

## STUDY ON MONITORING AND REPORTING OF ADRs OBSERVED IN A TERTIARY CARE HOSPITAL WITH CONTRAST TOWARDS ANALYSIS OF DRUG SAFETY ALERTS ISSUED BY REGULATORY AUTHORITIES

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### ABSTRACT

**Background:** Pharmacovigilance is an important area of healthcare that focuses on monitoring and evaluating the safety and efficacy of pharmacological drugs. Pharmacovigilance seeks to detect and avoid any possible dangers connected with drugs by collecting, analyzing, and interpreting adverse event data in a systematic manner. Regulatory authorities and organizations are accountable for the effective drug regulation necessary to assure the safety, effectiveness, and quality of pharmaceuticals, as well as the accuracy and appropriateness of drug information provided to the public. **Aim:** This study aims to evaluate the extent to which ADR monitoring and reporting practices in a tertiary care hospital align with the drug safety alerts issued by regulatory authorities, which can have significant implications for patient safety and healthcare outcomes. **Methods:** A Prospective and observational study was conducted at a tertiary care hospital over a period of 3 months (April 2023-june 2023). All patients visiting the Hospital over the age of 18 years, experiencing an ADR and willing to give consent, were enrolled in the study. Patients fulfilling the inclusion and exclusion criteria were considered. **Results and Discussion:** Out of the 120 Patients, 22 ADRs were collected and the total incidence of ADRs is 18.3%. Majority of ADRs were occurred in the Age group of (>58 years) i.e., Group-V. In this group 36.36% ADR were observed. As per causality assessment, 14 ADRs were probable (63.6%). As per the severity assessment Scale 12 ADRs reported were Mild which contributed to 54.5% of total ADRs. Most of the management of the ADRs is done by withdrawing of drug i.e. by 81.8% and majority of patients were recovered. From this study, we found 5 common drugs related ADRs which are already issued as Drug safety alerts by Indian Pharmacopoeia Commission (IPC). **Conclusion:** Reporting adverse drugs reactions is crucial to protecting patient safety and enhancing overall healthcare quality. Healthcare practitioners, regulatory agencies, and pharmaceutical firms can obtain vital information about the safety profile of medications and make educated decisions about their usage if adverse drug reactions are reported immediately and properly.

**KEYWORDS:** Adverse drug reactions, Drug safety alerts, Indian Pharmacopoeia commission, Health care practitioners.

### INTRODUCTION

The clinical and scientific field of drug safety and pharmacovigilance is still evolving. The World Health Organisation (WHO) defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem." Pharmacovigilance is essential in ensuring that physicians and patients have access to sufficient

information to make informed drug treatment decisions.<sup>[1][2]</sup> Pharmacovigilance is particularly concerned with ADRs, which are drug responses that are noxious and unintended, and which occur at doses normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.<sup>[3]</sup> On average, 6.7% of patients in India experience serious adverse drug reactions, and that percentage might reach 8% in rural South India.<sup>[4]</sup> ADRs cause between 0.7% to 3.4% of hospital admissions,

3.7% of hospital readmissions, and 1.3% of fatalities in South India.<sup>[5][6][7]</sup>

The cornerstone of drug safety monitoring in clinical practice is spontaneous (yellow card) reporting of ADRs, which is still the most popular and economical surveillance approach. It looks into causation, discovers previously unrecognized adverse events, and identifies risk variables that increase the likelihood of medication toxicity. It aids in facilitating risk-benefit assessments and comparisons within therapeutic categories in addition to recognizing medication safety issues.<sup>[8][9]</sup> In July 2010, the Ministry of Health and Family Welfare started the National Pharmacovigilance Programme (NPP), which is largely managed by CDSCO, New Delhi. The national coordinating centre will receive ADR reports gathered from the linked medical institutions. Causality testing will be done by the coordinating centre, and the findings will be uploaded into the pharmacovigilance programme. The consolidated ADR data will then be sent over the vigiflow software interface into the ADR database of the Uppsala Monitoring Centre, where signal processing will take place.<sup>[10][11]</sup>

PvPI also includes drug safety alerts so that patients, consumers, and healthcare professionals may keep a careful eye on any potential side effects when taking the

warning medication.<sup>[12]</sup> In the top ten nations under the WHO Programme for International Drug Monitoring, India is now the only nation with the greatest number of regional AMCs and one of the major contributors to adverse drug reactions (ADRs). All of these AMCs have strong connections to the global individual case safety report (ICSR) database of the WHO Programme for International Drug Monitoring, referred to as Vigibase, via their own ICSR management systems, referred to as Vigiflow.<sup>[13][14]</sup>

The present study was undertaken to (1) bring awareness among healthcare providers regarding advantages of documentation and reporting ADRs, (2) define the role of pharmacist, clinicians and nursing staff in ADR, (3) Identify ADRs in all the Departments of Hospital, (4) Reporting of ADRs (5) Identifying drug Safety Alerts.

## MATERIAL AND METHODS

The current Prospective and observational study was conducted at tertiary care hospital over a period of 3 months (April 2023-june 2023). All patients visiting the Hospital over the age of 18 years, experiencing an ADR and willing to give consent, were enrolled in the study. Patients fulfilling the inclusion and exclusion criteria were considered.

### Inclusion Criteria:

- All the patients above 18 years
- Patients with all genders
- Patients from in-patient department.
- Patients transferred from ICU to the general medicine ward are included.

### Exclusion criteria:

- Patients not willing to participate.
- Paediatric patients
- Patients in intensive care unit.
- Patients with psychiatric disorders.

**Study Methodology:** The type of side effects and other relevant data, including demographics, diagnoses, and treatments, were taken from the patient's medical records & the confidentiality of patients' data was maintained.

**Analysis:** Causality Assessment was performed by Naranjo Probability Assessment Scale and Hartwig Criteria was used for Severity Assessment. Data were represented in the form of tables & graphs using Microsoft Excel.

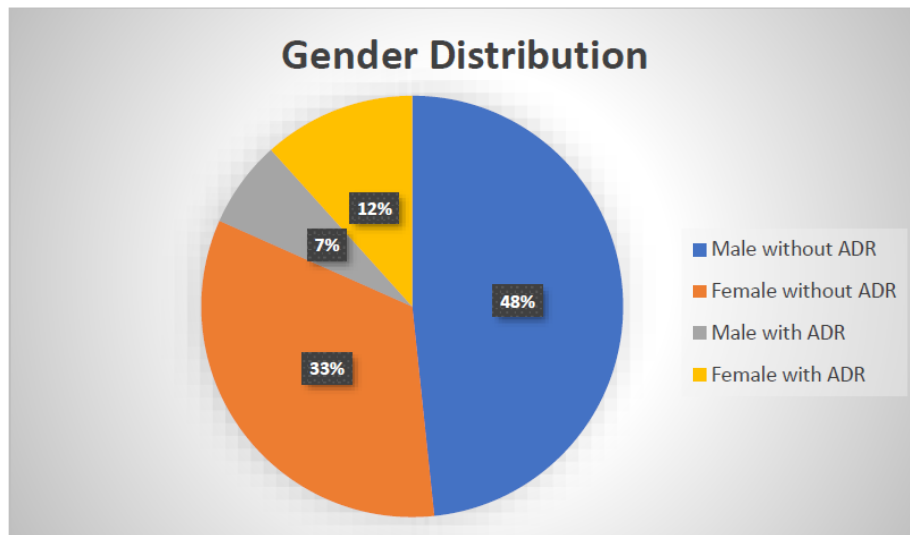
## RESULT

In this study, we have taken categorical data like age, causality, types of ADR, and Severity and expressed it in the form of percentages. A Total of 120 patients enrolled in our study. Data were collected from the inpatients of different departments, and the Patients were selected

based on the inclusion criteria, and the patients that didn't fit the selected criteria were excluded.

➤ **Gender Distribution in Study Population:** Out of the 120 Patients, 22 ADR were collected and the incidence of ADR is 18.3%. We have received a total of 66 Male Patients out of which 8 has shown the ADRs (6.6%) while the total number of female is 54 out of which 14 has shown the ADRs (11.6%). (as shown in Table-1 & Figure: 1)

Sex	With ADR	Without ADR	Total
Male	8	58	66
Female	14	40	54
<b>Total</b>	<b>22</b>	<b>98</b>	<b>120</b>



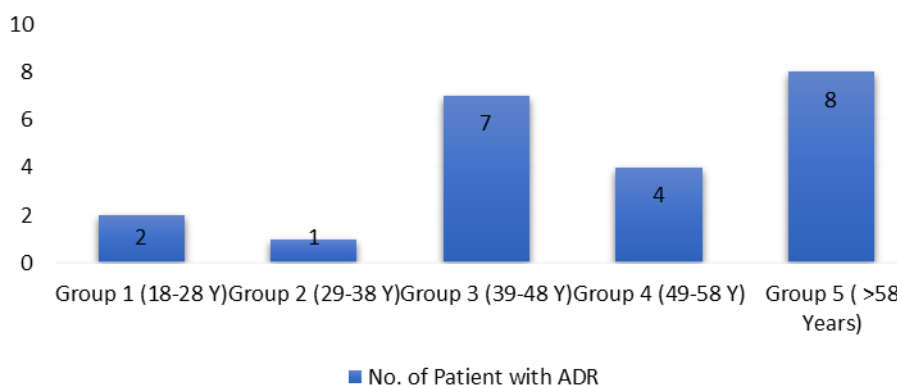
**Figure 1: Gender Distribution In Study Population.**

➤ **Age Wise Distribution of Patients with ADR:** Majority of ADRs were occurred in the Age group of (>58 years) i.e.; Group-V. In this group 8 (36.36%) ADR were observed. The patient between the age group I (18-28 years) shown 2 (9.0%) of ADRs and age group II (29-38 years) showed only 1

(4.54%) ADR and between the Age group III (39-48 years) showed 7 (31.84%) of ADRs. The Patients in Age group IV (49-58 years) shown 4(18.18%) of ADRs. Age related ADRs are shown in Table-2 & Figure 2.

Age Group	Total No. of Patients N = 120	No. of Patients with ADR (N= 22)
Group I (18-28 years)	12 (10%)	2 (9.0%)
Group II (29- 38 years)	15 (12.5 %)	1 (4.54%)
Group III (39-48 years)	35 (29.2 %)	7 (31.81%)
Group IV (49-58 years)	20 (16.7%)	4 (18.18%)
Group V ( More than 58)	38 (31.6%)	8 (36.36%)
<b>Total</b>	<b>120</b>	<b>22</b>

**Distribution of patients with ADR based on age group**

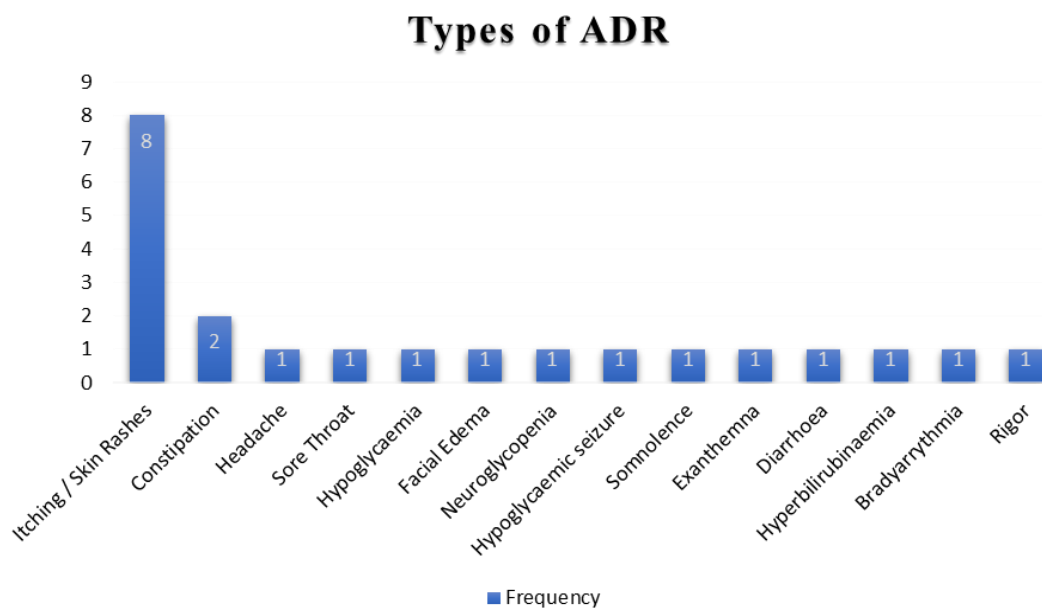


**Figure 2: Age wise Distribution of Patients.**

➤ **Types of ADR:** Most ADRs that occurred were mostly Mild, the most common ADR observed was Itching and skin rashes i.e. 8(36.8%) followed by Constipation i.e., 2(9.2%). Headache, Sore throat, Hypoglycaemia, Facial edema, Neuroglycopenia, hypoglycaemic Seizures, Somnolence, Exanthema,

Diarrhoea, Hyper bilirubinaemia, bradyarrhythmia, Rigor being only 1 each (4.5%). As shown in Table - 3 & Figure 3. This kind of ADR can be easily treated either by withdrawing the drug or replacing the drugs.

Types of ADR	Number	Percentage (n=22)
Itching / Skin rashes	8	36.8 %
Constipation	2	9.2 %
Headache	1	4.5 %
Sore Throat	1	4.5 %
Hypoglycaemia	1	4.5 %
Facial edema	1	4.5 %
Neuroglycopenia	1	4.5 %
Hypoglycaemic Seizures	1	4.5 %
Somnolence	1	4.5 %
Exanthema	1	4.5 %
Diarrhoea	1	4.5 %
Hyper bilirubinaemia	1	4.5 %
Bradyarrhythmia	1	4.5 %
Rigor	1	4.5 %



**Figure 3: Different types of ADR.**

➤ **Causality Assessment of ADR:** The Naranjo’s Causality Assessment scale was used to determine the causality of ADR’s. It shows that 14 ADRs were probable (63.6%) and 6 ADR were possible and

percentage is 27.2% and 2 ADR were definite i.e. 9.2%. The Assessment of ADR by Naranjo’s Scale is shown in Table 4 and figure 4.

Types	Number of ADR	Percentage (n=22)
Probable	14	63.6 %
Possible	6	27.2 %
Definite	2	9.2 %

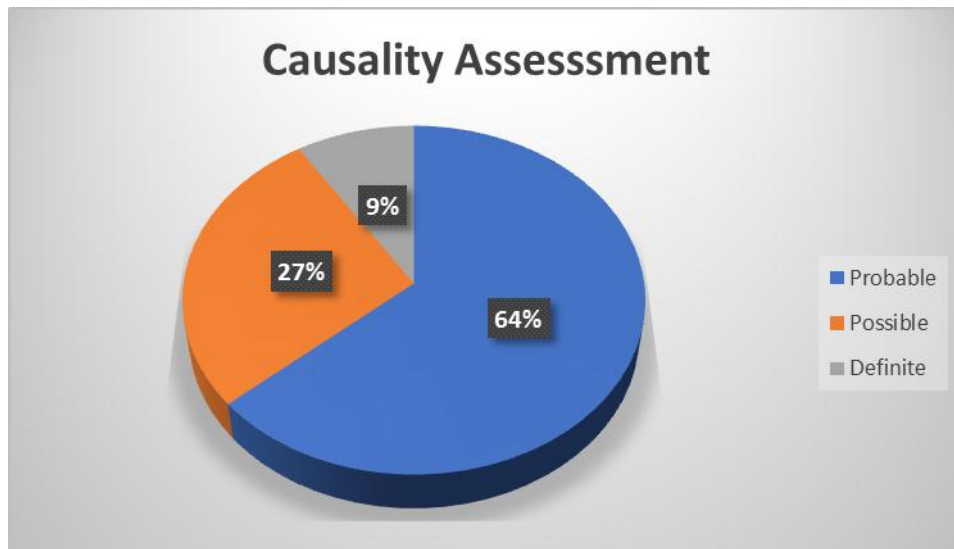


Figure 4: Pie chart Showing Causality Assessment.

➤ **Severity Assessment (Hartwig Severity Assessment Scale):** The Hartwig Severity Assessment Scale was used to determine the Severity of ADRs. As per the Assessment Scale 12 ADRs reported were Mild which contributed to

54.5% of total ADRs. The remaining 10 ADRs which were reported comes under Moderate i.e. 45.5%. There were no Severe ADRs reported in our study, as shown in table 5 & figure 5.

Severity	Number of ADR	Percentage (n=22)
Mild	12	54.5 %
Moderate	10	45.5 %
Severe	0	0 %

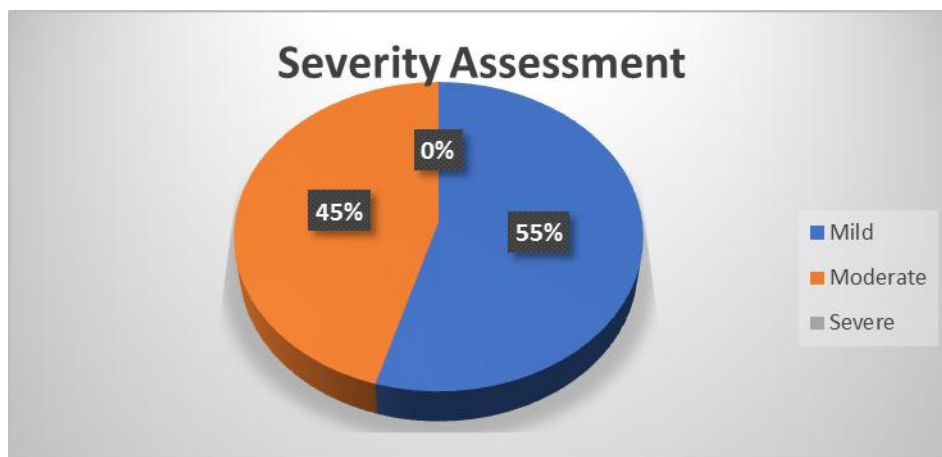


Figure 5: Pie chart Showing Severity of ADRs.

➤ **Drug Responsible for ADR:** The drugs which are showing the ADRs is shown in Table: 6.

S. No	Drug	ADR	Frequency	Percentage (n=22)
1	Pregabalin	Headache	1	4.5 %
2	Cetirizine	Sore Throat	1	4.5 %
3	Inj. Zonamax	Urticaria	1	4.5 %
4	Vildambic	Rigor	1	4.5 %
5	VOGS-Gm2	Hypoglycemia	1	4.5 %
6	Syp. Sucral	Constipation	1	4.5 %
7	Tab. Naxdom	Facial Edema	1	4.5 %
8	Inj. Taxim	Rashes	1	4.5 %

9	Tab. Gluconorm	Neuroglycopenia	1	4.5 %
10	Tab. Glycomet [GP-1]	Hypoglycaemic seizures	1	4.5 %
11	Aziwak [Azithromycin]	Rashes	1	4.5 %
12	Montek-BL [Montelukast]	Somnolence	1	4.5 %
13	Inj. Augmentin	Rashes	1	4.5 %
14	Inj. Monocef	Rashes	3	14.5 %
15	Inj. Clindamycin	Exanthema	1	4.5 %
16	LNZ/Linezolid	Diarrhoea	1	4.5 %
17	Inj. Azee [Azithromycin]	Itching	1	4.5 %
18	Inj. Diclofenac	Constipation	1	4.5 %
19	AKT-4 Kit	Hyperbilirubinemia	1	4.5 %
20	Met L3D[Metoprolol]	Bradyarrhythmia	1	4.5 %

➤ **Outcome and Management of ADRs:** This study shows that in most of the ADRs, management was shown by withdrawing the drug, i.e., 18 (81.8%), and the majority of patients recovered. The dose was reduced in 2 (9.2%) ADRs, and 1 (4.5%) of the ADRs remained unchanged and unknown. (See Table: 7 and Figure 7)

Management of ADR	Total	Percentage (n=22)
Drug Withdrawn	18	81.8 %
Drug Reduced	2	9.2 %
Drug Unchanged	1	4.5 %
Unknown	1	4.5 %

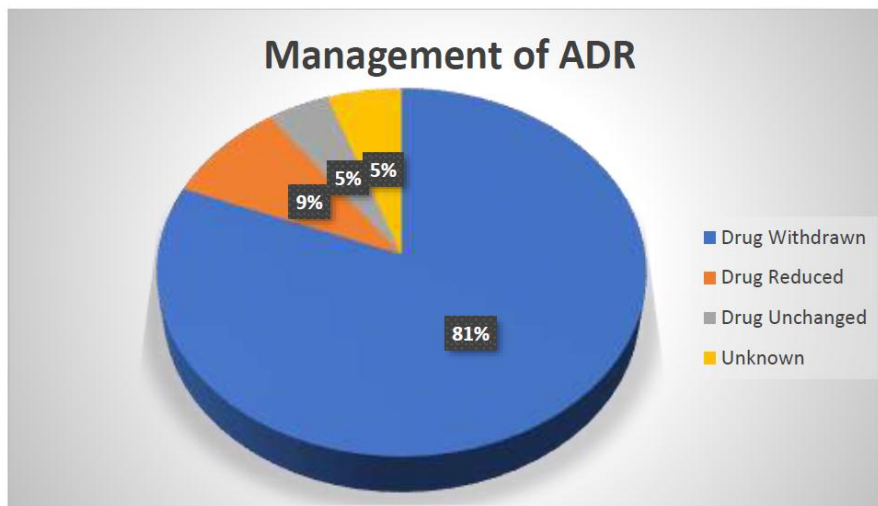


Figure 7: Pie Chart showing Management of ADR.

➤ **ADR reported in different Departments**  
 Maximum number of ADRs were reported from the General Medicine (8) followed by Dermatology (4), Pulmonology (3). The Departments of Cardiology (2) and Orthopedics (2) is affected with same no. of ADRs, While the departments of Neurology, Endocrinology and gastroenterology shows less ADRs i.e. 1 each.

Department	No. of ADRs	Percentage (n=22)
Cardiology	2	9.1 %
Neurology	1	4.54 %
Dermatology	4	18.18 %
Orthopedics	2	9.1 %
General Medicine	8	36.36 %
Pulmonology	3	13.63 %
Endocrinology	1	4.54 %
Gastroenterology	1	4.54 %

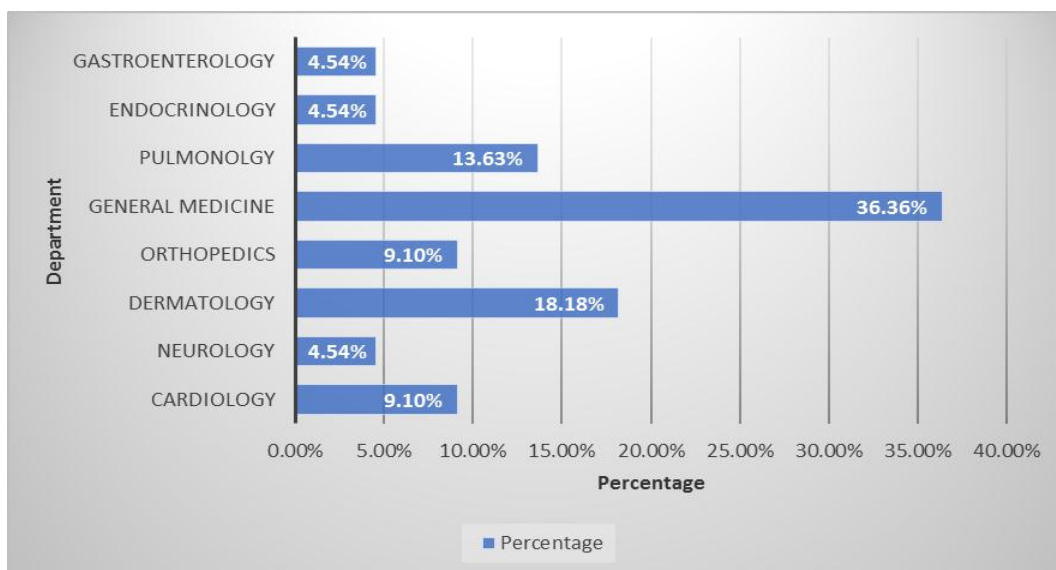


Figure 8: Bar graph showing departments affected by ADRs.

➤ **Drug Safety Alerts**

All partners and stakeholders of the NCC-PvPI are informed of the medication warnings, and the AMCs keep track of every patient who receives the drug-ADR combination mentioned in the alert at their individual

locations. PvPI notifies users of any ADR among its medication notifications, especially during follow-up. In our study, we have found 5 common drugs related ADRs which are already issued as Drug safety alerts by Indian Pharmacopoeia Commission. (See Table: 9)

Suspected Drug	ADR	Indication	Year
<b>Cetirizine</b>	Tachycardia	For the treatment of seasonal / perennial allergic rhinitis & chronic idiopathic urticaria in infants & children.	19-Feb,2019
	Acute Generalized Exanthematous Pustulosis	For the treatment of allergic rhinitis and chronic urticaria.	30-Oct,2019
	Hiccups	For the treatment of allergic rhinitis and chronic urticaria.	22-Nov,2019
<b>Inj. Diclofenac</b>	Skin hyperpigmentation	For the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout, painful post operative pain following dental surgery. migraine attack and post operative inflammation in patients who have undergone cataract operation.	30-Nov,2021
	Nicolau Syndrome	Acute Musculo-skeletal pain; arthritis, gout; spondylitis; migraine; post-operative pain	July,2017
<b>Metoprolol</b>	Lichenoid Drug Eruption	Supraventricular arrhythmia, angina pectoris, hypertension, myocardial infarction: migraine prophylaxis: hyperthyroidism, heart failure.	Feb,2017
	Hyponatraemia	For the treatment of essential hypertension in adults, functional heart disorders, migraine prophylaxis, cardiac arrhythmias, prevention of cardiac death and reinfarction after the acute phase of myocardial infarction, stable. symptomatic CHF.	29-Mar,2023
<b>Inj. Clindamycin</b>	Symmetrical Drug	Antibiotic-Indicated in the treatment of gram	5-oct,2020

	Related Intertriginous and Flexural Exanthema (SDRIFE)	+ve organism pathogens, staphylococcus & streptococci, pneumococci.	
	Acute Generalised Exanthematous Pustulosis	Respiratory tract infections, penicillin resistant staphylococcal infections and many anaerobes such as Bacteroides, skin, soft tissue and dental infections	July,2017
<b>Montek BL(Montelukast)</b>	Tinnitus	Prophylaxis of mild to moderate asthma	Dec,2016

## DISCUSSION

The current study tracked ADR among inpatients from several departments of a tertiary care hospital over the course of three months and reported cases. According to the results of this study, Females 14 (63.63%) reported more number of ADRs compared to males 8 (36.36%). There is no doubt that women appear to be much more likely than males to experience negative medication responses. This appears to be due to a variety of physiological variations between men and women, as well as variations in the way men and women take drugs. This result is consistent with the result of the study carried out by Watson, Sarah, et al.<sup>[15]</sup> Age has a significant impact on the likelihood of ADRs. In our analysis, the patients between the age of 49 to 70 years accounted for the majority of ADR occurrence i.e. 55.16%, as compared to the patients in age group of 18-48 years (45.45%). This finding is similar to the study conducted by Routledge, P A et al.<sup>[16]</sup>

The majority of ADRs were mild, with itching and skin rashes accounting for 36.8% of all reported cases, followed by constipation at 9.2%. Exanthema, diarrhoea, hyperbilirubinemia, bradyarrhythmia, sore throat, hypoglycemia, facial edema, neuroglycopenia, hypoglycemic seizures, somnolence, and rigor of just 4.5%. These ADRs are easily handled by either stopping the medicine or switching to another one. Similar kinds of result were reported from previous study of De Araújo Lobo et al.<sup>[17]</sup>

The causality of ADRs was established using the Naranjo's Causality Assessment scale. It demonstrates that the majority of ADRs were probable (63.6%), while 6 ADRs were possible (27.2%), and 2 ADRs were certain, or 9.2%. These types of results have been observed in prior studies of Mandavi et al.<sup>[18]</sup> As per the Hartwig severity assessment scale, Majority of ADR were mild in nature and were recovered during study period, The severity of adverse events observed in our study was only mild to moderate. No fatal cases reported. These findings are consistent with earlier research conducted by Arulmani, R et al and Shrivastava, Meena et al<sup>[19][20]</sup>, But the result of our study does not match with the studies of Jiang et al which also reported severe type of ADRs.<sup>[21]</sup> The main line of treatment for ADRs was drug withdrawal in 18 (81.8%) instances, while no modification was made with the suspected drug

in 1 (4.5%) cases and the dosage was changed in 2 (9.2%) cases.

Maximum number of ADRs were reported from general medicine department 8 (36.36%) compared to other departments. This is due to the fact that at our hospital, the general medicine department initially examined patients before referring them to other experts. Thus, compared to other departments, this department utilises more medications. This result was consistent with the study carried out by Venkatasubbaiah et al.,<sup>[22]</sup> but different from the study carried out by Thakare et al.<sup>[23]</sup> wherein highest percentages of ADRs were reported from pulmonology and dermatology department. The majority of ADRs in our study were linked to antibiotics (38%) followed by NSAIDs (13.5%). A research that was conducted by Giardina, Claudia et al had similar results.<sup>[24]</sup>

The study limitations include difficulty in identifying all ADRs that occur in a tertiary care hospital, as not all ADRs may be reported or documented in the medical records. And the small sample size and smaller duration of study would be another limitation.

## CONCLUSION

Reporting adverse drugs reactions is crucial to protecting patient safety and enhancing overall healthcare quality. Healthcare practitioners, regulatory agencies, and pharmaceutical firms can obtain vital information about the safety profile of medications and make educated decisions about their usage if adverse drug reactions are reported immediately and properly.

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**Conflict of Interest:** The author declares no conflict of interest.

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