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# PHARMACOVIGILANCE, ADR REPORTING AND IT'S AWARENESS

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## 1. ABSTRACT

Pharmacovigilance (PV) plays a vital role in ensuring the safe and rational use of medicines after they reach the market. Adverse drug reactions (ADRs) remain a major cause of morbidity, mortality and healthcare burden worldwide. Despite well-established regulatory frameworks, under-reporting of ADRs continues to be a global challenge. The lack of awareness, insufficient training, inadequate reporting infrastructure and low perception of reporting importance are among the major barriers faced by healthcare professionals and patients. This review discusses the burden of ADR-related morbidity and mortality, the methods used to quantify ADRs, available ADR reporting systems, and the challenges associated with them. The review also highlights the applications of pharmacovigilance in improving patient safety and provides recommendations to promote ADR reporting culture and awareness. Adverse drug reactions (ADRs) are a major global public health challenge, contributing significantly to morbidity, mortality, and economic burden across healthcare systems worldwide. Pharmacovigilance, defined as the science and activities relating to the detection, assessment, understanding, and prevention of ADRs, plays a crucial role in ensuring medication safety and protecting patient health. Studies estimate that ADRs account for 5–10% of hospital admissions, prolong hospital stay by 2–9 days, and represent one of the leading causes of death in many countries. Despite the establishment of

structured reporting systems such as the WHO Programme for International Drug Monitoring and national bodies like India's Pharmacovigilance Programme (PvPI), underreporting remains a universal issue, with only 5–10% of actual ADRs reported globally Multiple factors—including lack of awareness, insufficient training, fear of legal implications, lack of time, and uncertainty about causality—continue to hinder the effectiveness of pharmacovigilance activities.

**KEYWORDS:** Pharmacovigilance, Adverse Drug Reactions, ADR Reporting, PvPI, Awareness, Patient Safety, Drug Safety, Spontaneous Reporting.

## 2. INTRODUCTION

Pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems". It became globally important after the thalidomide disaster of 1961, which led to congenital deformities in thousands of infants. ADRs are unwanted, harmful reactions to medicines occurring at normal therapeutic doses. WHO estimates that ADRs are among the top 10 leading causes of morbidity and mortality in several countries.

Although clinical trials evaluate drug safety, they involve limited subjects, controlled conditions, and shorter follow-ups. Therefore, rare, delayed or population-specific ADRs are often detected only during post- marketing use. Spontaneous reporting systems (SRS), such as the WHO-UMC global database (VigiBase), the US FDA MedWatch, and the Pharmacovigilance Programme of India (PvPI), rely on voluntary reporting of suspected ADRs by healthcare professionals and patients.

Despite their importance, under-reporting is a major global concern, with only 5–10% of all ADRs actually reported. This review highlights why ADR reporting is vital, the extent of ADR-related burden, methods to quantify ADRs, challenges in reporting, and strategies for improvement.

Pharmacovigilance is a critical component of healthcare systems worldwide, aimed at ensuring the safety, efficacy, and rational use of medicines throughout their lifecycle. The World Health Organization (WHO) defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems". The discipline emerged strongly in response to

historical tragedies such as the thalidomide disaster of the 1960s, which highlighted the necessity for continuous post-marketing surveillance of medicines. Since then, pharmacovigilance has evolved into an essential public health tool that monitors the safety profile of drugs in real-world clinical practice, beyond the controlled environment of clinical trials.

Adverse drug reactions (ADRs) represent a major cause of morbidity and mortality across the globe. Studies have shown that ADRs account for nearly 5–10% of hospital admissions and are among the top ten leading causes of mortality in several developed countries. Moreover, the incidence of ADRs is significantly underestimated due to widespread.

Despite the presence of well-established global initiatives—such as the WHO Programme for International Drug Monitoring and the Uppsala Monitoring Centre (UMC)—underreporting remains one of the most persistent challenges, with only 5–10% of ADRs being reported worldwide. In India, the Pharmacovigilance.

Programme of India (PvPI), launched in 2010, has significantly advanced ADR monitoring by creating a network of Adverse Drug Reaction Monitoring Centres (AMCs) and promoting spontaneous reporting among healthcare professionals.

**Figure 1: Introduction of Pharmacovigilance.**

## 3. MORBIDITY AND MORTALITY OF ADRs

ADRs significantly contribute to disease burden across the globe.

### 3.1 Hospital Admissions and Morbidity

Studies show that ADRs account for 3–7% of hospital admissions in developed countries and up to 10% in India. Hospitalized patients face an additional 10–20% risk of developing new ADRs during treatment.

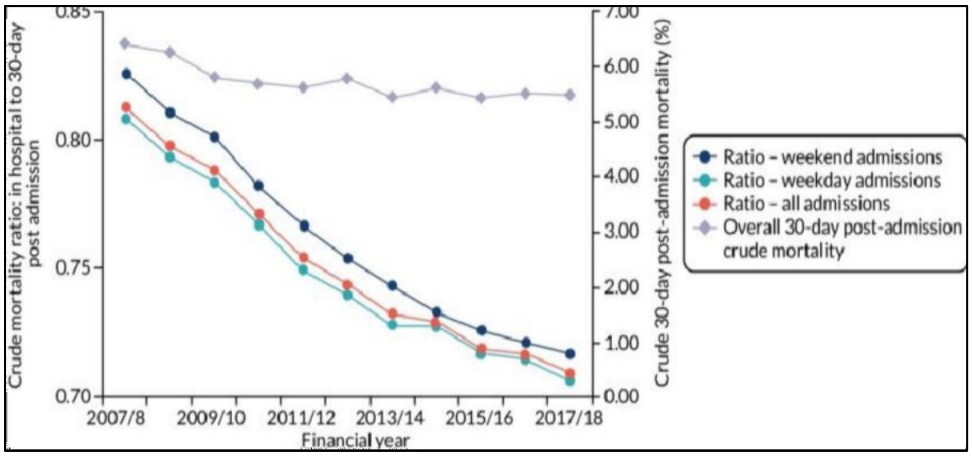



**Figure 2: Ratio in hospital of 30 day post admission mortality.**

### 3.2 Mortality due to ADRs

ADRs are responsible for 0.3–1% of hospital deaths globally. Meta-analyses estimate more than 100,000 deaths per year in the United States alone attributable to ADRs.

### 3.3 Economic Burden

ADR-related hospitalizations and prolonged stays significantly increase healthcare costs. In India, the average cost of an ADR-related hospitalization exceeds ₹6500 per patient, excluding indirect costs.

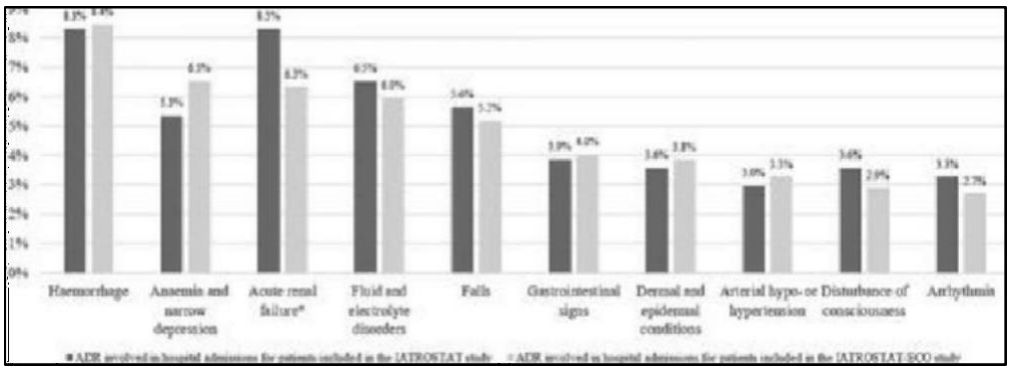


**Figure 3: Economic burden of ADR in hospitalization.**

Adverse drug reactions (ADRs) significantly increase healthcare expenditures worldwide due to additional diagnostic procedures, extended duration of hospital stay, and increased therapeutic interventions. ADRs not only burden healthcare systems financially but also reduce hospital efficiency by increasing bed occupancy and resource utilization. Several studies have shown that ADRs contribute to 5–10% of total hospital costs, depending on the population and healthcare system. ADR-related hospital admissions often incur higher medical expenditures than non-ADR admissions, as patients may require intensive monitoring, laboratory tests, specialist consultations, and sometimes emergency interventions. For example, economic analyses in Europe and the United States estimate that ADRs cost national health systems billions of dollars annually, making them one of the most economically impactful medication-related issues.

ADR-induced hospitalizations typically prolong patient stay by 2–9 additional days, which significantly increases daily hospitalization expenses including nursing care, medication usage, diagnostic imaging, and laboratory testing. In many low- and middle-income countries, including India, the financial impact is even more severe as patients often bear out-of-pocket expenditures for ADR management. Studies affiliated with India's Pharmacovigilance Programme (PvPI) have shown that ADR-related costs in tertiary hospitals include additional drug therapy (35–50% of cost), laboratory investigations (20–30%), and prolonged hospitalization (30–40%), leading to substantial economic strain on families.

### 3.4 Preventability

A notable proportion—30–60%—of ADRs is classified as preventable, highlighting the urgent need for better monitoring and reporting.

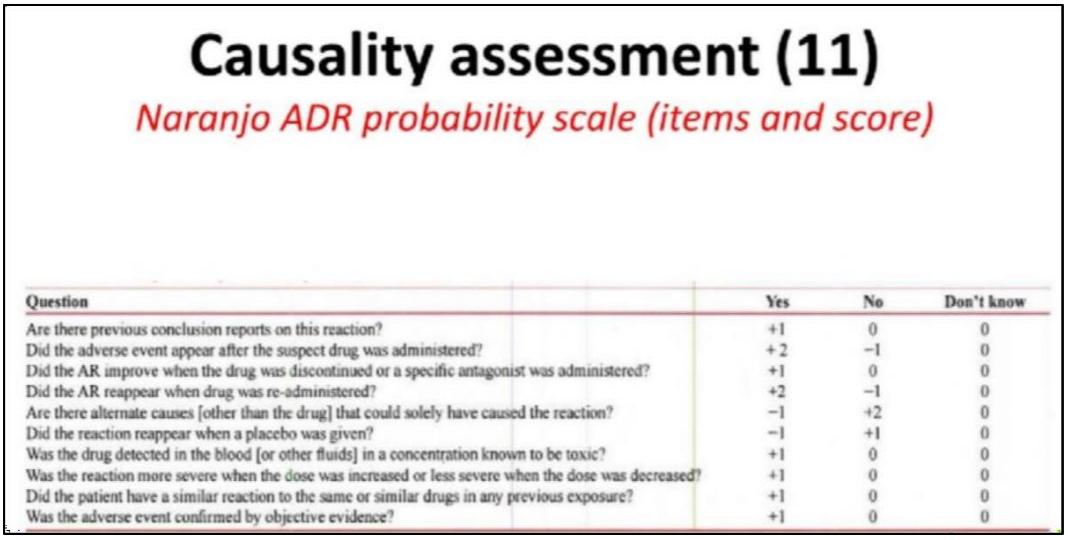
## 4. METHODS OF QUANTIFYING ADRs

Multiple structured tools and methods are used to identify, assess, and quantify ADRs:

### 4.1 Causality Assessment Scales

WHO–UMC Causality Scale (certain, probable, possible, unlikely).

Naranjo Algorithm, a widely used 10-point questionnaire classifying ADRs as definite, probable, possible, or doubtful.




| Question | Yes | No | Don't know |
|---|---|---|---|
| Are there previous conclusion reports on this reaction? | +1 | 0 | 0 |
| Did the adverse event appear after the suspect drug was administered? | +2 | −1 | 0 |
| Did the AR improve when the drug was discontinued or a specific antagonist was administered? | +1 | 0 | 0 |
| Did the AR reappear when drug was re-administered? | +2 | −1 | 0 |
| Are there alternate causes [other than the drug] that could solely have caused the reaction? | −1 | +2 | 0 |
| Did the reaction reappear when a placebo was given? | −1 | +1 | 0 |
| Was the drug detected in the blood [or other fluids] in a concentration known to be toxic? | +1 | 0 | 0 |
| Was the reaction more severe when the dose was increased or less severe when the dose was decreased? | +1 | 0 | 0 |
| Did the patient have a similar reaction to the same or similar drugs in any previous exposure? | +1 | 0 | 0 |
| Was the adverse event confirmed by objective evidence? | +1 | 0 | 0 |

**Figure 4: Causality assessment scale.**

### 4.2 Severity Assessment

Hartwig and Siegel Scale (mild, moderate, severe).

Severity assessment describes the clinical intensity of an adverse drug reaction (ADR) — how much the ADR affects the patient — and is distinct from seriousness (a regulatory/legal classification tied to outcomes such as death, hospitalization, disability, congenital anomaly or life-threatening events). Severity grading is essential for clinical management, triage, causality interpretation and for prioritizing pharmacovigilance follow-up and regulatory action.

### 4.3 Preventability Assessment

Schumock and Thornton Criteria to categorize ADRs as preventable or non-preventable.

Preventability assessment aims to determine whether an adverse drug reaction (ADR) could have been avoided by alternative clinical management, improved prescribing or monitoring, or different patient/health-system actions. Identifying preventable ADRs is crucial because it points to opportunities for improving medication safety through education, system redesign, guideline changes, and targeted interventions.

Determining preventability helps quantify the proportion of ADR burden that is amenable to intervention. A high proportion of preventable ADRs indicates that improvements in prescribing, monitoring, patient counselling or health-system processes could substantially reduce morbidity, mortality and costs associated with ADRs. Preventability information is therefore used to prioritise quality-improvement activities, stewardship efforts and

pharmacovigilance follow-ups.

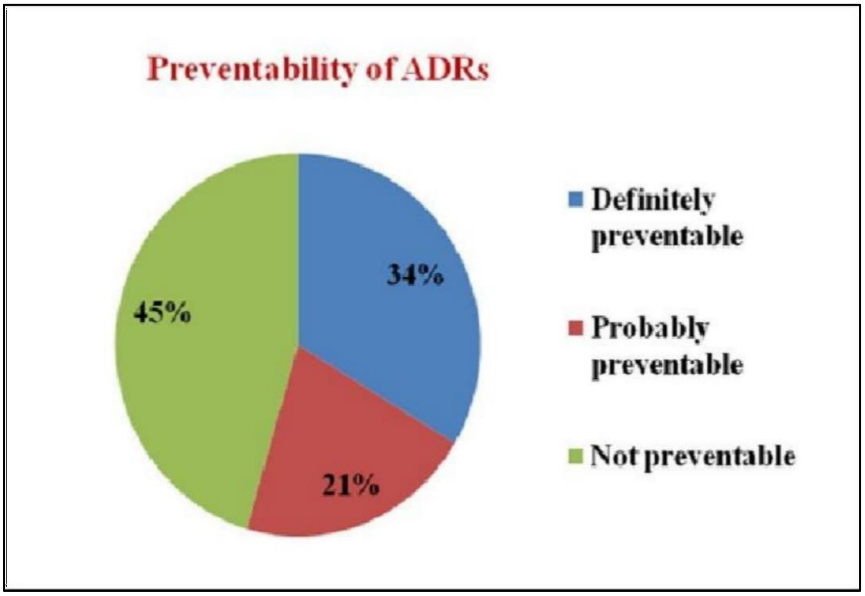



**Figure 5: Preventability of ADRS.**

Preventability is assessed using either explicit (criterion-based) tools or implicit (clinical judgement) approaches. The most widely used explicit tool in hospital pharmacovigilance is the Shamrock and Thornton criteria. Other methods and modifications are also used in research and practice.

## 5. ADR REPORTING FORM

In India, ADRs are reported using the PvPI ADR Reporting Form.

The Adverse Drug Reaction (ADR) Reporting Form is the central tool used in pharmacovigilance to collect standardized information about suspected drug-related adverse events. Properly completed forms help national and international pharmacovigilance centres detect early drug-safety signals, evaluate causality, and implement risk-minimization actions.

Most countries—including India under the Pharmacovigilance Programme of India (PvPI)—follow a structured form based on the WHO-UMC international standard. These forms ensure uniformity and completeness of clinical information essential for causality and preventability assessment.

Key components include

### 5.1 Patient Information (age, sex, weight)

Age, gender, weight Relevant medical history Known allergies

This information identifies vulnerable patient groups and supports causality analysis.

### 5.2 Suspected Drug Information

Drug name (brand and generic) Strength, dose, route and frequency Indication for therapy

Date and duration of administration

These details enable assessment of dose–response relationships, drug interactions and therapeutic appropriateness.

### 5.3 Description of ADR

Onset time, duration and clinical presentation Physical symptoms, lab values, diagnostic findings

Outcome of the reaction (recovered, recovering, death, unknown)

This section provides critical information required for severity assessment, causality assessment, and preventability evaluation.

### 5.4 Outcome of ADR

The outcome of an adverse drug reaction (ADR) refers to the final clinical status of the patient following the event. It reflects the severity of the reaction, the timeliness of intervention, and the patient's overall health condition. Documentation of the outcome is a mandatory component of ADR reporting forms, as it helps determine the clinical significance of ADRs, their burden on healthcare systems, and the need for regulatory action.

### 5.5 Concomitant Medications

All drugs taken alongside the suspected medication

OTC medicines, herbal products, nutritional supplements

Concomitant therapy helps identify drug–drug interactions, one of the major contributors to preventable ADRs.

### 5.6 Reporter Details (doctor/pharmacist/patient)

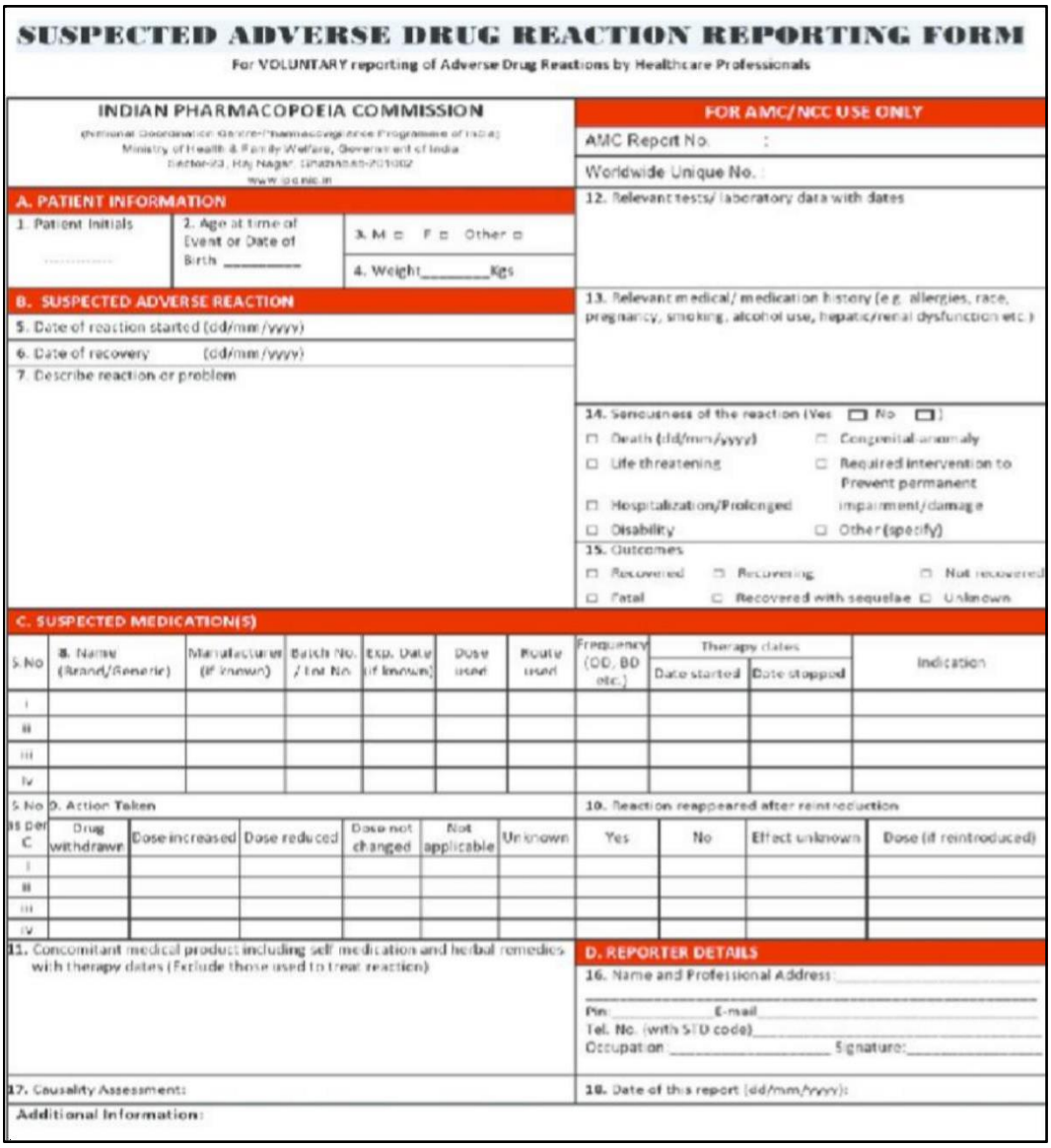
Name, designation (doctor, pharmacist, nurse, patient) Institution name and contact details

Signature and date

### 5.7 ADR Reporting form for health professions

The ADR reporting form for healthcare professionals is a standardized tool designed to systematically collect essential information required for assessing, monitoring, and

preventing adverse drug reactions. The primary purpose of this form is to ensure the prompt capture of safety signals and facilitate communication between healthcare institutions, national pharmacovigilance centre's, and regulatory authorities such as the CDSCO and WHO-UMC programs.



**SUSPECTED ADVERSE DRUG REACTION REPORTING FORM**

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION

FOR AMC/NCC USE ONLY

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials

2. Age at time of Event or Date of Birth _____

3. M ☐ F ☐ Other ☐

4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction (Yes ☐ No ☐)

☐ Death (dd/mm/yyyy) ☐ Congenital anomaly

☐ Life threatening ☐ Required intervention to Prevent permanent

☐ Hospitalization/Prolonged ☐ impairment/damage

☐ Disability ☐ Other (specify)

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered

☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

| S.No | 8. Name (Brand/Generic) | Manufacturer (If known) | Batch No. / Lot No. | Exp. Date (if known) | Dose used | Route used | Frequency (OD, BD etc.) | Therapy dates: Date started | Therapy dates: Date stopped | Indication |
|---|---|---|---|---|---|---|---|---|---|---|
| i | | | | | | | | | | |
| ii | | | | | | | | | | |
| iii | | | | | | | | | | |
| iv | | | | | | | | | | |

| S.No (as per C) | 9. Action Taken: Drug withdrawn | Dose increased | Dose reduced | Dose not changed | Not applicable | Unknown | 10. Reaction reappeared after reintroduction: Yes | No | Effect unknown | Dose (if reintroduced) |
|---|---|---|---|---|---|---|---|---|---|---|
| i | | | | | | | | | | |
| ii | | | | | | | | | | |
| iii | | | | | | | | | | |
| iv | | | | | | | | | | |

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

D. REPORTER DETAILS

16. Name and Professional Address: _____

Pin: _____ E-mail _____

Tel. No. (with STD code) _____

Occupation: _____ Signature: _____

17. Causality Assessment:

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

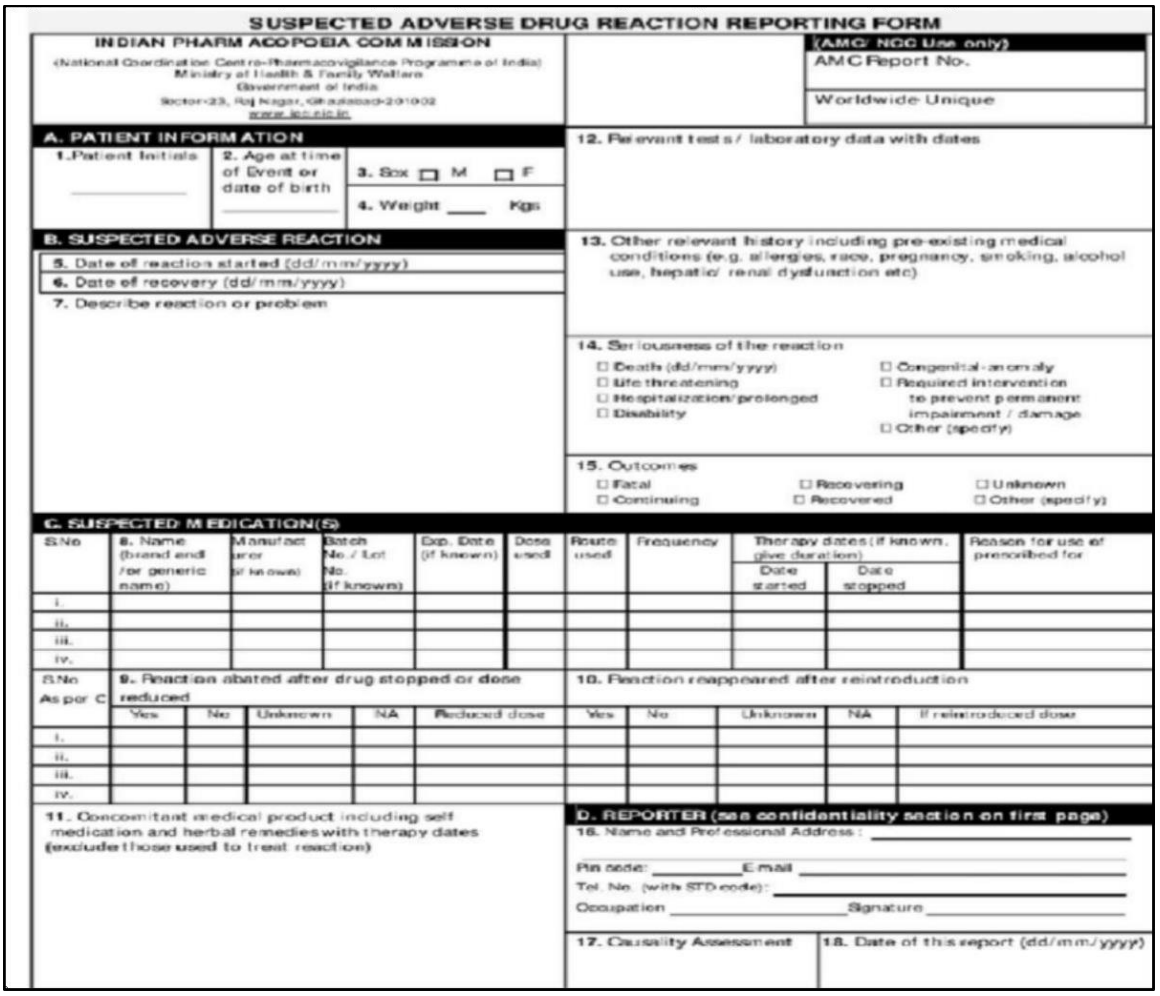
Additional Information:

**Figure 6: ADR Reporting Form for Health Professions.**

### 5.8 ADR Reporting form for patient

Patient-reported adverse drug reaction (ADR) forms are an essential component of modern pharmacovigilance systems, as they enable direct reporting from medicine users, caregivers, or family members. These forms complement reports submitted by healthcare professionals and help capture real-life experiences, including mild or moderate ADRs that may otherwise go unreported. International regulatory agencies such as WHO- UMC, EMA, FDA, and

India's PvPI have recognized patient reporting as a valuable source of safety data and have incorporated dedicated patient-friendly reporting systems.



SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

INDIAN PHARMACOPOEIA COMMISSION

(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
www.ipc.gov.in

(AMC/ NCC Use only)
AMC Report No.
Worldwide Unique

A. PATIENT INFORMATION
1.Patient Initials
2. Age at time of Event or date of birth
3. Sex ☐ M ☐ F
4. Weight ___ Kgs

12. Relevant tests / laboratory data with dates

B. SUSPECTED ADVERSE REACTION
5. Date of reaction started (dd/mm/yyyy)
6. Date of recovery (dd/mm/yyyy)
7. Describe reaction or problem

13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

14. Seriousness of the reaction
☐ Death (dd/mm/yyyy)
☐ Life threatening
☐ Hospitalization/prolonged
☐ Disability
☐ Congenital anomaly
☐ Required intervention to prevent permanent impairment / damage
☐ Other (specify)

15. Outcomes
☐ Fatal ☐ Recovering ☐ Unknown
☐ Continuing ☐ Recovered ☐ Other (specify)

C. SUSPECTED MEDICATION(S)

| S.No | 8. Name (brand and/or generic name) | Manufacturer (if known) | Batch No./ Lot No. (if known) | Exp. Date (if known) | Dose used | Route used | Frequency | Therapy dates (if known, give duration) Date started | Date stopped | Reason for use of prescribed for |
|---|---|---|---|---|---|---|---|---|---|---|
| i. | | | | | | | | | | |
| ii. | | | | | | | | | | |
| iii. | | | | | | | | | | |
| iv. | | | | | | | | | | |

| S.No As per C | 9. Reaction abated after drug stopped or dose reduced | | | | | 10. Reaction reappeared after reintroduction | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Yes | No | Unknown | NA | Reduced dose | Yes | No | Unknown | NA | If reintroduced dose |
| i. | | | | | | | | | | |
| ii. | | | | | | | | | | |
| iii. | | | | | | | | | | |
| iv. | | | | | | | | | | |

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

D. REPORTER (see confidentiality section on first page)
16. Name and Professional Address :
Pin code: ___ E mail ___
Tel. No. (with STD code): ___
Occupation ___ Signature ___

17. Causality Assessment
18. Date of this report (dd/mm/yyyy)

**Figure 7: ADR Reporting form for patient.**

The patient ADR reporting form is intentionally designed to be simple, non-technical, and easy to understand, enabling individuals without medical training to share suspected ADR information accurately. These forms typically begin with basic patient.

### 5.9 ADR forms can be submitted to: AMC

### ADR Monitoring Centres (AMCs)

ADR Monitoring Centres (AMCs) are specialized facilities established under national pharmacovigilance programs to collect, assess, and report suspected adverse drug reactions from healthcare settings. They serve as the foundational units of pharmacovigilance networks and function as the primary link between reporters (patients and health professionals) and national regulatory authorities. In India, AMCs operate under the Pharmacovigilance Programme of India (PvPI) and are coordinated by the National Coordination Centre (NCC-

PvPI) at the Indian Pharmacopoeia Commission.

AMCs are responsible for receiving ADR reports from diverse sources—including physicians, nurses, pharmacists, academic institutions, and patients—and entering them into standardized databases such as VigiFlow, a WHO-UMC-supported platform used globally for ADR data management. These centre's ensure that submitted ADR reporting forms are complete, accurate, and consistent with international pharmacovigilance standards.

A major function of AMCs is causality assessment, which involves analyzing the relationship between the suspected drug and the observed reaction using recognized tools like the Naranjo algorithm or the WHO- UMC causality scale. Trained pharmacovigilance associates and clinical experts evaluate each report to determine whether the event is certain, probable, possible, or unlikely to be drug-induced. This step ensures high-quality signal detection and prevents false or misleading entries into the national database.

Toll-free number: 1800-180-3024
Mobile app: PvPI–ADR Reporting
Email portals of IPC.

## 6. CHALLENGES OF ADR REPORTING

Despite its importance, numerous obstacles hinder effective ADR reporting:

### 6.1 Lack of Awareness & Training

Lack of awareness and inadequate training among healthcare professionals represent some of the most persistent and widely documented barriers to effective ADR monitoring. Multiple studies have shown that poor understanding of pharmacovigilance principles significantly reduces the quality and quantity of ADR reports submitted to national monitoring programs.

A major contributor to underreporting is the limited knowledge about the purpose and functioning of pharmacovigilance systems, including the role of ADR Monitoring Centres (AMCs), reporting platforms such as VigiFlow, and national bodies like PvPI. Many healthcare workers—including doctors, nurses, and even pharmacists—are unaware of where, how, and what to report, which directly impacts the reliability of ADR signal detection. Surveys conducted across tertiary care hospitals show that nearly half of healthcare professionals have never received formal training on ADR reporting procedures.

Another significant issue is that healthcare professionals often lack clarity about which reactions need reporting, mistakenly assuming that only severe or rare ADRs should be documented. This misconception leads to substantial underreporting of mild-to-moderate reactions, which are equally important for assessing drug safety trends.

Poor understanding of PV systems leads to low reporting rates.

### 6.2 Uncertainty in Causality

HCPs hesitate to report suspected—not confirmed—ADRs.

Causality assessment is one of the most complex components of pharmacovigilance, and uncertainty in determining whether a drug truly caused an adverse reaction is a major barrier to effective ADR monitoring. Despite the availability of standardized tools such as the Naranjo Algorithm and the WHO-UMC causality scale, establishing a definite relationship between drug exposure and an observed reaction remains challenging in real-world clinical practice.

A primary source of uncertainty arises from insufficient clinical information in ADR reports. Missing data regarding the onset time, dose, duration of therapy, concomitant medications, laboratory investigations, and challenge–rechallenge outcomes complicate accurate assessment. Incomplete documentation prevents evaluators from confirming temporality—an essential criterion for causality assessment.

### 6.3 Time Constraints

Heavy workloads leave little time for voluntary reporting.

Time constraints are one of the most frequently cited and universally recognized barriers to effective ADR reporting among healthcare professionals. In busy clinical environments, physicians, nurses, and pharmacists often struggle to allocate time for detailed documentation of ADRs, leading to significant underreporting in both hospital and community settings.

A major factor contributing to time pressure is the high patient load in healthcare facilities, especially in government hospitals and tertiary care canters where patient-to-provider ratios are extremely high. Clinicians prioritize direct patient care, emergencies, and administrative responsibilities over pharmacovigilance activities, reducing the time available for identifying, investigating, and documenting suspected ADRs.

### 6.4 Fear of Legal Consequences

Some clinicians fear blame, litigation or administrative repercussions.

Healthcare professionals often fear that reporting an ADR may be interpreted as a medical error or professional incompetence, especially when the ADR occurs after off-label prescribing or polypharmacy. This perceived threat to professional image reduces reporting rates even when clinicians recognize the importance of pharmacovigilance.

Many clinicians assume—incorrectly—that ADR reporting could expose them to legal investigation or malpractice lawsuits. Research from multiple countries shows that misunderstanding pharmacovigilance regulations leads professionals to believe that ADR reports are legally binding documents and may be used against them in court.

### 6.5 Complex Reporting Procedures

Lengthy forms discourage busy healthcare workers.

Many ADR reporting forms—whether national (PvPI), institutional, or international—require extensive clinical information, patient history, drug exposure details, laboratory tests, and causality assessment.

Healthcare professionals often feel that these forms are too long, difficult to complete, or require unnecessary details, discouraging prompt reporting.

Although PvPI and WHO-UMC promote electronic reporting tools, many hospitals still rely on paper forms or outdated reporting systems.

Studies show that without simple app-based or integrated EMR systems, clinicians perceive reporting as an extra, non-clinical burden.

### 6.6 Lack of Feedback

Reporters rarely receive updates, reducing motivation.

In many settings, reporters do not receive even a simple acknowledgment confirming that the ADR report has been received.

This makes healthcare workers feel that their effort did not matter and discourages them from participating again.

Many physicians and pharmacists expect feedback about:
the evaluated causality category, seriousness classification, preventability outcome,

## 7. AIM AND OBJECTIVES

### AIM

To review the significance of pharmacovigilance, ADR reporting systems and barriers affecting ADR awareness and reporting.

One of the fundamental aims of pharmacovigilance is the early detection of rare, unusual, or unexpected ADRs that may not appear during pre-marketing trials due to limited sample size and controlled environments.

Spontaneous reporting systems help identify new safety signals promptly.

### OBJECTIVES

1. To understand the global burden of ADRs.
2. To evaluate methods of identifying and quantifying ADRs.
3. To summarize available ADR reporting systems.
4. To analyze challenges affecting ADR reporting.
5. To highlight the importance of awareness among healthcare professionals and patients.
6. To provide strategies for improving ADR reporting culture.
7. To identify, detect, and monitor adverse drug reactions (ADRs) Ensures early detection of unknown or rare side effects of medicines.
8. To assess the risk–benefit ratio of medicines

Helps determine whether a drug is safe and beneficial for continued use.

## 8. APPLICATIONS OF PHARMACOVIGILANCE

Pharmacovigilance contributes to:

### 8.1 Early Detection of Unknown ADRs

New safety issues, rare reactions, or long-term effects are identified post-marketing.

Early detection of previously unknown or unexpected adverse drug reactions (ADRs) is one of the core purposes of pharmacovigilance. Because pre-marketing clinical trials cannot detect every possible reaction, post-marketing surveillance becomes essential for identifying rare, delayed, or population-specific ADRs that only emerge after widespread drug use.

Clinical trials usually involve limited sample sizes (typically 500–3000 patients) and often exclude special populations such as children, pregnant women, elderly patients, and those with comorbidities. As a result, many ADRs with low incidence (e.g., 1 in 10,000) remain undetected until after drug approval.

### 8.2 Regulatory Actions

Examples include safety alerts, contraindications, dose restrictions or drug withdrawals.[40]

Regulatory action refers to the official steps taken by drug regulatory authorities—such as the WHO-UMC, US FDA, EMA, MHRA, and CDSCO (India)—after evaluating safety signals emerging from ADR reports, post-marketing surveillance, clinical studies, and risk–benefit assessments. These actions are essential for protecting public health and ensuring that marketed drugs continue to be safe and effective.

Early and accurate ADR reporting strengthens pharmacovigilance systems and enables regulatory authorities to respond promptly and appropriately to new safety risks.

For example, the FDA added boxed warnings on fluoroquinolones for serious tendon damage and aortic rupture after accumulating ADR evidence.

### 8.3 Strengthening Public Health

National databases assist in policy decisions and drug-use strategies.

Pharmacovigilance plays a central role in safeguarding public health by enabling the early detection, assessment, and prevention of adverse drug reactions (ADRs) at the population level. A strong pharmacovigilance system improves patient safety, optimizes therapeutic outcomes, prevents drug-related morbidity and mortality, and supports evidence-based policy making.

Effective ADR reporting and analysis enhance overall healthcare quality and ensure that medicines remain safe throughout their life cycle. This leads to improved clinical decision-making and reduction in preventable ADR-related hospitalizations.

### 8.4 Enhanced Rational Drug Use

Supports evidence-based prescribing and prevents irrational polypharmacy.

Rational drug use refers to prescribing, dispensing, and consuming medicines in a way that

ensures maximum therapeutic benefit with minimum risk, based on evidence, patient characteristics, and updated safety information. Pharmacovigilance systems play a vital role in improving rational drug use by continuously updating clinicians about new ADR patterns, high-risk drugs, drug interactions, and population-specific toxicities.

Pharmacovigilance promotes rational therapy by enabling prescribers to select safer alternatives, optimize dosing regimens, and avoid unnecessary polypharmacy. These actions significantly reduce preventable adverse drug reactions (ADRs) and optimize clinical outcomes.

This ensures that prescribers rely not only on premarketing clinical trials but also on post-marketing safety evidence, which forms the backbone of rational drug therapy. This allows clinicians to avoid harmful combinations, especially in elderly and multi-morbid.

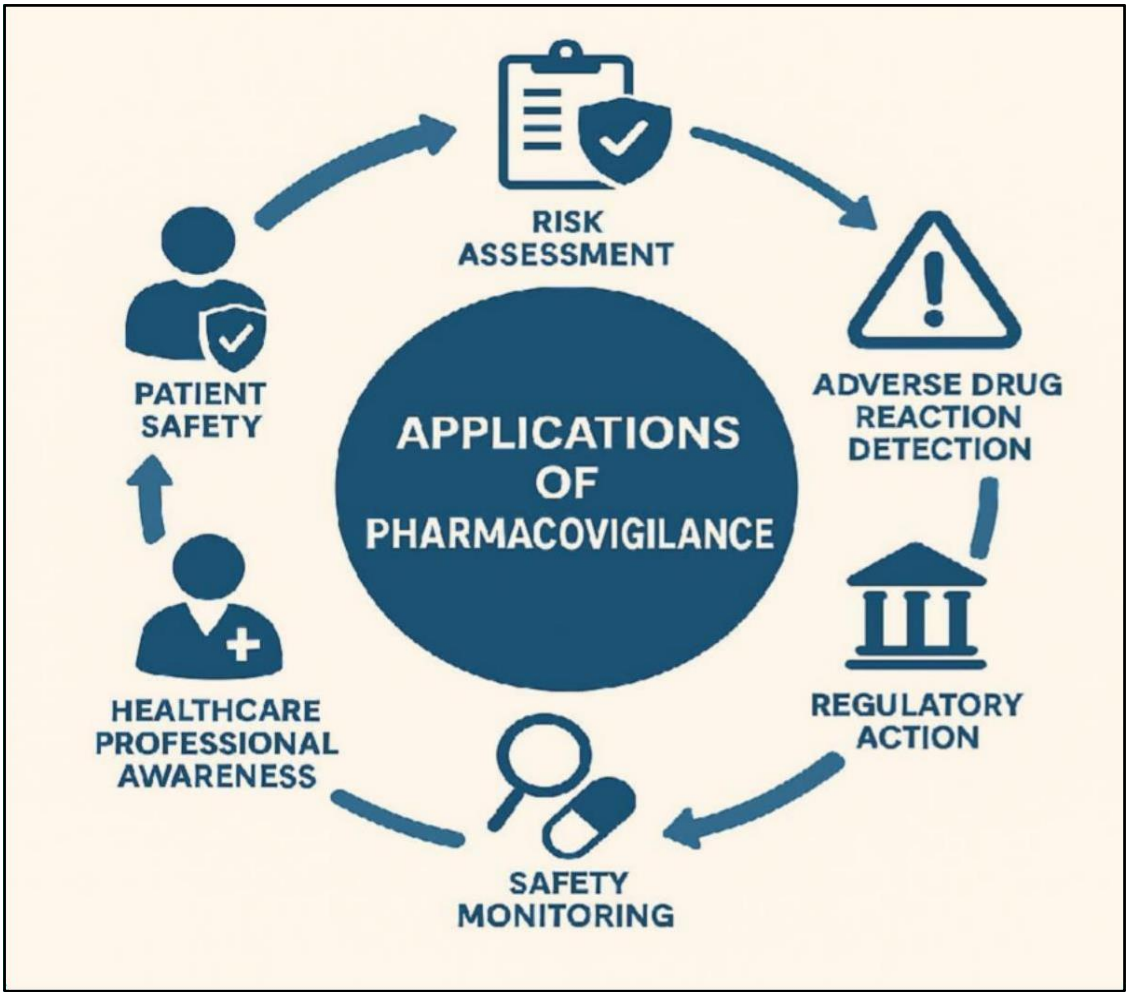



**Figure 5: Application of pharmacovigilance.**

## 9. CONCLUSION

Pharmacovigilance is essential for ensuring medication safety, preventing avoidable ADRs, and improving the overall quality of healthcare. Despite global efforts, significant challenges remain—primarily related to low awareness, under-reporting and lack of training. Strengthening PV systems requires education, simplification of reporting processes, institutional support and integration of digital tools. Creating a culture of safety among healthcare professionals and empowering patients to report ADRs can significantly enhance drug safety monitoring.

Pharmacovigilance plays a vital role in ensuring the safety, quality, and effectiveness of medicines throughout their life cycle. Despite the availability of structured reporting systems, the rate of Adverse Drug Reaction (ADR) reporting remains significantly low, mainly due to a lack of awareness, inadequate training, fear of legal consequences, and the misconception that reporting is only required for serious reactions. Strengthening pharmacovigilance therefore requires a collective commitment from healthcare professionals, regulatory authorities, and the community.

Improving awareness through targeted educational programs, continuous professional training, and the inclusion of pharmacovigilance topics in healthcare curricula can greatly enhance reporting practices. In addition, creating simple, user-friendly, and digital ADR reporting platforms can encourage voluntary participation and increase transparency. Patient engagement is also essential, as informed patients can contribute valuable real-world data that help in early detection of drug-related problems.

Overall, a strong, proactive pharmacovigilance system not only reduces morbidity and mortality associated with ADRs but also supports rational drug use, protects public health, and builds trust in the healthcare system. Continuous efforts to improve awareness, reporting culture, and regulatory support will ensure safer and more effective therapeutic outcomes for the entire population.

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