HOSPITAL PHARMACOLOGY
International Multidisciplinary Journal

ISSN 2334-9492 (Online)

Hospital Pharmacology. 2026; 13(1):1773-1783

UDC: 615.065(540)

doi:10.5937/hpimj2601773P

Original Study

Analysis of Spontaneously Reported Suspected Adverse Drug Reactions Reported at a Tertiary Care Teaching Hospital

Jigar Popatlal Modi[1], Shivani Pradipkumar Trivedi[2], Disha Sanjaykumar Mehta[1], Darshan Jitendrabhai Dave[1]

[1] Department of Pharmacology,GMERS Medical College, Gandhinagar, Gujarat, India
[2] ADR Monitoring Centre,Department of Pharmacology, GMERS Medical College, Gandhinagar, Gujarat, India

SUMMARY

Introduction: Adverse drug reactions (ADRs) are a significant cause of morbidity, mortality, and economic burden in healthcare. In India, the ADR reporting rate remains low despite the Pharmacovigilance Programme of India (PvPI).

Aim: To analyze spontaneously reported suspected ADRs in a tertiary care teaching hospital with respect to demographic characteristics, drug classes, organ systems affected, severity, seriousness, causality, and outcome.

Material and Methods: A retrospective, academic, observational, record-based study was conducted at the ADR Monitoring Centre, GMERS Medical College and General Hospital, Gandhinagar. All spontaneously reported ADR forms received between April 2022 and March 2023 were analyzed. Data were evaluated for completeness and categorized by patient demographics, organ system classification (MedDRA SOC), suspected drugs, severity (Hartwig-Siegel scale), seriousness (PvPI criteria), and causality (WHO-UMC scale). Descriptive statistics were applied.

Results: A total of 1,004 drug encounters were analyzed. ADR occurrences were similar in males (51.09%) and females (48.91%), with most reports from adults aged 18–35 years (47.41%). Antibiotics (33.27%), analgesics (12.15%), and antidepressants (7.67%) were the leading drug classes. The skin (33.33%), gastrointestinal (28.77%), and nervous systems (8.31%) were most frequently affected. Most ADRs were mild (85.25%), non-serious (86.45%), and classified as probable in causality assessment (64.64%). Recovery occurred in 66.43% of cases, while outcomes were unknown in 29.98%.

Conclusion: Cutaneous ADRs were most common, primarily due to antimicrobials and NSAIDs. Strengthening ADR documentation and fostering a reporting culture are essential for enhancing patient safety and optimizing pharmacotherapy.

Keywords: Adverse Drug Reactions, Pharmacovigilance Program of India, WHO-UMC Causality Assessment, Tertiary Care Hospital, Spontaneous Reporting System

Corresponding author:
Professor Darshan Jitendrabhai Dave, MBBS, MD
Department of Pharmacology, GMERS Medical College, Gandhinagar, Gujarat, India
E-mail: darshanjd79@yahoo.com

INTRODUCTION

The county's health care system bears a significant financial burden from the morbidity and mortality linked to adverse drug reactions (ADRs), but the main cause for concern is the significantly low number of ADR reports that result from inadequate knowledge and communication. Therefore, voluntary reporting of adverse drug reactions (ADRs) is critical to the society's future health [1].

Indian pharmaceutical industry values around $18 billion dollar, one of the largest in the world, growing at the rate of 12-14% per annum and exporting 40% of generic medicine to the world [2]. Globally Indian pharmaceutical industry ranks third, represented by over 6000 licensed drugs and still increasing day by day [3]. But there is lack of a formal culture for monitoring and reporting of adverse drug reactions (ADRs) in India, with ADR reporting rate being only 1% as compare to 5% in world [4]. Thus proactive Pharmacovigilance (PV) throughout the life cycle of drug is need of the hour. PV deals with the detection, assessment, understanding and prevention of ADRs [5]. The primary goal of PvPI is to protect the health of the Indian populace by making sure that the advantages of medication use exceed the risks. Pharmacovigilance Programme Of India(PvPI) aims to decrease the risk associated with medication use by improving patient safety [6]. ADRs can also lead to a lower quality of life, more doctor visits, hospitalizations, and even death. They also result in higher health care costs, which significantly strain health care resources [7]. Good pharmacovigilance helps in the minimization or prevention of ADRs through early detection and effective communication, which ultimately help each patient to receive optimum therapy [8]. It can generate evidence that will inspire public confidence and trust in drugs. ADRs are more common with multiple drug therapy, and the risk of an ADR episode increases by 1.14 for every additional medication taken by the patient, which directly lengthens the length of stay [9]. A study conducted in a tertiary referral hospital in south India found that 1.8% of all admissions were fatal ADRs, and 0.7% of all admissions were drug-related. As a PvPI-designated AMC (adverse drug reaction monitoring center), we strive to protect patient safety and well-being by promptly and appropriately managing adverse drug reactions (ADRs) and detecting, reporting, and monitoring them in the hospital setting since last 3 years. Till now there is not a single study available on this important aspect of treatment from our institution.

AIM

One of the aims of the study is to create awareness among clinicians of this institution and with this we can move forward to inculcate the culture of ADR reporting. In this study, ADRs were analyzed retrospectively for the type and pattern of ADR reported, demographic profile of patients, organ system involved, causative drugs, and severity, outcome, management and causality assessment.

MATERIAL AND METHODS

The study was an academic, retrospective, observational, record-based analysis (nointerventional).

The study was conducted at GMERS Medical College and General Hospital, Gandhinagar.

The study protocol (Protocol No. IEC 52.2023) was reviewed and approved by the Institutional Ethics Committee, GMERS Medical College, Gandhinagar. The protocol was considered at the full board meeting held on 13 December 2023, and approval was granted on 14 December 2023. This was an academic study with no funding or sponsorship. The authors declare no conflict of interest. This retrospective study was conducted by analyzing spontaneous ADR forms collected over a period of 12 months (April 2022 to March 2023) at GMERS Medical College and General Hospital, Gandhinagar.

As this was a retrospective, record-based study, data had already been collected in ADR forms. Therefore, no additional data collection was required.

The ADR Monitoring Centre at GMERS Medical College, Gandhinagar, is one of the ADR monitoring centers under the Pharmacovigilance Programme of India (PvPI). It is coordinated by the Department of Pharmacology. The study commenced after obtaining approval from the Institutional Human Ethics Committee. All spontaneously reported ADR forms collected during April 2022 to March 2023 were evaluated. When necessary, the reporting physician was contacted to

Age group[years]	Encounters in male	Encounters in female	Total
<18	19	08	27 [2.69]
18-35	204	272	476 [47.41]
36-60	210	153	363 [36.15]
>60	80	58	138 [13.74]
TOTAL	513	493	1004 [100.00]

Table 1. Data evaluation based on demographics of the patient

collect further information.

Inclusion and Exclusion Criteria:

- Inclusion: All spontaneously reported ADR forms collected during the study period.
- Exclusion: Cases of drug poisoning, medication errors, doubtful causality, and ADR forms with insufficient information.

Descriptive analysis of the data was performed using Microsoft Excel 2013 and results were expressed as numbers and percentage.

Data from spontaneously reported ADRs were collected from healthcare professionals carefully evaluated.

The study analyzed the demographic profile of patients, completeness of data in reported ADR forms, duration of ADR, description of the reaction, organ systems involved, suspected medications, dechallenge, rechallenge, severity, outcome, management, and causality assessment. The reactions were categorized based on patient demographics (age and gender) and ADR characteristics.

Adverse drug reaction characteristics

The ADRs were analyzed for their seriousness, severity, causality and the organ system affected. The seriousness of the ADRs was assessed by using the PvPI criteria [8] i.e. life-threatening, required intervention to prevent permanent impairment/damage, hospitalization/prolonged hospital stay, disability, congenital anomaly, and death.

The severity of the reaction was determined and categorized as mild, moderate or severe according Hartwig and Siegel Severity Assessment Scale [9]. As no single method is universally accepted for assessing the causal relationship between a drug and adverse reactions, various algorithms and methods are used based on individual or institutional preference. We have assessed the causality to establish the relationship between the drug and the reaction by using WHO Causality assessment scale, as it is recommended by Uppsala Monitoring Centre (UMC) and PvPI [8,10,11].

Duration	Encounters	Percentage
Duration not mentioned	328	33
Duration less than 1 day	0	0
1	217	22
2	139	14
3	128	13
4	68	7
5	35	3
6	26	3
7	11	1
8	10	1
9	5	0
10	6	1
>10	31	3

Table 2. Distribution according duration of ADR

Prescribed by brand name	Prescribed by generic name
189 [18.82%]	815 [81.18%]

Table 3. Suspected medication prescribed by drug nomenclature

Dosage form	Encounters
Not mentioned	0
Topical	76 [7.56%]
Oral	729 [72.60%]
Parenteral	199 [19.82%]

Table 4. Dosage form

Severity level	Encounters
Mild	856 [85.25%]
Moderate	145 [14.44%]
Severe	3 [0.31%]

Table 5. Severity Assessment

Rechallenge	Encounters	Percentage
Not mentioned	539	53.69
Yes	25	2.49
No	27	2.69
Effect unknown	413	41.14

Table 6. Rechallange level

Dechallenge	Encounters	Percentage
Not mentioned	402	40.04
Yes	511	50.90
No	32	3.19
Effect unknown	59	5.88

Table 7. Dechallange level

Table 8a. Classes of Drugs Causing ADRs

Class	Encounters	Percentage
Antimicrobials	334	33.27
NSAIDS	122	12.15
Anti-depressants	77	7.67
Haematinics	75	7.47
Vitamins	50	4.98
Antiepileptics	40	3.98
Antihypertensives	38	3.78
Antihistaminic	33	3.29
Antipsychotics	30	2.99
Antidiabetics	20	1.99
Diuretic	16	1.59
Ant anxiety/sedatives	15	1.49
Estrogen and Progesterone analogues	14	1.39
Anti-manic/drugs for BPD	13	1.29
PPIs/H2 blocker	13	1.29
Vaccine/anti-sera	13	1.29
Calcium	8	0.80
Opioids	6	0.60
Antimigraine	6	0.60
Antimetabolite	6	0.60
Cognitive enhancers	6	0.60
Antiparkinsonian	6	0.60
Prostaglandin analogues	5	0.50
Beta-agonist	5	0.50
Antitussive	5	0.50
Steroid	5	0.50
Thyroid analogues	4	0.40
Hypolipidemic	4	0.40
Vasodilator	4	0.40
Ashwagandha/Ayurveda	3	0.30
Calcium channel blocker	3	0.30
Anticoagulant	3	0.30
Antiemetic	3	0.30
Laxative	3	0.30
Anticholinergic	3	0.30
Blood and blood products	2	0.20
Fluids	2	0.20
Anesthetic	2	0.20
Faecal Microbial Transplant	2	0.20
CNS stimulant	2	0.20
Antithyroid	2	0.20
Tocolytic	1	0.10
Total	1004	100

Further, ADRs were categorized based on de-challenge/rechallenge, class of the causative drug, duration of therapz, nomenclature followed in drug prescription, dosage form, duration of ADR, system organ class according MedDRA classification, outcomes and management.

RESULTS

In this study, we retrospectively analyzed a total of 1,004 drug encounters suspected to be associated with ADRs, reported between April 2022 and March 2023 through our AMC to PvPI. Each prescribed drug was considered a separate encounter for the associated adverse drug reaction. Accordingly, the prescribing patterns of these 1,004 drugs were analyzed in relation to their respective reported ADRs.

We found no significant difference in the occurrence of ADR encounters between males (51.09%) and females (48.91%) in our study. majority of reports in our study were from adults, with 47.41% in the 18-35 year age group and 36.15% in the 36-60 year age group.

Out of the 1,004 encounters we analyzed, the duration of ADR was not mentioned in 33% (n=328) of the forms, while in 22% (n=217) of the forms, the duration was reported as 1 day. Only 3% of encounters documented a duration of more than 10 days.

In this study, 815 drugs were prescribed by their generic names, while only 189 drugs were prescribed by their brand names.

In our study all in all reports dosage form was mentioned while most common dosage form was oral (n=729) followed by parenteral (n=199).

The majority of ADRs (85.25%, n=856) were classified as mild, while 14.44% (n=145) were categorized as moderate.

In this study, rechallenge was not mentioned in 53.69% of encounters, and in 41.14% of encounters, the effect of rechallenge was unknown.

Regarding dechallenge, it was not documented in 40.04% of encounters, while it was mentioned in 50.90% of encounters.

A higher number of ADRs were reported for antibiotics 334 (33.27%) followed by analgesics 122(12.15%) and antidepressants 77(7.67%). Detailed list of offending drugs is shown in detail in Table 8a.

We observed that 329 (33.33%) encounters were related to Skin organ class

System organ class	Number of encounters	Percentage
Skin And Subcutaneous Tissue Disorders	329	33.33
Gastrointestinal Disorders	284	28.77
Nervous System Disorders	82	8.31
General Disorders and Administration Site Conditions	50	5.07
Thoracic And Mediastinal Disorders	40	4.05
Immune System Disorders	24	2.43
Renal And Urinary Disorders	22	2.23
Hepatobiliary Disorders	19	1.93
Musculoskeletal And Connective Tissue Disorders	19	1.93
Ear And Labyrinth Disorders	17	1.72
Metabolism And Nutrition Disorders	17	1.72
Blood And Lymphatic System Disorders	14	1.42
Eye Disorders	14	1.42
Reproductive System And Breast Disorder	14	1.42
Respiratory, Thoracic And Mediastinal Disorders	14	1.42
Vascular Disorders	13	1.32
Cardiac Disorders	11	1.11
Endocrine Disorders	4	0.41
Congenital, Familial And Genetic Disorders	0	0
Infections And Infestations	0	0
Injury, Poisoning And Procedural Complications	0	0
Investigations	0	0
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	0	0
Pregnancy, Puerperium And Perinatal Conditions, Product Issues	0	0
Psychiatric Disorders	0	0
Social Circumstances	0	0
Surgical And Medical Procedures	0	0
Total	987	100

Table 8b. MedDRA Classification System organ class (SOC)

* In 17 encounters, more than two systems were involved; therefore these encounters were not included in this table.

followed by Gastro- Intestinal (GI) system 284(28.77%) and Nervous System 82(8.31%), the involvement of other systems is illustrated in Table 8b.

In this study, out of 1,004 encounters, the duration of the drug was not mentioned in 251 encounters, indicating incomplete data reporting. In 143 encounters, the drug duration was reported as one day.

Among the 1004 encounters, 66.43% of encounters recovered after the withdrawal of the offending drugs (72.91%), while the outcomes were unknown for 29.98% of adverse drug reaction encounters.

Seriousness was assessed using the standard criteria povided by the PvPI and the majority of ADRs were found to be non serious (86.45%). Distribution of ADR encounters based on seriousness in accordance with criteria is presented in Table 11.

Among the 1,004 encounters, 667 (66.43%) patients recovered from the reactions, 301 (29.98%) had unknown outcomes, and no ADRs were fatal, as demonstrated in Table 12.

Causality assessment is vital to determine whether an ADR is solely caused by the drug or if other factors contributed to its occurrence. In our study, we employed the WHO-UMC causality assessment scale and found that 64.64% of ADR encounters were classified as probable while 32.57 %were possible.

DISCUSSION

Our institution has seen a steady rise in ADR reporting over the years as more providers have become involved. This may be explained by increased awareness brought about by

Table 9. Duration of Suspected Medication

Duration in Days	Encounters	Percentage
Less than 1 day	65	6.47
Not Mentioned	251	25.00
1	143	14.24
2	115	11.45
3	143	14.24
4	95	9.46
5	45	4.48
6	18	1.79
7	9	0.90
8	10	1.00
9	12	1.20
10	2	0.20
11	5	0.50
12	1	0.10
13	3	0.30
14	4	0.40
15	10	1.00
16	5	0.50
20	2	0.20
21	1	0.10
27	1	0.10
28	1	0.10
29	8	0.80
30	4	0.40
>30	51	5.08

Table 10. Action Taken after ADRs

Action Taken	Encounters	Percentage
Not mentioned	4	0.40
Drug withdrawn	732	72.91
Dose increased	7	0.70
Dose reduced	59	5.88
Dose not changed	152	15.14
Not applicable	15	1.49
Unknown	35	3.49
Grand Total	1004	100.00

Table 11. Seriousness of ADRs

Seriousness	Encounters	Percentage
Not Mentioned	51	5.08
Non-Serious	868	86.45
Serious	85	8.47
Grand Total	1004	100.00

educational initiatives and institutional campaigns. However, underreporting remains the primary issue in pharmacovigilance efforts, as the literature suggests, with strategies such as incentives, campaigns, and even legislative reforms having little impact on reporting [12,13,14].

In this study, we found no significant difference in the occurrence of ADR encounters between males (51.09%) and females (48.91%). Similarly, studies conducted in Northeast India by Lihite et al. and in South India by Vijayakumar et al. reported only a slightly higher occurrence of ADRs in females compared to males, with an 8% difference noted in the latter study. While research has indicated that older and pediatric patients have a higher prevalence of adverse drug reactions (ADRs) [15,16,17], the majority of reports in our study were from adults, with 47.41% in the 18-35 year age group and 36.15% in the 36-60 year age group. The higher rate of ADRs reported in males can also be explained by the higher rate of drugs being prescribed for males especially in the adult age group.

Out of the 1,004 encounters we analyzed, the duration of ADR was not mentioned in 33% (n=328) of the encounters, while in 22% (n=217) of the encounters, the duration was reported as 1 day. Only 3% of encounters documented a duration of more than 10 days. These findings can be compared with other studies, which have reported similar trends in incomplete documentation and shorter durations of ADRs.

In this study, 815 drugs were prescribed by their generic names, while only 189 drugs were prescribed by their brand names.

In our study, the dosage form was mentioned in all the reports (Table 4). The most common dosage form was oral (n=729), followed by parenteral (n=199).

Assessment of severity is essential to guide decisions regarding continuation, modification, or discontinuation of the suspected drug In this study, we also analyzed the severity levels of adverse drug reactions (ADRs). The majority of ADR encounters (85.25%, n=856) were classified as mild, while 14.44% (n=145) were categorized as moderate. Fortunately, the incidence of severe ADRs was low, consistent with findings from similar studies conducted by other researchers [7,18,19].

Different clinical environments and the specialist healthcare services offered by different institutions may be the cause of the variation in the severity of the reported instances across different studies [20,21,22].

The system organ class (SOC) associated with the ADRs was coded using the

Medical Dictionary for Regulatory Activities (MedDRA) classification system. Table 8b lists ADRs by the type of SOC affected. Out of the 27 MedDRA system organ classes, only 18 were involved in the ADRs reported.

The primary system organ class affected was skin and subcutaneous tissue disorders, with reactions ranging from severe to mild rashes. These findings are consistent with previous studies reporting a higher overall occurrence of ADRs in any system organ class were higher in this age group [23,24]. Occurrence of cutaneous ADRs were in conformity with other studies [20,25,26,27]. These ADRs were expected to be the most frequently reported due to their immediate onset and the ease of establishing a temporal association with the administered drug, compared to ADRs that are delayed or less commonly attributed to a drug.

Antimicrobials and NSAIDs accounted for the majority of skin and subcutaneous tissue-related ADR encounters (33.33%), with the most frequent manifestations being itching, rashes, and skin redness. Gastrointestinal tract-related ADRs followed closely (28.77%), predominantly presenting as nausea, vomiting, and diarrhea. The nervous system was the third most commonly affected, representing 8.31% of ADR encounters, with symptoms such as headache, sedation, and drowsiness.

Diclofenac (n=67) was the most frequently reported drug, primarily prescribed for muscle and bone-related pain. It was followed by Azithromycin (n=51) and third-generation cephalosporin, including Ceftriaxone (n=26) and Cefixime (n=20) which were indicated for respiratory tract infections and various other infections. These drugs are also among the most commonly prescribed at our institution. During the study period, iron sucrose (n=37), commonly used to treat anemia, was the most frequently associated with immunological reactions. Another similar study, in terms of organ system classification, found that immunological-related ADRs accounted for 84.8%, with reactions ranging from severe anaphylaxis to mild rashes [28]. In that same study, analgesics, diagnostic agents, and antimicrobials were the most commonly associated drugs with immunological-related ADRs. Among analgesics, morphine was the most frequently reported, accounting for 43% of the cases in this class. Antimicrobials contributed the highest number of immunological-related ADRs, with Ceftriaxone being the most commonly reported drug, followed by Piperacillin/Tazobactam and Vancomycin [28]. These findings are consistent with those observed in our study.

Table 12. Outcome of ADRs

Outcome	Encounters	Percentage
Not mentioned	2	0.20
Recovered	667	66.43
Recovering	3	0.30
Not recovered	23	2.29
Fatal	0	0.00
Recovered with sequalae	8	0.80
Unknown	301	29.98
Grand Total	1004	100.00

Table 13. Causality Assessment

Causality	Encounters	Percentage
Not mentioned	15	1.49
Certain	2	0.20
Probable	649	64.64
Possible	327	32.57
Unlikely	11	1.10
Grand Total	1004	100.00

In our study, Escitalopram (n=19), a drug often prescribed for depression and migraine, was also commonly reported. The majority of adverse drug reactions (ADRs) were observed in admitted patients, with antibiotics being implicated in most encounters (33.27%). These findings are consistent with the study done by Jung et al [29]. This is likely due to the fact that nearly all inpatients received antibiotic therapy, either for prophylactic or curative purposes. NSAIDs were the second most commonly associated class of drugs (12.15%). These findings align with the results of previous studies [9,30,31,32,33,34,35,36].

In this study, out of 1,004 encounters, the duration of the drug was not mentioned in 251 encounters, indicating incomplete data reporting. In 143 encounters, the drug duration was reported as one day.

Causality assessment is vital to determine whether an ADR is solely caused by the drug or if other factors contributed to its occurrence. In our study, we employed the WHO-UMC causality assessment scale and found that the 64.64% of ADR encounters were classified as probable while 32.57% were possible. These findings are consistent with those of Konda VCR et al., who also used the WHO-

UMC scale and reported that 75% of the cases were classified as probable. Similarly, other observational studies conducted in South Indian tertiary care teaching hospitals [30,33,36] have found that the majority of ADRs were classified as possible using the same scale.

The seriousness of the reaction gives information on the risk involved, which is an important parameter to be considered in the marketing of drugs. The seriousness was assessed by using PvPI criteria and found the 86.45% of ADRs were non-serious reactions. An Indian study conducted by Sneha et al. also reported that the majority of ADRs led to hospitalization or prolonged hospital stay (52.33%) and required intervention (38.31%), with a significant number of serious ADRs identified. In another Indian study conducted by Singh et al. reported that 6.5% ADRs were of life-threatening.

Among the encounters, 66.43% recovered after the withdrawal of the offending drugs (72.91%), while the outcomes were unknown for 29.98% of adverse drug reaction encounters (Table 12).

In this study, we also analyzed rechallenge and dechallenge, which are critical for causality assessment. Additionally, we evaluated the completeness of ADR form information. We found that rechallenge was not mentioned in 53.69% of encounters, and in 41.14% of encounters, the effect of rechallenge was unknown. Regarding dechallenge, it was not documented in 40.04% of encounters, while it was mentioned in 50.90% of encounters. These results align with another study, where dechallenge was mentioned in 58.70% of cases. These findings highlight certain gaps in the completeness of ADR form documentation, emphasizing the need for more accurate and consistent reporting.

We agree with our esteemed colleagues Slobodan M. Janković, Ljubinka I. Nikolić, Srdjan Z. Marković and Dragana A. Kastratović, who noted that the reporting of adverse drug reactions reflects the robustness of a country's healthcare system and its overall efficiency in medical treatment [37,38,39,40]. Therefore, there is a clear need to conduct more academic studies focusing on the reporting of adverse drug reactions.

Since this is a retrospective analytical investigation, we could examine the suspected drugs and responses that were reported on the reporting form. Only a small number of reports provide information on all the concurrent drugs that patients take for different diseases. Additionally, the study design prevents us from obtaining additional information, such as the duration of recovery from adverse responses and details on all medications used to treat the observed adverse reactions. Regarding the reported ADRs, only a small number of reports lacked pertinent laboratory data. A study that is planned prospectively will get over these restrictions.

Improving medication safety and preventing harm are the ultimate goals of having an active institutional ADR team. A spontaneous ADR reporting system has drawbacks, but it's a useful tool for tracking internal trends and sending out alerts about medication safety concerns that may be resolved by internal policies and programs.

CONCLUSION

This study is the first to document patterns of adverse drug reactions (ADRs) reported independently at one of the largest hospitals in the region. The most commonly reported ADRs were cutaneous reactions. This could be attributed to their immediate onset, facilitating the establishment of a temporal association with the offending drug. An analysis of the data revealed that antimicrobial agents were the most frequent cause, followed by NSAIDs and antidepressant medications.

The trends in reported ADRs are evolving due to the annual introduction of new medications and shifts in prescribing practices. Consequently, continuous ADR monitoring is essential.

Every institution should support and maintain an active ADR team responsible for incident evaluation, trend analysis, and most importantly identifying opportunities to improve patient and medication safety.

CONFLICT OF INTEREST

All authors declare no conflict of interest.

ACKNOWLEDGEMENT

The authors sincerely acknowledge the Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission, Ghaziabad, under the Ministry of Health and Family Welfare, Government of India, for providing

the platform through the ADR Monitoring Centre, GMERS Medical College, Gandhinagar, to conduct this study.

REFERENCES

1. Alomar M, Tawfiq AM, Hassan N, Palaian S. Post marketing surveillance of suspected adverse drug reactions through spontaneous reporting: current status, challenges and the future. Ther Adv Drug Saf. 2020 Aug 10;11:2042098620938595. doi:10.1177/2042098620938595. PMID: 32843958; PMCID: PMC7418468.

2. Biswas P. Pharmacovigilance in Asia. J Pharmacol Pharmacother. 2013 Dec;4(Suppl 1):S7-S19. doi:10.4103/0976-500X.120941. PMID: 24347987; PMCID: PMC3853674.

3. Shamna M, Dilip C, Ajmal M, Linu Mohan P, Shinu C, Jafer CP, Mohammed Y. A prospective study on adverse drug reactions of antibiotics in a tertiary care hospital. Saudi Pharm J. 2014 Sep;22(4):303-8. doi:10.1016/j.jsps.2013.06.004. PMID: 25161373; PMCID: PMC4142362.

4. Upadhyaya HB, Vora MB, Nagar JG, Patel PB. Knowledge, attitude and practices toward pharmacovigilance and adverse drug reactions in postgraduate students of tertiary care hospital in Gujarat. J Adv Pharm Technol Res. 2015 Jan-Mar;6(1):29-34. doi:10.4103/2231-4040.150369. PMID: 25709967; PMCID: PMC4330609.

5. World Health Organization. The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva: World Health Organization; 2002.

6. Pharmacovigilance Programme of India. PvPI reaches out to rural masses [Internet]. Ghaziabad: Indian Pharmacopoeia Commission; [cited 2017 Sep 3]. Available from: http://www.ipc.gov.in/PvPI/newsletter3/newsletter3.html#page/4

7. Pritchard D, Petrilla A, Hallinan S, Taylor DH Jr, Schabert VF, Dubois RW. What contributes most to high health care costs? Health care spending in high resource patients. J Manag Care Spec Pharm. 2016 Feb;22(2):102-9. doi:10.18553/jmcp.2016.22.2.102. PMID: 27015249; PMCID: PMC10397786.

8. Indian Pharmacopoeia Commission. Guidance document for spontaneous adverse drug reaction reporting [Internet]. Ghaziabad: Indian Pharmacopoeia Commission; 2014 [cited 2025 Aug 7]. Available from: http://ipc.nic.in/writereaddata/mainlinkFile/File268.pdf

9. Singh H, Dulhani N, Kumar B, Singh P, Tewari P, Nayak K. A pharmacovigilance study in medicine department of tertiary care hospital in chhattisgarh (jagdalpur), India. J Young Pharm. 2010 Jan;2(1):95-100. doi: 10.4103/0975-1483.62222. PMID: 21331200; PMCID: PMC3035895.

10. World Health Organization. The use of the WHO-UMC system for standardized case causality assessment [Internet]. Uppsala: WHO Collaborating Centre for International Drug Monitoring; [cited 2025 Aug 7]. Available from: https://www.who-umc.org/media/2768/standardised-casecausality-assessment.pdf

11. Rehan HS, Chopra D, Kakkar A. Physician's guide to pharmacovigilance: terminology and causality assessment. Eur J Intern Med. 2009;20(1):3–8.

12. Karlsson SA, Jacobsson I, Boman MD, Hakkarainen KM, Lövborg H, Hägg S, Jönsson AK. The impact of a changed legislation on reporting of adverse drug reactions in Sweden, with focus on nurses' reporting. Eur J Clin Pharmacol. 2015 May;71(5):631-6. doi: 10.1007/s00228-015-1839-6. Epub 2015 Apr 7. PMID: 25845655.

13. Hazell L, Shakir SA. Under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2006;29(5):385-96. doi:10.2165/00002018-200629050-00003.

14. Li R, Zaidi STR, Chen T, Castelino R. Effectiveness of interventions to improve adverse drug reaction reporting by healthcare professionals over the last decade: a systematic review. Pharmacoepidemiol Drug Saf. 2020;29(1):1-8. doi:10.1002/pds.4906.

15. Beijer HJ, de Blaey CJ. Hospitalisations caused by adverse drug reactions (ADR): a meta-analysis of observational studies. Pharm World Sci. 2002;24(2):46-54. doi:10.1023/a:1015570104121.

16. Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, Farrar K, Park BK, Breckenridge AM. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ. 2004 Jul 3;329(7456):15-9. doi: 10.1136/bmj.329.7456.15. PMID: 15231615; PMCID: PMC443443.

17. Aagaard L, Christensen A, Hansen EH. Information about adverse drug reactions reported in children: a qualitative review of empirical studies. Br J Clin Pharmacol. 2010;70(4):481-91. doi:10.1111/j.1365-2125.2010.03682.x.

18. Yeaw J, Lee WC, Aagren M, Christensen T. Cost of self-monitoring of blood glucose in the United States among patients on an insulin regimen for diabetes. J Manag Care Pharm. 2012;18(1):21-32. Available from: http://www.amcp.org/JMCP/2012/January-February/14481/1033.html

19. Roos LL, Stranc L, James RC, Li J. Complications, comorbidities, and mortality: improving classification and prediction. Health Serv Res. 1997;32(2):229-38.

20. Manjhi PK, Mohan L, Dikshit H, Mishra H, Kumar M, Dokania S. Cutaneous drug reactions notified by ADR monitoring centre in a tertiary care hospital of Bihar. Int J Basic Clin Pharmacol. 2017;6(1):80-4.

21. Dhanani JG, Sukhlecha A. A study of adverse cutaneous drug reactions in the department of der-

matology of a teaching hospital in Jamnagar, India. Int J Basic Clin Pharmacol. 2017;6(9):2259-64.

22. Thakkar S, Patel TK, Vahora R, Bhabhor P, Patel R. Cutaneous adverse drug reactions in a tertiary care teaching hospital in India: an intensive monitoring study. Indian J Dermatol. 2017;62(6):618-25.

23. Kharb P, Mittal N, Gupta MC. An evaluation of adverse drug reactions monitoring at a pharmacovigilance unit under pharmacovigilance program of India in a tertiary care hospital of Haryana. Int J Basic Clin Pharmacol. 2017 Jan 18;4(3):556-60.

24. 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 Dec;49(6):432-7.

25. Sharma VK, Sethuraman G, Kumar B. Cutaneous adverse drug reactions: clinical pattern and causative agents—a 6-year series from Chandigarh, India. J Postgrad Med. 2001;47(2):95-9.

26. Pudukadan D, Thappa DM. Adverse cutaneous drug reactions: clinical pattern and causative agents in a tertiary care center in South India. Indian J Dermatol Venereol Leprol. 2004;70(1):20-4.

27. Noel MV, Sushma M, Guido S. Cutaneous adverse drug reactions in hospitalized patients in a tertiary care center. Indian J Pharmacol. 2004;36(5):292-3.

28. Abu Esba LC, Al Mardawi G, AlJasser MI, Aljohani B, Abu Alburak A. Adverse Drug Reactions Spontaneously Reported at a Tertiary Care Hospital and Preventable Measures Implemented. J Clin Pharm Ther. 2021 Apr;46(2):460-469. doi: 10.1111/jcpt.13306. Epub 2020 Dec 7. PMID: 33285001; PMCID: PMC8247361.

29. Jung IY, Kim JJ, Lee SJ, Kim J, Seong H, Jeong W, Choi H, Jeong SJ, Ku NS, Han SH, Choi JY, Song YG, Park JW, Kim JM. Antibiotic-Related Adverse Drug Reactions at a Tertiary Care Hospital in South Korea. Biomed Res Int. 2017;2017:4304973. doi: 10.1155/2017/4304973. Epub 2017 Dec 31. PMID: 29457026; PMCID: PMC5804292.

30. Gangisetty S, Nadendla S, Goka PK, Zahedabano, Prasanthi NL, Rao NVR, Nadendla RR. An observational prospective study on prevalence and monitoring of adverse drug reactions in a tertiary care teaching hospital. J Pharm Res Int. 2016;11(2):1-9. doi:10.9734/BJPR/2016/24288.

31. Neha T, Mohd I, Syedazizullah G, Ashok R, Mohd M. Dermatological adverse drug reactions in a tertiary care hospital. IJPSR. 2015;6:816-824.

32. Vijayakumar TM, Dhanaraju MD. Description of adverse drug reactions in a multi-specialty teaching hospital. Int J Integr Med. 2013;1:1-6.

33. Kiran R, Divya S, Prathiba N, Bhanu P. Monitoring and analysis of drug reactions in a private tertiary care teaching hospital. Asian J Pharm Clin Res. 2015;8:335-337.

34. Marcia GAdeAL, Sandra MBP, Jose GD, Valeria GM, Maria CSP. Adverse drug reaction monitoring: support for pharmacovigilance at a tertiary care hospital in northern Brazil. BMC Pharmacol Toxicol. 2013;14:5.

35. Palanisamy S, Arul KG, Aiyalu R. A study on adverse drug reactions at a tertiary care teaching hospital. Int J Pharm Teach Pract. 2011;2:96-101.

36. Sivanandy P, Arul KSG, Aiyalu R. A study on assessment, monitoring, and reporting of adverse drug reactions in an Indian hospital. Asian J Pharm Clin Res. 2011;4:112-116.

37. Janković SM, Nikolić LI, Marković SZ, Kastratović DA. Multidisciplinary teams in healthcare. Hospi tal Pharmacology - International Multidisciplinary Journal . 2024;11(1):1370-6. doi: 10.5937/hpimj2401370J

38. Kastratović DA, Marković SZ, Janković SM. Clinical pharmacology: Developmental path, regula tions, education, practical management: Generally and in Serbia. Hospital Pharmacology - Internation al Multidisciplinary Journal . 2022;9(3):1215-30. doi: 10.5937/hpimj2203215K

39. Marković SZ, Kastratović DA, Kubiak C, Demotes MJ. Ecrin: Needed in European science. Hospital Pharmacology - International Multidisciplinary Journal . 2015;2(2):279-82. doi: 10.5937/hpimj1502279M

40. Vasiljević AR, Bakić Oršit DN, Zdelar Stojanović LM, Matić MG, Rajković DM, Kastratović DP, Petrović AD, Čolak ES, Nikolić LjI, Aleksić GM, Jelovac MD, Rašković AL, Kastratović D A, Janković SM. Effects of local and systemic medications on eye health: Adverse reactions. Hospital Pharmacology - International Multidisciplinary Journal . 2025;12(3):1744-57. doi: 10.5937/hpimj2503744V

Analiza spontano prijavljenih sumnji na neželjene reakcije na lekove u univerzitetskoj bolnici tercijernog nivoa zdravstvene zaštite

Jigar Popatlal Modi[1], Shivani Pradipkumar Trivedi[2], Disha Sanjaykumar Mehta[1], Darshan Jitendrabhai Dave[1]

[1] Department of Pharmacology,GMERS Medical College, Gandhinagar, Gujarat, India
[2] ADR Monitoring Centre,Department of Pharmacology, GMERS Medical College, Gandhinagar, Gujarat, India

KRATAK SADRŽAJ

Uvod: Neželjena dejstva lekova (eng. ADR) predstavljaju značajan uzrok morbiditeta, mortaliteta i ekonomskog opterećenja u zdravstvenom sistemu. U Indiji, stopa prijavljivanja ADR ostaje niska uprkos inicijativama Programa farmakovigilancije Indije (PvPI).
Cilj: Analizirati spontano prijavljena sumnjiva neneželjena dejstva u tercijarnoj obrazovnoj bolnici u odnosu na demografske karakteristike pacijenata, klase lekova, pogođene organske sisteme, težinu, ozbiljnost, uzročnost i ishod.
Materijal i metode: Sprovedena je akademska , retrospektivna, opservaciona studija zasnovana na podacima iz evidencije u ADR Monitoring Centre, GMERS Medical College and General Hospital, Gandhinagar. Analizirani su svi spontano prijavljeni ADR obrasci primljeni između aprila 2022. i marta 2023. Podaci su evaluirani po potpunosti i kategorizovani prema demografiji pacijenata, klasifikaciji organskih sistema (MedDRA SOC), sumnjivim lekovima, težini (Hartwig-Siegel skala), ozbiljnosti (PvPI kriterijumi) i uzročnosti (WHO-UMC skala). Primenjena je deskriptivna statistika.
Rezultati: Analizirano je ukupno 1.004 slučajeva interakcije sa lekovima. Pojavljivanje ADR bilo je slično kod muškaraca (51,09%) i žena (48,91%), sa većinom izveštaja iz populacije odraslih u dobi od 18-35 godina (47,41%). Antibiotici (33,27%), analgetici (12,15%) i antidepresivi (7,67%) bili su vodeće klase lekova. Najčešće pogođeni organski sistemi bili su koža (33,33%), gastrointestinalni trakt (28,77%) i nervni sistem (8,31%). Većina ADR bila je blaga (85,25%), neozbiljna (86,45%) i klasifikovana kao verovatna po uzročnosti (64,64%). Oporavak je zabeležen u 66,43% slučajeva, dok je ishod bio nepoznat u 29,98%.
Zaključak: Kožna neželjena dejstva su bila najčešća, prvenstveno izazvana antimikrobnim lekovima i NSAID-ima. Jačanje dokumentacije ADR i negovanje kulture prijavljivanja su od ključnog značaja za poboljšanje bezbednosti pacijenata i optimizaciju farmakoterapije.

Ključne reči: neželjeni efekti lekova, program farmakovigilancije Indije, WHO-UMC procena uzročnosti, tercijarna bolnica, sistem spontanog prijavljivanja

Received: December 24, 2025
Accepted: January 17, 2026