Review Article

Spontaneous Reporting Schemes for Drug Adverse Reactions - A Review

Ramdeni Kavya[1]*, Dr. K. Bhavyasri[2], Mogili Sumakanth[3], Dr. Venkatesh Kalapala[4]
*1. Research Student Department of Pharmaceutical Analysis, RBVRR Women's College of Pharmacy, Hyderabad-500027, India.
2. Associate Professor, Department of Pharmaceutical Analysis, RBVRR Women's College of Pharmacy, Hyderabad-500027, India.
3. Professor and Principal Department of Pharmaceutical Chemistry, RBVRR Women's College of Pharmacy, Barkatpura, Hyderabad-500027, India.
4 Scientist, Aurobindo Pharma Ltd (R&D Centre), Bachupally, Hyderabad-500090, India.
***Corresponding author's E-mail:** bhavya.khagga@gmail.com

Received: 03-06-2025; **Revised:** 26-08-2025; **Accepted:** 02-09-2025; **Published online:** 20-09-2025.

ABSTRACT

Health professionals play an essential part in encouraging voluntary reporting of adverse drug reactions (ADRs), which is an effective way to ensure post-marketing surveillance of pharmaceuticals. But there are serious problems with under reporting pharmacovigilance system, which creates concerns about public health. Reporting ADRs is a critical patient safety concern. ADRs remain to remain a problem in contemporary medicine, particularly despite rising multimorbidity, aging populations, and more sophisticated therapies. While examining issues with ADR management, reporting, diagnosis, and prevention in modern clinical practice, this article provides an overview of some of most of the important information relating to them. ADR reporting has increased in importance as part of the hospital monitoring and evaluation of the procedures.

Keywords: Pharmacovigilance, Adverse Drug Reactions reporting systems, clinical pharmacology, adverse reactions.

INTRODUCTION

Drugs are a major part of managing sickness. Nevertheless, even when prescribed according to a therapeutic dosage plan, medications can have unwanted side effects that endanger patients' lives. ADRs are undesired side effects that might happen during a drug's pharmacological action. These side effects are known as such. ADR has an important, irreversible impact on society and the economy. In accordance with projections, antimicrobial drug resistance is a major cause of illness and mortality in every age category and hospital admissions.

Drugs are examined for safety via a series of clinical trials before being approved for sale to diminish the incidence of adverse reactions to drugs. However, because of the stringent inclusion along with exclusion criteria as well as time constraints, the safety findings resulting from these clinical studies are compiled under closely regulated circumstances and could be biased. For instance, the implications of these medications are frequently not investigated in some demographic segments, such as extremely old people, pregnant women, and children under the age of five, leading to results that might not be entirely generalizable. The cornerstone of pharmacovigilance, which aids in addressing safety concerns following drug delivery, is spontaneous reporting of ADRs. As opposed to clinical trials, where some participants are excluded as well as the safety of the treatment is investigated over a short period of time, the study offers information from actual clinical practice[1,3]

Healthcare professionals voluntarily provide case reports of ADRs; pharmaceutical companies or the consumer provide data to national pharmacovigilance centres around for the evaluation to lessen the impact of ADRs on society. This is a low-cost, flexible, and highly effective method of information gathering. More than 200 reported cases of adverse effects per 1,000,000 population is recommended by the World Health Organization's (WHO) for a system of pharmacovigilance to properly monitor ADRs of both newly launched and existing medications.

Any unanticipated, unintentional, undesirable, or overwhelming response to a medication that: Demands stopping the medication, it involves modifying the medication regimen, must be admitted to the hospital, and prolongs the duration of hospital stay, treatment that is supportive is required, profoundly impacts prognosis, significantly impedes diagnosis, Adversely impacts the prognosis and cause injury, impairment, or death, either temporary or permanent.[4,7]

MATERIALS AND METHODS

Schemes for reporting adverse drug reactions that arise spontaneously:

When compared with small molecule medications, biological drugs also referred to as biologics may have distinct safety profiles since they originate from living things. The entire drug usage system of an organization should include extensive ADR monitoring and reporting. Adverse Drug Reactions reporting as well as monitoring should have the following components:

The program ought to provide:

A continuous and concurrent (during medication therapy) surveillance system that relies on patients, doctors, nurses, and pharmacists reporting suspected ADRs, A prospective surveillance strategy (prior to drug therapy) for patients or high-risk medications that carry a high risk of adverse drug reactions and a system of concurrent surveillance to keep an eye on orders that are changing. Using "tracer"

medications to address frequent adverse drug reactions (such as prescriptions for quick dosages for antihistamines, epinephrine, and even corticosteroids) is one example of altering an order. Other examples include abruptly stopping or lowering a medication's dosage, or using stat orders to measure therapeutic drug levels in a lab.[8,11]

Concerning possible adverse drug reactions, prescribers, caregivers, as well as patients should be informed, Complete collection and analysis of data, including the patient's name, medical along with medication histories, the description for the suspected ADR, the event's temporal sequence, any necessary corrective action, and any aftereffects, needs to be reported at the pharmacy regarding suspected ADRs, Patients at high risk ought to be recognized and treated differently. Patients who are considered high risk may include individuals who are getting many medications, elderly, or pediatric patients, or those who have organ failure, It is important to identify and closely monitor the usage of medications that are "high-risk" for ADRs. A few examples are warfarin, heparin, phenytoin, theophylline, amphotericin, antineoplastic, corticosteroids, and aminoglycoside, It is necessary to devise a system for classifying ADRs according to severity, The patient's medical records ought to include a description of each potential adverse drug reaction together with the results of the incident, The FDA (Food and Drug Administration) or the drug makers (or both) should be notified of any serious or unexpected adverse drug reactions, It is recommended that a specific interdisciplinary group, such as the pharmacy and therapeutics committee, study and assess each and every ADR report, Staff personnel who work with health care professionals should be given access to ADR-report information and instruction. Avoiding ADRs and providing patients with appropriate and efficient care when an ADR occurs are good subjects for medical staff education, Educational programs might take the form of multidisciplinary assessments of drug use evaluations, morning "report" talks, "grand rounds" presentations, and treatment algorithms. Patient privacy needs to be maintained, When feasible, a pharmacy-coordinated Adverse Drug Reaction a team or committee made up of a doctor, nurse, administrator, quality improvement leader, and pharmacist is advised, The group should be reorganized by adopting an organizational definition, raising awareness of the effects of ADRs, setting up procedures for locating and reporting ADRs, examining ADR trends or patterns, and creating treatments that are both preventive and remedial, Therefore, essential to continuously assess patient outcomes and ADR patterns and The organization's on-going quality improvement initiatives should consider the results of an ADR monitoring as well as reporting program.[12,14]

The pharmacist's role in ADR reporting and monitoring: Pharmacists must to take the initiative in creating, maintaining, and continuously assessing ADR programs. They must to get official approval or endorsement for these programs from the organization's administration and relevant committees. Where appropriate, the medical record department, risk managers, nursing staff, medical personnel, and quality improvement staff should all have contributed to the program's design.

The following should be facilitated by the pharmacist: Analysis of every recorded ADR, Drugs and patients who are more likely to be involved in ADRs are identified, The creation of guidelines and protocols for the scheme of ADR monitoring and reporting, An explanation of the roles and interactions that risk managers, doctors, nurses, pharmacists, along with other health professionals have in the ADR program, Programs for education ought to start in the early, As with traditional medications, spontaneous reporting programs are necessary for tracking adverse events to biopharmaceuticals, In these programs, individuals, healthcare providers, and occasionally even manufacturers voluntarily notify regulatory bodies such as the FDA about any possible negative effects, This information facilitates the identification of possible safety issues and enables additional research and, if required, action, Biological medications, also referred to as biologics, originate from living things and, in contrast to small molecule medications, may have different safety profiles, and As a result, it is critical to have reliable spontaneous reporting mechanisms in place to record any unfavourable incidents related to their use.[15]

As with other pharmaceuticals, spontaneous reporting of biopharmaceutical adverse effects is an essential component of pharmacovigilance. This is how it usually operates:

Healthcare Practitioners:

In identifying and disclosing adverse responses, physicians, nurses, and pharmacists are crucial. It is suggested for them to notify regulatory bodies or the drug maker of any unexpected or severe adverse effects they witness in patients receiving biopharmaceuticals.

In patients:

Adverse reaction reports from patients themselves can be sent to regulatory bodies directly or with their healthcare practitioners. Regarding the real-life experiences of biopharmaceutical users, patient-reported data can offer important insights.[16]

Authorities Regulatory:

The safety of bio drugs is regulated by organizations like the European Medicines Agency (EMA) and the U.S. FDA. They depend on patients and medical professionals to report adverse events. These organizations gather and examine this information to spot potential safety issues and, if required, implement the relevant regulations.

Drug Producers:

As part of the post-marketing surveillance obligations, manufacturers are required to gather and submit adverse effect data to regulatory bodies. Additionally, they haveprocedures in place to keep an eye on and investigate

complaints of negative reactions from patients and medical professionals.[17,19]

Continuous Observation:

The process of spontaneous reporting is continuous. Even when biopharmaceuticals are licensed and put on the market, regulatory bodies continue to keep an eye on their safety. To guarantee patient safety, they evaluate the data to spot trends, flag possible safety concerns, and offer advice or enforce rules.[20]

Because they aid in identifying adverse reactions that could not have been seen for clinical trials due to inadequate sample sizes or limited observation periods, spontaneous reporting programs are crucial. These programs improve our knowledge of the safety characteristics of biological medicines through the gradual collection of real-world data, resulting in patient treatments that are safer and more efficient.[21,22]

RESULTS AND DISCUSSION

Drug interaction types include:

Drug-drug interactions are typically the first thing that spring to mind. Drugs and food (drug-food interactions), drugs and herbs or medicinal plants (drug-plant interactions), and drugs and diseases (drug-disease interactions) can also interact.

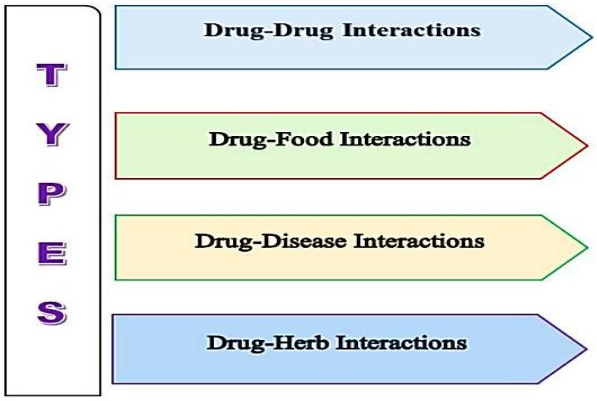


Figure 1: Drug Interaction types

The working mechanism of drug-herb interactions:

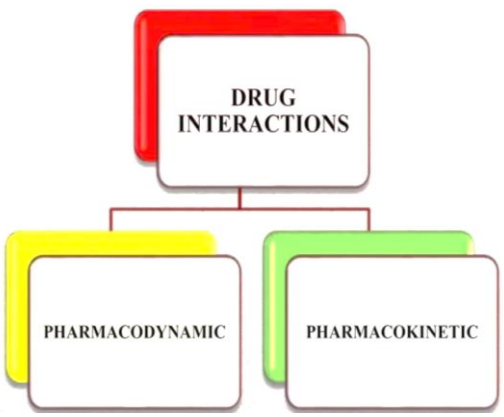


Figure 2: Drug-herb interactions

Herb-drug interactions involve the following mechanisms. Types of drug interactions are Pharmacodynamic and Pharmacokinetic

Pharmacodynamic:

In pharmacodynamic interactions, the existence of different drug acting at the exact same biochemical processes. or a molecular the site, with a similar target organ, or on different targets but one that is linked to a prevalent physiological effect of another drug's by producing additive, synergistic, or antagonistic effects, modifies the effect of the first drug.[23,25]

Additive outcome:

A situation where the combined effects of two drugs or activities are equal to the sum of their separate effects.

Synergistic outcome: Interactions that result in a bigger effect than the sum of an individual's effects of two or more pharmacological agents, organizations, factors, or substances.

Adversary Impact: Interaction between two or more pharmacological compounds that reduce or lessen the effect of any among them of them on cells in living condition or tissues.

The pharmacokinetic:

Pharmacokinetic interactions refer to the ways in which a medicine affects the concentration of another substance in the body. Pharmacokinetic interactions can have an impact on several characteristics, including as a drug's volume of distribution, clearance, half-life, peak level, and bioavailability. Such alterations may result in modifications to the plasma concentration of medications, which may raise the possibility of adverse effects or reduce the effectiveness of one or more medications. Because the interacting medications frequently have unrelated activities, pharmacokinetic interactions between them are more complex and challenging to anticipate.

- Interactions involving pharmacokinetics include: Absorption, Distribution, Metabolism and Excretion.

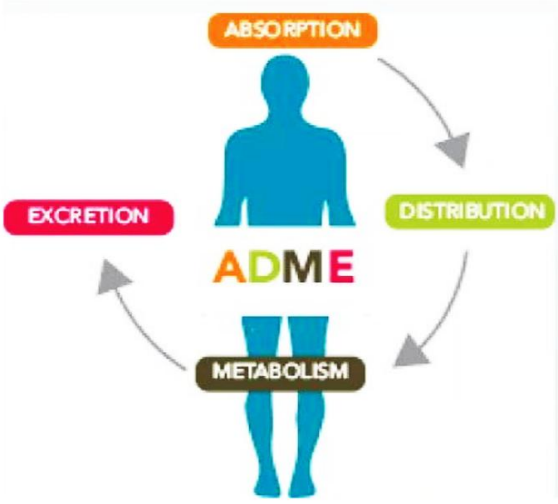


Figure 3: Pharmacokinetic interactions

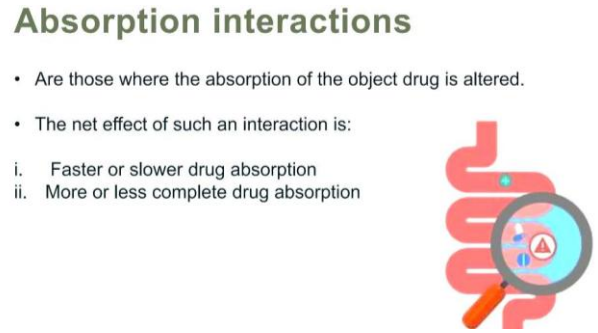


Figure 4: Absorption interactions

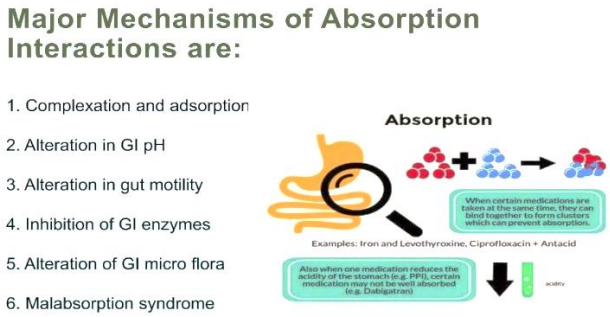
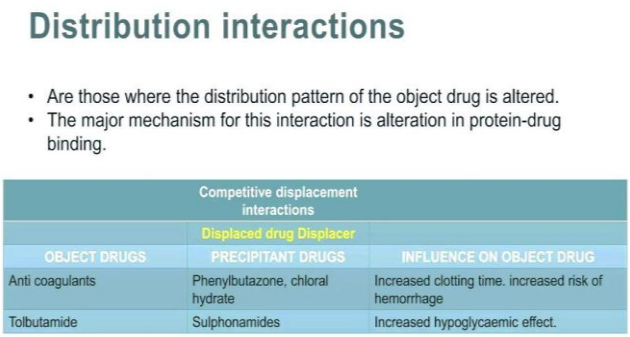


Figure 5: Mechanism of Absorption interactions



Competitive displacement interactions		
	Displaced drug Displacer	
OBJECT DRUGS	PRECIPITANT DRUGS	INFLUENCE ON OBJECT DRUG
Anti coagulants	Phenylbutazone, chloral hydrate	Increased clotting time. increased risk of hemorrhage
Tolbutamide	Sulphonamides	Increased hypoglycaemic effect.

Table 1: Distribution interactions

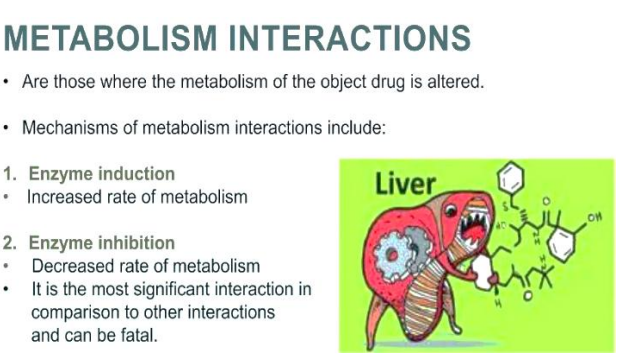
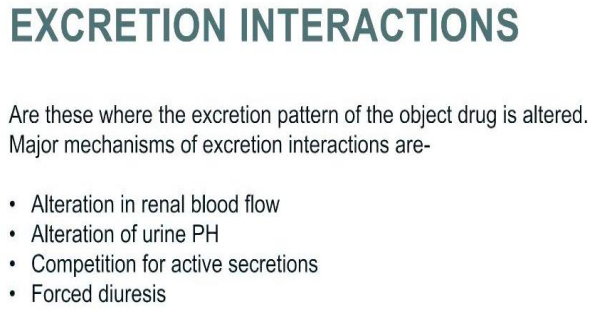


Figure 6: Metabolism interactions



Pharmacodynamic and Pharmacokinetic Interaction

The pharmacodynamic and pharmacokinetic interactions are of two types and are: Bio Drug-Drug Interactions and Bio Drug-Food Interactions.[26,28]

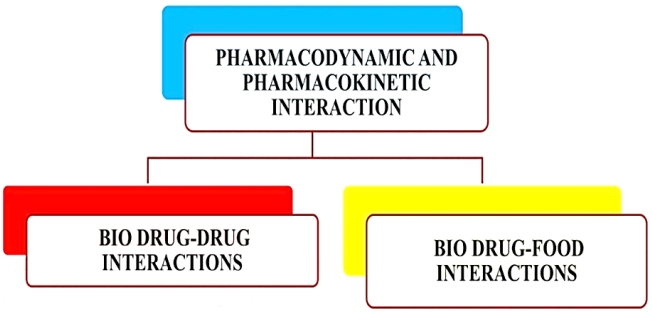


Figure 7: Pharmacodynamics and Pharmacokinetic Interaction

Drug-Drug Interactions in Bio:

When one drug interacts or interfering with another, this is known as a drug-drug interaction. This may result in unanticipated adverse effects or change how any one or both at the medications function in the body.

Figure 8: Drug-Drug Interactions

Examples:

Case study 1: Prolonged bleeding period caused by a combination of aspirin and warfarin.

Case study 2: Antibiotic + Blood thinner = Antagonism = Less impact.

Case study 3: Additive action: Codeine plus Paracetamol increases the analgesic effect.

Case study 4: The combination of tranquilizers and antiemetic drugs may cause breathing difficulties or unknown side effects.

Food and Bio drug Interactions:

A drug-food interaction occurs when the substances in a medication you are taking are affected by the food you eat, making the medication less effective than it should be.

Examples:

Case study 1: Meals high in calcium and acetaminophen can reduce the absorption of drugs.

Case study 2: Aspirin plus milk = unpleasant stomach.

Case study 3: Alcohol and Oxycodone = Asthma and Coma.

Case study 4: Fast heartbeat: caffeine and food.

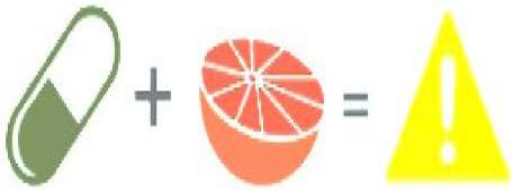


Figure 9: Food-Drug Interactions

INFLUENCE OF FOOD ON DRUG INTERACTION

- Food effects the rate and extent of absorption of drugs from the GI tract.

Example: Many anti biotics should be given at least 1hr before or 2hr after meals to achieve Optimal absorption.

- The type of food may be important with regard to the absorption of concurrently administered Drugs.

Example: Dietary items such as milk and other dairy products that contain calcium may decrease the absorption of tetracycline and fluoroquinolone derivatives.

- Diet also may influence urinary pH values.

Typical other kinds of adverse reactions include:

Biologics sometimes referred to as bio medicines, can cause a variety of unintended reactions or adverse effects.

These medications can cause adverse responses because they have been derived from living things and frequently have complicated structures.

The following are a few typical adverse reaction types linked to biopharmaceuticals:

Reactions to Infusion/Infusion: A lot of bio medicines are given by injections or an infusion, which can cause instant side effects like a chills, fever, rash, or trouble breathing.

Immunogenicity: Antibodies against bio-drugs may form because of an immunological response triggered by the drug. This may have negative consequences and lower the drug's effectiveness.

Infections: Certain biologics have the potential to weaken the immune system, leaving patients more vulnerable to infections.

Organ Damage: Certain organs or systems may be impacted by biopharmaceuticals. Certain ones, for instance, may result in cardiac issues or liver poisoning.

Blood Conditions: Some bio medicines might cause irregular coagulation or changes in blood cell counts and also causes skin reactions.

Gastrointestinal Conditions: It is possible to witness vomiting, diarrhoea, nausea, or other digestive issues.

Symptoms related to the nervous system: Certain bio medicines have the potential to cause headaches, vertigo, or neurological problems.

Risk of Cancer: Rarely, biopharmaceuticals have been linked to a higher risk of developing certain cancers.

It is crucial to remember that the precise side effects differ based on the kind of bio-drug and unique patient characteristics. When patients are prescribed bio medicines, medical personnel keep a careful eye on them and inform them of any possible negative effects. It is recommended that patients rapidly report any unexpected symptoms to their healthcare practitioners to appropriately treat and reduce adverse effects.

Healthcare professionals carefully weigh the advantages and disadvantages of these medications for each patient, keeping a close eye on them during therapy to reduce side effects.[29,31]

Challenges in ensuring the safety of natural medicines: It is also acknowledged that several aspects, like the plant material's geographical origin, processing methods, administration route, and compatibility with some other drugs, confound the determination of safety.

Exterior challenges: The three primary issues with external quality are adulteration, misidentification, and contamination. Patients may suffer significant injury because of these issues.

Interior challenges: The phytochemicals in herbal remedies that are pharmacologically active are what produce any negative health consequences. While external quality concerns are intricate, internal ones might provide much greater difficulties.

Challenges in Monitoring Herbal Medicines for Safety: Many obstacles frequently arise during the establishment and execution of regulations pertaining to traditional or herbal remedies in various regions of the world. Regulatory status, safety and efficacy assessment, quality control, safety monitoring, and insufficient or insufficient awareness about traditional, complementary/alternative, as well as herbal remedies within national drug regulatory authorities are challenges that are frequently faced and shared by many countries.

Challenge 1: Difficulties with the Regulatory Situation of Herbal Medicines

Challenge 2: Difficulties in Evaluating Safety and Effectiveness

Challenge 3: Obstacles in Herbal Medicines' Quality Control

Challenge 4: Difficulties in Herbal Medicine Safety Monitoring.

CONCLUSION

As with traditional medications, spontaneous reporting programs are essential for tracking adverse events to biopharmaceuticals. In these programs, individuals, healthcare providers, and occasionally even manufacturers voluntarily notify regulatory bodies such as the FDA about any possible bad effects. This information facilitates the identification of any safety issues and enables additional research and, if required, action. As a result, it is critical to

have reliable spontaneous reporting mechanisms in place to record any unfavourable incidents related to their use.

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

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

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