

**A REVIEW ON ADVERSE DRUG REACTION****Neha Pharate<sup>1\*</sup>, Sushama Vidhate<sup>2</sup>, Monika Ovol<sup>3</sup> and Payal Kadus<sup>4</sup>**

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**ABSTRACT**

During the post-marketing phase of a drug's life cycle, pharmacovigilance is a practice aimed at monitoring drug safety in real-world situations and capturing adverse drug occurrences. Underreporting of adverse responses, on the other hand, is a major source of concern and a threat to pharmacovigilance systems. The current paper examines the key roadblocks to spontaneous reporting of adverse drug reactions (ADRs) in India, as well as potential alternatives. The biggest hurdles to ADR reporting, according to existing scientific research, include a lack of information and awareness among health professionals, physicians' attitudes regarding reporting, issues creating reporting systems in hospitals, and insufficient training to recognize ADRs. Pharmacovigilance also known as drug safety is defined as the

science and activities relating to the collection, detection, assessment, monitoring, and prevention of adverse effects or any other drug related problems. The occurrence of ADR is a price the patient pays for the benefits increasing health care cost, modern medicine. **Objective:-** To study detailed information on Adverse Drug Reaction (ADR).

**KEYWORD:-** Adverse drug Reaction it's type, mechanism, factor predisposing, affecting factor, ADR monitoring, management, detection, prevention etc.

**BACKAROUND**

Medicine-related adverse events, often known as adverse drug reactions (ADRs), are undesirable side effects that occur as a result of taking a medication. The World Health Organization (WHO) defines adverse drug reactions (ADRs) as "a response to a treatment that is noxious and unintendedly employed in man to treat". ADRs can occur as a result of a preventable drug error, such as a side effect after medicine delivery, or an unforeseeable error,

such as an allergic reaction. ADRs could have a significant impact on patients' quality of life while also putting a strain on the healthcare system,<sup>[1]</sup> ADRs are one of the leading causes of morbidity and mortality worldwide, and they will continue to be a major public health concern as medication becomes more sophisticated to treat numerous diseases in an ageing society. According to a recent study, ADRs account for about 3.5 percent of hospital admissions. Furthermore, ADRs were responsible for around 197,000 deaths in Europe each year.<sup>[2]</sup> Adverse medication reactions are frequently complicated and multifactorial in origin. Dose/drug-related, allergic, and idiosyncratic reactions are the occurrences are linked to prescription errors. According to a major retrospective case review research, medication mistakes in general practice occur at a rate of 5% in England. With the adoption of technology in the healthcare system, computerized prescribing systems have a variety of medication mistake rates that might result in moderate or severe adverse drug events. Off label use of unusual drugs in children and patients is another cause of adverse outcomes. Off-label prescribing is the practice of agencies such as the Therapeutic Goods Administration in Australia or the Food and Drug Administration in the United States prescribing pharmaceuticals for non- approved reasons.<sup>[3,4]</sup>

## INTRODUCTION

ADRs (adverse drug reactions) are significantly more common than one might expect After heart disease, cancer, and stroke, ADRs are thought to be the fourth biggest cause of mortality in the United States and Canada. Furthermore, ADRs are thought to be the world's sixth leading cause of death. According to a recent meta-analysis of prospective ADR research, over 180,000 Americans will die from ADRs in 2008, and over one million will be wounded. Although these figures are debatable, and it is impossible to estimate the true prevalence of ADRs, there is no doubt that ADRs have a considerable impact on both the healthcare and drug research industries. The monetary losses to society as a result of these ADRs are also difficult to quantify. The drug's ADR is recognized in clinical trials, but the reactions that occur after a lengthy period of time in a specific group go unreported. As a result, pharmacovigilance (PV) is an activity that keeps a constant eye on a medicine over its entire life cycle. In India, the PV activity is regulated by the I PC and NCC through the CDSCO. Then, in 2010, a Pharmacovigilance program was proposed in India. Anyone can report an ADR by filling out a suspected ADR reporting form, which is available online or offline, and submitting it to the nearest ADR reporting Centre in the appropriate language. The reported ADRs are then gathered and analysed via vigil software at the centers. Signals are detected and reported to

CDSCO and WHO by the centers.<sup>[5,6]</sup>

### Definition

Adverse drug reaction According to WHO, an adverse drug reaction defined as, "Any response to a drug which is noxious unwanted effect of drug doses used in human for prophylaxis, diagnosis and therapy". For example, (when drug metabolism is temporarily inhibited by a disorder or another drug.<sup>[7]</sup>

### Classification of adverse drug reaction

Adverse medication reactions are classified according to their severity. ADRs have traditionally been divided into two categories:

Type A reactions, which are 'dose & dependent' and predicted based on the drug's pharmacology. are also known as enhanced reactions.

Type B reactions, often known as weird reactions, are distinctive and unpredictable in terms of pharmacology.<sup>[8]</sup>

Class	Description	Example
Type A (Augmented)	ADRs are related to the pharmacological properties of the medicine. Dose related. The ADRs are attributed to genetic variations e.g. (hepatic and glomerular disorder.	Nephrotoxicity caused by aminoglycosides. Anticholinergic effect of tricyclic antidepressants.
Type B (Bizarre)	Adverse reaction unforeseen and unpredictable. ADRs have less or no relationship with the dosage.	Penicillin induced urticaria.
Type C (Chronic)	The cumulative toxic effect of drug used overtime. Chronic in nature and include the adaptive change and the withdrawal effects.	Hyperadrenocorticism in chronic corticosteroid use.
Type D (Delayed)	Reaction that appears after sometime of treatment Time-related.	Secondary cancers caused by the use of Alkylating agents. E.g., Cyclophosphamide
Type E (End of use)	ADRs occurring on sudden termination of treatment	Convulsion as a result of stopping anticonvulsants
Failure of therapy (Failure)		

### Adverse drug reactions are affected by the following factors

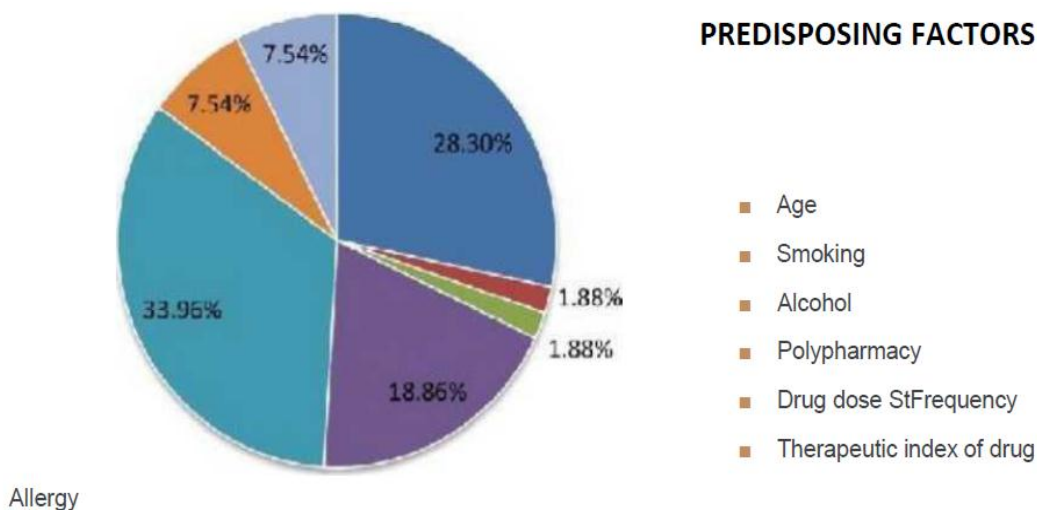
- Age
- Gender
- Genetic effects
- Concurrent disorders (renal, hepatic, and cardiac)
- Adverse drug reactions in the past
- Dosing regimen compliance
- Total number of medications
- Miscellaneous (diet, smoking, environmental exposure)

Children under the age of 18 may be at danger of developing Reye's syndrome if administered acetylsalicylic acid (aspirin) while sick with chickenpox or influenza, because their capacity to metabolize medicines is usually not completely developed.

### Elderly

1. ADRs, such as drug interactions, are a common reason for hospitalization in the elderly.
2. Causes of ADRs in the elderly: multiple medications taken at the same time; decreased drug ADME activity due to age
3. Malnutrition and dehydration, which are frequent in the elderly, aggravate these diseases.<sup>[15]</sup>

### Predisposing factors



## Adverse Reaction Reporting Form

For Voluntary Reporting of Adverse Reaction by Healthcare Professionals

## INDIAN PHARMACOPOEIA COMMISSION

(National Commission on Drugs, Ministry of Health &amp; Family Welfare, Government of India)

www.pmc.in

FOR AMC/NCC USE ONLY

AMC Report No.

Worldwide Unique No.

## A. PATIENT INFORMATION

1. Patient Name	2. Age / Sex	3. Date of Birth
4. Address	5. Contact No.	6. Referring Doctor

## B. SUSPECTED ADVERSE REACTION

7. Date of Onset	8. Duration
9. Site of Reaction	10. Severity

11. Medical History / Pre-existing Conditions (e.g., liver/kidney disease, pregnancy, alcohol use, etc.)

## 12. Suspected Cause of Reaction (Yes/No)

- ☐ Life threatening ☐ Required hospitalization ☐ Permanent damage ☐ Other (specify)

## 13. Outcome

- ☐ Fatal ☐ Recovered with sequelae ☐ Unknown

## C. SUSPECTED MEDICATION(S)

Sl. No.	Medicine Name	Dose	Frequency	Duration	Route	Manufacturer	Batch No.	Expiry Date	Reaction
1									
2									
3									
4									

Sl. No.	Reaction	Onset	Duration	Severity	Outcome	Reappeared	Reintroduced
1							
2							
3							
4							

14. Signature of Reporting Person (Name, Designation, Institution)

## D. REPORTER DETAILS

15. Name and Professional Address

Name: \_\_\_\_\_ E-mail: \_\_\_\_\_  
 Designation: \_\_\_\_\_  
 Institution: \_\_\_\_\_

## 16. Causality Assessment

Additional Information

X = Jatech report ; &lt;id/mm.VAY&gt;

## Causality assessment

**Confidentiality:** The patient's identity is held in strict confidence and protected to the fullest extent possible. It is not expected that the patient's identity will be disclosed to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer of the product caused or contributed to the reaction.

## Reatment



## ADR prevention

1. Avoid using drugs in any way that isn't necessary.
2. Adequate dosing, route, and frequency of drug administration.
3. Obtain a history of drug reactions and consider it.
4. Investigate h/o allergic diseases and proceed with caution.
5. Make sure there's no chance of a drug interaction.
6. Use proper medication administration techniques.
7. Conduct a thorough laboratory investigation.
8. Keep in mind that certain foods, alcohol, and even household chemicals can interact with one another.<sup>[32]</sup>

## CONCLUSIONS

I studied about Adverse Drug Reaction and found that the most causes of ADR's were drug related allergies. Idiosyncratic adverse drug reaction not very commonly reported. This review has identified knowledge of mechanism of ADR's, healthcare professionals, their attitude and perception with facility level.

The detection, management, and reporting of ADR's have all been explored in this article we have talked about how current technology is changing, how ADR is prevented, predicted, identified, and managed and how we are still trying to enhance these processes with new technology.

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