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THE ROLE OF PHARMACISTS IN MANAGEMENT, MONITORING AND REPORTING OF ADVERSE DRUG REACTIONS

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- **ABSRACT**

Pharmacovigilance is an important area of healthcare focused on managing, monitoring, and evaluating the safety and efficacy of pharmacological drugs. It aims to detect and prevent potential dangers associated with medications through systematic collection, analysis, and interpretation of adverse event data. Regulatory authorities and organizations ensure drug safety, effectiveness, and the accuracy of drug information provided to the public. Aim: This study evaluates the alignment of adverse drug reaction (ADR) monitoring and reporting practices in a tertiary care hospital with drug safety alerts issued by regulatory authorities, aiming to enhance patient safety and healthcare outcomes. Methods: A prospective observational study was conducted at Owaisi Hospital over three months, enrolling patients aged 1-58 years who experienced ADRs and consented to participate. Results and Discussion: Out of 104 patients, 79 ADRs were documented, resulting in an incidence rate of 75.9%. A significant proportion occurred in patients aged 1-18 years (36.7%). Causality assessment classified 49 ADRs as probable (62.0%), and severity assessment indicated 40 ADRs were moderate (50.6%). Withdrawal of the drug was the primary management approach (63.3%), with most patients recovering. The study identified five common ADRs previously flagged by the Indian Pharmacopoeia Commission (IPC). Conclusion: Reporting ADRs is critical for patient safety and healthcare quality improvement, enabling informed decisions by healthcare providers, regulatory agencies, and pharmaceutical firms regarding medication use.

Or

Background: Pharmacovigilance is an important area of healthcare that focuses on management, monitoring and evaluating the safety and efficacy of pharmacological drugs. Pharmacovigilance seeks to detect and avoid any possible dangers connected with drugs by collecting, analysing, 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 Owaisi hospital over a period of 3 months (April 2024-june 2024). All patients visiting the Hospital over the age of 1 - > 58 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 104 Patients, 79 ADRs were collected and the total incidence of ADRs is 75.9%. Majority of ADRs were occurred in the Age group of (1 - 18 years). In this 36.7% ADR were observed. As per causality assessment, 49 ADRs were probable (62.0%). As per the severity assessment Scale 40 ADRs reported were Moderate which contributed to 50.6% of total ADRs. Most of the management of the ADRs is done by withdrawing of drug i.e. by 63.3% 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.[1,2]

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.[3] On average, 6.7% of patients in India experience serious adverse drug reactions, and that percentage might reach 8% in rural South India.[4] ADRs cause between 0.7% to 3.4% of hospital admissions, 3.7% of hospital readmissions, and 1.3% of fatalities in South India.[5,6,7] 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.[8,9] 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.[10,11] 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.[12] 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.[13,14]

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 2024-june 2024). All patients visiting the Hospital over the age of 1- >58 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

- Patients experiencing at least one ADR (any age and/or gender) and reporting to clinical pharmacist from inpatient department
- Patients from in-patient department.
- Patients transferred from ICU to the general medicine ward are included
- Case with full information after receiving the ADR forms using Naranjo scale designed by WHO

Exclusion criteria

- It excludes overdose (accidental or intentional), drug abuse, and treatment failure and drug administration errors**.**
- Use of elective arrangement of prescriptions.
- Patient conceded in basic consideration unit.
- Medication errors, over prescribing, over dosing /excess consumption.
- Drug-Drug interaction, Drug-food interaction, Drug interaction with a use of alternative system of medicine.

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 104 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 those patients that didn't fit the selected criteria were excluded.

Gender Distribution in Study Population

Out of the 104 Patients, 79 ADR were collected and the incidence of ADR is 75.9%. We have received a total of 49 Male Patients out of which 41 has shown the ADRs

(83.6%) while the total number of females is 55 out of which 38 has shown the ADRs (69.0%). (shown in Table-1 & Figure: 1)

Table 1: Gender Distribution.

Sex	With ADR	Without ADR	Total
Male	41	8	49
Female	38	12	55
Total	79	20	104

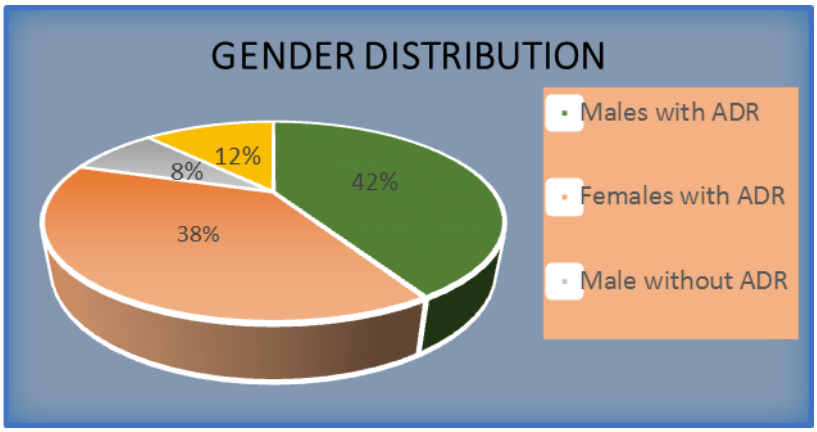

Figure 1: Gender Distribution.

Age Wise Distribution of Patients With ADR

Majority of ADRs were occurred in the Age group of (1-18 years) i.e.; Group-I. In this group 36.7% ADR were observed. The patient between the age group II (19-28 years) shown 15.1% of ADRs and age group III (29-38 years) showed only 11.4% ADR and between the Age group IV (39-58 years) showed 8.9% of ADRs. The Patients in Age group V (>58 years) shown 20.2% of ADRs. Age related ADRs are shown in Table-2 & Figure 2.

Table 2: Age wise ADRs.

Age Group (years)	Total No. of Patients (N)	No. of Patients with ADR (N= 79)
1-18	38 (36.5%)	29 (36.7%)
19- 28	20 (19.2 %)	12 (15.1%)
29-38	12 (11.5 %)	9 (11.4%)
39-58	19 (18.2%)	7 (8.9%)
More than 58	15 (14.4%)	16 (20.2%)
Total	**104**	**79**

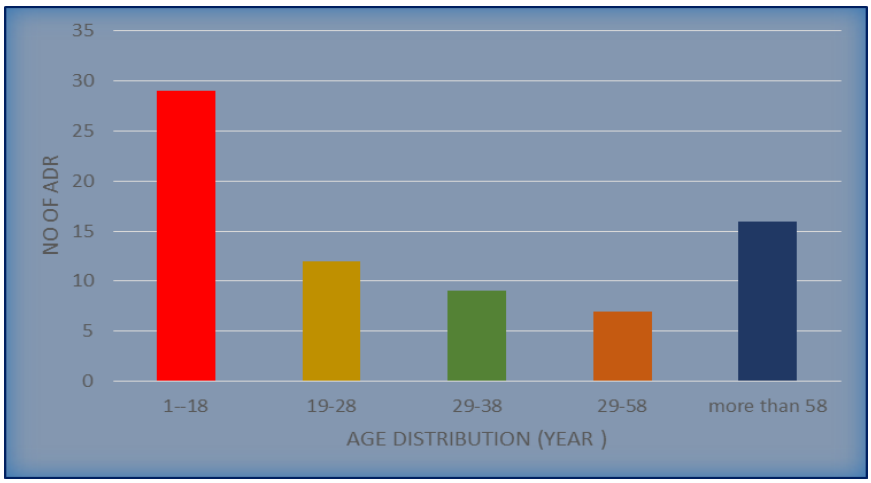

Figure 2: Age Distribution.

Types of ADR

Most ADRs that occurred were mostly Mild, the most common ADR observed was Acne i.e. 17 (21.5%) followed by Diarrhoea i.e., 15 (18.9%). Headache 1 (1.3%), Constipation 4(5.1%), Itching / Skin rashes 5 (6.3%), edema (2), Hyperpigmentation (2), Hypersensitivity reaction 5 (6.3 %), Hypokalaemia 2 (2.5 %), CNS depression 2(2.5 %), Irritant contact dermatitis 2 (2.5 %), Cerebral haemorrhage 1 (1.3%), Anaemia 3 (3.8 %), Bradycardia 1 (1.3%) (as shown in Table -3 & Figure 3).These kind of ADR can be easily treated either by withdrawing the drug or replacing the drugs.

Table 3: Type of ADR.

Types of ADR	Number	Percentage (n=79)
Diarrhoea	15	18.9 %
Constipation	4	5.1 %
Itching / Skin rashes	5	6.3 %
Hyperpigmentation	2	2.5 %
Hypersensitivity reaction	5	6.3 %
edema	2	2.5 %
Acne	17	21.5 %
Hypokalaemia	2	2.5 %
CNS depression	1	1.3 %
Irritant contact dermatitis	2	2.5 %
Headache	1	1.3 %
Cerebral haemorrhage	1	1.3 %
Anaemia	3	3.8 %
Bradycardia	1	1.3 %

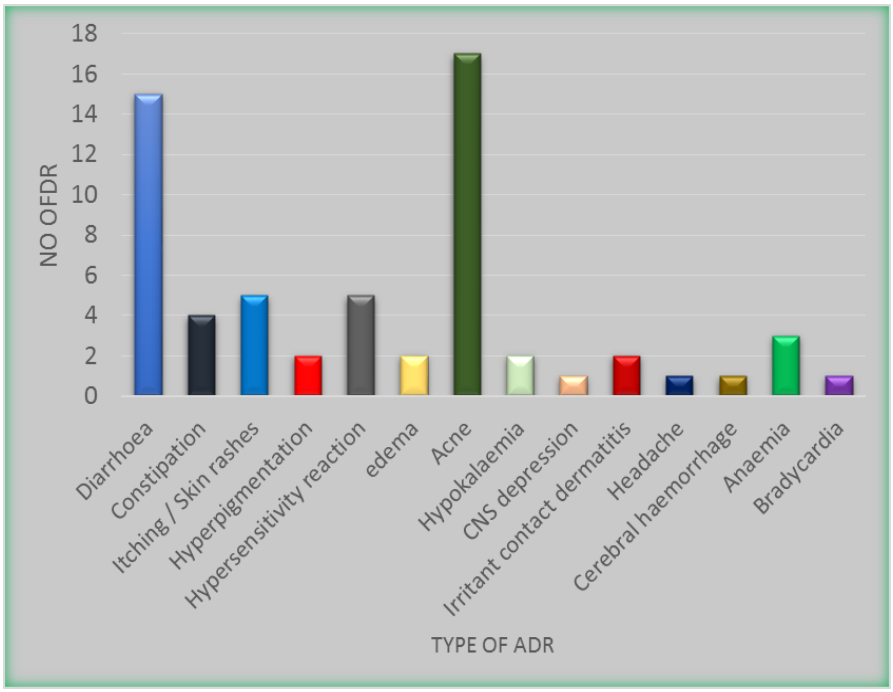

Figure 3: Types of ADR.

Causality Assessment of ADR

The Naranjo's Causality Assessment scale was used to determine the causality of ADR's. It shows that 49 ADRs were probable (62.0%) and 21 ADR were possible and percentage is 26.5% and 6 ADR were definite i.e. 7.6 % and 3 ADR were doubtful i.e. 3.8 %. The Assessment of ADR by Naranjo's Scale is shown in Table 4 and figure 4.

Table 4: Causality Assessment.

Types	Number of ADR	Percentage (n=79)
Probable	49	62.0 %
Possible	21	26.5 %
Definite	6	7.6 %
Doubtful	3	3.8%

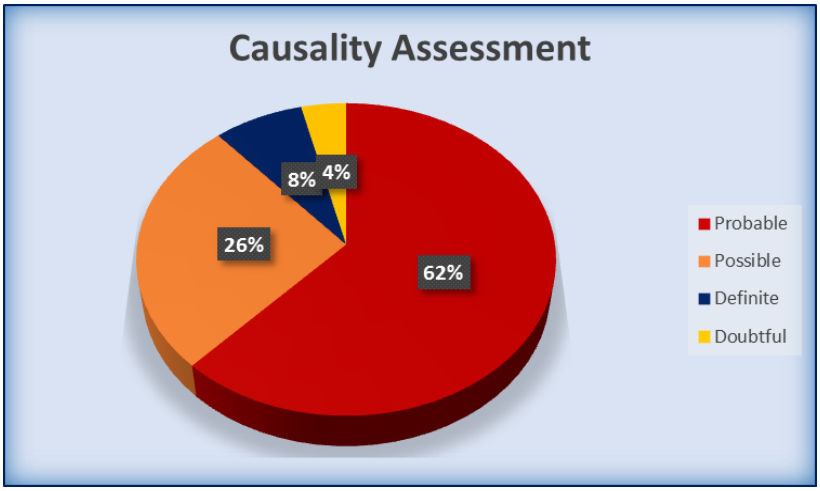

Figure 4: Causality Assessment of ADR.

Severity Assessment

The Hartwig Severity Assessment Scale was used to determine the Severity of ADRs. As per the Assessment Scale 25 ADRs reported were Mild which contributed to 31.6% of total ADRs. The remaining 40 ADRs which were reported comes under Moderate i.e. 50.6%. There were 14 ADR i.e., 17.7% are Severe ADRs reported in our study, shown in table 5 & figure 5.

Table 5: Severity Assessment.

Severity	Number of ADR	Percentage (n=79)
Mild	25	31.6 %
Moderate	40	50.6 %
Severe	14	17.7%

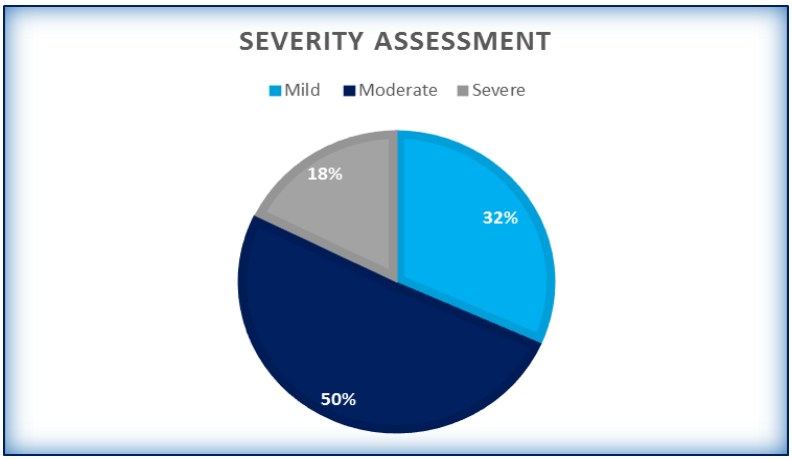

Figure 5: Severity Assessment of ADR.

Drug Responsible for ADR

The drugs which are showing the ADRs is shown in Table: 6.

Table 13: Drug Responsible for ADR.

S. No	Drug	ADR	Frequency	Percentage (n=79)
1	Pregabalin	Headache	1	1.3 %
2	Cetirizine	Sore Throat	1	1.3 %
3	Inj. Zonamax	Urticaria	1	1.3 %
4	Vildambic	Rigor	1	1.3 %
5	VOGS-Gm2	Hypoglycemia	1	1.3 %
6	Syp. Sucral	Constipation	4	5.0 %
7	Tab. Naxdom	Edema	2	2.5 %
8	Inj. Taxim	Rashes	1	1.3 %
9	Tab. Gluconorm	Neuroglycopenia	1	1.3 %

10	Tab. Glycomet [GP-1]	Hypoglycaemic seizures	1	1.3 %
11	Aziwak [Azithromycin]	Rashes	1	1.3 %
12	Montek-BL [Montelukast]	Somnolence	1	1.3 %
13	Inj. Augmentin	Rashes	1	1.3 %
14	Inj. Monocef	Rashes	3	3.8 %
15	Inj. Clindamycin	Exanthema	1	1.3 %
16	LNZ/Linezolid	Diarrhoea	1	1.3 %
17	Inj. Azee [Azithromycin]	Itching	1	1.3 %
18	Inj. Diclofenac	Constipation	1	1.3 %
19	AKT-4 Kit	Hyperbilirubinemia	1	1.3 %
20	Met L3D[Metoprolol]	Bradyarrhythmia	1	1.3 %
21	Benzyl peroxide	Irritant contact dermatitis	2	2.5 %
22	Betamethasone	Acne	1	1.3 %
23	Acenocoumaril	Cerebral haemorrhage	1	1.3 %
24	Zidovudine	Anemia	2	2.5 %
25	Amlodipine	Acne	1	1.3 %
26	Paracetamol	Necrosis	1	1.3 %
27	Phenytoin	Acne form eruptions	1	1.3 %
28	Aceclofenac	Hypersensitivity reaction	1	1.3 %
29	Acenocoumaril	Bradycardia	1	1.3 %
30	Torsemide	Hypokalemia	1	1.3 %

Outcome and Management of ADRs

This study shows that in most of the ADRs, management was shown by withdrawing the drug, i.e., 50 (63.3 %), and the majority of patients recovered. The dose was reduced in 4(5.0 %) ADRs, and 22 (27.8%) of the ADRs remained unchanged and 3 (3.8%) ADRs were unknown. (See Table: 7 and Figure 7)

Table 7: Management of ADR.

Management of ADR	Total	Percentage (n=79)
Drug Withdrawn	50	63.3 %
Drug Reduced	4	5.0 %
Drug Unchanged	22	27.8 %
Unknown	3	3.8 %

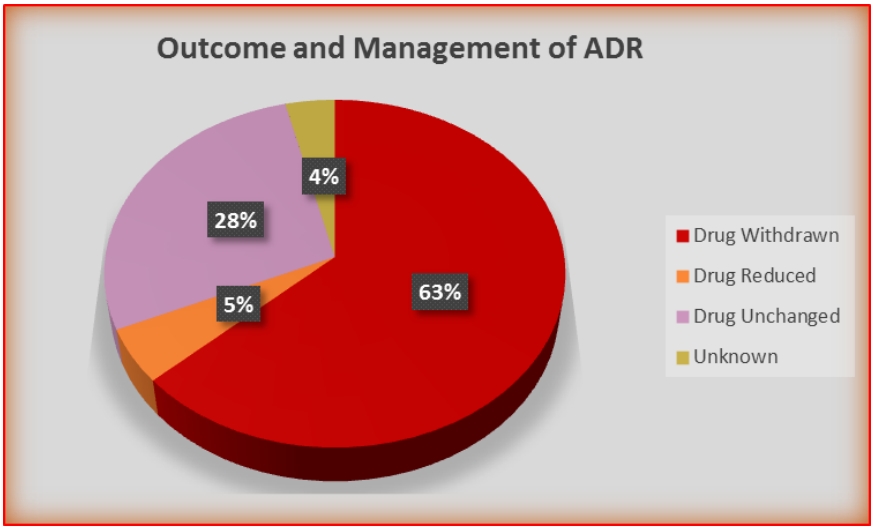

Figure 7: Outcomes and management of ADR.

ADR reported in different Departments

Maximum number of ADRs were reported from the Dermatology (28) followed by General Medicine (21), Gastroenterology (7) Endocrinology (6), Pulmonology (5), Neurology (3). The Departments of Cardiology (2) and Orthopaedics (2) is affected with same no. of ADRs.

Table 8: Departments affected by ADRs.

Department	No. of ADRs	Percentage (n=79)
Cardiology	2	2.5 %
Neurology	3	3.79 %
Dermatology	28	35.44 %
Orthopedics	2	2.5 %
General Medicine	21	26.58%
Pulmonology	5	6.3 %
Endocrinology	6	7.59%
Gastroenterology	7	8.87 %

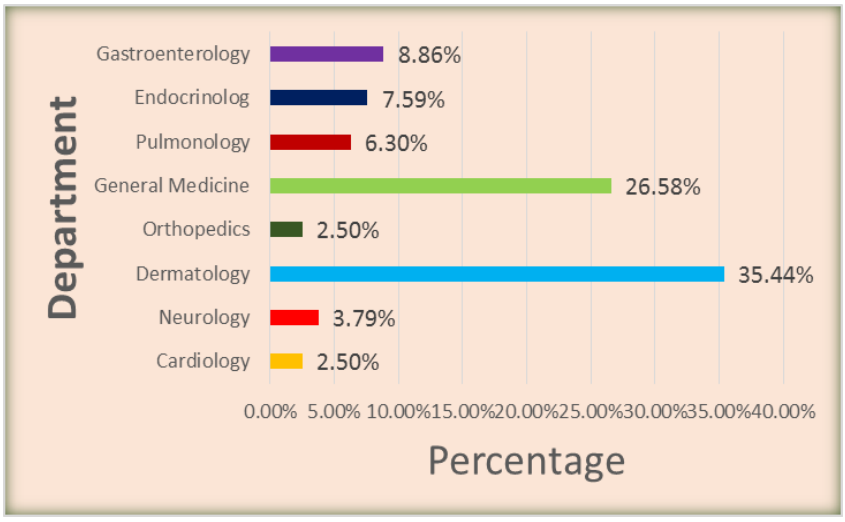

Figure 8: Bar graph showing departments affected by ADR.

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.

Table 9: Drug Safety Alerts.

Suspected Drug	ADR	Indication	Year
Metoprolol	Lichenoid Drug Eruption Hyponatraemia	Supraventricular arrhythmia, angina pectoris, hypertension, myocardial infarction: migraine prophylaxis: hyperthyroidism, heart failure. 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.	Feb,2017 29-Mar,2023
Montek BL(Montelukast)	Tinnitus	Prophylaxis of mild to moderate asthma	Dec,2016
Inj. Diclofenac	Skin hyperpigmentation Nicolau Syndrome	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. Acute Musculo-skeletal pain; arthritis, gout; spondylitis; migraine; post-operative pain	30-Nov,2021 July,2017

Inj. Clindamycin	Symmetrical Drug Related Intertriginous and Flexural Exanthema (SDRIFE) Acute Generalised Exanthematous Pustulosis	Antibiotic-Indicated in the treatment of gram +ve organism pathogens, staphylococcus & streptococci, pneumococci. Respiratory tract infections, penicillin resistant staphylococcal infections and many anaerobes such as Bacteroides, skin, soft tissue and dental infections	5-oct,2020 July,2017
Cetirizine	Tachycardia Acute Generalized Exanthematous Pustulosis Hiccups	For the treatment of seasonal / perennial allergic rhinitis & chronic idiopathic urticaria in infants & children. For the treatment of allergic rhinitis and chronic urticaria. For the treatment of allergic rhinitis and chronic urticaria.	19-Feb,2019 30-Oct,2019 22-Nov,2019

- **DISCUSSION**

The current study tracked ADR among inpatients from several departments of a Owaisi hospital and Research center over the course of three months and reported cases. According to the results of this study, Males 41 (83.6 %) reported a greater number of ADRs compared to Females 38 (69.0%). There is no doubt that men appear to be much more likely than females 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.[15]

Age has a significant impact on the likelihood of ADRs. In our analysis, the patients between the age of 1 to 18 years accounted for the majority of ADR occurrence i.e. 36.7%, as compared to the patients in age group of 19 – more than 58 years (55.69%). This finding is similar to the study conducted by Routledge, P A et al.[16]

The majority of ADRs that occurred were mostly Mild, the most common ADR observed was Acne i.e. 17 (21.5%) followed by Diarrhoea i.e., 15 (18.9%). Headache 1 (1.3%), Constipation 4(5.1%), Itching / Skin rashes 5 (6.3%), Edema (2), Hyperpigmentation (2), Hypersensitivity reaction 5 (6.3 %), Hypokalaemia 2 (2.5 %), CNS depression 2(2.5 %), Irritant contact dermatitis 2 (2.5 %), Cerebral haemorrhage 1 (1.3%), Anaemia 3 (3.8 %), Bradycardia 1 (1.3%). These ADRs are easily handled by either stopping the medicine or switching to another one. Similar kinds of result where reported form previous study of De Araújo Lobo et al.[17]

The causality of ADRs was established using the Naranjo's Causality Assessment scale. It demonstrates that the majority of ADRs were probable 49 (62.0%), while 21 ADRs were possible (26.5%), and 6 ADR were definite i.e. 7.6 % and 3 ADRs were Doubtful, or 3.8%. These types of results have been observed in prior studies of Mandavi et al.[18]

The Majority of ADR were moderate 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.[19,20], But the result of our study does not match with the studies of Jiang et al which also reported severe type of ADRs.[21]

The study limitations include difficulty in identifying all ADRs that occur in a 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. In pharmacovigilance, regulatory bodies are crucial. They offer essential oversight and guidance to guarantee the safety and efficacy of medicinal products. They offer a system that fosters the collection, analysis, and reporting of adverse occurrences through its rules, recommendations, and enforcement. Their participation in pharmacovigilance serves to preserve public health, establish trust in pharmaceuticals, and maintain high standards of patient safety.

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- **REFERENCE**

1. WHO Policy Perspectives on Medicines. Geneva: WHO; 2004. Geneva: World Health Organization. Looking at the Pharmacovigilance: ensuring the safe use of medicines. Available from: https://www.who.int/publications/i/item/WHOEDM 2004.8
2. Härmark, L, and A C van Grootheest. "Pharmacovigilance: methods, recent developments and future perspectives." European journal of clinical pharmacology, 2008; 64(8): 743-52. doi:10.1007/s00228-008-0475-9
3. Coleman, Jamie J, and Sarah K Pontefract. "Adverse drug reactions." Clinical medicine (London, England), 2016; 16(5): 481-485. doi:10.7861/clinmedicine.16-5-481
4. Ahmad, Akram, et al. "Incidence of adverse drug reactions with commonly prescribed drugs in tertiary care teaching hospital in India." Int J Pharm Sci., 2011; 3: 79-83.
5. Arulmani, R et al. "Adverse drug reaction monitoring in a secondary care hospital in South India." British journal of clinical pharmacology, 2008; 65(2): 210-6. doi:10.1111/j.1365-2125.2007.02993.x
6. Ahmad, A et al. "A study on drug safety monitoring program in India." Indian journal of pharmaceutical sciences, 2014; 76(5): 379-86.
7. Ahmad, Akram et al. "An evaluation of knowledge, attitude and practice of Indian pharmacists towards adverse drug reaction reporting: A pilot study." Perspectives in clinical research, 2013; 4(4): 204-10. doi:10.4103/2229-3485.120168
8. Rawlins, M D. "Spontaneous reporting of adverse drug reactions. I: the data." British journal of clinical pharmacology, 1988; 26(1): 1-5. doi:10.1111/j.1365-2125.1988.tb03356.x
9. Dukes, M N. "The importance of adverse reactions in drug regulation." Drug safety, 1990; 5(1): 3-6. doi:10.2165/00002018-199005010-00002.
10. Elizabeth, S. T., et al. "Knowledge, attitude and skills of nurses of Delhi towards adverse drug reaction reporting." Indian Journal of Pharmacy Practice, 2012; 5(1).
11. Kalaiselvan, Vivekanandan et al. "Pharmacovigilance Programme of India: Recent developments and future perspectives." Indian journal of pharmacology, 2016; 48,6: 624-628. doi:10.4103/0253-7613.194855
12. Indian Pharmacopoeia Commission Newsletter PvPI., 2015; 5(12): 4. Available at: www.ipc.gov.in/PvPI/newsletter/Newsletter%20Vol %205%20Issue%2012%202015%20PDF.pdf
13. Lindquist, M. VigiBase, the WHO Global ICSR Database System: Basic Facts. Ther Innov Regul Sci., 2008; 42: 409–419. https://doi.org/10.1177/009286150804200501
14. Van Stekelenborg, John et al. "Individual Case Safety Report Replication: An Analysis of Case Reporting Transmission Networks." Drug safety, 2023; 46(1): 39-52. doi:10.1007/s40264-022-01251-7 15.
15. Watson, Sarah, et al. "Reported Adverse Drug Reactions in Women and Men: Aggregated Evidence from Globally Collected Individual Case Reports during Half a Century." EClinical Medicine, 2019; 17: 100188, https://doi.org/10.1016/j.eclinm.2019.10.001.
16. Routledge, P A et al. "Adverse drug reactions in elderly patients." British journal of clinical pharmacology, 2004; 57(2): 121-6. doi:10.1046/j.1365-2125.2003.01875.x
17. De Araújo Lobo, Márcia Germana Alves, et al. "Adverse Drug Reaction Monitoring: Support for Pharmacovigilance at a Tertiary Care Hospital in Northern Brazil." BMC Clinical Pharmacology, Springer Science+Business Media, Jan., 2013; 14(1). https://doi.org/10.1186/2050-6511-14-5.
18. Mandavi et al. "Adverse drug reactions & their risk factors among Indian ambulatory elderly patients." The Indian journal of medical research, 2012; 136(3): 404-10.
19. Arulmani, R et al. "Adverse drug reaction monitoring in a secondary care hospital in South India." British journal of clinical pharmacology, 2008; 65(2): 210-6. doi:10.1111/j.1365-2125.2007.02993.x
20. Shrivastava, Meena et al. "Adverse drug reactions reported in Indira Gandhi Government Medical College and Hospital, Nagpur." The Journal of the Association of Physicians of India, 2011; 59: 296-9. 21.
21. Jiang, Huaqiao, et al. "Adverse Drug Reactions and Correlations with Drug–Drug Interactions: A Retrospective Study of Reports from 2011 to 2020." Frontiers in Pharmacology, 2022; 13. https://doi.org/10.3389/fphar.2022.923939.
22. Venkatasubbaiah, Meda, et al. "Analysis and Reporting of Adverse Drug Reactions at a Tertiary Care Teaching Hospital." Alexandria Journal of Medicine, 2018; 54(4): 597–603, https://doi.org/10.1016/j.ajme.2018.10.005.
23. Thakare, Vaishali, et al. "Adverse Drug Reactions Reporting: Five Years Analysis from a Teaching Hospital." Journal of Family Medicine and Primary Care, 2022; 11(11): 7316, https://doi.org/10.4103/jfmpc.jfmpc_1043_22.
24. Giardina, Claudia et al. "Adverse Drug Reactions in Hospitalized Patients: Results of the FORWARD (Facilitation of Reporting in Hospital Ward) Study." Frontiers in pharmacology, 11 Apr., 2018; 9: 350. doi:10.3389/fphar.2018.00350