Journal of Advanced Scientific Research

Available online through https://sciensage.info

ISSN

0976-9595

Review Article

A Comprehensive Study on Adverse Drug Reactions (ADRs) and Their Monitoring Approaches

Md Zakir Alam, Abdullah*, Anwar Salik, Md Quamar Niyaz, Md Afaque

School of Pharmacy, Al-Karim University, Katihar, Bihar, India

*Corresponding author: mdabdullah.556600@gmail.com

Received: 05-12-2025; Accepted: 10-01-2026; Published: 31-01-2026

https://doi.org/10.55218/JASR.2026170101

ABSTRACT

This investigation utilizes a knowledge assessment questionnaire (KAQ) to gauge patients' understanding of their health issues and to spot possible adverse drug reactions (ADRs). On a global scale, ADRs are among the top factors driving illness and death rates, while also raising healthcare expenses considerably. The goals here include: (a) assessing how common ADRs are in hospital settings via proactive tracking, and (b) examining the nature and medical features of these responses. The review further assesses the existing pharmacovigilance systems for identifying and overseeing ADRs. It outlines the functional setup, advantages, drawbacks, and key elements of India's ADR surveillance mechanism. The Central Drugs Standard Control Organization (CDSCO) manages the safety, standards, and effectiveness of drugs via over 200 Adverse Drug Reaction Monitoring Centres (AMCs) nationwide. As part of the Pharmacovigilance Programme of India (PvPI), these units must submit ADR information to the National Coordination Centre (NCC) at the Indian Pharmacopoeia Commission (IPC) in Ghaziabad. Medical experts and everyday people can notify the NCC of potential ADRs through a uniform, multi-language form aimed at promoting ease and broad participation.

Keywords: Adverse drug reaction, Reporting, Monitoring & management, Predictable and unpredictable

INTRODUCTION

Background

Medications serve as vital instruments in healthcare—they can ward off illnesses, ease pain, and preserve lives, yet they may also trigger severe undesired outcomes. According to the World Health Organization (WHO), an adverse drug reaction (ADR) is defined as "a harmful and unintended response to a medication that happens at standard doses used for prevention, diagnosis, treatment, or altering bodily functions in humans."[1] In recent years, drug usage has greatly improved health results and life quality. Nevertheless, no drug treatment is completely risk-free. Every medical agent holds the chance of causing negative or damaging impacts, known together as Adverse Drug Reactions (ADRs).[2] A similar idea, the Adverse Drug Event (ADE), is outlined as "any unfavorable health incident during drug therapy that isn't always linked causally to the treatment."[3] This wider scope stresses the need to log all adverse health occurrences first, then assess causation via thorough examination (Fig 1).

Medication Errors

Medication mistakes add another key aspect to drug safety concerns. The U.S. National Coordinating Council for Medication Error Reporting and Prevention (US NCC MERP) describes a medication error as "any avoidable occurrence that could result in improper drug use or harm to the patient while the medication is managed by a medical professional, patient, or user."[4] These errors might happen at any point in the drug-handling process, such as ordering, copying, marking, packing, preparing, distributing, giving, teaching patients, or overseeing clinically. They could stem from personal errors, structural issues, or communication gaps in medical environments. Medication errors are a leading avoidable source of patient injury in global healthcare. Per the US NCC MERP, such an error is "any preventable incident that might cause or result in unsuitable medication application or patient damage while under the oversight of a healthcare worker, patient, or consumer." These mistakes can emerge at various stages of medication oversight from ordering and transcribing to labeling, packaging, compounding, dispensing, distributing, administering, and educating patients. Moreover, failures in communication of orders, naming of products, and clinical supervision can lead to drug-related problems. Such issues may come from shortcomings in expert practices, healthcare setups, or procedural lapses, highlighting the importance of ongoingalertness and strong safety measures for medications (Fig 2).[4]

Understanding of ADR

Understanding of adverse drug reactions (ADRs) involves identifying the relationship between drug exposure and the resulting harmful effects. It requires evaluating the type, severity, mechanism, predictability, and preventability of reactions. A systematic understanding of ADRs helps healthcare professionals in early detection, appropriate management, and prevention through rational

Fig 1: Conceptual framefwork of Adverse Drug Reactions (ADRs)

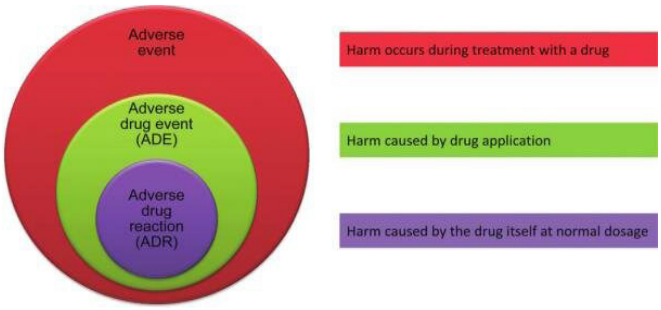


Fig. 2: Difference between Adverse Drug Reaction (ADR) and Adverse Drug Event (ADE)

drug use and pharmacovigilance practices (Fig 3).

History of ADR

The awareness and oversight of adverse drug reactions (ADRs) have advanced notably over the last hundred years, mainly due to devastating medical incidents that underscored drug safety and oversight needs.

Back in 1922, Salvarsan—an arsenic-based compound for syphilis treatment—was linked to jaundice cases, representing an early noted drug toxicity event.[5]

In 1937, a sulfanilamide solution mixed with diethylene glycol caused 107 fatalities in the U.S., sparking widespread anger and leading to enhanced safety rules. This gave the Food and Drug Administration (FDA) the duty to check new drugs' safety prior to market entry.[6]

Thalidomide entered the West German market in 1958 as a sedative and nausea reliever for pregnant women, despite warning signs in animal tests. From 1959 to 1961, numerous phocomelia cases—birth defects with limb issues—surfaced in infants, creating the Thalidomide crisis.[7] Affecting 4,000 to 100,000 children worldwide, this event marked a pivotal moment, establishing contemporary drug regulators, tougher pre-testing and trials, and greater focus on spotting, recording, and avoiding ADRs.[8]

Classification of ADR

The broadly recognized ADR classification by Rawlins and Thompson

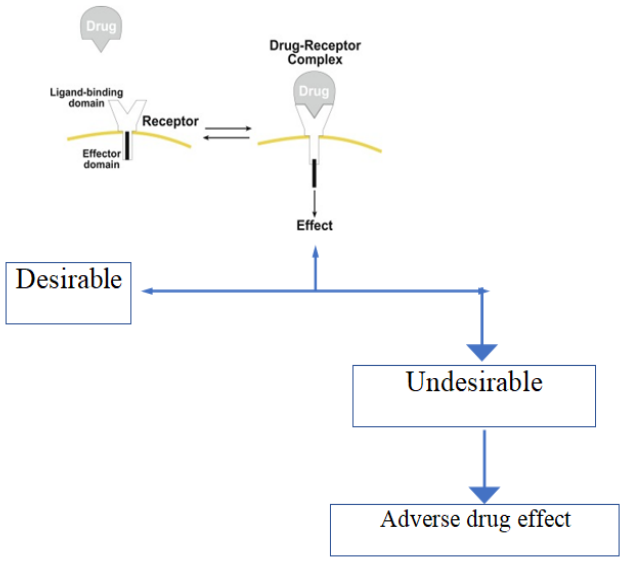


Fig. 3: Overview illustrating the understanding and classification of ADRs

(1977) divides them into two main groups by dose reliance and foreseeability (Fig 1).

Type A (Augmented or Dose-Dependent Reactions)

These are amplified versions of a drug's typical effects, tied to dosage. Predictable and common, they make up about 80% of ADRs.

They result from extended normal drug actions, like antimuscarinic effects from tricyclic antidepressants. Though potentially harmful, they can often be avoided via dose tweaks or checks.

Type B (Bizarre or Dose-Independent Reactions)

These are unusual responses not linked to standard drug effects, often unique or immune-based, and hard to predict.

For example, liver damage from isoniazid is unrelated to dose. These can be grave and may only show post-market. The classification has evolved with new ADR insights.[9]

More Recent Categorization

As suggested by Rene J Royer (1997): Type A: Augmented Type B: Bizarre Type C: Chronic Type D: Delayed effects.[10]

Wills and Brown Classification

Rene J. Royer (1997) extended the Rawlins-Thompson system to cover more drug effects: [10]

- Type A: Linked to the drug's action, dose-related.
- Type B: Unforeseeable, not dose-linked.
- Type C: From extended therapy or buildup.
- Type D: Appearing later, due to hidden toxicity.This highlights time and long-term aspects not fully covered before.

Wills and Brown offered a detailed setup with nine groups based on mechanisms, overcoming prior limits:[11]

- Type A: Predictable from drug effects.
- Type B: Unpredictable, unrelated to pharmacology.
- Type C: From ongoing treatment.

- Type D: After delay or stop.
- Type E: Withdrawal after ending.
- Type F: Therapy failure.
- Type G: Genetic damage.
- Type H: Allergic.
- Type U: Not classified

Type A Reactions (Predictable or Mechanism-Based)

Foreseeable from drug traits, including toxicity, side effects, and withdrawal.

Dose-tied, avoidable via adjustments or education.

Type B [Unpredictable or Bizarre] Reaction

These are based on the patient's quirks rather than the drug's established activities; idiosyncrasies and allergies are two examples. They require drug withdrawal since they are less frequent, usually unrelated to dose, and generally more severe. If the genetic basis is identified and the proper tests are performed to characterize the individual's phenotype, some of these reactions can be anticipated and prevented (Fig 4).[12]

Type C [Chemical] Reaction

The chemical composition of a medication or excipient determines these responses, not its pharmacological effects. Although not pharmacologically foreseeable, understanding the drug's physicochemical properties can help identify these effects. The severity of a type C reaction depends on the offending chemical rather than the dosage. Local irritants can cause damage to the stomach mucosa.

Type C [Chemical] Reaction

The chemical composition of a medication or excipient determines these responses, not its pharmacological effects. Although not pharmacologically foreseeable, understanding the drug's physicochemical properties can help identify these effects. The severity of type-C reaction depends on the offending chemical rather than the dosage. Local irritants can cause damage to the stomach mucosa.

Type D (Delayed or Delivery-Related Reactions)

Not from drug chemistry but formulation or delivery. Vary by admin route, resolve with changes. E.g., injectables causing blockages.

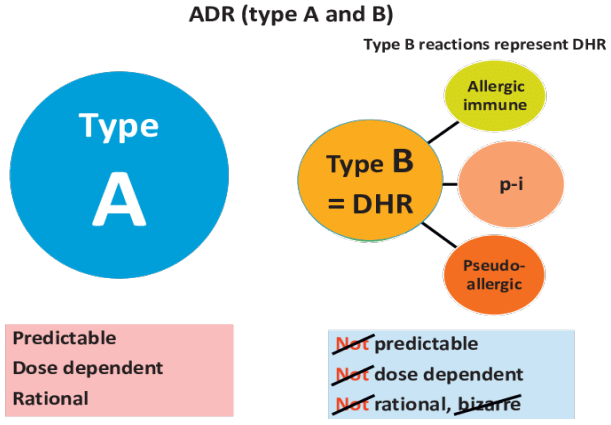


Fig. 4: Comparison between Type A and Type B adverse drug reactions

Type E (End of Use or Exit Reactions)

From sudden stop after long use, due to dependence. Resolve with a restart or taper. E.g., seizures from an abrupt phenytoin halt.

Type F (Failure or Familial Reactions)

In genetic metabolic issues, safe drugs become harmful. E.g., primaquine causes anemia in G6PD deficiency. Screening helps prevent.

Type G (Genotoxicity Reactions)

Causes lasting DNA harm, leading to cancer or defects. E.g., thalidomide's birth issues. Require thorough testing.

Type H (Hypersensitivity Reactions)

Unpredictable, immune-driven, not dose or action-related. Stop the drug; dose cut ineffective. Asthma and lupus increase risk. [13,14] see in Fig 5.

Type U (Unclassified Reactions)

Mechanisms unclear, e.g., nausea from anesthetics.

Classification of ADRs Based on Severity[15,16]

- **Minor:** Mild, no treatment/hospital needed. E.g., opioid constipation.
- **Moderate:** Needs adjustment/management, possible extended stay. E.g., thrombosis from contraceptives.
- **Severe:** Potentially deadly, stop treatment. E.g., enalapril angioedema.
- **Lethal:** Causes death directly/indirectly. E.g., anticoagulant bleeding.

Classification of ADR Based on Mechanism

- Idiosyncrasy
- Hypersensitivity
- Intolerance
- Drug Interaction

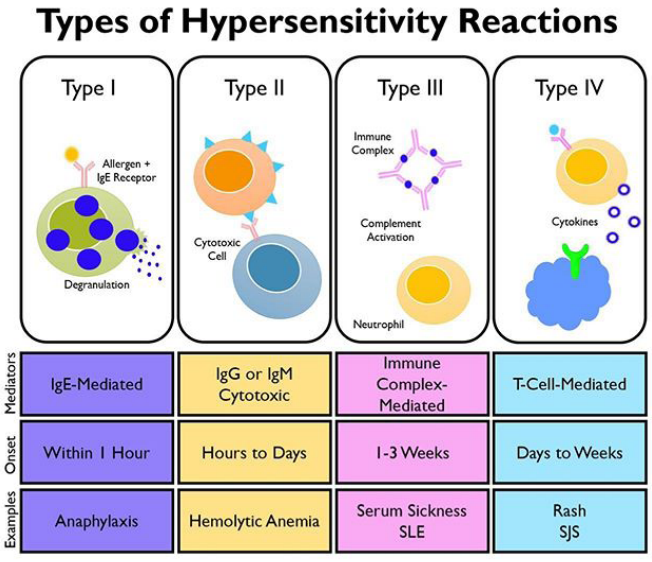


Fig. 5: Mechanism and examples of hypersensitivity reactions

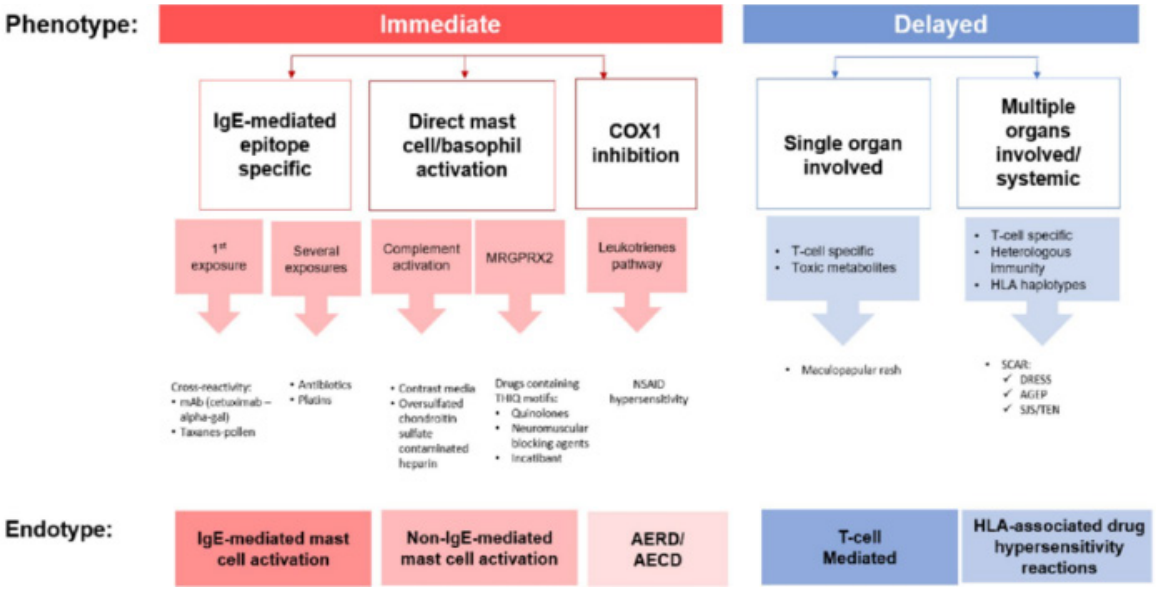


Fig. 6: Pharmacovigilance process for detection and prevention of ADRs

Idiosyncrasy

Genetic unusual response, limited to specific genotypes. E.g., barbiturates cause excitement.

Hypersensitivity

An allergy is an immune system hypersensitivity condition. Stereotype symptoms that are unrelated to the drug's pharmacodynamic profile are being produced by an immunologically mediated reaction. Even at lower pharmacological dosages, the symptoms may manifest, and their onset and duration may vary. When a person's immune system naturally responds to innocuous substances in their surroundings, an allergic reaction occurs. Allergens are substances that trigger hypersensitive reactions. Examples of Drugs which causes hypersensitivity reaction includes Penicillins, Cephalosporins, sulfonamides, aspirin, indomethacin, hydralazine, antitubercular drugs, etc (Fig 6).

Intolerance

Typical side effects at normal doses, high sensitivity. E.g., trifluprom azine dystonia in kids.[17]

Drug Interaction

The main ADR cause is from negative mixes, reducing efficacy or increasing toxicity. Types: pharmacokinetic, pharmacodynamic, chemical[18] (Tables 1 and 2).

Classification of ADR based on Frequency

It is also called the European classification of ADR The European classification is presented as percentage probabilities of developing an ADR and is shown in Table 3.

Risk Factors of ADR

Age of the Patient

ADR risk ties closely to age. The elderly face higher chances of multiple illnesses and many drugs, with changes in metabolism, liver/kidney function, and interactions. Type A is more common than B. [22–24] Pediatrics is also at risk from immature systems, leading to buildup. [25,26]

Gender

Biological differences affect drug responses. Women are often higher risk due to body composition and slower clearance. E.g., antiretrovirals vary by gender. Higher CYP3A4 in women alters metabolism.[27,28]

Dosing Frequency and Organ Function

Timing impacts ADRs, e.g., evening aspirin better antiplatelet, bedtime bisphosphonates cause esophagitis.[29] Liver/renal issues lead to buildup; adjust doses, avoid certain drugs.[30]

Polypharmacy

WHO defines as ≥5 meds. Risk rises with more drugs from interactions, toxicity. Up to 70% ADRs linked. Review regimens essential.[31]

Aim

Main goal for ADRs: prevent and manage. Some are unpredictable (e.g., penicillin anaphylaxis), but many are avoidable via careful practice.

Preventability: ADRs are avoidable with evidence-based actions. 1/3–1/2 preventable, often assessed post-event.[32]Strategies cut morbidity/costs.

Steps for ADR Prevention:

- Determine which subset of patients is most likely to encounter the adverse effect, and then adjust the treatment strategy accordingly.
- Verify that the treatment strategy minimizes any possible side effects.[33]

Table 1: How ADR caused by drug interaction[18,19]

Mechanism	*Description*	*Example*
CYP450 Inhibition	Decreased metabolism → increased drug levels	Clarithromycin + simvastatin → myopathy
CYP450 Induction	Increased metabolism → decreased drug levels	Phenytoin + contraceptives → contraceptive failure
Protein-Binding Displacement	More free drug → increased effect/toxicity	Naproxen displacing warfarin → increased bleeding
Excretion Competition	Reduced elimination → accumulation	NSAIDs impair methotrexate excretion → toxicity
Additive Pharmacodynamics	Combined drug effects → exaggerated response	SSRIs + NSAIDs → elevated bleeding risk
Antagonistic Pharmacodynamics	One drug blocks another's effect	NSAIDs reduce diuretic efficacy
Comorbidities & Genetics	Altered handling or response due to patient factors	Liver/kidney dysfunction or CYP polymorphisms influence ADR risk
Food Interactions	Inhibit metabolism/transporters → altered drug levels	Grapefruit juice + various drugs → toxicity risk

Table 2: Examples of drugs that cause ADR via drug interaction[20]

First Drugs	*Second Drug*	*Effect*	*Type of drug-interac*^{n}	*Interaction*	*Severity*
Aspirin	Clopidogrel	Hematuria, Hemoptysis, Hematemesis, Gum bleeding	PD	Additive effect-antiplatelet action	Major
Dexamathasone	Cyclosporine	Hyperglycemia	PK	impacts CYP3A4 metabolism and P-glycoprotein (MDR1) efflux trafficking to raise serum Dexamethasone levels.	Major
Diclofenac	Furosemide	Edema	PD	Reduce renal function to counteract the natriuretic effects of loop diuretics. PG Synthesis	Major
Digoxin	Furosemide	Ventricular tachycardia	PD	Digoxin toxicity may worsen if digoxin and a loop diuretic are taken together. Hypokalemia can cause calcium release, which can lead to arrhythmias.	Moderate
Risperidone	Clonazepam	Tremor, Rigidity	PD	Depression of CNS	Moderate

Table 3: Examples of drugs that cause ADR[21]

Frequency Category	*Definition*	*Incidence Rate*
Very common	Occurs in ≥ 1 in 10 patients	≥ 10%
Common (frequent)	Occurs in ≥ 1 in 100 but < 1 in 10	1% to < 10%
Uncommon	Occurs in ≥ 1 in 1,000 but < 1 in 100	0.1% to < 1%
Rare	Occurs in ≥ 1 in 10,000 but < 1 in 1,000	0.01% to < 0.1%
Very rare	Occurs in < 1 in 10,000	< 0.01%
Unknown	Frequency cannot be approximated from data.	No reliable estimate available

Approach to ADR Management

Reduce/stop the drug. Varies by clinician, reaction. Includes interventions, vigilance, and antidotes (Table 4).

MATERIALS AND METHODS

Pharmacovigilance

Pharmacovigilance involves science and actions for spotting, assessing, understanding, and preventing adverse events or drug issues.[35]

In 2012, the EU updated rules for better vigilance, defining roles, a black triangle for new drugs needing extra watch, and proactive risk management.

Monitoring of ADR

Detecting ADRs involves hypothesis creation, data strengthening, signal testing.

Table 4: Examples of agents used in the management of specific ADR.[34]

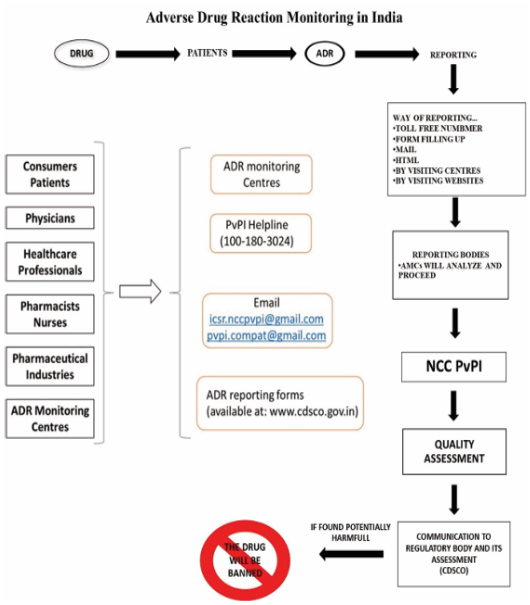
Specific Treatment	*Drug/Class Causing ADR*
Naloxone	Opioids
Acetylcysteine	Acetaminophen
Flumazenil	Benzodiazepines
Thiosulfate	Cyanide
Glucagon	β-blockers

Signal

Data suggesting drug-event link, from clinical/epidemiology/pathology.

Qualitative Signals (Individual)

Spontaneous reports, literature cases, hospital monitoring, cohort studies.



Resources: ipc.gov.in, forms PDF, emails, helpline 1800-180-3024, app on Play Store.

Fig. 7: Adverse Drug Reaction (ADR) monitoring framework in India under PvPI

Quantitative Signals (Population)

Large datasets, case-control, PEM, databases (WHO-UMC, FDA).

Experimental

Trials, in vitro assays, animal tox.[36]

ADR Monitoring Framework in India[Fig 7]

Healthcare pros are key to safety via reporting. PvPI promotes reports of any ADRs. Clinicians submit to AMCs; the public to NCC/IPC. Forms: Professional form, public form. Submit via email/post/online. Helpline, app (ADR PvPI) (Fig 7). [37–39]

Causality Assessment

Association degree between reaction and drug. Scales: Naranjo, WHO-UMC. [40,41]

Naranjo's causality assessment scale

Tables 5 and 6 represent Naranjo's scale and interpretation of scores. The Naranjo Algorithm One popular technique for determining the cause of ADRs is the Naranjo algorithm.

WHO-UMC Causality Assessment Scale

The World Health Organization worked with the Uppsala Monitoring Centre to create a causality scale. Based on the evaluation criteria, theyseparated the scale into multiple categories. Table 7 explains the scale:

Severity Assessment Scale

The severity of adverse drug reactions is evaluated using the Hartwig scale. The severity of the reaction is represented by each of the scale's many levels. There are three categories for the ADR reaction: mild, moderate, and severe. Table 8 explains the scale.

Preventability Scale

Schumock and Thornton's preventability scale determines if an ADR is definitelyavoidable, possibly preventable, or not preventable. Table 9 explains the scale.[42]

Reporting of ADR

Reporting an ADR is a vital step. ADR reporting raises awareness of post-marketing surveillanceamong healthcare professionals, pharmaceutical companies, researchers, medication users, and students.

Components

- Product info

Table 5: Naranjo's causality assessment scale.

Question	*Yes*	*No*	*Don't Know / Not Done*
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 (dechallenge)?	+1	0	0
4. Did the adverse event reappear when the drug was re-administered (rechallenge)?	+2	–1	0
5. Are there alternative causes that could solely explain the reaction?	–1	+2	0
6. Did the reaction reappear upon administration of placebo?	–1	+1	0
7. Was the drug detected in blood (or other fluids) at toxic concentrations?	+1	0	0
8. Was the reaction more severe with increased dose, or less severe with decreased dose?	+1	0	0
9. Did the patient have a similar reaction to the same or similar drugs previously?	+1	0	0
10. Was the adverse event confirmed by objective evidence (e.g., lab tests)?	+1	0	0

Table 6: Interpretation of scores

Total Score	*Interpretation*	*Key Clinical Insight*
≥ 9	Definite	The reaction (1) was a known reaction to the suspected drug, (2) happened in a plausible temporal sequence after a drug or when a toxic drug level had been determined in bodily fluids or tissues, and (3) was confirmed by improvement after stopping the drug and reappearance upon reexposure.
5–8	Probable	The reaction was (1) a recognized response to the suspected drug, (2) it happened in a decent temporal sequence after a drug, (3) it was confirmed by withdrawal but not by exposure to the drug, and (4) it was not sufficiently explained by the known features of the patient's clinical state.
1–4	Possible	The reaction (1) happened in a sequential order after a substance, (2) might have followed a known pattern to the suspected medication, and (3) might be explained by the patient's medical characteristics.
≤ 0	Doubtful	The reaction was most likely caused by reasons other than the medicine.

Table 7: WHO-UMC causality assessment scale

Category	*Key Criteria*
Certain	• abnormal occurrences or test findings that are connected to drug use but cannot be attributed to illness or other causes. • likely withdrawal reaction (pathological or pharmaceutical) • challenge that is satisfactory, if required.
Probable/Likely	• Abnormal event or laboratory test within a realistic time frame related to drug intake. • Clinically appropriate response to withdrawal • No need for rechallenge.
Possible	• Abnormal event or laboratory test results within a reasonable timeframe related to drug intake. • Possible causes include sickness or drug use. • There may be little or unclear information available regarding drug withdrawal.
Unlikely	• A relationship between a period to drug usage and abnormal events or lab test results is uncommon, but not impossible. • Medication or medical issues are examples of potential explanations.
Conditional/Unclassified	• Unusual occurrences or findings from lab tests • Extra information needed for a thorough evaluation, or currently being investigated.
Unassessable/Unclassifiable	• Report indicates negative reaction • Insufficient or inconsistent information prevents judgment • Data cannot be added to or verified.

Table 8: Hartwig severity assessment scale

Level	*Description*
1	ADR happened, but no treatment modification was required.
2	There was no need for an antidote or extra therapy, and the length of stay (LOS) was not increased, but ADR mandated that the treatment be stopped, modified, or held.
3	ADR required cessation/change of therapy and/or a specific treatment (e.g., antidote). No increase in LOS.
4	Hospital admission was due to a Level 3 reaction that increased LOS by ≥1 day or an adverse drug reaction.
5	any Level 4 ADR that necessitates critical medical attention, such as an ICU stay.
6	The patient was permanently harmed by ADR.
7	The patient died as a direct or indirect result of ADR.

- Patient details
- Event description
- Dates, seriousness
- Dose
- Labs, etc.

Types

Country-specific forms (CDSCO India, Yellow Card UK, MedWatch US, Blue Card Australia).

Suspected Adverse Drug Reporting Form[43]

Patient Information

Field	Details
Patient initials	
Age/Date of Birth	
Sex	☐ Male ☐ Female ☐ Other
Weight (if known)	
Hospital/ID number	

Table 9: Schumock and Thornton preventability scale

Preventability category	*Criteria*
Definitely Preventable	If you answered "yes" to any of the Section A requirements listed below: 1. Past medication reactions or allergy history 2. The medication is not suitable for the clinical condition of the patient. 3. The frequency, technique, and dosage are inappropriate for the patient's age, weight, or condition. 4. The presence of toxic serum drug concentrations or the omission of lab monitoring 5. The ADR has recognized remedies.
Probably Preventable	Section A has all the answers. No, although any of the requirements listed in Section B are true. 6. The necessary laboratory testing or therapeutic medication monitoring was not finished. 7. Interactions between drugs happen. 8. The level of compliance was low. 9. Preventive measures were either ineffective, not recommended, or not provided.
Not Preventable	If all questions in Sections A and B are answered no, the ADR is categorized as not preventable (Section C).

Reaction Details

Field	Details
Description of reaction(s)	
Date of onset of reaction	
Date of recovery/resolution	
Outcome	☐ Recovered ☐ Ongoing ☐ Fatal ☐ Unknown
Seriousness (if applicable)	☐ Death ☐ Life-threatening ☐ Hospitalization ☐ Disability ☐ Congenital anomaly ☐ Other serious

Suspected Drugs

Drug Name	Dose	Route	Frequency	Start Date	Stop Date	Indication

Concomitant Medications (if any)

Include all medicines (prescribed, OTC, herbal) the patient was taking at the time of the reaction.

Useful Laboratory Information and Test Findings

(e.g., tests for liver function, blood counts, and imaging,

Reporter Information

Field	Details
Name	
Designation	☐ Doctor ☐ Pharmacist ☐ Nurse ☐ Other
Department / Institution	
Contact information	Phone/Email
Date of report	
Signature (if required)	

| Assessment | ☐ Certain ☐ Probable ☐ Possible ☐ Unlikely ☐Unassessable |

☑ Note: All personal identifiers must be kept confidential. Reporting is encouraged even if you are not sure the drug caused the reaction.

RESULTS AND DISCUSSION

Results

This review synthesizes data from various sources indicating that ADRs contribute significantly to global morbidity and mortality, with estimates suggesting they account for 5 to 10% of hospital admissions worldwide [1,2]. In India, under PvPI, over 200 AMCs have reported increasing ADR cases, with common types being Type A (80% dose-dependent) and hypersensitivity reactions prominent [37]. Classifications show Type B as unpredictable but severe, while severity scales reveal moderate ADRs as frequent, often requiring intervention without fatality [15,16]. Risk factors highlight elderly and polypharmacy patients as high-risk, with up to 70% ADRs linked to multiple drugs [31]. Causality assessments via Naranjo/WHO-UMC classify most as "possible" or "probable" in reports[40,41]. Reporting tools like apps have boosted submissions, with qualitative signals from spontaneous reports dominating detection[36].

DISCUSSION

The findings underscore the preventable nature of many ADRs through enhanced pharmacovigilance, as one-third to half are avoidable[32]. India's framework, with NCC and digital tools, aligns with global standards like the EU's black triangle but faces underreporting challenges due to awareness gaps[38]. Classifications evolve to include genetic and delivery aspects, aiding targeted prevention[9-11]. However, limitations include reliance on retrospective data and variable reporting quality. Future efforts should integrate AI for signal detection and pharmacogenomics for personalized medicine, reducing risks in vulnerable groups like pediatrics and females[25-28]. Overall, robust monitoring transforms ADRs from threats to actionable insights, improving safety and efficacy in drug use.

CONCLUSION

ADRs pose ongoing challenges in healthcare, raising illness, stays, and costs. Many are predictable from pharmacology, others are sudden and severe. Prevention via careful prescribing, patient factors, and education. Monitoring/reporting essential for safety. Pharmacovigilance enables detection/prevention. Surveillance, spontaneous reports, and digital tools improve outcomes. Three-pronged: Prevent baseline risk, monitor early, report for knowledge. Leads to better results, rational use, prepared system.

REFERENCES

1. WHO, Medicines areas quality safety efficacy Pharmacovigilance; 2016.
2. Zehravi M, Maqbool M, Ara I. An overview about safety surveillance of adverse drug reactions andpharmacovigilance in India. The IndianJournal of Nutrition and Dietetics. 2021:408-18.
3. Tripathi, K. D. "Essentials of Medical Pharmacology", 8th ed., Jaypee Brothers Medical Publishers, New Delhi, 2019, page no.. 92.
4. National Coordinating Council for Medication Error Reporting and Prevention. What is a medication error? New York, NY: National Coordinating Council for Medication Error Reporting and Prevention;

2015. Available at: http://www.nccmerp.org/aboutmedication-errors, accessed 19 September 2016).
5. https://www.ncbi.nlm.nih.gov/books/NBK548692/#:~:text=Noncirrhotic%20portal%20hypertension%20generally%20arises,skin%2C%20liver%20and%20lung%20carcinoma.
6. https://en.wikipedia.org/wiki/Elixir_sulfanilamide #:~:text=Elixir%20sulfanilamide%20%2D%20Wikipedia,s%20powers%20to%20regulate%20drugs.
7. https://encyclopedia.pub/entry/33611#:~:text=Thalidomide%20Scandal%20%7C%20Encyclopedia%20MDPI&text=In%20the%20late%201950s%20and,market%20in%20Europe%20that%20year.
8. https://pmc.ncbi.nlm.nih.gov/articles/PMC4737249/
9. Rawlins MD, Thompson JW. Pathogenesis of adverse drug reactions. In: Davies DM, editor. Textbook of adverse drug reactions. Oxford: Oxford University Press; 1977. p.10.
10. Wills, S.; Brown, D. A proposed new means of classifying adverse reactions to medicines. Pharm. J. 1999, 262, 163–165.
11. Arulmani R, Rajendran SD, Suresh B. Adverse drug reaction monitoring in a secondary care hospital in South India. British J of Clin Pha. 2007;65(2):210-16.
12. Tripathi KD. Essentials of Medical Pharmacology. 8th ed. New Delhi: Jaypee Brothers Medical Publishers; 2019. p.92.
13. Lang DM, Alpern MB, Visintainer PF, Smith ST. Increased risk for anaphylactoid reaction from contrast media in patients on beta-adrenergic blockers or with asthma. Ann Intern Med. 1991;115:270-6.
14. Petri M, Allbritton J. Antibiotic allergy in systemic lupus erythematosus: a case-control study. J Rheumatol. 1992;19:265-9.
15. Gholami K, Gloria S. Factors Associated with Preventability, Predictability, and Severity of Adverse Drug Reactions. Annals of Pharmacotherapy. 1999;33(2):236-40
16. Tripathi, K. D. "Essentials of Medical Pharmacology", 8th ed., Jaypee Brothers Medical Publishers, New Delhi, 2019, page no. 92.
17. Tripathi, K. D. "Essentials of Medical Pharmacology", 8th ed., Jaypee Brothers Medical Publishers, New Delhi, 2019, page no. 94.
18. Wiffen, P., Mitchell, M., Snelling, M., Stoner, N. (2017) Oxford handbook of clinical pharmacy. Oxford: Oxford University Press
19. Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press
20. Palappallil DS, Ramnath SN, Gangadhar R. Adverse drug reactions: Two years' experience from a tertiary teaching hospital in Kerala. Natl J Physiol Pharm Pharmacol; 7(4):403-11 (2017).
21. https://www.researchgate.net/publication/265057046_Words_or_numbers_Communicating_risk_of_adverse_effects_in_written_consumer_health_information_a_systematic_review_and_meta-analysis
22. Barry PJ, Gallagher P, Ryan C. Inappropriate prescribing in geriatric patients. Curr Psychiatry Rep. 2008;10(1):37-43.
23. Bowman L, Carlstedt BC, Hancock EF, Black CD. Adverse drug reaction (ADR) occurrence and evaluation in elderly inpatients. Pharmacoepidemiol Drug Saf. 1996;5(1):9-18.
24. Leach S, Roy SS. Adverse drug reactions: an investigation on an acute geriatric ward. Age Ageing. 1986;15(4):241-6.
25. Alomar MJ. Factors affecting the development of adverse drug reactions (Review article). Saudi Pharm J 2013;22(2):83-94.
26. Ibáñez L, López-Bermejo A, Díaz M, Marcos MV, Casano P, de Zegher F. Abdominal fat partitioning and highmolecular-weight adiponectin in short children born small for gestational age. J Clinical EndocrinologyMetab. 2009;94(3):1049-52.
27. Ofotokun I, Pomeroy C. Sex differences in adverse reactions to antiretroviral drugs. Top. HIV Med. 2003;11(2):55-9.
28. El-Eraky H, Thomas SHL. Effects of sex on the pharmacokinetic and pharmacodynamic properties of quinidine. Br. J. Clin. Pharmacol. 2003;56:198-204.
29. Hermida RC, Ayala DE, Calvo C, Lo′pez JE. Aspirin administered at bedtime, but not on awakening has an effect on ambulatory blood pressure in hypertensive patients. J. Am. Coll. Cardiol. 2005;46(6):975-83.
30. Lewis JH, Stine JG. Review article. Review article: prescribing medications in patients with cirrhosis. Aliment Pharmacol Ther. 2013;37:1132-56.
31. Ahmed B, Nanji K, Mujeeb R, Patel MJ. Effects of polypharmacy on adverse drug reactions among geriatric outpatients at a tertiary care hospital in Karachi: a prospective cohort study. PloS one. 2014 Nov 17;9(11):e112133.
32. Ferner RE , Aronson JK . Preventability of drug-related harms - part I: a systematic review . Drug Saf 2010 ;33 : 985 – 94 .
33. Coleman JJ , Ferner RE , Evans SJ . Monitoring for adverse drug reactions . Br J Clin Pharmacol2006 ;61 : 371 – 8
34. Prakash J, Joshi K, Malik D, et al. "ADR PvPI" Android mobile app: Report adverse drug reaction at any time anywhere in India. Indian journal of pharmacology. 2019;51(4):236-42.
35. World Health Organization . The importance of pharmacovigilance .Geneva : World Health Organization ,2002 .
36. Goyal RK, Bhatt PA, Burande MD. Adverse drug reactions and Pharmacovigilance: Elements of Clinical Pharmacy: published by S. B Shah, 3rd Ed: 2006-2005:126-127.
37. Jose J, Rao PG. Pattern of adverse drug reactions notified by spontaneous reporting in an Indian tertiary care teaching hospital. Pharmacological research. 2006;54(3):226-33.
38. PvPI-Frequently asked questions Available:
39. https://www.ipc.gov.in/PvPI/faq.html#: ~:text=Toll%20free%20helpline%20number%20(1800,to%20directly%20report%2 0an%20ADR.
40. Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther. 1981;30(2):239–245. Available from: doi.org/10.1002/cpt.1981.30.2.239
41. World Health Organization (WHO). The Use of the WHO-UMC System for Standardized Case Causality Assessment. Geneva: WHO; 2014.
42. Hartwig SC, Siegel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions. Am J Hosp Pharm. 1992;49:2229-32.
43. Kessler DA, Natanblut S, Kennedy D, Lazar E, Rheinstein P, Anello C, et al. Introducing MEDWatch: a new approach to reporting medication and device adverse effects and product problems. Jama. 1993 Jun 2;269(21):2765-8.
44. https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPvPI/ADRnewReporting_Form_1.4.pdf
45. https://www.pharmaceuticalpress.com/resources/article/what-is-an-adr/
46. Pandit, Anala and Shiksha, Ieee and Dubey, Shiksha, 2025, 06,Acomprehensive review on Adverse Drug Reactions (ADRs) Detection and PredictionModels:https://www.researchgate.net/publication/392739875_A_comprehensive_review_on_Adverse_Drug_Reactions_ADRs_Detection_and_Prediction_Models
47. https://ars.els-cdn.com/content/image/3-s2.0-B9780128198698000392-f19-02-9780128198698.jpg
48. https://www.researchgate.net/figure/ADR-are-subclassified-as-type-A-and-B-reactions-Type-B-reactions-correspond-to-DHR_fig2_311624838
49. https://www.grepmed.com/images/6381/hypersensitivity-diagnosis-classification-reactions-types
50. https://www.researchgate.net/publication/388301117_Drug_allergy
51. Amale PN, Deshpande S, Nakhate Y, et al. Pharmacovigilance process in India: An overview. J Pharmacovigil. 2018;6(2):259

HOW TO CITE THIS ARTICLE: Alam MZ, Abdullah, Salik A, Niyaz MQ, Afaque M. A Comprehensive Study on Adverse Drug Reactions (ADRs) and Their Monitoring Approaches. *J Adv Sci Res.* 2026;17(1): 1-9 **DOI:** 10.55218/JASR.2026170101