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ANALYSIS AND REPORTING OF ADVERSE DRUG REACTIONS AT A TERTIARY CARE TEACHING HOSPITAL IN MEWAT REGION OF NORTHERN INDIA

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ABSTRACT: Introduction: Adverse drug reactions (ADRs) poses an unforeseeable menace associated with all the prescribed medicines. Thus, ADRs are monitored and assessed on a large scale in our country by the Pharmacovigilance Programme of India through adverse drug reaction monitoring centres (AMCs). **Objectives:** This study was done to assess the pattern of ADRs reported in a tertiary care teaching hospital in Haryana by applying various aspects of ADR monitoring such as clinical presentation, causality, and severity assessment in various Inpatient departments at SHKM GMC. **Material and Methods:** A Prospective, Observational study was conducted in all the inpatient clinical departments of SHKM Govt. Medical College, Haryana for a duration of 12 months. ADRs were recorded in pre-designed proforma along with ADR reporting form "Version 1.3". Processing & analysis of data was done using SPSS version 20. **Results:** A total of 189 ADRs among 120 patients were reported during the study period. Females were affected more than males. Maximum ADRs were reported in the age group of 19-60 years. ENT department had maximum number of ADRs. Antibacterials implicated for major number of ADRs. GI tract was the most affected organ system. Of the total ADRs, 50.9% were probable. Regarding the severity, 3% ADRs were severe, while 60% were mild. On applying preventability scale, 90% of ADRs were not preventable. **Conclusion:** By keeping a careful and timely watch majority of ADRs can be prevented by early intervention. This will be a step towards improving patient safety.

INTRODUCTION: All drugs have therapeutic benefits and none are completely devoid of adverse effects. An adverse Drug Reaction (ADR) may be defined as "any harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of dosage regimen or withdrawal of the product [1].

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The need for the monitoring of ADRs arise as Clinical Trials focused mainly on the safety and efficacy of the therapeutic substance on the selected population. Many aspects of the drug thus remained unexplored.

The process of identifying and preventing ADRs is associated with post marketed drugs *i.e.*, pharmacovigilance, which is extremely important to protect patient health, economic burden associated with ADRs and circulation of large number of over-the-counter and counterfeit drugs in the market. According to the World Health Organisation (WHO), Pharmacovigilance is the science and activity related to the detection, assessment, understanding and prevention of

adverse effects or any other possible medicine related problem [2].

Consequences of ADRs: Adverse drug reactions (ADR) are a public health issue, due to their great impact on morbidity, mortality, and economic costs [3]. Due to their potential side effects, till date a total of 344 drugs have been banned in India by ministry of health and family welfare (MoHFW) [4].

The estimated annual cost of drug-related morbidity and mortality resulting from non-optimized medication therapy was $528.4 billion, equivalent to 16% of total US health care expenditures in 2016 [5]. A study conducted at a medical emergency department of a tertiary referral centre in Mumbai, India, concluded that the average hospitalization cost incurred per patient was INR 6197/- (USD 150) [6]. Hence, the consequences of ADRs burden the healthcare system with increased cost of therapy and prolongation of hospitalization.

Need for Pharmacovigilance in India: India is known as the Pharmacy of Third World [7]. Recently, the US Trade Representative (USTR) has placed India and 12 other countries on the 'Priority Watch List' [8]. They allege 20% of drugs in the Indian market to be counterfeit drugs which can cause major adverse effects [9].

Pharmacovigilance has not picked up well in India and is in its initial stages. This is due to ignorance about the subject and dearth of training of drug safety monitoring in healthcare professionals. A study conducted at a tertiary care teaching hospital in north India to assess the Awareness of Pharmacovigilance among Young Health-care Professionals concluded that only 9.8% doctors and 26.1% nurses were aware of ADR reporting system in India, of which 6 (26%) nurses and none of the doctors were aware of its name [10].

In March 2018, the NITI Aayog ranked Mewat as India's most backward district of India [11]. A large percentage of population of Nuh region (erstwhile Mewat) relied on traditional systems of medicine and has been exposed to modern medicines since last one decade only. The present work is a maiden Pharmacovigilance study that was conducted at our teaching hospital. Also, study of this kind has strengthened various aspects of ADE monitoring such as clinical presentation, causality and severity assessment in various Inpatient departments at SHKM GMC. The data will help to shape useful long term and more extensive ADE monitoring in the hospital.

MATERIALS AND METHODS:

Study Design: This is a prospective, non-interventional study conducted over a period of 1 year after getting approval from the Institutional Ethics Committee EC/OA – 09/2021 of SHKM government medical college.

Study Site: The study was conducted in the patients admitted in all the clinical departments of SHKM Govt. Medical College, Nalhar, Nuh\ Mewat, Haryana, a 600 bedded tertiary care hospital and medical college located in Northern region of India.

Study Population: Patients of all age groups and gender experiencing adverse drug events following drug use and admitted in the IPD wards were enrolled in the study with written informed consent. Demographic records of all the patients admitted during the study period in all the clinical departments of SHKM-GMC were obtained from the Medical Records Department (MRD), SHKM-GMC.

Collection of Data: The data for the study was taken from case sheets, investigation reports of in-patients who had experienced a suspected ADR. It was recorded in pre-designed proforma along with ADR reporting form "Version 1.3" and was duly signed by the supervisor on day-to-day basis. Personal interviews with reporting persons or clinicians, personal interviews with patient or patient's attendant, history of medication use, which were generally obtained from prescriptions from the past reports of Medical and surgical interventions, referral letters, *etc*. was recorded.

To monitor an adverse drug event, patient's data from the wards was collected daily. All the nursing stations were provided with ADR reporting forms. All nurses, JRs and interns have been trained in ADR reporting. An informed consent for participating in the study was obtained from all the patients who had experienced adverse drug events during the study period.

Inclusion Criteria: In-patients of all age- groups and gender from all the clinical departments with suspected ADRs that may be due to medications.

Exclusion Criteria:

1. Outpatient department.

2. The study subjects who were not willing to participate were excluded from the study.

3. Adverse drug events due to vaccines.

4. Adverse drug events due to medical devices.

5. Adverse drug events due to blood products.

6. Adverse drug event reports from any other alternative system of medicine including herbal medicines.

Data Management and Statistical Analysis: During the data collection process, periodic quality checks of collected data was done. All the collected data were checked and coded for computer entries; then it was entered in to excel sheet. The data were analyzed using SPSS 20.0 version. The results were expressed using descriptive statistics (mean, numbers, and percentages).

Monitoring of Adverse Drug Events: WHO definition of adverse drug reaction was used for all suspected ADRs. This includes any untoward event\Lab values or lack of effect suspected by the reporting physician following drug use. Total number of patients with ADE/ADR as well as total number of ADE/ADR were calculated. In suspected cases, past medical\medication history of patients was collected. Patients were interviewed, monitored daily throughout their hospital stay and their medical records were reviewed.

Assessment of Causality: An assessment of causality of the reported adverse events was done by using UMC–WHO scale and Naranjo's scale. In the Naranjo algorithm, the drug reaction can be classified as definite, probable, possible and doubtful [12]. The WHO-UMC scale classifies ADE as certain, probable, possible, unlikely, unclassified, and unclassifiable based on standard criteria. ADRs were differentiated from ADE. The confirmed ADRs were included in certain, probable, and possible scales of the WHO-UMC classification [12]. Several criteria were used to assess and categorize the identified ADRs in patients.

- Time relationship between drug use and the adverse reaction.
- Absence of other competing causes.
- Response to drug on withdrawal or dose reduction (de-challenge).
- Response to drug on re-administration (re-challenge).

After the causality assessment by the Causality Assessment Committee (CAC) (Committee formed as per the SOP of IPC) of the SHKM-GMC the data of the suspected ADR reports was entered in to the vigiflow software. The committee panel met once every month to do causality assessment of the adverse events. The Individual case safety reports (ICSR) generated was then sent to National coordinating centre, IPC.

Assessment of Severity: The modified Hartwig and Siegel scale classifies severity of a confirmed ADR as mild, moderate and severe with various levels according to factors like requirements for change in treatment, duration of hospital stay, and the disability produced by the Adverse Drug Reaction [13].

Classification of ADRs: Classification of the reported ADRs was done by using Wills and Brown classification [14].

Assessment of Preventability: The preventability assessment was done by using Modified Schumock and Thornton scale [15]. Adverse reactions will be coded using WHO adverse drug terminologies. Data was evaluated to determine the class of drugs and the organ systems associated with ADEs within the settings of the institute.

Ethical Consideration: Ethical clearance for the study was obtained from the institutional ethics committee of SHKM, GMC, Nuh. Institutional Ethics Committee EC/OA – 09/2021. Study was started after obtaining ethical clearance from the institutional ethics committee of SHKM GMC, Nuh. Written informed consent were taken from all the study participants.

RESULTS: A total of 189 suspected ADRs among 120 patients from different In-patient departments of SHKM Government medical college were analysed and reported to PvPI during the study period of 12 months. Reports were scrutinized based on patient demographics, drug characteristics, type of ADRs, outcomes, Causality, Severity and Preventability.

TABLE 1: DATA EVALUATION BASED ON DEMOGRAPHICS OF THE PATIENT

Demographic Parameters	Number of Patients (n=120)	Number of ADRs (n=189)	Percentage of ADRs
Gender			
Male	52	91	48%
Female	68	98	52%
Age group			
Paediatric (0-12 years)	9	12	6.34%
Adolescent (13-17 years)	5	07	3.70%
Adult (18-65 years)	95	154	81.48%
Geriatric (>65 years)	11	16	8.48%
Educational status			
Illiterate	58	93	49.20%
Primary school	10	20	10.58%
Middle school	12	16	8.46%
Secondary school	07	8	4.23%
Higher-secondary school	17	28	14.81%
Graduate & above	16	24	12.72%
Smoking status			
Smoker	33	58	30.68%
Non-smoker	87	131	69.32%
Alcohol intake			
Yes	21	42	22.22%
No	99	147	77.78%

Table 1 depicts that out of 189 ADRs, 98(52%) were experienced by females and 91(48%) by male patients. The majority of ADRs were reported in adults 154(81.48%) followed by the geriatric 16(8.48%), paediatric 12(6.34%), and adolescent 7(3.70%) patients.

A large number of ADRs 93(49.20%) were experienced by illiterate patients followed by patients who had higher secondary school education 28(14.81%).Out of total 189 ADRs, non-smokers had 131 (69.32%) ADRs as compared to 58 (30.68%) ADRs in smokers. Similarly, non-alcoholic patients had 147 (77.78%) ADRs as compared to alcoholic patients which had 42 (22.22%) ADRs.

TABLE 2: CAUSALITY ASSESSMENT OF ADRs BASED ON WHO-UMC SCALE

Parameter	Number of ADRs (n=189)	Percentage
Probable	105	55.60%
Possible	84	44.40%

Table 2 depicts that upon causality assessment using WHO-UMC scale, we found the majority of ADRs as Probable 105 (55.6%) followed by Possible 84 (44.4%).

TABLE 3: CAUSALITY ASSESSMENT OF ADRs BASED ON NARANJO SCALE

Parameter	Number of ADRs (n=189)	Percentage
Probable	112	59.20%
Possible	77	40.80%

Table 3 Upon Causality assessment using Naranjo's scale, we found the majority of ADRs as Probable 112 (59.2%) followed by Possible 77 (40.8%).

TABLE 4: SEVERITY ASSESSMENT OF ADRs BASED ON HARTWIG'S SEVERITY ASSESSMENT SCALE

Parameter	Number of ADRs (n=189)	Percentage
Mild	66	35%
Moderate	120	63.40%
Severe	03	1.60%

Table 4 Assessment of severity is essential to take necessary action against the drug continuation, in our study most of the ADRs were moderate 120(63%) followed by mild 66(35%) and only a few were severe.

TABLE 5: PREVENTABILITY ASSESSMENT OF ADRs BASED ON MODIFIED SCHUMOCK AND THORNTON PREVENTABILITY SCALE

Parameter	Number of ADRs (n=189)	Percentage
Definitely Preventable	20	10.58%
Probably Preventable	74	39.20%
Not Preventable	95	50.26%

Table 5 depicts that, out of 189 ADRs, most were not preventable 95(50.26%) followed by probably preventable 74(39.15%) and only 20(10.58%) were not definitely preventable. Preventability assessment helps in improving drug use.

TABLE 6: CLASSIFICATION OF ADRs ACCORDING TO WILLS & BROWN

Type of Reaction	Number of ADRs	Percentage
Type A Augmented reactions	143	75.63%
Type B Bugs reactions	–	–
Type C Chemical reactions	–	–
Type D Delivery reactions	–	–
Type E Exit reactions	–	–
Type F Familial reactions	–	–
Type G Genotoxicity reactions		–
Type H Hypersensitivity reactions	37	19.57%
Type U Unclassified reactions	9	4.80%

Table 6 Classification of ADRs showed that most of the reactions 143(75.63%) were of type A followed by type H 37(19.57%) and type U 09(4.80%).

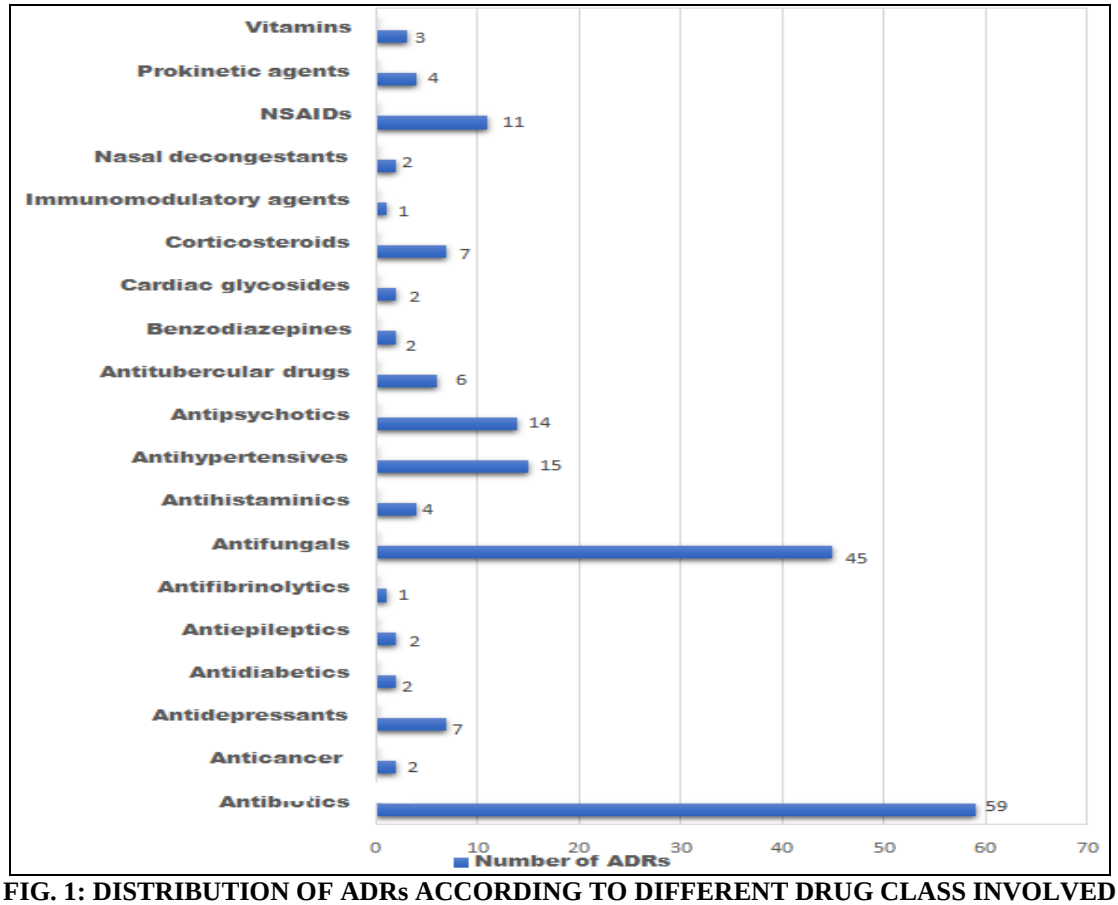

FIG. 1: DISTRIBUTION OF ADRs ACCORDING TO DIFFERENT DRUG CLASS INVOLVED

Fig. 1: illustrates that a higher number of ADRs were reported with antibiotics 59 (31.05%) followed by antifungals 45 (23.80%), antihypertensives 15 (8%) and antipsychotics 14 (7.40%).

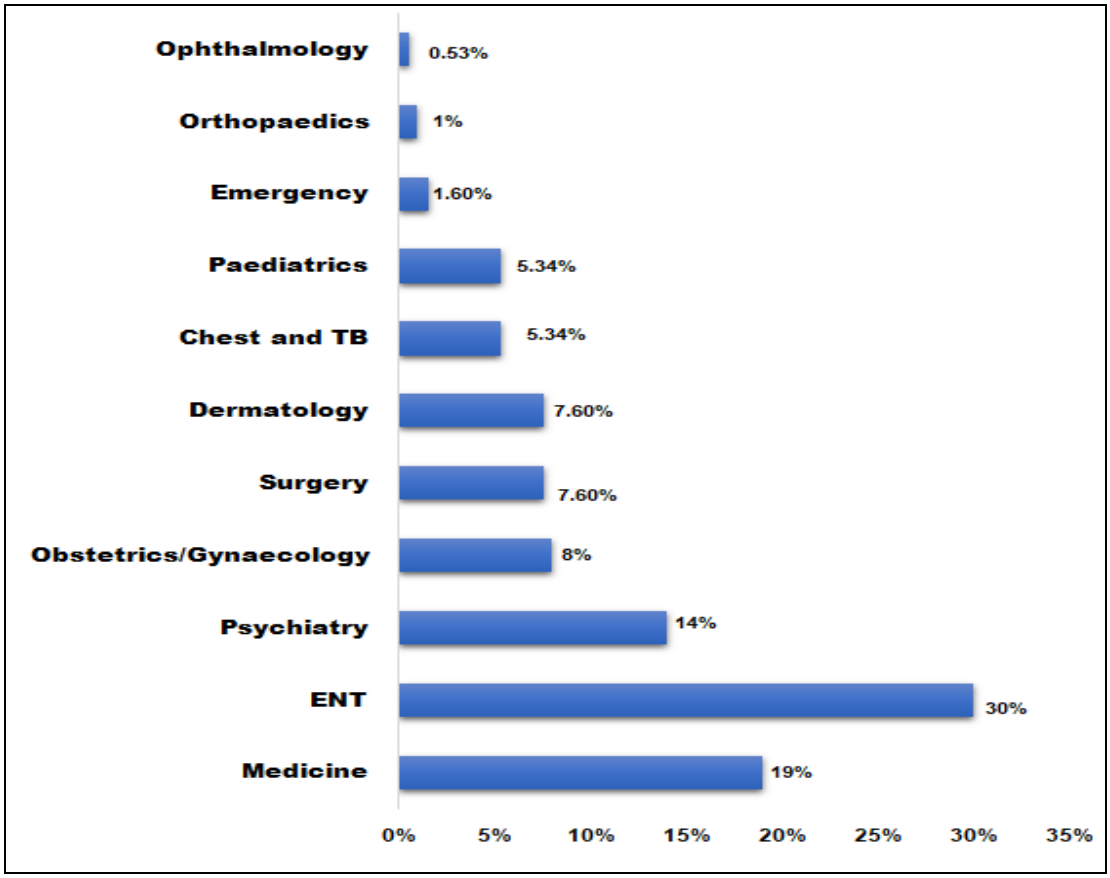

FIG. 2: DEPARTMENT WISE DISTRIBUTION OF ADRs

As illustrated in **Fig. 2,** Out of 189 ADRs, 30.0% ADRs were reported from the ENT department followed by Medicine (19.0%), Psychiatry (14.0%), Obstetrics & Gynaecology (8.0%), Surgery (7.60%), Dermatology (7.60%), Paediatrics (5.34%), Chest and TB (5.34%), Emergency (1.60%), Orthopaedics (1.0%) and Ophthalmology (0.53%).

TABLE 7: DISTRIBUTION OF ADRs ACCORDING TO SYSTEM OF ORGAN CLASS INVOLVED

System of organ class involved	ADR	Number of ADRs	Total no. of ADRs (System-wise)	Percentage
Gastro-intestinal disorders	Vomiting	15	58	29.0%
	Diarrhoea	13		
	Nausea	13		
	Gingival Hyperplasia	2		
	Abdominal pain	8		
	Mouth ulceration	4		
	Constipation	1		
	Dry mouth	2		
Skin and Subcutaneous tissue disorders	Rashes	10	30	16%
	Pruritis	11		
	Toxic Epidermal Necrolysis	3		
	Hyperhidrosis	1		
	Alopecia	1		
	Red man syndrome	2		
	Swelling Lip	1		
Nervous system disorders	Dizziness	6	22	12%

	Tremors	7		
	Dysgeusia	2		
	Headache	3		
	Somnolence	2		
	Sedation	1		
	Anosmia	1		
General disorders and administration site conditions	Pyrexia	11	21	11%
	Swelling Face	1		
	Administration site reaction	2		
	Fatigue	1		
	Edema Peripheral	5		
	Chills	1		
Respiratory,Thoracic and Mediastinal disorders	Dyspnoea	11	15	8%
	Cough	3		
	Rhinorrhoea	1		
Musculoskeletal and connective tissue disorders	Myalgia	9	12	6.40%
	Arthralgia	3		
Psychiatric disorders	Suicidal ideation	1	6	3.2%
	Abnormal dreams	1		
	Agitation	2		
	Sleep disorder	2		
Hepatobiliary disorders	Drug-induced liver injury	7	7	3.80%
Vascular disorders	Flushing	5		3.20%
	Orthostatic hypotension	1	6	
Metabolic and nutritional disorders	Decreased Appetite	4		2.70%
	Weight gain	1	5	
Cardiac disorders	Palpitations	2	2	1%
TOTAL			189	

Table 7 demonstrates that the maximum number of ADRs 58 (29%) were related to Gastro- Intestinal (GI) system organ class followed by Skin & subcutaneous tissue disorders 30 (16.0%) and Nervous System disorders 22 (12%).

DISCUSSION: Pharmacovigilance Program of India (PvPI) gathers the ADRs from all healthcare setups and the public in India, and communicates the significant data to drug regulatory authorities for necessary action on the drugs; it also communicates with the healthcare professionals and the public regarding the risk of ADRs, by this it improves the patient safety and welfare, and it is the responsibility of all healthcare professionals to support the PvPI in promoting safe use of medicine, In this regard we have reported a total of 189 ADRs found in this study to the PVPI through AMCs according to the standard criteria given by National Coordinating Centre (NCC) for monitoring ADR.

A prospective analysis of the ADRs that had been reported in the period of 1 year in the department of Pharmacology, Shaheed Hasan Khan Mewati Government Medical College was done. During this period 120 patients were included in the study from all inpatient departments of the hospital.

A total of 189 ADRs were reported among 120 patients. Although ADRs were observed in both the genders but there was a slight female preponderance. A study conducted by Sharma *et al* (2018) [16] and Meda *et al* (2018) [17] also showed similar distribution. They attributed this alteration to more weight and body mass index, hormonal changes, which are unique to females such as through puberty, menstrual cycles, and menopause, and the consequence of these variations on drug metabolism [17]. They also determined that genomic constitutional differences can impact the levels of several enzymes involved in drug metabolism amid the females.

Age is considered a risk factor for the manifestation of ADRs. Hence, children and the elderly, due to metabolic system alterations, necessitate careful orientation and follow-up to evade ADR occurrences and complications. However, in our study, the number of ADRs in adults (61.0%) was higher than that in the other age groups, which is in

concordance with the similar study conducted by Kaur *et al* (2019) [18], who observed (75.8%) in adult age group. Likewise, another study conducted by Meda *et al (2018)* [17] quoted that the occurrence of ADRs in adult patients (71.26%) was significantly higher than other age groups.

But these results seem to contradict those of Jayanthi *et al (2017)* [19], who found that the elderly have a higher risk of ADRs. These conflicting results may be due to the higher number of young adults who are hospitalised at our setting during the study period. In our study, out of total 120 patients, (48.3%) are illiterates. The study conducted by Shrestha *et al* (2017) [20] comprised of similar number of patients. The reason could be that our tertiary care teaching hospital lies in the rural part of Haryana, where average literacy rate in rural areas is (52%) as compared to urban population [21]. Furthermore, literacy rate in female population in this part is only (33.7%) as compared to male population [21]. Also, in our study, maximum number of patients were female (56.6%).

Causality assessment is vital to authorize whether the reaction is because of drug alone or other factors are also involved in ADR occurrence, we did causality assessment using WHO-UMC causality assessment scale and found that the majority of ADRs were probable (55.6%), other observational studies conducted by Tejas *et al* (2020) [22] and Singh *et al* (2010) [23] have also reported that the majority of the reported ADRs were probable with the same scale. Since, all the patients included in our study were IPD patients, therefore, day to day monitoring of ADRs was possible. Causality assessment on applying Naranjo's scale revealed that most of the ADRs in our study were classified as probable (59.2%) which is in concordance with the results observed by Nirumalla *et al* (2019) [24].

Assessment of severity is also crucial to take essential action against the drug continuation, in our study severity assessment of ADRs was done by Modified Hartwig and Siegel scale. Most of the ADRs were assessed as moderate (63.40%) in severity followed by mild and severe. Studies conducted by Kumar *et al (2017)* [25] also bear the same results. However, study conducted by Meda *et al (2018)* **[17]** reported most of ADRs as mild in severity. In the study of ADRs, a key facet is the possibility of prevention. Preventability assessment helps in improving rational drug use; in our study, the majority of ADRs were not preventable (50.26%) followed by probably preventable (39.20%). The studies conducted by *Keche et al (2021)* [26] and *Basavaraj et al (2017)* [27] had quoted similar results. However, other studies conducted in Ethiopia and Italy by *Ersulo et al (2022)* [28] and *Giardina et al (2018)*[2] [9] identified majority of ADRs as probably preventable (59%) and (69.4%) respectively. Also, only (10%) of ADRs in our study were preventable, this may be since in our tertiary care hospital, ADRs could have been prevented at three checkpoints, that is, at the level of prescribing, dispensing and administration. In our study, upon classification of ADRs according to Wills & Brown, large fractions of ADR fall in Type A (Augmented) reactions (75.63%) followed by Type H (Hypersensitivity) reactions (19.57%). A study conducted by *Sahu et al (2020)***[30]** observed similar results that is (81.36%) of Type A reactions.

However, study conducted by *Ponnusankar et al (2015)* [31] had observed a greater number of Type H reactions that is (51%). This could be explained using large number of antibiotics in their hospital setting as compared to our is (31%). In our study, antibiotics (31%) were involved in causing majority of ADRs, this is due to the reason, that almost all inpatients have received antibiotic therapy either for prophylactic or curative therapy. The results were consistent with previous studies. A study conducted by *Ingale et al (2018)* [32] observed that (21%) of all ADRs were caused by antibiotics. Majority of the ADRs were reported from the Department of ENT (30%) followed by the General medicine department (19%).

This result is contrary to other observational studies conducted in India by *Nirumalla et al (2019)* [24] and *Meda et al (2018)* [17] that identified most of the ADRs from the General medicine Department that is (55%) and (56.6%) respectively. In other study conducted by *Sangeetha et al (2017)* [33], ADRs reported from the Department of General medicine (37.5%) had outnumbered all other departments. This discrepancy in our result might be explained by a sudden rise in cases of COVID-19 associated mucormycosis (CAM) that were admitted in the ENT department of our tertiary care hospital during

second wave of COVID-19. Such serious complications of COVID-19 were limited to individuals with low immunity such as patients with uncontrolled diabetes, end-stage renal diseases, hematologic malignancies, and/or organ transplantation. After the COVID-19 outbreak, many case reports of COVID-19-associated mucormycosis (CAM) have been reported to our hospital. In our study, Amphotericin-B was used for the treatment of CAM, found to be the most common medication causing ADRs in ENT department. The most frequent system of organ class (SOC) influenced by ADRs in our study were in line with other recent studies. In the present study, the gastrointestinal (29%) and skin and subcutaneous tissue disorders (16%); followed by Nervous system disorders (12%), and General disorders and administration site conditions (11%) were among the most frequently affected organ systems. This result is consistent with reports of a study conducted by *Saqib et al (2018)* [34] in four tertiary care public sector hospitals in Pakistan, in which the gastrointestinal tract accounted for one-third (33.3%) of organ systems affected by ADRs. Also, in agreement with the current study, gastrointestinal (46%) and neurological (23%) disorders were the commonest system organ classes affected in a study conducted by *Kiguba et al (2107)*[35]in Uganda. In our study, among gastrointestinal side effects, nausea (10%), vomiting (9%) and diarrhoea (10%) were most common

Strength & Limitations: This is a maiden ADR monitoring study in our tertiary care teaching hospital, an important population to study for the estimation of the burden of clinically impactful ADRs. The prospective follow-up of the admitted patients allowed a more reliable recording of both the medication history and symptoms and the assessment of causality and using of standard scales given. Our study took place at the largest tertiary care teaching hospital in Mewat region, which is a remote area of Haryana and we believe these findings have generated baseline data for comparison with similar studies at state, national and international level and similar type of studies in the future in this institution. There are certain limitations like the lack of inclusion of patients from the outpatient departments, also this study was conducted at a single centre only.

CONCLUSIONS: The number of ADRs observed in our study were comparable to other studies in India with a slight female preponderance. Like other studies in India, ADRs involving antimicrobial drugs being the most common. Most of our patients experience moderate ADRs and were not preventable.

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CONFLICT OF INTEREST: Nil

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