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ORIGINAL RESEARCH ARTICLE

Analysis of Adverse Drug Reactions Reported at the Adverse Drug Monitoring Centre of the Tertiary Care Hospital

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ABSTRACT

Introduction: The drugs developed during the recent years lead to incredible benefits for the patients but causes increased incidence of adverse drug reaction (ADR). ADR is an undesirable, unintended consequence of drug administration.[2] It is well known that "No drug is absolutely void of side effects", so to monitor such ADR, we have AMC at the tertiary care hospital. Aim of our studywas to analyzeADRs reported at the AMC centre of the tertiary care hospital.

Material & Methods: This retrospective study was carried out at the AMC of Shri Ram Murti Smarak Institute of Medical Sciences, Bareilly, for a period of 3 years. Patients of all ages and either sex were included. Adverse drug reactions were reported by the healthcare professionals and patients were included in our study. The reported ADRs were analyzed according to the demographic profile, department-wise, class of drug and system organ class involved. Data collected was analyzed and expressed in percentages.

Results: Total 197 ADRs were reported from various departments. Most of the adverse drug reactions were observed in females in the age group of 18 to 65 years. A maximum number (29) of ADR's were reported from the oncology department, followed by Orthopedic, paediatric and voluntary reporting by the patients. Most of the ADRs were reported from antibiotics 72 (36.54%). The causality assessment of ADRs were assessed according WHO-UMC causality assessment scale, according to which the maximum were probable,116 (58.8%) followed by possible, 75 (38.07%) and certain, 6 (3.04%).

Conclusion: The study concluded that the spontaneous reporting of ADR's is satisfactory. Reporting from HCP's needs to be enhanced by sensitization and creating awareness by imparting training and conducting workshops on pharmacovigilance.

Keywords: Adverse drug reaction, AMC causality, Pharmacovigilance

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INTRODUCTION

Medications prescribed for the management of diseases can themselves produce unintended and sometimes serious adverse effects, contributing significantly to patient morbidity and mortality. Although drugs are intended to provide therapeutic benefit, they may also result in harmful outcomes. It has been aptly stated that every drug possesses three actions: the intended therapeutic effect, an unwanted but recognized effect, and an unforeseen effect that becomes apparent only after wider clinical use.[1] This dual nature of pharmacotherapy remains a major concern in clinical medicine. Adverse drug reactions (ADRs) constitute a substantial public health problem worldwide. It has been reported that ADRs account for approximately 5% of hospital admissions and occur in nearly 10 to 20% of hospitalized patients.[2] The overall incidence of serious ADRs among hospitalized patients is estimated to be around 6.7%, while fatal reactions occur in about 0.32% of cases.[3] In addition to clinical consequences, ADRs impose a significant economic burden due to increased hospital stays, additional treatments, and loss of productivity, sometimes exceeding the cost of the medications themselves. The increasing introduction of medicine over the past few decades has intensified the need for continuous monitoring of both known and unknown adverse effects. For this purpose Pharmacovigilance Program was launched in 2010.[5] According to the World Health Organization (WHO), pharmacovigilance refers to the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. Despite the recognized importance of ADR monitoring among healthcare professionals, regulatory authorities and the pharmaceutical industry, reporting of ADRs in India remains insufficient. To strengthen drug safety surveillance, the Government of India initiated the Pharmacovigilance Programme of India (PvPI), establishing ADR Monitoring Centers across tertiary care hospitals nationwide. Our region has a

Table 1: Distribution based on demographics

Parameter	*Number of ADRs n = 197*	*Percentage*
Gender		
Male	87	44.16
Female	110	55.84
Age group		
Pediatrics	17	8.62
Adolescents	12	6.09
Adults	157	79.69
Geriatrics	11	5.58

Table 2: Department-wise distribution of ADR

Departments	*Number of ADRs(N=197)*	*%*
Cardiology	5	2.53
Dermatology	7	3.55
E.N.T	4	2.03
Gen. Surgery	12	6.09
Gynecology	20	10.15
Medicine	22	11.16
Neurology	11	6
Oncology	29	14.72
Orthopedic	26	13.19
Pediatric	25	12.69
Respiratory medicine	9	4.56
Voluntary reported	26	13.19
Psychiatry	1	0.50

diverse population with unique healthcare challenges; however, ADR reporting from this region remains limited. Therefore, the present study was undertaken in a tertiary care hospital in SRMS IMS, Bareilly, to document and analyze reported ADRs, along with assessment of their causality according to the WHO–UMC scale, to strengthen the ADR database through analysis and to upgrade the reporting culture among HCPs.

MATERIAL AND METHODS

A retrospective observational study was carried out over a period of 36 months from July 2022 to June 2025 in the Department of Pharmacology (AMC) at Shri Ram Murti Smarak Institute of Medical Sciences (SRMS-IMS) and hospital, Bareilly district, Uttar Pradesh. The study included all the suspected ADRs that were reported to the SRMS AMC centre from both IPD and OPD patients from Medicine, Surgery, OBG, Pediatrics, Orthopedics, Psychiatry, Dermatology, ENT, and Ophthalmology.

ADRs were collected from OPD and ward of all departments and filled the ADR's in the ADR reporting form (ADR Form) prescribed by the National Coordination Centre (NCC)-PvPI from the treating physicians and nurses. If any ADR was noticed by the patients himself/herself, he/she filled the patient form and sent it to our AMC. The study was conducted after obtaining the ethical approval from the Institutional Ethics Committee of SRMS-IMS, reference no. SRMS

Table 3: Reporting of ADR according to drug class

Class of drug	*Offending drug*	*Number of ADRs (%) N=197*
Analgesic	Tramadol	7 (3.55%)
Antipyretic	Paracetamol	2 (1.01%)
Analgesic & Antipyretic	Aceclofenac + Serratiopeptidase	5 (2.53%)
Analgesic & Antipyretic	Diclofenac	5 (2.53%)
Analgesic & Antipyretic	Ibuprofen+ Paracetamol	1 (0.50%)
Analgesic & Antipyretic	Ketorolac tromethamine	1 (0.50%)
Antibiotic	Vancomycin	20 (10.15%)
Antibiotic	Ciprofloxacin	6 (3.04%)
Antibiotic	Cefixime	2 (1.01%)
Antibiotic	Ceftriaxone	17 (8.62%)
Antibiotic	Doxycycline	2 (1.01%)
Antibiotic	Meropenem	1 (0.50%)
Antibiotic	Teicoplanin	1 (0.50%)
Antibiotic	Levofloxacin	6 (3.04%)
Antibiotic	Clindamycin	3 (1.52%)
Antibiotic	Piperacillin + Tazobactum	4 (2.03%)
Antibiotic	Amoxicillin + Clavulanic acid	1 (0.50%)
Antibiotic	Cefopodoxime	1 (0.50%)

Antibiotic	Oxytetracycline	2 (1.01%)
Antibiotic	Cefuroxime + Potassium clavulanate	1 (0.50%)
Antibiotic	Cefoperazone + Sulbactam	2 (1.01%)
Antibiotic	Linezolid	2 (1.01%)
Antibiotic	Streptomycin	1 (0.50%)
Anticholinergic	Hyoscine butylbromide	2 (1.01%)
Anticholinergic	Camylofin dihydrochloride	1 (0.50%)
Anticoagulant	Heparin sodium	1 (0.50%)
Anticonvulsant	Pregabalin	4 (2.03%)
Antispychotics	Escitalopram	1 (0.50%)
antidiabetic	Voglibose	1 (0.50%)
Antiemetic	Ondansetron	1 (0.50%)
Antiemetic	Fosaprepitant dimeglumine	3 (1.52%)
Antiemetic	Metoclopramide	1 (0.50%)
Antiemetic	Aprepitant	1 (0.50%)
Antiepileptic	Sodium Valproate	1 (0.50%)
Antiepileptic	Phenytoin	2 (1.01%)
Antifungal	Itraconazole	1 (0.50%)
Antifungal	Terbinafine	1 (0.50%)
Antifungal	Fluconazole	1 (0.50%)
Antihistamine	Cetrizine	3 (1.52%)
Antihistamine	Ranitidine	1 (0.50%)
Antihistamine	Levocetrizine	2 (1.01%)
Antihistamine	Fexofenadine hydrochloride	2 (1.01%)
Antihistamine	Montelukast sod. + Levocetirizine hydrochloride	2 (1.01%)
Antihistamine	Cyproheptadine Hydrochloride +Richoline Citrate+ Sorbitol	1 (0.50%)
Antihypertensive	Amlodipine	2 (1.01%)
Antihypertensive	Carvedilol	1 (0.50%)
Contrast Agent	Gadopentetate dimeglumine	1 (0.50%)
Antineoplastic	Oxaliplatin	2 (1.01%)
Antineoplastic	Docetaxel	1 (0.50%)
Antineoplastic	Cisplatin	2 (1.01%)
Antineoplastic	Tivantinib	1 (0.50%)
Antineoplastic	Paclitaxel	4 (2.03%)
Antineoplastic	Irinotecan	1 (0.50%)
Antineoplastic	Carboplatin	3 (1.52%)
Antineoplastic	Ifosfamide	1 (0.50%)
Antioxidant / Antiepileptic	Vitamin C + Phenytoin	1 (0.50%)
Antiparkinsonian	Entacapone	1 (0.50%)
Antiprotozoal	Metronidazole	7 (3.55%)
Antirheumatic	Sulfasalazine	2 (1.01%)
Antiseptic	Potassium Permanganate	1 (0.50%)
Antitubercular	AKURIT-4	4 (2.03%)
Diuretic	Furosemide	1 (0.50%)
Diuretic	Thiazide	1 (0.50%)

Expectorant	Ambroxol	2 (1.01%)
Antitussive/ Expectorant	Dextromethorphan + Guaifenesin	2 (1.01%)
Carbohydrate	Dextrose 5%	1 (0.50%)
Expectorant	Guaifenesin + Dextromethorphan +Chlorpheniramine	1 (0.50%)
Glucocorticoid	Dexamethasone	1 (0.50%)
Corticosteroid	Dapsone	1 (0.50%)
Corticosteroid	Prednisolone	1 (0.50%)
Hematinic	Ferric carboxymaltose	2 (1.01%)
Hematinic	Iron	2 (1.01%)
Laxative	Lactulose	1 (0.50%)
Mineral supplement	Calcium + Vitamin D□	1 (0.50%)
Mineral supplement	Cholecalciferol	1 (0.50%)
Mineral supplement	Potassium chloride	1 (0.50%)
Oral contraceptive pill	Levonorgestrel + Ethinylestradiol	1 (0.50%)
Plasma volume expander	Human Albumin	2 (1.01%)
Proton Pump Inhibitor	Pantoprazole	1 (0.50%)
Sedative–hypnotic	Midazolam	1 (0.50%)
skeletal muscle relaxant	Thiocolchicoside	2 (1.01%)
Topical Retinoid	Tazarotene	1 (0.50%)
Vasodilator	IsosorbideMononitrate	2 (1.01%)
Vitamine	Phytonadione	2 (1.01%)
Vitamine	Methylcobalamin	1 (0.50%)
Adrenergic	Levosalbutamol	1 (0.50%)
Antispasmodic	Drotaverine hydrochloride	2 (1.01%)
Adrenergic	Terbutaline	1 (0.50%)

Table 4: Frequency and types of ADR's reported according to system organ class (SOC)

SOC (System organ class)	*Number of ADRs N=197*	*Type of ADRs*
Cardiac disorder	2	Palpitation, central cyanosis
Ear and labyrinth disorder	1	Vertigo
Eye disorders	2	Blurry vision, periorbital edema
Gastrointestinal disorder	42	Nausea, vomiting, bloating, abdominal pain, gastritis, heaviness in abdomen, glossitis, dry mouth, throat irritation
General disorders and administration site condition	19	Shivering, flushing, rigors, swelling of body/face and injection site, chills, weight gain, fever, burning sensation, breast pain
Hepatobiliary disorders	1	Jaundice
Nervous system disorder	31	Anxiety, unconsciousness, sedation, dizziness, drowsiness, tingling senasation, tremors, headache
Respiratory, thoracic, and mediastinal disorders	6	Breathlessness.
Skin and subcutaneous tissue disorder	93	Itching, rashes, urticaria, redness, fluid filled lesion, hives, bullae all over body

IMS/ECC/2026/01. Data collected was categorized based on patient demographics (age and gender), ADR characteristics, causality assessment-wise, department-wise, type of reaction, class of drug, and system organ class involved.

RESULTS

A total of 197 reported ADRs from different departments were analyzed. Reports were scrutinized based on patient demographics, causality, type of reaction, class of drug and system organ class involved.

Table 5: Analysis of ADR

Parameter	*Number of ADRs N = 197*	*Percentage*
Causality*		
Certain	6	3.04
Possible	75	38.07
Probable	116	58.88

UMC-WHO Scale is used.

Data Evaluation-based on the Demographics of the Patient

Out of the 197 ADRs, 87 (44%) were reported among males and 110 (56%) among female patients. The majority of ADRs were reported in adults (79.69%), pediatric patients (8.62%), adolescents (6.09%), and geriatric patients (5.58%), as shown in Table 1.

Department-wise Distribution

Out of 197 ADRs, 14.72% ADRs were reported from the Oncology department followed by Orthopaedic/ voluntary reporting (13.19%), pediatric (12.69%), medicine (11.16%), OBG (10.15%) surgery (6.09%), neurology (5.58%), respiratory medicine (4.56%), dermatology (3.55%), cardiology (2.53%), ENT (2.03%) and psychiatry (0. 50%). shown in Table 2.

Drug Class

Maximum number of ADR's were reported for antibiotics 72 (36.54%) followed by analgesics & antipyretics 21 (10.65%) and antineoplastics 15 (7.61%). A complete list showing the class of drugs involved is given in Table 3.

Types of ADR in Various Organ Systems (SOC) According to Vigiflow

Types of ADR's analyzed according to various organ systems involved are summarized in Table 4 and showing that the maximum number of ADR's are from skin and subcutaneous tissue disorders consisting of itching,rashes, urticaria and redness.

Causality

After causality assessment, we found the majority of the reported ADRs were probable (58.88%), followed by possible (38.07%) and certain (3.04%), as shown in Table 5.

DISCUSSION

PvPI collects the ADRs from all healthcare setups and the public in India, and transfers the significant data to drug regulatory authorities for appropriate action on the drugs; it also communicates to healthcare professionals and the public regarding the risk of ADRs, by this it enhances the patient safety and welfare. It is the responsibility of all healthcare professionals to support the PvPI in promoting safe use of medicines. In this view, we have reported a total of 197 ADR's to the PVPI through our AMC according to the standard criteria given by the National Coordinating Centre (NCC) for monitoring ADR's.

We have found a small difference in the occurrence of ADR among males (44.16%) and females (55.84%). Our study coincides with studies conducted in northeast India by Lihite *et al*.[7] and in a south Indian study conducted by Vijaya Kumar *et al*.[8], which have reported only 8% more ADRs in females than in males.

The incidence of ADRs were more in the adult population than in pediatrics, adolescents and geriatrics. These findings were consistent with the study carried out by Venkatasubbaiah M *et al*.[9]and Manju K Mathew *et al*.[10]

In our study, antibiotics were responsible for the majority of the ADRs seen in the majority of the admitted patients of our hospital. The results were also encountered in previous studies.[9,11,12]

Most of the ADRs were reported from the Department of Oncology compared to other departments, where the rate of consultation is almost the same as other clinical departments like Medicine and Surgery. Observational studies conducted in India and abroad have also reported that most of the ADRs identified were from the Oncology Department.[13,14]

In the present study, the system organ class (SOC) involved in more than half of the ADRs was skin and subcutaneous tissue, followed by gastrointestinal and nervous system disorders, as was highlighted in the study done by Sruthi S *et al*.[13,15]

Causality assessment is necessary to confirm whether the reaction is because of the drug alone or other factors are also involved. We conducted causality assessment using the WHO-UMC causality assessment scale and observed that the majority of ADRs were probable. Other observational studies conducted in South Indian tertiary care teaching hospitals have also reported that the majority of the reported ADRs were probable with the same scale.[16,17]

This study highlights the importance of spontaneous ADR reporting from all the departments of this tertiary care hospital for monitoring and assessment of ADRs. This study also entails further research for the development of possible intervention strategies to reduce the burden of ADRs.

Our study suggests an increase in database at AMC by sensitization of heath care system by increasing awareness programmes, training workshops, so that reporting of ADR becomes a habit.

CONCLUSION

The present study provides an overview of the various types of ADRs reported from a tertiary care hospital. The findings indicate that ADRs were more commonly reported among adult female patients. Chemotherapeutic agents from the oncology department were identified as the most frequent causes of ADRs, with skin and subcutaneous tissue disorders being the most commonly observed ADRs.

The study concludes that the current level of spontaneous ADR reporting is satisfactory; however, greater participation from other clinical departments, such as medicine and surgery, is required. Furthermore, ADR reporting should continue to be voluntary and healthcare professionals should be encouraged to be more aware of the importance of spontaneous reporting in order to strengthen pharmacovigilance activities.

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