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Review Paper

Regulatory Process of Adverse Drug Reporting Case Studies in India

Dr. Surykant Jadhav, Dr. Vijay Navghare, Harshada Gore*, Shraddha Ratanwar

SSS Indira College of Pharmacy, Vishnupuri, Nanded

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ABSTRACT

Adverse drug reactions (ADRs) are an important issue affecting patient safety. Pharmacovigilance helps in detecting, assessing, and preventing these reactions. In India, ADR reporting is mainly managed by the Pharmacovigilance Programme of India under the regulation of the Central Drugs Standard Control Organization.This review paper focuses on the regulatory process of ADR reporting in India and explains it with the help of case studies. Information was collected from research articles, official guidelines, and reports from organizations like the World Health Organization. The study describes steps such as identification, reporting, and evaluation of ADRs.Some case studies are included to understand how ADR reporting works in real situations. The review also highlights problems like underreporting and lack of awareness. Overall, improving reporting systems and awareness can help in better drug safety and patient care

INTRODUCTION

According to the WHO, an adverse drug reaction (ADR) is "a response to a drug that is noxious and unintended, and which occurs at doses normally used for prophylaxis, diagnosis, or therapy".

- **Noxious and Unintended:** The response is harmful and not the desired effect of the medication.
- **Normally used doses:** The definition is based on standard dosage amounts, not from drug abuse or overdose.
- **Prophylaxis, diagnosis, or therapy:** It applies to drugs used to prevent, diagnose, or treat disease, or to modify a physiological function[1].

In view of the under declaration of adverse drug reactions (ADRs) there is a need for optimizing their reporting. Among the objectives is to study the cases of Adverse Drug Reactions (ADRs) and describe them. It's a study who makes health professionals aware of the importance of the notification to avoid serious consequences on the health of the pediatric population. Doctors are often required to prescribe medicines designed for

***Corresponding Author:** Harshada Gore
Address: *Department of Regulatory Affair, SSS Indira College of Pharmacy, Vishnupuri, Nanded..*
Email ✉: hgore9763@gmail.com
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adults who can have even dramatic consequences. The objective also was to propose preventive strategies and encourage regulatory authorities to carry out corrective actions[2].

➢ Mechanisms of adverse drug reactions

An adverse drug reaction (ADR) refers to an unintended, harmful, and undesirable response that occurs following the administration of a medication at normal therapeutic doses. ADRs may develop due to different mechanisms, including the direct toxic effects of drugs or hypersensitivity reactions. These reactions are often associated with alterations in the pharmacokinetic processes such as absorption, distribution, metabolism, and elimination, as well as pharmacodynamic changes that influence the body's response to the drug[3]. Direct toxicity reactions occur when a drug or its metabolites produce harmful effects on body tissues and organs. These reactions may lead to cellular injury, physiological disturbances, chemical damage, or impairment of normal organ function. In some cases, toxic compounds can also cause damage to DNA and other cellular structures, resulting in tissue injury and adverse clinical outcomes[4]. Hypersensitivity reactions occur when the immune system produces an exaggerated response to a drug or its metabolites. These immune-mediated reactions may manifest as allergic responses ranging from mild skin eruptions to severe life-threatening conditions such as anaphylaxis[5].

➢ Different Classifications of Adverse Drug Reactions:

Adverse drug reactions (ADRs) are commonly classified into five major categories based on their characteristics and mechanisms. Type A (Augmented) reactions are dose-dependent and occur due to an exaggerated pharmacological effect of a drug; these reactions are common and generally predictable. Type B (Bizarre) reactions are uncommon, unpredictable, and often associated with genetic predisposition, hypersensitivity, or allergic mechanisms and they may result in serious outcomes. Type C (Chronic) reactions develop following long-term use of medications, whereas Type D (Delayed) reactions appear after a prolonged period and may include effects such as teratogenicity and carcinogenicity. Type E (End of use) reactions occur when a drug is withdrawn abruptly, leading to withdrawal or rebound effects[6].

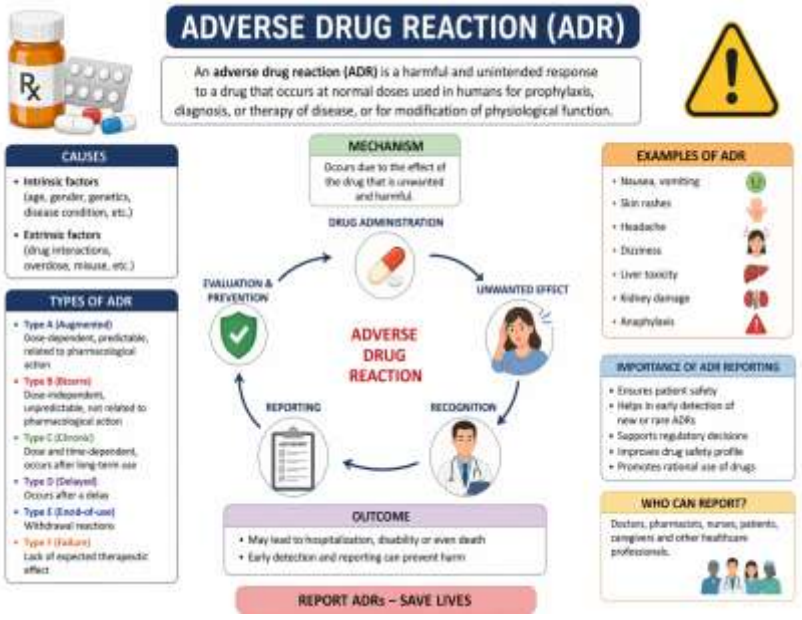

Figure No. 1: Classification and Mechanism of Adverse Drug Reactions (ADRs).

Table no.1: Classification of ADR with Characteristics and Examples.

Type of ADR	Characteristics	Examples
Type A (Augmented)	Dose-related, predictable, related to the pharmacological action of the drug	Nephrotoxicity caused by aminoglycosides; anticholinergic effects of tricyclic antidepressants
Type B (Bizarre)	Not dose-related, uncommon, unpredictable, not related to the known pharmacological action	Penicillin-induced urticaria; anticonvulsant hypersensitivity syndrome
Type C (Chronic)	Associated with long-term exposure to drugs	Hypothalamic-pituitary-adrenal axis suppression caused by corticosteroids
Type D (Delayed)	Occurs after prolonged exposure or appears after some time	Tardive dyskinesia caused by antipsychotic medications
Type E (End of use)	Associated with withdrawal or termination of treatment	Tachyphylaxis or withdrawal reactions after stopping drugs

- **Methods of Quantifying ADRs:**

Several methods are used to quantify and monitor adverse drug reactions (ADRs), including spontaneous reporting systems, ecological studies, prescription-event monitoring, medical claims database analysis, and meta-analysis. Among these, spontaneous ADR reporting is the most widely used method in pharmacovigilance and plays an important role in detecting new and rare adverse reactions. However, this system has several limitations such as poor-quality reports, difficulty in estimating incidence rates, and under-reporting of ADRs. Studies have shown that lack of awareness, inadequate training, and poor knowledge regarding pharmacovigilance contribute significantly to under-reporting among healthcare professionals. Educational programmes and training workshops have been found to improve ADR reporting practices and strengthen pharmacovigilance activities[7].

- **Pharmacovigilance:**

Pharmacovigilance (PV) refers to the scientific discipline and activities involved in identifying, evaluating, understanding, and preventing adverse effects or other problems associated with the use of medicines[8]. The World Health Organization established the Programme for International Drug Monitoring in 1968 after the thalidomide disaster to improve medicine safety worldwide.

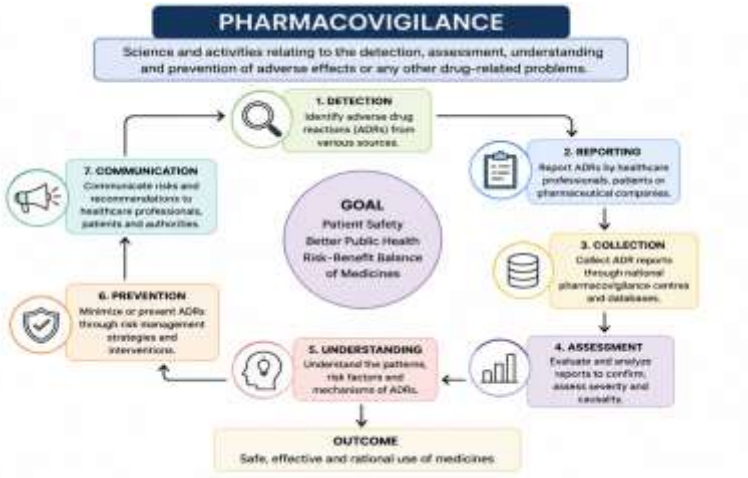

Figure No. 2: Pharmacovigilance Workflow Diagram

The Uppsala Monitoring Centre was later created in Sweden to coordinate global pharmacovigilance activities. Pharmacovigilance focuses on the detection, assessment, understanding, and prevention of adverse drug reactions and other medicine-related problems. Although medicines and vaccines undergo clinical trials before approval, some adverse effects may appear only after widespread use in larger populations, making continuous drug safety monitoring essential for protecting public health[9]. Although pharmacotherapy provides significant therapeutic benefits, adverse drug reactions (ADRs) remain an important risk associated with medication use. ADRs are common and, in many cases, preventable causes of morbidity, disability, and mortality. An ADR refers to a harmful or unpleasant response associated with the use of a medicinal product that may require dose modification, specific treatment, discontinuation of therapy, or preventive measures to avoid future harm[10].

- **Importance of Case Studies in Adverse Drug Reaction Research:**

Case studies are important for identifying rare adverse drug reactions (ADRs) that may not be detected during clinical trials due to limited study populations. Rare reactions such as localized erythema caused by clotrimazole ear drops may become evident only after widespread clinical use. Elderly patients may be more susceptible because of skin changes and delayed healing. Early recognition of such ADRs helps clinicians provide timely management and improve patient safety. The WHO-UMC and Naranjo scales demonstrated a probable association between the drug and the reaction[11].Case reports provide valuable real-world clinical information that may not be observed under controlled trial conditions. Detailed patient histories, symptoms, examination findings, and treatment outcomes help clinicians understand the actual behavior of drugs in routine practice. Reports describing fever, rash, edema, and jaundice in pediatric patients receiving long-term therapy contribute to better recognition and management of ADRs in clinical settings[12].ADR case reports play a key role in pharmacovigilance by helping detect new safety signals and rare drug reactions. Well-documented case studies support post-marketing surveillance and may alert healthcare professionals about previously unrecognized adverse effects. Accumulation of similar reports can lead to regulatory actions such as prescribing restrictions or drug withdrawal, thereby improving public safety[13].Case studies provide comprehensive clinical information

including patient demographics, drug exposure, laboratory findings, diagnostic investigations, treatment, and outcomes. Such detailed documentation assists in causality assessment and understanding the mechanism of ADRs. Reports of terbinafine-induced liver injury, for instance, help clinicians identify drug-related hepatotoxicity and guide appropriate management strategies[14]. Case reports help identify populations at increased risk of developing ADRs, such as children, elderly patients, and individuals with liver disease. Studies involving anti-tubercular therapy and other hepatotoxic medications demonstrate that prolonged multidrug treatment and patient-specific factors can increase susceptibility to liver injury. Recognition of these risk factors supports closer monitoring and safer prescribing practices[15]. Case studies assist in evaluating the severity of adverse drug reactions by describing clinical presentations ranging from mild skin reactions to severe organ damage such as liver failure. Classification of ADRs into mild, moderate, or severe categories helps healthcare professionals determine the need for treatment modification, hospitalization, or drug discontinuation[16]. Case studies serve as important educational tools for doctors, pharmacists, and students by improving diagnostic skills, clinical knowledge, and patient safety awareness. Real-world ADR examples help healthcare professionals better understand pharmacovigilance practices and encourage accurate reporting and management of adverse reactions[17]. ADR case reports contribute significantly to regulatory decision-making by generating evidence regarding drug safety. Repeated reports of serious adverse effects may result in label warnings, dose modifications, prescribing restrictions, or withdrawal of drugs from the market. Therefore, pharmacovigilance data are essential for maintaining a favorable risk-benefit profile of medicines[18]. Case studies are particularly valuable in understanding drug-induced liver injury because hepatic reactions are often unpredictable and potentially severe. Reports describing jaundice, elevated liver enzymes, and acute liver failure help clinicians recognize early signs of hepatotoxicity and establish associations between specific drugs and liver injury[19]. Underreporting of ADRs remains a major challenge in India despite the establishment of pharmacovigilance programs. Publication of ADR case reports increases awareness among healthcare professionals and promotes active participation in ADR monitoring systems. Improved reporting strengthens pharmacovigilance activities and supports early detection of drug safety concerns[20].

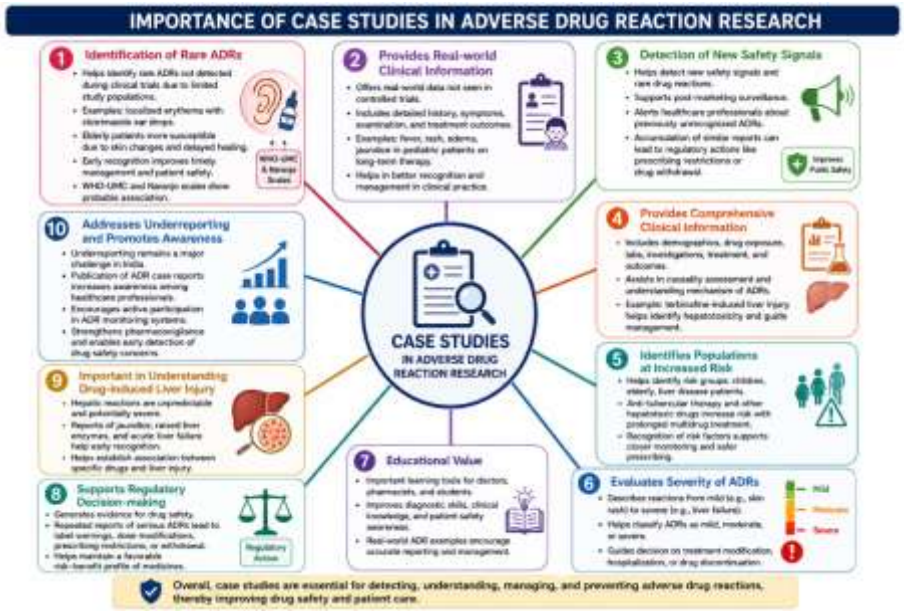

Figure No. 3: Importance of Case Studies in Adverse Drug Reaction (ADR) Research

1. Materials and Methods:

➢ Study Area:

The present review study titled "Drug Reporting Case Studies in India**"** was carried out with special emphasis on the adverse drug reaction (ADR) reporting system and pharmacovigilance practices in India. The study mainly focused on the Pharmacovigilance Programme of India (PvPI) and the regulatory framework governed by the Central Drugs Standard Control Organization (CDSCO). The review aimed to understand the process of ADR reporting, monitoring, causality assessment, and regulatory decision-making associated with drug safety in India.

➢ Research Design:

A narrative review design was adopted for the study to systematically collect, evaluate, and summarize available scientific literature related to pharmacovigilance and ADR reporting. This design was selected because it allows comprehensive analysis and interpretation of previously published information from different sources. The review focused on published evidence related to ADR mechanisms, classifications, pharmacovigilance systems, methods of ADR monitoring, and the importance of case studies in identifying drug-related safety concerns.

➢ Data Collection:

Relevant data and literature were collected from various authentic and reliable sources, including peer-reviewed research articles, review papers, official publications, pharmacovigilance guidelines, and scientific online databases. Published literature related to causality assessment methods, spontaneous adverse drug reaction reporting systems, drug safety monitoring, and pharmacovigilance practices in India was critically reviewed and analyzed to obtain evidence-based information relevant to the study.

➢ Case studies:

Published ADR case reports were selected from previously published research articles to understand the practical aspects of adverse drug reaction reporting and pharmacovigilance activities in India. The selected cases included different categories of ADRs affecting various organ systems such as hematological, neurological, endocrine, and dermatological systems. These published case reports were

reviewed to study the clinical presentation, suspected drugs, causality assessment, management, and patient outcomes associated with adverse drug reactions. The collected information was further analyzed to identify important trends and challenges related to ADR reporting and drug safety monitoring.

1. **Case 1: Carbamazepine-Induced Aplastic Anemia:**

A 44-year-old male with a known history of seizure disorder had been receiving carbamazepine therapy for seizure control. After prolonged use of the drug, the patient developed generalized weakness, fatigue, pallor, and breathlessness on exertion. Hematological investigations revealed severe pancytopenia with anemia, leukopenia, and thrombocytopenia. Bone marrow biopsy demonstrated hypocellularity suggestive of aplastic anemia. Other possible causes such as infections, malignancy, and autoimmune disorders were excluded, confirming carbamazepine-induced aplastic anemia. The drug was discontinued immediately, and the patient was managed with blood transfusions and supportive therapy, leading to gradual clinical improvement. This case highlights a rare but serious hematological adverse drug reaction associated with carbamazepine therapy[21].

2. **Case 2: Topiramate in Alcohol Dependence with Withdrawal Seizures:**

A 31-year-old male with chronic alcohol dependence presented with relapse and recurrent withdrawal seizures after discontinuing his medications. The patient had a long history of alcohol abuse associated with craving, tremors, and repeated episodes of withdrawal. On admission, he experienced recurrent seizures related to alcohol withdrawal. Considering its anticonvulsant and anticraving properties, topiramate therapy was restarted along with supportive management including benzodiazepines, hydration, nutritional supplementation, and counseling. Clinical improvement was observed with reduction in seizure frequency and alcohol craving. This case demonstrates the importance of medication adherence and the therapeutic role of topiramate in managing alcohol withdrawal-related complications[22].

3. **Case 3: Acitretin-Induced Hypothyroidism:**

A 41-year-old male receiving acitretin therapy for Darier's disease developed symptoms such as fatigue, lethargy, weight gain, and cold intolerance after approximately three months of treatment. Laboratory findings showed elevated thyroid stimulating hormone (TSH) levels indicating hypothyroidism. There was no previous history of thyroid disease. Acitretin was discontinued, and thyroxine therapy was initiated, resulting in symptomatic improvement and normalization of thyroid function tests. Rechallenge with acitretin led to recurrence of hypothyroid symptoms and elevated TSH levels, confirming a probable dose-dependent adverse drug reaction. This case emphasizes the need for monitoring endocrine function during long-term retinoid therapy[23].

4. **Case 4: Phenytoin-Induced Toxicity (Ataxia):**

A 16-year-old male with epilepsy on phenytoin therapy presented with dizziness, slurred speech, unsteady gait, and difficulty in coordination. Neurological examination revealed signs of cerebellar dysfunction suggestive of ataxia. Serum phenytoin levels were significantly elevated above the therapeutic range, confirming drug toxicity. Other neurological causes were ruled out. Phenytoin therapy was discontinued, and supportive management was provided, following which the patient showed gradual symptomatic

improvement. According to WHO-UMC causality assessment criteria, the reaction was classified as probable. This case highlights the narrow therapeutic index of phenytoin and the importance of therapeutic drug monitoring[24].

5. **Case 5: Ciprofloxacin-Induced Fixed Drug Eruption:**

A 45-year-old female developed multiple erythematous, fluid-filled skin lesions within two hours of taking oral ciprofloxacin for urinary tract infection. The lesions were associated with itching and burning sensation, and clinical evaluation supported the diagnosis of fixed drug eruption. The patient also reported a similar reaction after previous exposure to ciprofloxacin. The suspected drug was discontinued immediately, and treatment with antihistamines, corticosteroids, and supportive care was initiated. The lesions resolved gradually after withdrawal of the drug. This case demonstrates a hypersensitivity-related dermatological adverse drug reaction associated with ciprofloxacin therapy[25].

- Data Analysis:

The collected information was carefully reviewed and analyzed to understand the patterns, reporting practices, and challenges related to adverse drug reactions (ADRs) in India. The analysis also helped identify the strengths and limitations of the current pharmacovigilance and ADR reporting system.

CONCLUSION

Pharmacovigilance (PV) ensures patient safety by detecting, assessing, and preventing adverse drug reactions (ADRs) post-marketing, as clinical trials cannot identify all potential risks. India's Pharmacovigilance Programme of India (PvPI) has bolstered monitoring through a strong regulatory framework, with the Indian Pharmacopoeia Commission as the national center. However, challenges like underreporting, lack of awareness, and limited infrastructure persist. Key steps forward include leveraging EHRs and AI for reporting, intensifying training for healthcare professionals, and enhancing patient-centric reporting to improve public health outcomes.

RESULT

The present review identified that adverse drug reactions (ADRs) remain a major challenge in clinical practice and significantly affect patient safety. Analysis of the selected case studies demonstrated that ADRs can involve multiple organ systems including hematological, neurological, endocrine, dermatological, and hepatic systems. The reviewed cases showed that drugs such as carbamazepine, phenytoin, acitretin, ciprofloxacin, and topiramate may produce serious adverse effects ranging from mild hypersensitivity reactions to severe organ toxicity. The findings also highlighted that spontaneous ADR reporting and case studies play an important role in early detection of rare ADRs, causality assessment, identification of risk factors, and regulatory decision-making. Underreporting, lack of awareness, and insufficient pharmacovigilance training were identified as major limitations affecting ADR reporting practices in India.

DISCUSSION

The review emphasizes the importance of pharmacovigilance in improving drug safety and patient care. Case studies provide valuable real-world clinical evidence that helps healthcare professionals recognize rare and serious ADRs that may not be detected during clinical trials. Detailed clinical documentation and causality assessment support better understanding of ADR mechanisms and aid in timely management. The reviewed literature suggests that continuous

monitoring, patient counseling, therapeutic drug monitoring, and early withdrawal of suspected drugs are essential for preventing severe complications. Furthermore, strengthening the Pharmacovigilance Programme of India (PvPI), increasing awareness among healthcare professionals, and encouraging active ADR reporting can improve pharmacovigilance practices and support safer use of medicines in India.

Conflicts of Interest

The authors declare no conflict of interest. This review is based on publicly available regulatory and scientific literature, and no financial or personal relationships have influenced its preparation or conclusions.

REFERENCES

1. Kumar A. Pharmacovigilance and adverse drug reaction (ADR): a case study. *Int J Res Inform Sci Appl Tech (IJRISAT).* 2018; 2(2):28.
2. Torissi L, Soulaymani A, Mokhtari A, Soulaymani R. Cases of adverse drug events in pediatrics: prospective study at a hospital in Rabat (Morocco). *J Young Pharm*. 2015; 10(3):362–366.
3. Ramesh KG, Parloop AB, Mahesh DB. *Elements of Clinical Pharmacy*. 4th ed. Pune: B.S. Shah Prakashan; 2008-2009. p. 109-114.
4. Tarantino G. Drug-induced liver injury: is it somehow foreseeable? World Journal of Gastroenterology. 2009; 15:2817-2833.
5. Schnyder B, Pichler WJ. Mechanisms of drug-induced allergy. Mayo Clinic Proceedings. 2009;84:268-272.
6. Rohilla A, Yadav S. Adverse drug reactions: an overview. International Journal of Pharmacological Research. 2013;3(1):10-12.
7. Campbell JE, Gossell-Williams M, Lee MG. A review of pharmacovigilance. *West Indian Med J.* 2017;63(7):771. doi:10.7727/wimj.2013.251.
8. Heamavathi S, Shankar S, Karthi S, Kanagavalli K. Case studies of adverse drug reactions (ADR) in AYUSH. *LAPIN Journal.* 2025; volume(issue):page–page. ISSN: 3048-9598.
9. Khattri S, Balamuralidhara V, Kumar PTM, Valluru R, Venkatesh MP. Pharmacovigilance regulations in India: a step forward. *Clin Res Regul Aff.* 2012;29(2):41–45
10. Shukla S. Current scenario and future prospects of adverse drug reaction monitoring and reporting mechanisms in rural areas of India. *Journal of Pharmacovigilance & Drug Safety*. 2024.
11. Sarma I, Ray N, Banerjee P, Das S, Brahma DK. A case report on clotrimazole-induced localized erythema. Cureus. 2024 Jan 21;16(1):e52645. doi:10.7759/cureus.52645.
12. Meghana V, Ravindran D, Pasupathy U. Untangling a case of dapsone-induced acute liver injury. Journal of Family Medicine and Primary Care. 2025;14(1):498-501. doi:10.4103/jfmpc.jfmpc_885_24.
13. Kolupoti A, Chakraborty A, Shahistha K. ADR in journals: are they translated into regulatory frameworks? Current Drug Safety. 2022;17(1):34-39. doi:10.2174/1574886316666210609115148.
14. Choudhary NS, Kotecha H, Saraf N, Gautam D, Saigal S. Terbinafine induced liver injury: a case report. Journal of Clinical and Experimental Hepatology. 2014;4(3):264-265. doi:10.1016/j.jceh.2014.03.040.
15. Kumar PS, Vidya R, Tabassum, Jageer M. Anti-tuberculosis treatment induced hepatotoxicity: a case report. Electronic Journal of the International Federation of

Clinical Chemistry and Laboratory Medicine. 2020;31(3):242-247.
16. Dhingra M, Ghosh A. Drug-induced liver injury following prolonged use of nitrofurantoin. Annals of African Medicine. 2024;23(3):515-517.
17. Alkofide H, Almalag HM, Alromaih M, Alotaibi L, Altuwaijri N, Al Aloola N, et al. Pharmacovigilance practices by healthcare providers in oncology: a cross-sectional study. Pharmaceuticals. 2024;17(6):683. doi:10.3390/ph17060683.
18. Valinciute A, Gerbutaviciene RJ, Paukstaitiene R, Kubiliene L. Pharmacovigilance and adverse drug reaction reporting among the general public in Lithuania: a cross-sectional study. Healthcare. 2023;11(8):1133. doi:10.3390/healthcare11081133.
19. Sharma S, Sharma A, Surya M, Guleria S, Bansal N. Clinician's dilemma: naproxen-induced liver injury. Indian Journal of Pathology and Microbiology. 2023;66(1):168-170. doi:10.4103/ijpm.ijpm_766_21.
20. Gupta PK, Kaur J, Devi G, Chaudhary S, Maria J. The pattern of adverse drug reaction reporting at a regional pharmacovigilance center in North India: a retrospective observational study. Cureus. 2025 Sep 8;17(9):e91812. doi:10.7759/cureus.91812.
21. Kushwah A, Tomar APS, Shinde M, Acharya P. Carbamazepine-induced aplastic anemia: A rare reported adverse drug reaction. Journal of Family Medicine and Primary Care 2026;15(1):[pages pending]. doi:[DOI not available in provided text].
22. Khivsara A, Raj JP, Hegde D, Rao M. Topiramate-induced acute liver injury: A rare adverse effect. Indian Journal of Psychiatry 2017;59(3):374-376. doi:10.4103/psychiatry.IndianJPsychiatry_239_16.
23. Babu BS, Fernandes CZ, Bhat B. Acitretin induced primary hypothyroidism in Darier's disease: A rare case report. Indian Journal of Pharmacology 2024;56(3):220-222. doi:10.4103/ijp.ijp_250_23.
24. Haji AG, Sharma S, Vijaykumar DK, Paul J. Transfusion related acute lung injury presenting with acute dyspnoea: a case report. Journal of Medical Case Reports 2008;2:336. doi:10.1186/1752-1947-2-336.
25. Meghana V, Ravindran D, Pasupathy U. *Untangling a case of dapsone-induced acute liver injury*. J Fam Med Prim Care. 2025. doi:10.4103/jfmpc.jfmpc_885_24.

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