacokinetic changes of special population as children and elderly patients and those with lover and kidney diseases. Monitoring and understanding ADRs are crucial in healthcare, as they can impact patient safety and treatment outcomes. Pharmacovigilance, the process of monitoring and evaluating drug safety, plays a major role in detecting and managing adverse drug reactions. Through Pharmacovigilance, healthcare professionals and regulatory authorities can collect and analyze the data on ADRs to assess drug safety profiles, update drug label profiles, and make informed decisions about the continued use of medications. The reporting of adverse drug reactions Is essential to identify potential safety issues with medications, ensure patient well-being and improve overall drug safety. Both healthcare professionals and patients are encouraged to report suspected ADRs to relevant authorities or healthcare institutions to enhance patient care and contribute to safer medication practices.[2]

PHARMACOVIGILANCE:

Pharmacovigilance, the science and activities related to the detection, assessment, understanding and prevention of ADRs, plays crucial role in monitoring the safety of medication after they are approved for public use.[4]

To improve drug safety and patient care, healthcare professionals and patients are encouraged to report suspected ADRs to the appropriate regulatory authority or healthcare institutions.[5]

Timely and accurate reporting of ADRs contributes to the ongoing evaluation of drug safety profiles and may lead to necessary changes in drug labeling usage guidelines or even withdrawal of medications from the market if deemed necessary for patient safety.[6]

HISTORICAL BACKGROUND:

Pharmacovigilance has a rich history that spans several decades.

Here is an overview of key mileposts in history of Pharmacovigilance.[2]

THALIDOMIDE TRAGEDY (Late 1950s – Early 1960s):

The Thalidomide tragedy stands as a pivotal event in history of Pharmacovigilance.

Thalidomide was a drug prescribed to pregnant women for monitoring sickness and sleeplessness (sedative and antiemetic). However, it was later discovered that Thalidomide caused severe birth defects, leading to limb deformities in thousands of newborns.

Figure 1: Malformations due to thalidomide

- This Catastrophe underscored the necessity for systemic monitoring of drug safety.
- The aftermath led to increased awareness of potential harm drugs could cause, especially during pregnancy.[2]

KEFAUVER-HARRIS AMENDMENT (1962):

In response to Thalidomide disaster the United States passed the Kefauver–Harris amendment, which strengthened drug regulation and required pharmaceutical companies to demonstrate the efficacy and safety of their products before approval. It also established the requirement for Post – marketing surveillance to monitor adverse drug reactions after drug were on the market.[2]

Formation of WHO Program (1968):

In response to the thalidomide incident, WHO established the international Drug Monitoring Program in 1968. This program laid the foundation for a global network of pharmacovigilance centers, fostering collaboration in collecting and analyzing data on adverse drug reactions[2]

FDA and AERS (1970s):

The FDA initiated the Adverse Event reporting system (AERS) in 1970s. AERS become a pivotal tool for collecting, managing, and analyzing data on adverse events associated with drugs, enabling the FDA to monitor and regulate drug safety in united states. [2]

ICH guidelines (1990s):

The international conference on harmonization (ICH) played a crucial role in standardizing pharmacovigilance practices globally. ICH guidelines, such as E2B, provided a harmonized framework for the collection and exchange of safety data, fostering international cooperation among regulatory authorities.[2]

U PHARMACOVIGILANCE SYSTEM (2005):

The European Union introduced a comprehensive pharmacovigilance system, strengthening the monitoring and supervision of medicinal products. The European medicinal agency (EMA) played a central role in coordinating safety assessments and risk management strategies.[2]

PERIODIC SAFETY UPDATE REPORTS (PSURs):

PSURs become a standard requirement for marketing authorization holders. These reports involve the regular submission of safety data to regulatory authorities, ensuring continuous evaluation of a drug's safety profile throughout its lifecycle.[2]

DIGITALERA ANDSIGNAL DETECTION(21st century):

Technological advancement in the 21st century facilitated the integration of big data and digital platforms in pharmacovigilance. Automated signal detection system, utilizing algorithms and data mining techniques, enhanced the efficiency of identifying potential safety concerns from large datasets.[2]

CLASSIFICATION

Type A (Augmented):

- Usually exacerbation of the pharmacological effects of a drug
- Dose dependent
- Predictable due to known of pharmacology of a drug
- Preventable
- Incidence of type A is high however, less serve so associated with less morbidity and mortality
- E.g.: Insulin included hypoglycemia, hypotension caused by anti-hypertensives, dehydration caused by diuretics.[5]

Type B (Bizarre):

- Usually hypersensitivity reactions
- Nor dose dependent
- Often not predictable and not preventable (unless present with a known past history)
- Incidence of type A is low however, more severe so associated with high morbidity and high mortality.

E.g.: Penicillin's induced hypersensitivity reactions (pirohamed 2003; Edwards 2000)

Two further types of reactions were eventually added: chronic reactions, which relates to both dose and time (type C), and delayed reactions (type D).[5]

Type C (Chronic/Continuous):

- Occurs after prolonged exposure to a drug
- Higher frequency among exposed patients than unexposed
- Exact mechanism is unknown

E.g.: Higher frequency of cardiovascular events among patients exposed to the COX-2 inhibitor rofecoxib, osteoporosis caused by corticosteroids.[5]

Type D (Delayed):

- Delayed until long after drug exposure, making diagnosis difficult

E.g.: Malignancies that occurs after immunosuppressive treatment pos transplantation, vaginal cancer occurring many years after exposure to diethylstilbestrol…….

Withdrawal later becomes the fifth category (type E), and most recently, unexpected failure of therapy became the sixth (type F).[5]

Type E (End of treatment):

- Occurring after abrupt drug withdrawal

E.g.: Alcohol withdrawal – anxiety, panic delusions, visual and auditory hallucinations.[5]

Type F (Failure of treatment):

Common to all

Often caused by drug interactions

E.g.: Inadequate dosage of an oral contraceptive when used with an enzyme inducer.[5]

Resistance to antimicrobial agents

CLASSIFICATION OF ADR'S DEPENDING UPON SEVERITY:

Minor ADRs: No therapy, antidote or prolongation of hospitalization is required.

Moderate ADRs: Requires change in drug therapy, specific treatment or prolongs hospital stay by a least 1 day.

Serve ADRs: Potentially life threatening causes permanent damage or requires intensive medical treatment.

Lethal: Directly or indirectly contributes to dearth of patient.

Causality Assessment:

The causality relationship between suspected drug and reaction was established by using WHO and Naranjo's causality assessment scales.[9]

WHO Assessment Scale:

Certain, probable, possible, unassessable/unclassifiable, unlikely, conditional/unclassified.

Causality term Assessment criteria*

Certain

• Event or laboratory test abnormality, with plausible time relationship to drug intake

• Cannot be explained by disease or other drugs

• Response to withdrawal plausible (pharmacologically, pathologically)

• Event definitive pharmacologically or phenomenologically

(i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon)

• Rechallenge satisfactory, if necessary

Probable / Likely

• Event or laboratory test abnormality, with reasonable time relationship to drug intake

• Unlikely to be attributed to disease or other drugs

• Response to withdrawal clinically reasonable

• Rechallenge not required

Possible

• Event or laboratory test abnormality, with reasonable time relationship to drug intake

• Could also be explained by disease or other drugs

• Information on drug withdrawal may be lacking or unclear

Unlikely

• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible)

• Disease or other drugs provide plausible explanations

Conditional / Unclassified

• Event or laboratory test abnormality

• More data for proper assessment needed, or

• Additional data under examination

Unassessable / Unclassifiable

• Report suggesting an adverse reaction

• Cannot be judged because information is insufficient or contradictory

• Data cannot be supplemented or verified[9]

Naranjo's Assessment Scale:

Question	Yes	No	Do Not Know	Score
1. Are there previous conclusive reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	
3. Did the adverse event improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	
4. Did the adverse event reappear when the drug was readministered?	+2	-1	0	
5. Are there alternative causes that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in blood or other fluids in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	
	Total Score:			

Figure 2: Naranjo's Assessment Scale

Assessment of Severity:

The severity of reported reactions was assessed by using Hartwig scaleand was categorized into mild, moderate and severe.

Assessment of Predictability:

The predictability of the reported ADRs was assessed by using developed criterion for determining predictability of an ADR and was categorized as predictable or not predictable based on the incidence rate of reported adverse drug reaction.

Assessment of Preventability:

The preventability of reported ADRs was assessed by using Modified Schumock and Thornton scale and was categorized as definitely preventable, probably preventable and not preventable. When an event was reported, all patients who experienced an ADR were followed from the day of reporting of an ADR until the discharge of patients to gather updated information regarding the changes and the progress in the

patients' condition and management. Also, at the time of discharge "alert card" was provided to those patients who met the criteria for the issue of alert card.[1]

ROLE OF HEALTH PROFESSIONALS IN DETECTING ADRs:

Possibility of an ADR should always be considered during differential diagnosis. ADR may be detected during ward round with the medical terms. Patient counselling, medication history interview and communicating with other healthcare professional may provide additional clues.

Patients who are at higher risk should be monitored closely

1. Patients with renal or hepatic impairment.
2. Patient who had a history of allergic reactions.
3. Patients taking multiple drugs.
4. Pregnant and breastfeeding women.

The current study aims to examine HCPs' practices and barriers in severe ADR monitoring and reporting, as well as to assess their attitudes towards the monitoring and related factors.[24]

REPORTING OF AN ADR:-

A) Who can Report?

All health care professionals (clinicians, dentists, pharmacists, nurses, etc) and

Non-healthcare professionals including consumers can report suspected adverse drug reaction.[1]

B) When to report?

Any spontaneous events needed to be reported within 10 days.

Any adverse drug event which is suspected needs to be reported as soon as possible.

Unfortunate death due to adverse reaction should be reported immediately.

Other adverse drug reactions should be reported within one week.

Any adverse drug reactions which are non-serious should be reported within 30 days.

Reporting delay leads to create more problems.

So, as far as possible immediate reporting considered as ideal decision.[1]

C) Where to Report?

Duly filled suspected Adverse Drug Reaction Form can be sent to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).

Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.[25]

Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com

A list of nationwide AMCs is available at:

http://www.ipc.gov.in,
http://www.ipc.gov.in/PvPL/pv_home.html

D) What to Report?

Report serious adverse drug reactions. A reaction is serious when the patient outcome is:

Life-threatening

Hospitalization (minor or prolonged)

Disability (significant, persistent or permanent)

Congenital anomaly

Required intervention to prevent impairment or damage

Report non-serious known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.[10]

E) How to report?

There is a form called "Suspected Adverse Drug Reaction Reporting Form" available for healthcare professionals. (Given in "adverse drug reaction monitoring in India) The for which is available for consumers is "Medicines Side Effect Reporting Form" (given in "adverse drug reaction monitoring in India.

F) Mandatory field for suspected ADR reporting form.

Patient initials,

Age at onset of reaction,

Reaction term(s),

Date of onset of reaction,

Suspected medication(s)

Reporter information.

G) What happens to the submitted information?

Information provided in this form is handled in strict confidence.

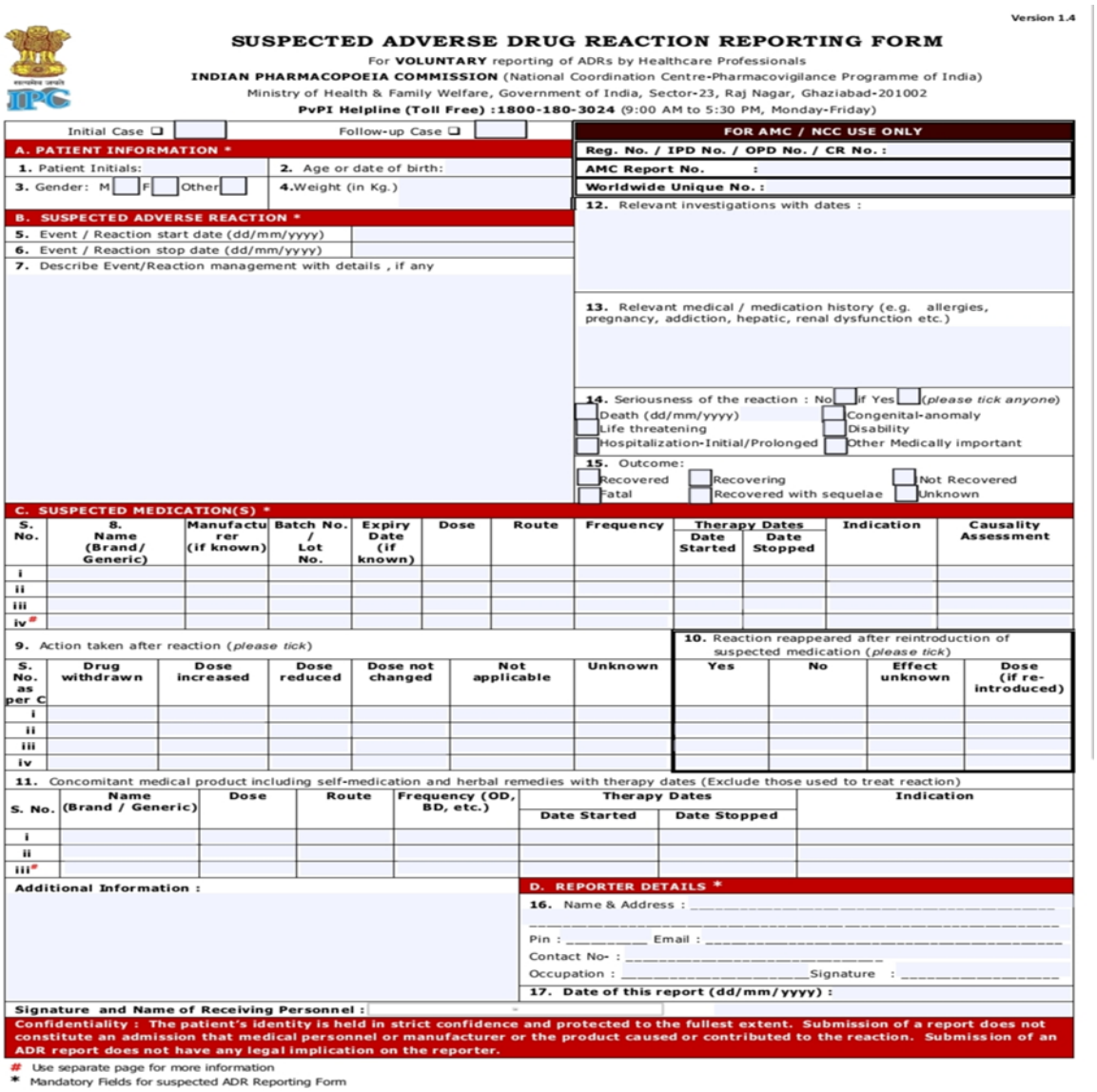
The causality assessment is carried out at AMCs by using WHO-UMC scale.

The analyzed forms are forwarded to the NCC through ADR database.

Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.

The reports are periodically reviewed by the NCC-PvPI.

The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines. [2]



Version 1.4

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For **VOLUNTARY** reporting of ADRs by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India)

Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002

PvPI Helpline (Toll Free) :1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ❑ Follow-up Case ❑

FOR AMC / NCC USE ONLY

Reg. No. / IPD No. / OPD No. / CR No. :

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION *

1. Patient Initials: 2. Age or date of birth:

3. Gender: M ❑ F ❑ Other ❑ 4.Weight (in Kg.)

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy)

6. Event / Reaction stop date (dd/mm/yyyy)

7. Describe Event/Reaction management with details , if any

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ❑ If Yes ❑ *(please tick anyone)*

❑ Death (dd/mm/yyyy) ❑ Congenital-anomaly

❑ Life threatening ❑ Disability

❑ Hospitalization-Initial/Prolonged ❑ Other Medically important

15. Outcome:

❑ Recovered ❑ Recovering ❑ Not Recovered

❑ Fatal ❑ Recovered with sequelae ❑ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	B. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication	Causality Assessment
i											
ii											
iii											
iv #											

9. Action taken after reaction *(please tick)*

10. Reaction reappeared after reintroduction of suspected medication *(please tick)*

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Yes	10. No	10. Effect unknown	10. Dose (if re-introduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication
i							
ii							
iii #							

Additional Information :

D. REPORTER DETAILS *

16. Name & Address : _____

_____

Pin : _____ Email : _____

Contact No- : _____

Occupation : _____ Signature : _____

17. Date of this report (dd/mm/yyyy) :

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

Use separate page for more information

* Mandatory Fields for suspected ADR Reporting Form

Figure 3: Suspected ADR reporting form

Functions of the Pharmacovigilance Programme of India (PvPI)

1. Adverse Drug Reaction (ADR) Monitoring:

The PvPI focuses on the systematic collection and analysis of ADR reports submitted by healthcare professionals and patients. This monitoring is crucial for identifying unexpected or severe side effects associated with medications that may not have been evident during clinical trials. By creating a robust database of ADRs, the program can evaluate patterns and trends, leading to informed decisions about drug safety.[1]

2. Signal Detection:

Signal detection involves the identification of potential safety issues from the accumulated ADR data. This process uses statistical techniques and algorithms to analyze large datasets for unusual patterns or signals that may indicate a new or previously unrecognized risk. Once a signal is detected, it undergoes further evaluation to determine its clinical significance and whether regulatory action is warranted. [1]

3. Data Management:

The PvPI maintains a centralized database to manage ADR reports effectively. This database allows for systematic tracking, storage, and analysis of adverse events. Efficient data management is essential for timely access to safety information, which facilitates prompt decision-making regarding drug safety and risk communication.[2]

4. Training and Education:

The program conducts regular training sessions and workshops aimed at healthcare professionals, educating them about the importance of pharmacovigilance and ADR reporting. These educational initiatives help increase awareness of the program, improve reporting rates, and enhance the quality of data collected.[2]

5. Public Awareness Campaigns:

To promote drug safety, the PvPI engages in public awareness campaigns aimed at both healthcare providers and patients. These campaigns highlight the importance of reporting ADRs and provide information on how todo so. By

empowering patients to report their experiences, the program aims to capture a more comprehensive dataset on drug safety.[2]

6. Collaboration with Stakeholders:

The PvPI actively collaborates with various stakeholders, including regulatory agencies, healthcare institutions, pharmaceutical companies, and research organizations. This collaboration ensures comprehensive approach to pharmacovigilance, facilitating the exchange of information and best practices that enhance drug safety monitoring.[3]

7. Development of Guidelines:

The program formulates and updates guidelines for ADR reporting and management, aligning them with national and international standards. These guidelines provide clear protocols for healthcare professionals on how to report ADRs, thereby standardizing practices across different regions and institutions.[3]

8. Research and Analysis:

The PvPI conducts research on drug safety, including epidemiological studies and data analysis. This research helps understand the incidence and impact of ADRs, contributing to the overall body of knowledge in pharmacovigilance. Insights gained from research can inform policy decisions, improve clinical practices, and enhance patient safety.[3]

9. Periodic Safety Reports:

The program prepares and disseminates periodic safety updates and reports, summarizing findings from the collected ADR data. These reports inform stakeholders about the current safety profiles of medications, emerging safety concerns, and recommended actions, ensuring transparency and enhancing public trust in the healthcare system.[4]

10. Regulatory Compliance:

The PoPl ensures adherence to national and international regulations related to drug safety monitoring and reporting. This compliance is essential for maintaining the integrity of the pharmacovigilance system and ensuring that safety data is accurately reported and acted upon in accordance with regulatory standards.[4]

11. Integration with Global Networks:

By collaborating with international pharmacovigilance organizations, the PvPI can share data and learn from global practices. This integration allows India to align its pharmacovigilance efforts with international standards, facilitating the exchange of information about safety signals and enhancing global drug safety.[5]

12. Risk Management:

The program develops and implements risk management strategies to address identified safety issues associated with medications. This may involve recommending changes to drug labeling, issuing safety alerts, or advising on the appropriate use of medications. Effective risk management is critical for minimizing harm to patients and ensuring the safe use of pharmaceuticals.

Through these detailed functions, the Pharmacovigilance Program of India aims to enhance drug safety, promote effective healthcare practices, and protect public health by ensuring ongoing monitoring.[5]

Source of Support: The author(s) received no financial support for the research, authorship, and/or publication of this article

Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

REFERENCES

1. Tripathi DK, Shiv S. *Pharmacovigilance*. Nirali Prakashan; 2017. p. 262.
2. R Dr. *History and development of pharmacovigilance*. p. 110.
3. Nimesh S. Pharmacovigilance program of review article. *Acta Scientific Pharmaceutical Sciences*. 2022.
4. Sahu RK, Yadav R. Adverse drug reaction monitoring: Prospects and impending challenges for pharmacovigilance. *Int J Pharm Sci*. 2014;06:15-23.
5. Sutar MR, Gawne DR. Review article of study of drug regulatory approval process and comparative requirement of common technical document in Europe, USA, and India in coordination with drug development process. *Int J Pharm Sci*. 2013;20:26879.
6. Sachdev Y. Pharmacovigilance safety matter. *Indian Pharmacology*. 2008.
7. Mohiuddin AK. Department of Pharmacy, World University of Bangladesh, Green Road, Dhaka, Bangladesh. 2020.
8. Caffrey S, Paul C. Generic drugs: The Indian scenario. *Postgrad Med*. 2019;65:2679.
9. Lakshmi I, Aashritha M, Teja A. A review on pharmacovigilance and its importance. *World J Pharm Pharm Sci*. 2017;6(1):30010.
10. Mackay FJ. Post-marketing studies: The work of the drug safety research unit. *Drug Saf*. 1998;19:343.
11. Hall M, McCormack P, Arthurs N, Feely J. The spontaneous reporting of ADRs by nurses. *Br J Clin Pharmacol*. 1995;40:173-5.
12. Folb PI, ten Ham M. Drug monitoring in developing countries: A drug regulator's perspective. *Drug Inf J*. 1995;29:303-5.
13. Talbot JC, Nilsson BS. Pharmacovigilance in the pharmaceutical industry. *Br J Clin Pharmacol*. 1998;45:427-31.
14. Moore N. The role of the clinical pharmacologist in the management of ADRs. *Drug Saf*. 2001;24:1-7.
15. Hornbuckle K, Wu HH, Fung MC. Evaluation of spontaneous adverse event reports by primary reporter: A 15-year review (1983–1997). *Drug Inf J*. 1999;33:1117-24.
16. Goms CH. Benefit-risk balance for marketed drugs: Evaluating safety signals. *CIOMS Working Group IV Report*.

Geneva: CIOMS; 1998. Available from: http://www.cioms.ch/publications/g4-benefit-risk.pdf. Cited 2010 Jan 15.

17. Lazarou J, Pomeranz BH, Corey PN. Incidence of ADRs in hospitalized patients: A meta-analysis of prospective studies. *J Am Med Assoc*. 1998;279:1200-5.
18. White TJ, Arakelian A, Rho JP. Counting the costs of drug-related adverse events. *Pharmacoeconomics*. 1999;15:445-58.
19. Avorn J, Solomon DH. Cultural and economic factors that (mis)shape antibiotic use: The non-pharmacologic basis of therapeutics. *Ann Intern Med*. 2000;133:128-35.
20. Ball LK, Evans G, Bostrom A. Risky business: Challenges in vaccine risk communication. *Pediatrics*. 1998;101:453-8.
21. Bapna JS, Tripathi CD, Tekur U. Drug utilization patterns in the third world. *Pharmacoeconomics*. 1996;9:286-94.
22. Kane A, Lloyd J, Zaffran M, Simonsen L, Kane M. Transmission of hepatitis B, hepatitis C, and human immunodeficiency virus through safe injections in the developing world: Mode-based regional estimates. *Bull World Health Organ*. 1999;78:801-7.
23. Sleath B, Svarstad B, Roter D. Physician motivation for non-scientific drug prescribing. *Soc Sci Med*. 1997;44:541-8.
24. Vaccine Safety Advisory Committee. Vaccine safety. *WklyEpidemiol Rec*. 1999;74:337-40.
25. Effective communications in pharmacovigilance. *The Erice Report*. International Conference on Developing Effective Communications in Pharmacovigilance, Erice, Sicily. 1997. Available from: http://www.who-umc.org/DynPage.aspx?id=22690. Cited 2010 Jan 20.