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Original Research Article

Evaluation of adverse drug reactions in a tertiary care hospital in India

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ABSTRACT

Background: Adverse drug reaction (ADR) is a major concern in the healthcare system and has been a persistent issue in the health sector. This study aimed to evaluate and assess the ADRs reported, the system organ class (SOC) affected, seriousness, outcomes, causality.
Methods: A retrospective observational study in a tertiary care hospital from April 2021 to May 2024. A descriptive analysis of reactions, causality of suspected drugs was carried out according to the setting analysed.
Results: Out of 7,396 individual case safety report (ICSR) reported, the highest number of ADRS was reported in the age group of 18-65 years (57.8%) and male patients (51.1%). Using World Health Organization-Uppsala Monitoring Centre (WHO-UMC) causality assessment scale, 67.1% events were possible**.** A significant majority of drug reported as 'certain' were of anti-infective class (51.03%). Most frequently affected SOC was blood and lymphatic system disorders (15.9%), Of all events, greater part of the reactions was non-serious (95.3%), the most drugs causing ADRs was anti neoplastic and immunodulating agents (40.4%) and 47.2% of drugs were high alert medications. The greater part of ADRs reporting was carried out by clinical pharmacists (95.9%).
Conclusions: The results highlighted the importance of clinical pharmacist in monitoring and spontaneous reporting of ADRs. Awareness and educational programs may help in active reporting among all healthcare providers.

Keywords: Adverse drug reactions, Pharmacovigilance, Anti-infective, Clinical pharmacist, Causality

INTRODUCTION

World Health Organization (WHO) defines adverse drug reactions (ADRs) as ''a response to a medicinal product which is noxious, unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function". ADRs are a major concern in the healthcare system and has been a persistent issue in the health sector.[1]

Throughout medical history, ADRs has affected the majority of people, caused significant morbidity and mortality, and posed a significant burden on healthcare resources.[2] It is widely acknowledged that "no medication is completely free from side effects." According to studies, 10–20% of hospitalized patients experience ADRs, and 5% of hospital admissions are attributable to drug-induced issues.[1]

According to a fundamental meta-analysis by Lazarou et al, ADRs were the fourth to sixth most common cause of mortality in the United States, after ischemic cardiopathy, cancer, and stroke.[3] ADRs are more common with the multiple drug therapy and with each additional medication taken by the patient the hazard of a ADRs episode gets multiplied by 1.14 thereby directly increasing the length of stay.[1] ADRs risk factors include age, gender, and length of hospital stay, comorbidities, medication intolerance, and number of medications, hereditary factor, dietary influences, environmental factors, and the skills of

physicians, nurses, pharmacists, and other health professionals.[2]

As stated by WHO, "Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problem, particularly long-term and short-term adverse effects of medicines".[1] Spontaneous reporting of ADRs is the cornerstone of pharmacovigilance that helps address safety concerns after drug administration. Although healthcare professionals are generally aware of the importance of reporting ADRs, instances of spontaneous reporting remain limited. Advantages of spontaneous reporting includes flexibility and low cost.[4] It provides information from real-life clinical practice as opposed to that of clinical trials where some subjects are excluded and the safety of the drug is studied under a limited time.[5]

Health professionals, pharmaceutical companies, or consumers voluntarily submit case reports of ADRs to the national pharmacovigilance centers for examination in an effort to lessen the impact of ADRs on society. It is an effective technique for information gathering.[4] Although health professionals have enough knowledge and are aware of the need to report ADRs, smaller proportions spontaneously report ADRs. Pharmacovigilance employs data from reporting systems to optimize the use of medications. Additionally, it effectively reduces ADRs through early detection and communication. Consequently, this system ensures that patients receive the most appropriate therapy.[1]

This study aimed to evaluate and assess the ADRs reported, the system organ class (SOC) affected, seriousness, outcomes, causality. In addition, this study also identify the stakeholders involved in ADRs reporting, the drugs which are frequently associated with ADRs and managements of ADRs.

METHODS

Setting

We conducted a retrospective observational study in Rajagiri Hospital, Aluva to analyse all suspected ADRs reported from April 2021 to May 2024 in a tertiary care hospital submitted to National Coordination Centre – Pharmacovigilance Programme of India (NCC PvPI).

Data collection

The events were analysed based on patient demographics (age and gender), drug characteristics (drug class, route of administration, high alert medicines), ADRs characteristics (reaction, system organ class (SOC), comorbidities, outcome, management, seriousness of the reaction, causality assessment and type of reporter).

Patients were divided into four age groups such as paediatrics (0–12 years), adolescents (13–17 years), adults (18–65), and geriatrics >65.

The ADRs were analysed for their seriousness, causality, outcome and action taken after reaction. The seriousness of the ADRSs was assessed by using the PvPI criteria 1.4 i.e. life-threatening, other medically important, hospitalization/prolonged hospital stay, disability, congenital anomaly, and death.

According to World Health Organization-Uppsala Monitoring Centre (WHO-UMC), causality assessment scale the categories of causality includes certain, probable/likely, possible, unlikely, conditional/ unclassified, and un-assessable/unclassifiable.

ADRs were codified as detailed by the medical dictionary for regulatory activities (Med DRA) and organized according to the SOC classification.

Additionally, we assessed the classifications **(**anatomical therapeutic chemical class**)** of the products involved, the route of administration and involvement of high alert medication. The ATC system categorizes medicinal products based on their primary active ingredient, the organ or system they target, and their chemical, pharmacological, and therapeutic characteristics. The current study represents ATC level I data. We utilized the Institute for Safe Medication Practices list (ISMP) to systematically classify the involvement of high-alert medications in the occurrence of ADRs. Descriptive analysis was carried out.

RESULTS

We analysed 7,396 incidents of ADRs case reports recorded between January 2021 and May 2024. The year wise trend of ADRs is depicted in Figure 1.

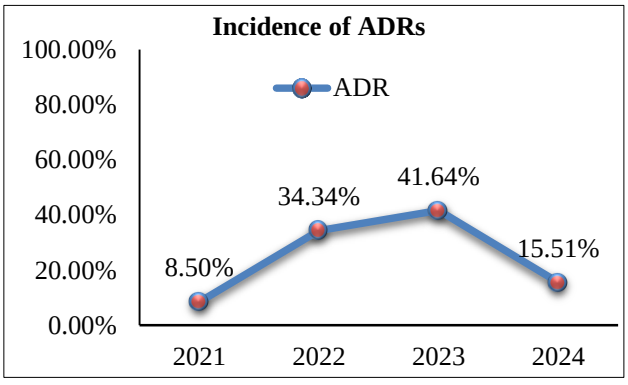

Figure 1: Year wise trend of adverse drug reaction reported in the study period.

Social-demographics characteristics of the participants

The overall mean age of participants in this study was 57 years. The highest number of ADRs were reported in the

age group of 18-65 years (57.79%) followed by age more than 65 years. (37.56%). Majority of ADRs was found in male patients (51.11%) than in female patients (48.89%). Nonetheless, the proportion of total serious ADRs reports was comparable between men (49.86%) and women (50.14%). Table 1 depicts socio-demographics distribution of participants.

Table 1: Social-demographics characteristics of the participants.

Variables	Frequency	Percentage
Age group (years)		
0–12	262	3.54
13–17	82	1.11
18–65	4274	57.79
>65	2778	37.56
Gender		
Male	3780	51.11
Female	3616	48.89

Adverse drug events and related factors

On assessment with WHO-UMC causality assessment scale, 67.05% events were found possible, 24.06% were un-assessable, 5.68% of events were probable, and 2.69% of events were certain (Table 2).

Table 2: Causality and adverse drug events.

Causality	Frequency	Percentage
Possible	7267	67.05
Un-assessable/ unclassifiable	2608	24.06
Probable/possible	616	5.68
Certain	292	2.69
Unlikely	52	0.48
Conditional/unclassified	3	0.03
Total	10838	

With respect to class of drug, the most drugs causing ADRs was anti neoplastic and immunodulating agents (40.4%) followed by anti-infective for systemic use (15.6%) and cardiovascular system (12.2%). Table 3 provides a comprehensive overview of the drugs involved.

The highest medication reported as certain (2.7%) adverse event was anti – infectives for systemic use (51.03%) (Table 3).

Among these, piperacillin + tazobactam had the highest incidence, with 40 cases (26.28%), followed by ceftriaxone, which accounted for 25 cases (16.78%) (Table 4).

Most frequently affected SOC was blood and lymphatic system disorders (15.87%), followed by gastrointestinal disorders (15.25%) and metabolism and nutrition disorders (15.09%). The involvement of other systems is illustrated in Table 5. Of all events, greater part of the reactions was non-serious (95.3%).

Table 3: Drug class, frequency of adverse drug reaction and certain-causality, anatomical therapeutic chemical (ATC) classification.

Drug class	Frequency	Percentage
Drug class and frequency of adverse drug reaction		
L: Antineoplastic and immunomodulating agents	4376	40.38
J: Anti-infective for systemic use	1690	15.59
C: Cardiovascular system	1321	12.19
N: Nervous system	852	7.86
A: Alimentary tract and metabolism	849	7.83
B: Blood and blood forming organs	742	6.85
R: Respiratory system	287	2.65
M: Musculo-skeletal system	263	2.43
H: Systemic hormonal preparation, excluding sex hormones and insulin	213	1.97
V: Various	101	0.93
G: Genitourinary system and sex hormones	66	0.61
D: Dermatologicals	51	0.47
P: Antiparasitic products, insecticides and repellents	20	0.18
S: Sensory organs	7	0.1
Total	10838	
Certain-causality and anatomical therapeutic chemical (ATC) classification		
ATC class		
J: Anti-infective for systemic use	149	51.03
L: Antineoplastic and immunomodulating agents	33	11.30
M: Musculo-skeletal system	23	7.88
C: Cardiovascular system	21	7.19
A: Alimentary tract and metabolism	20	6.85
N: Nervous system	19	6.51
V: Various	10	3.42
R: Respiratory system	9	3.08
B: Blood and blood forming organs	5	1.71
H: Systemic hormonal preparation, excluding sex hormones and insulins	3	1.03
Total	292	

Table 4: Certain-causality and anti-infectives for systemic use.

Drug name	Frequency	Percentage
Piperacillin tazobactam	40	26.85
Ceftriaxone	25	16.78
Cefoperazone + sulbactam	15	10.07
Levofloxacin	8	5.37
Cefazolin	7	4.70
Amoxicillin + clavulanic acid	5	3.36
Ciprofloxacin	5	3.36
Ofloxacin	5	3.36
Cefuroxime	4	2.68
Rifampicin	4	2.68
Vancomycin	4	2.68
Amikacin	3	2.01
Doxycycline	3	2.01
Meropenem	3	2.01
Ambhotericin B	2	1.34
Cefotaxime	2	1.34
Teicoplanin	2	1.34
Azithromycin	1	0.67
Cefepime	1	0.67
Cefoperazone	1	0.67
Ceftazidime avibactam	1	0.67
Clindamycin	1	0.67
Colistin	1	0.67
Ethambutol	1	0.67
Gentamycin	1	0.67
Isoniazid	1	0.67
Ornidazole	1	0.67
Polymyxin b	1	0.67
Voriconazole	1	0.67
Total	149	

The mortality and hospitalization due to ADRs documented in the study was one and 3.1% respectively. Of the 7396 events 39.8% of outcome of the event were unknown, 28.2% patients were recovering from the event and 24.6% patients recovered. One event tragically resulted in a fatal outcome (Table 6).

Following the occurrence of the ADRs, various measures were implemented regarding the suspected drug. Most of the suspected drugs were continued without any change (53%). In 38.1% and 2.6% of cases the suspected drug was withdrawn and dose was reduced respectively. Medical and non-medical management was given 9.30% and 0.45% of cases documented.

Table 6 clearly illustrates the management strategies for ADRs.

Table 5: System organ class and adverse drug events.

System organ class	Frequency	Percentage
Blood and lymphatic system disorders	1174	15.87
Gastrointestinal disorders	1128	15.25
Metabolism and nutrition disorders	1116	15.09
Skin, subcutaneous tissue disorder	769	10.40
Investigations	595	8.04
Nervous system disorders	554	7.49
General disorders and administration site conditions	496	6.71
Immune system disorders	282	3.81
Renal and urinary disorders	281	3.80
Cardiac disorders	223	3.02
Respiratory thoracic and mediastinal disorders	212	2.87
Vascular disorders	169	2.29
Muscoskeletal and connective tissue disorders	110	1.49
Hepatobiliary disorders	75	1.01
Psychiatric disorders	56	0.76
Infections and infestation	52	0.70
Endocrine disorders	43	0.58
Eye disorders	28	0.38
Injury, poisoning and procedural complications	14	0.19
Ear and labyrinth disorders	8	0.11
Reproductive, system and breast disorders	8	0.11
Neoplasms benign, malignant and unspecified (cysts, polyps)	2	0.03
Surgical and medical procedures	1	0.01
Congenital, familial and genetic disorder	0	0.00
Pregnancy, puerperium and perinatal	0	0.00
Product issues	0	0.00
Social circumstances	0	0.00
Total	7396	

Table 6: Seriousness, outcome of the reaction and action taken after reaction, management of the reaction.

Variables	Frequency	Percentage
Seriousness of the reaction		
Non-serious	7049	95.3
Hospitalization-initial/prolonged	227	3.1
Life threatening	59	0.8
Other medically important	34	0.5
Required intervention to prevent permanent impairment	25	0.3
Congenital-anomaly	1	0.01
Death	1	0.01
Disability	0	0.0
Total	7396	
Outcome		
Unknown	2941	39.76
Recovering	2089	28.24
Recovered	1822	24.63
Not recovered	485	6.56
Recovering with sequelae	58	0.78
Fatal	1	0.01
Total	7396	
Action taken after reaction		
No change	5745	53.01
Drug withdrawn	4128	38.09
No information	661	6.10
Dose reduced	287	2.65
Substituted with another drug	11	0.10
Dose increased	6	0.06
Surgery	0	0.00
Total	10838	
Management		
Medical management	1014	95.3
Non-medical treatment	50	4.7
Total	1064	

Medication related factors in ADRs

Among 10,838 suspected drugs in the events, 47.2% of drugs were high alert medications (Table 7).

In the context of route of administration, IV route drugs (42.3%) were highly suspected for causing ADRs followed by oral route (42.3%) and subcutaneous route (3.5%) (Table 7).

Reporter status and department wise distribution

The greater part of ADRs reporting were carried out by clinical pharmacists (95.9%) followed by nurse (2.5%) and doctors (1.4%) (Figure 2).

Table 7. Route of administration, frequency of adverse drug reaction and distribution of high alert medication among adverse drug events.

Route	Frequency	Percentage
IV	5613	51.79
Oral	4587	42.32
Subcutaneous	374	3.45
Nebulization	112	1.03
IM	37	0.34
Topical	30	0.28
ID	27	0.25
Other	20	0.18
Epidural	19	0.18
Rectal	19	0.18
Total	10838	
High risk medications		
Presence of high-risk medications	5116	47.20
Absence of high-risk medications	5722	52.80

Out of 7396 ADRs the department of oncology recorded majority (36.2%) of cases followed by department of general medicine (14.3%) and gastro-enterology (7.5%) (Table 8).

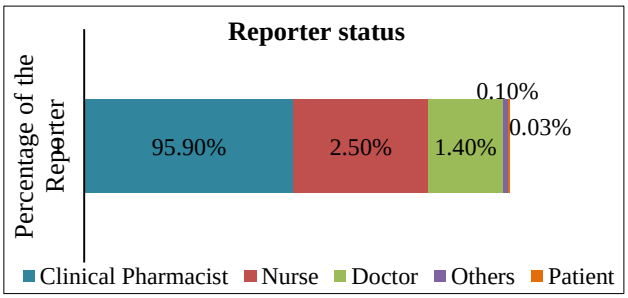

Figure 2: Reporter status of the ADRs reports.

Table 8: Distribution of adverse drug reaction among departments.

Department	Frequency	Percentage
Oncology	2675	36.17
General medicine	1054	14.25
Medical gastroenterology and hepatology	552	7.46
Cardiology	482	6.52
Pulmonology	431	5.83

Continued.

Department	Frequency	Percentage
Neurology	399	5.39
Paediatrics	234	3.16
Orthopaedics and spine surgery	218	2.95
HPB and multi organ transplant surgery	211	2.85
Critical care medicine	198	2.68
OBG	188	2.54
Nephrology	180	2.43
Urology	98	1.33
General surgery	85	1.15
Dermatology	72	0.97
PMR	64	0.87
ENT	48	0.65
Emergency	35	0.47
Plastic, reconstructive and micro vascular surgery	31	0.42
Clinical immunology	30	0.41
Diagnostic radiology	27	0.37
CVTS	23	0.31
Endocrinology	21	0.28
Bariatric surgery	16	0.22
Pain and palliative medicine	10	0.14
Psychiatry	9	0.12
Implantology and dental sciences	3	0.04
Neonatology	1	0.01
Nuclear medicine	1	0.01
Anesthesiology	0	0.00
Ophthalmology	0	0.00
Total	7396	

DISCUSSION

Age and gender

In the current study 57.79% of ADRs reported were from adult patients and 37.56% of ADRs were from geriatric patients. This is in line with the study from South Africa that showed the most common age for which ADRs was reported is 19-64 years.[6] Another study from India also indicated the most prevalent age group, in which ADRs were reported in the age group of 19-60 years.[7] On contrary, it is important to take into consideration that ADRs are mostly reported in geriatric patient due to co-morbidities, inappropriate prescription, inadequate monitoring and poly-pharmacy.[8] Therefore, the age group of adults that exhibits a higher incidence of ADRs warrants further investigation in future research.

There may be a significant difference in the prevalence of ADRs between males and females due to various factors such as body mass index, fat composition, hormonal changes, drug susceptibility, and genetic variations in enzyme level.[9] Even though, the current study did not find any notable difference in the incidence of ADRs between males (51.11%) and females (48.89%), this trend was similar with the studies by Venkatasubbaiah et al and Sendekie et al.[1,2] Various studies have produced conflicting results regarding the higher incidence of ADRs in male and female populations. However, the study by Bhavishya et al and Alenzi et al found predominance of male populations than females in patterns of ADRs reported.[7,8] However, another study by Zakir et al observed more in females than males.[9]

ATC class and route of administration

Medications from all fourteen ATC categories were identified as causes for ADRs. Over 60% of all reported ADRs were linked to ATC drug classes of anti-neoplastic and immunomodulating agents and cardiovascular system. A retrospective analysis of a 9-year study from 96 countries reported higher number of ADRs from anti-neoplastic and immunomodulating agents. This data from high income countries was in similar trend with the current study.[10] Similarly, Ozcan et al also stated that antineoplastic agents is frequently associated with ADRs.[11] Nonetheless, the higher incidences of reports for these therapeutic classes might be due to the greater exposure to these drugs. Therefore, these requires a greater need of monitoring while prescribing.

The results of current study indicate that drugs given through the intravenous route (IV) are more often implicated in causing ADRs. A study by Zhang et al in 2022 also produced similar results. Possible explanations for this finding include the immediate onset of action;

variations in pH, osmotic pressure, and endo-toxin levels in the injection; higher drug concentrations associated with intravenous administration; the speed at which drugs are administered; and the large volume of injections typical administered to hospitalized patients.[12]

Causality

Evaluating the causality of ADRs is essential to determine if the drug is the exclusive cause of the reaction or any other factors were involved in its occurrence.[1] Establishing the causal relationship is a key element in pharmacovigilance, as it contributes to improved assessment of the risk-benefit profiles of medicines and is indispensable for regulatory objectives. The current study found a significant number of possible cases in the causality assessment scale. Studies by Venkatasubbaiah et al, Gangisetty et al, from South India also demonstrated same pattern.[1,13] In contrast, Bhavishya et al showed increased probable cases rather than possible.

System organ class

When assessing the causality of a ADRs, the SOC level provides a logical starting point for data retrieval and analysis.[14] The SOC findings from the current study showed a substantial number of cases under blood and lymphatic system disorders, gastrointestinal disorders, metabolism and nutrition disorders, skin and subcutaneous tissue disorder. Prior studies corroborate the high incidence of ADRs categorized under the SOCs of gastrointestinal disorders, skin and subcutaneous tissue disorders.[6,8,10,11,15]

The higher incidence of blood, lymphatic system disorders and metabolism, nutrition disorders observed in our study was not consistent with findings from other researches. This discrepancy can be attributed to the higher prevalence of anti-neoplastic drugs usage in study participants. As a result, this divergence warrants further exploration of the underlying factors contributing to these differences.

Seriousness and outcome of the reaction

The seriousness of the reaction provides insight into the associated risks, which is a crucial factor to consider when marketing pharmaceuticals.[1] The current study revealed major part of the events reported were non – serious (95.3%) and 3.10% of events led to hospitalizations. In contrary, another study conducted in India found that the majority of the reactions were serious (64.56%)[1] The difference in these results may be due to variation in the study population as they included only selected departments. In the outcome of events a significant number (39.76%) of ADRs remained unknown. Most of the patient recovered from the event after withdrawing offending drug. This trend was similar in a study conducted in India, in which they showed that after discontinuing the offending drug, the patients recovered from the ADRs.[1]

Reporter status and department

The reliable spontaneous reporting systems for ADRs commonly employed by prescribers, nurses, pharmacists, and publics are vital for the detection of serious ADRs in hospitals.[9] All the healthcare providers need to be actively involving in the ADRs reporting to increase the reporter base.[16] The reporting pattern of ADRs in studies varies greatly due to differences in healthcare structures, along with the awareness and commitment of healthcare professionals.[12] The findings of this study indicated that clinical pharmacists were the most significant reporters, with nurses ranking next. This finding was inconsistent with that of Jiang et al, which indicated physicians (43.98%) contributed more than nurses (0.33%).[12]

Plausible explanations for differences in reporting by nurses from the current study may be due the periodic training from the pharmacology department. This resulted in a greater volume of reporting from their side. Additionally, in the current study clinical pharmacist are involved in active surveillance rather passive surveillance.

According to current the study, a large portion of ADRs were identified in the oncology department, while the general medicine department also reported a substantial amount. Prior studies report a significant amount of ADRs from general medicine departments. This variation can be attributed to the highly established from oncology department. A study Dilip et al demonstrated most ADRs were reported from the general medicine department, primarily because patients are typically evaluated there before being referred to specialists.[17]

Limitations

The results of the current study were obtained from healthcare providers and not on clinical judgement, observations therefore, the odds of underreporting are likely and ADRs from outpatient area are underreported due to busy schedule of doctors. Another limitation is that the data on preventability of ADRs were not included in the study, which would have a greater impact to the study.

CONCLUSION

The current study shows antineoplastic and immunomodulating agents are common drug in occurence of ADRs in the study population. Monitoring and managing ADRs along with future research initiatives will significantly enhance patient care and safety. The regional database for spontaneous reports underscores the significance of ADRs in tracking safety information for approved medications and highlights their importance in exploring the indicators linked to ADRs. Consequently, educational initiatives and campaigns focused on methods for recognizing and reporting any potential ADRs are crucial to prevent the under reporting of adverse drug events.

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REFERENCES

1. Venkatasubbaiah M, Dwarakanadha Reddy P, Satyanarayana SV. Analysis and reporting of adverse drug reactions at a tertiary care teaching hospital. Alex J Med. 2018;54(4):597-603.
2. Sendekie AK, Netere AK, Tesfaye S, Dagnew EM, Belachew EA. Incidence and patterns of adverse drug reactions among adult patients hospitalized in the University of Gondar comprehensive specialized hospital: A prospective observational follow-up study. PLoS One. 2023;18(2):e0282096.
3. Giardina C, Cutroneo PM, Mocciaro E, Russo GT, Mandraffino G, Basile G, et al. Adverse Drug Reactions in Hospitalized Patients: Results of the FORWARD (Facilitation of Reporting in Hospital Ward) Study. Front Pharmacol. 2018;9:350.
4. Asiamah M, Akuffo KO, Nortey P, Donkor N, Danso-Appiah A. Spontaneous reporting of adverse drug reaction among health professionals in Ghana. Arch Public Health. 2022;80(1):33.
5. Sultana J, Cutroneo P, Trifirò G. Clinical and economic burden of adverse drug reactions. J Pharmacol Pharmacother. 2013;4(1):S73-7.
6. Steyn H. Profile of adverse drug reaction reports in South Africa: An analysis of VigiBase® for the year 2017. S Afr Med J. 2023;113(6):26-33.
7. Valder B, Neelamma P, Nalini GK, Sahana GN. A study to assess, monitor, and reporting of adverse drug reactions in a tertiary care teaching hospital: HIMS, Hassan. Asian J Pharm Clin Res. 2023;16(7);201-3.
8. Alenzi KA, Alanazi NS, Almalki M, Alomrani H, Alatawi FO. The evaluation of adverse drug reactions in Saudi Arabia: A retrospective observational study. Saudi Pharm J. 2022;30(6):735-41.
9. Khan Z, Khan ZH, Khan Z, Karataş Y, Karataş Y, Kıroğlu O, et al. Evaluation of Adverse Drug Reactions in Paediatric Patients: A Retrospective Study in Turkish Hospital. Front Pharmacol. 2021;12:786182.
10. Aagaard L, Strandell J, Melskens L, Petersen PSG, Hansen EH. Global Patterns of Adverse Drug Reactions Over a Decade: Analyses of Spontaneous Reports to VigiBaseTM. Drug Saf. 2012;35(12):1171-82.
11. Ozcan G, Aykac E, Kasap Y, Nemutlu NT, Sen E, Aydinkarahaliloglu ND. Adverse Drug Reaction Reporting Pattern in Turkey: Analysis of the National Database in the Context of the First Pharmacovigilance Legislation. Drugs - Real World Outcomes. 2016;3(1):33-43.
12. Jiang H, Lin Y, Ren W, Fang Z, Liu Y, Tan X, et al. Adverse drug reactions and correlations with drug–drug interactions: A retrospective study of reports from 2011 to 2020. Front Pharmacol. 2022;13:923939.
13. Gangisetty S, Nadendla S, Goka P, Zahedabano, Prasanthi N, Rao N, et al. An Observational Prospective Study on Prevalence and Monitoring of Adverse Drug Reactions in Tertiary Care Teaching Hospital. Br J Pharm Res. 2016;11(2):1-9.
14. MedDRA®. Data Retrieval and Presentation: Points to Consider. Available at: https://alt.meddra.org/files_acrobat/001007_datretptc_r3_24_mar2024.pdf. Accessed on 12 November 2024.
15. Teketel Alemu Ersulo, Teketel Alemu Ersulo, Mengist Awoke Yizengaw, Awoke M, Behailu Terefe Tesfaye, Tesfaye BT. Incidence of adverse drug events in patients hospitalized in the medical wards of a teaching referral hospital in Ethiopia: a prospective observational study. BMC Clin Pharmacol. 2022 May 17;23(1).
16. Singh P, Agrawal M, Hishikar R, Joshi U, Maheshwari B, Halwai A. Adverse drug reactions at adverse drug reaction monitoring center in Raipur: Analysis of spontaneous reports during 1 year. Indian J Pharmacol. 2017;49(6):432.
17. Dilip C, Lisa MM, Divya R. Adverse drug reaction monitoring in a tertiary level referral hospital, Kerala. Indian J Pharm Pract. 2012;5(2):28-32.

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