Research Article

A Retrospective Study on Adverse Drug Reaction Monitoring in a Tertiary Care Hospital

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ABSTRACT

Adverse drug reactions (ADRs) are a major concern in clinical practice. Reporting of ADRs either through health care professionals or the patients themselves is of utmost importance to give an accurate estimate of the prevalence, severity and preventability of ADRs. Present study was conducted to evaluate the prevalence of adverse drug reactions in a tertiary care hospital in Hyderabad, Telangana, India. This was a retrospective observational study, extending over 3 months (December 2020 to February 2021). A total of 41 cases comprising patients of either sex or age group were studied. The data was collected using CDSCO ADR reporting form. A total of 41 ADRs were reported during the three months period of study. During the study period a total of 41 ADR reports were received from various departments of the hospital. We observed 25 ADRs in females and 16 ADRs in males from our study. Among the age groups, 3 ADRs in age group 0 – 19 Yrs., 28 ADRs were seen in age group 20 – 59 Yrs., and 10 ADRs were seen in age group >60 Yrs. Maximum number of ADRs came from General Medicine department 17 (41.46%). Drug therapy 41 (100%) and diseases 19 (46.34%) were the most prominent predisposing factors of ADRs seen in our hospital. Causality assessment of suspected drugs was assessed using Naranjo scale. According to Naranjo scale most of the reported ADRs were found to be probable 23 (56.9%) followed by possible 16 (39.02%) and definite 2 (4.8%). The severities of the reactions were done using Hart Wig Scale. Majority of the reactions were mild 25 (60.97%). Withdrawal of the drug 5 (12.19%) was the main line of the management of the adverse drug reactions in the present study. Majority of serious ADRs were preventable in our study. ADRs are a major cause of morbidity worldwide. Frequency of ADRs can be reduced by careful follow up and a robust hospital-based pharmacovigilance setup. A measure to improve detection and reporting of adverse drug reactions by all health care professional is recommended.

Keywords: Adverse drug reactions, reporting, Causality Assessment, Preventability, Predictability, Severity.

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INTRODUCTION

In any healthcare organization patient safety is the prime responsibility of all healthcare providers. Patients seeking any healthcare system are mainly treated with the drug. The drugs that are used to alleviate the suffering of a patient sometimes can cause a reaction which can be eventually fatal. According to the World Health Organization (WHO), an adverse drug reaction (ADR) is any noxious or unintended and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis or therapy [1]. The mortality and morbidity rates are high due to adverse drug reaction, which has been identified by numerous studies in the last decade and increases the economic burden globally. Prompt screening, monitoring, evaluation and appropriate reporting of adverse drug reaction is essential to render a safe treatment and to provide a cos effective care. Adverse drug reaction is influenced by variety of factors like type of drug, gender, drug sensitivity, route of administration, duration of therapy, different types of population, function of excreting organs genetic makeup of the patients[2]. Many prevalence studies have estimated that the admission into hospital due to drug reaction, length of the hospital stay and medical emergencies are mainly related to the adverse reaction. In a retrospective study conducted in this study has identified that most of the patients were affected with adverse drug reaction and medication error was the common reason followed by therapeutic failure of the drug[3]. A study results conducted in China also confirms that in the database report of 1079 patients, 12.14% were associated with potential and actual drug to drug interactions. The serious adverse drug reaction was significantly higher among the actual drug to drug interactions[4]. The main aim of the study was to find out the number of adverse drug reactions in a tertiary care hospital, to identify the type of drug leading to adverse

drug reaction and the adverse effects caused in the last one year.

Aims and Objectives

1. To identify ADR in all departments of a tertiary care hospital
2. To monitor and treat the ADR's caused due to medication, disease and food.
3. To assess the casualty and severity of ADR using Naranjo Scale.
4. To document and report suspected ADR.

Methodology

Study Site

All the inpatient departments of tertiary care hospital.

Study Population: 30 - 42

Study Period: 2 Months.

Study Type: Retrospective Study.

Criteria

Inclusion Factors

All the suspected ADR's that may be due to medications in all departments.

Exclusion factors

- Pregnant and lactating women.
- Drug addicts.
- Use of alternative system of medications.
- Patient admitted in critical care unit.

Plan of Work

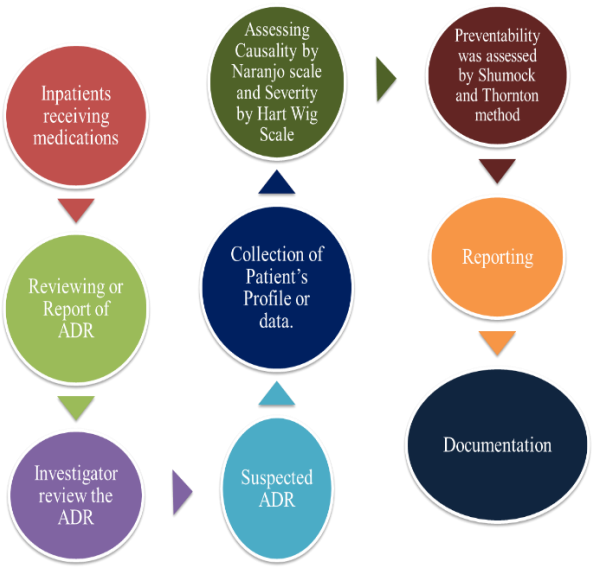


Figure 1: Plan of Work

RESULTS

- Out of 41 cases, Females 25 (60.97%) reported a greater number of ADRs compared to males 16 (39.02%).

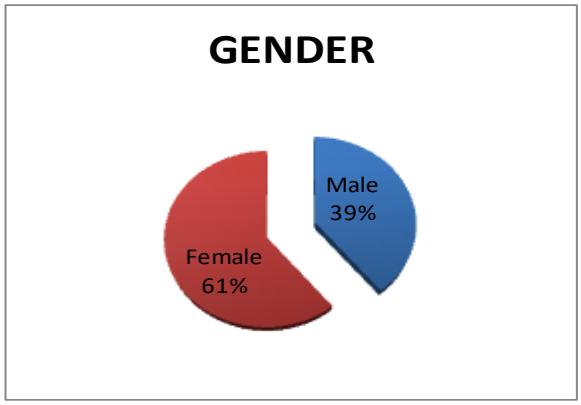


Figure 2: Percentage of Gender

- Maximum number of ADRs were reported from adults (20-59) – 28 (68.29%) followed by geriatrics (>60) – 10 (24.39%) and children (0-19) –3 (7.317%). Results are summarized in Figure.

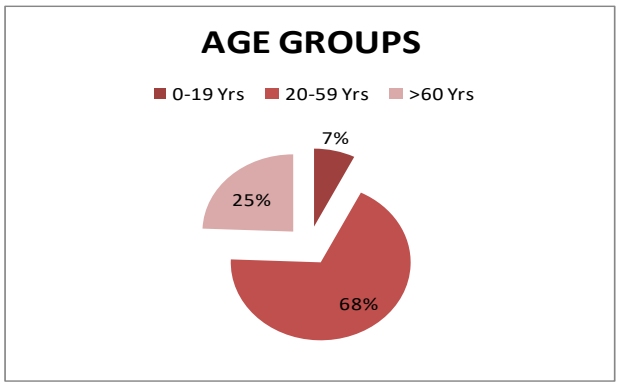


Figure 3: Percentage of Age group showing ADR

- Majority of patients with an ADR were receiving more than 2-4 drugs at the time of experiencing an ADR. Of the reported ADRs 41 (100%) occurred due to the drug therapy followed by diseases 19 (46.34%), age 3 (7.317%) and gender 3 (7.317%).

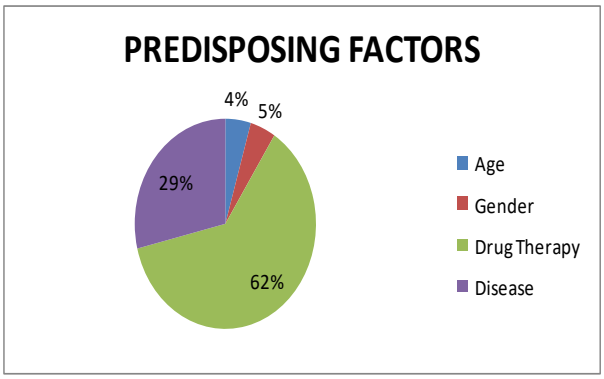


Figure 4: Percentage of Predisposing factor

A total of 41 ADRs were reported during the three months period of study. 41 patients reported 41 ADRs.

Suspected Drugs and their ADR'S

S. No.	Suspected drugs	Adverse drug reactions
1.	Injection Tramadol (500 mg)	Nausea.
2.	Injection Neomol (150mg) Injection Metrogyl (500mg)	2-3 episodes of Vomiting.
3.	Cefoperazone	Neutropenia.
4.	Injection Metrogyl (500mg)	Cough and expectoration.
5.	Inj.Metrogyl (metronidazole)(500mg)	Headache.
6.	Injection Linezolid (600mg)	Maculopapular rash all over the body.
7.	Injection Linezolid (600mg)	Rashes all over the body
8.	Betnesol (12mg)	Acne, dry skin and skin discoloration issues.
9.	Tablet Esclo Plus (5mg)	Restlessness and insomnia.
10.	Tablet Scopolamine.	Dry mouth and skin rashes.
11.	Nifidipine (20mg)	Swelling ankles and feet.
12.	Amikacin (500mg)	Muscle twitching, convulsions
13.	Ceftriaxone	Burning sensation in genital areas.
14.	Injection Dynapar (325 mg)	Tachycardia.
15.	Zofer (4mg)	Headache, constipation, Diarrhoea.
16.	Medrol (4mg)	Gastritis and osteoporosis.
17.	Injection PAN (40 mg) Injection Zofer (10 mg)	Constipation.
18.	Inj.Metronidazole (500 mg)	Dizziness.
19.	Injection Arachitol (1mg)	Constipation.
20.	Tab Dynapar (diclofenac sodium-50mg, paracetamol-325mg)	Constipation.
21.	Inj. Zonomax	Neutropenia
22	Combutol (600mg)	Jaundice
23	Pantoprozole and Alprazolam	Constipation
24	Metronidazole (400mg)	Peripheral Neuropathic symptoms with sensory disturbance at hands and feet, nausea, metallic taste, Upper abdominal pain and Headache.
25	Tab Atorva (80mg)	Fibromyalgia
26	Inj Enoxaparin sodium	Nausea and Diarrhea
27	Tab Disperzyme, (Bromolainin 180mg), Trypsin (96mg) , Rutoside (200mg)	Diarrhea
28	Inj.Hydrpcortisone (100mg)	Facial Puffiness
29	Inj.Streptomycin	Rashes
30	Levosalbutanol	Restlessness
31	Clopitab-A (150mg) (Clopidogrel)	Dizziness (Hypotension)
32	Tab Azithromycon (500mg)	Neck pain and sore throat
33	Injection Ranitidine	Constipation and abdominal pain
34	Injection Piptaz, (4,5gm), IV Stat (Piperacillin/Tazobacyam)	Diarrhea
35	Rosuvastatin (10mg)	Abdominal pain
36	Augmentin	Constipation
37	Injection Cefriaxone	Induration, warmth and tightened skin
38	Injection Lasix (Furosemide) 20 mg	Hyperuricemia
39	Clarithromycin (500mg) and Hydrocortisone (100mg)	Skin rash and slight increase in Blood Pressure
40	Injection Cefotaxime	Hard lump with inflammation at site of administration on injection
41	Injection Clezane	Bleeding gums

- Maximum number of ADRs were reported from the General Medicine 17 (41.46%) followed by Gastroenterology 9 (21.95%), Cardiology 5 (12.2%), Pulmonology 4 (9.75%), Dermatology 2 (4.87%), Orthopedics, 2 (4.87%), Nephrology 1 (2.44%), Gynecology 1 (2.44%).

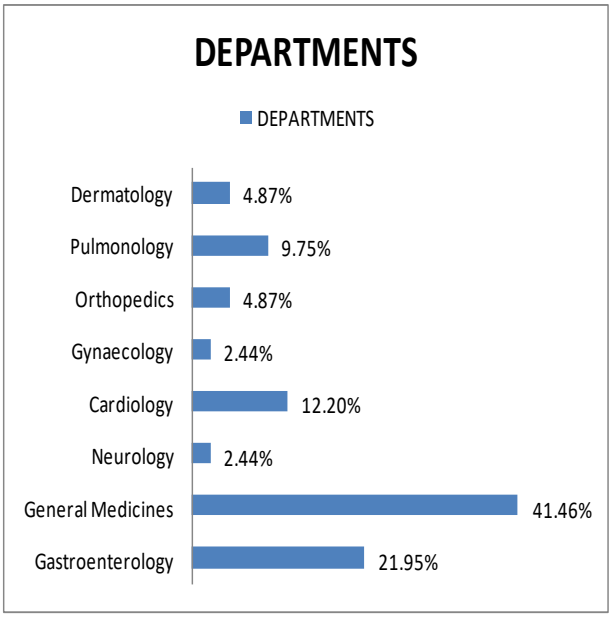
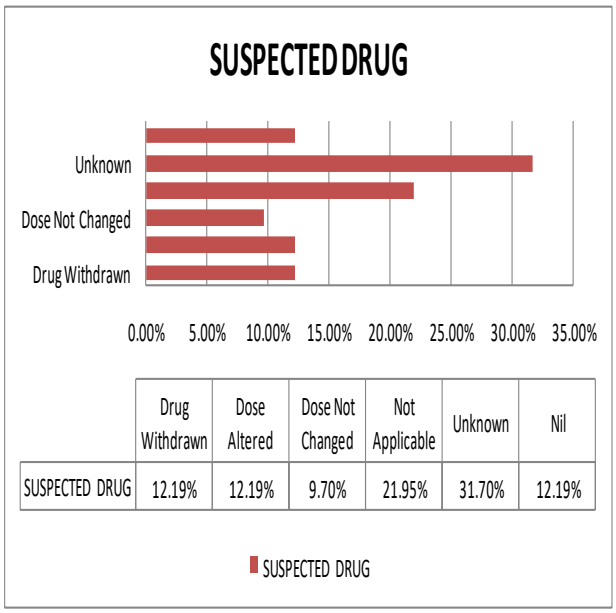


Figure 5: Percentage of ADR reported in hospital departments

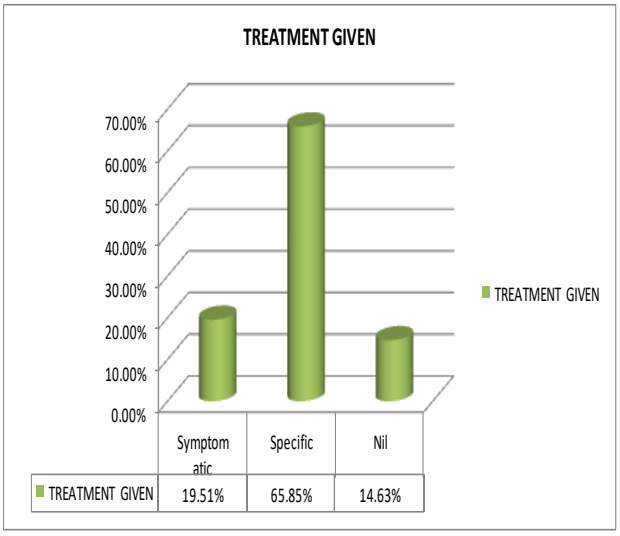
- In 5 (12.19%) cases the suspected drug was withdrawn while no change was made with the suspected drug in 5 (12.19%) and the dose was altered in 5 (12.19%) cases.



	Drug Withdrawn	Dose Altered	Dose Not Changed	Not Applicable	Unknown	Nil
SUSPECTED DRUG	12.19%	12.19%	9.70%	21.95%	31.70%	12.19%

Figure 6: Percentage of Suspected Drugs

- Specific treatment was given in 27 (65.85%) while 8 (19.51%) cases required symptomatic treatment and 6 (14.63%) cases required no treatment.



	Symptomatic	Specific	Nil
TREATMENT GIVEN	19.51%	65.85%	14.63%

Figure 7: Percentage of Treatment Given

- Predictability of the reactions was based on the incidence of the reactions and literature reports. Analysis showed that most of them were predictable 31(75.609%) while, 10 (24%) were not predictable. Results are shown in Figure.

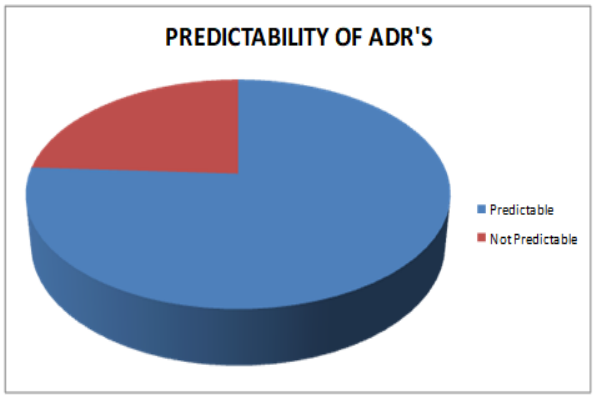


Figure 8: Percentage of Predictability of ADR's

- Severities of the reactions were done using Hart wig scale. Of the reported ADRs 16 (39.02%) moderate reactions accounted of followed by mild reactions 25 (60.97%). None of the reactions was severe.

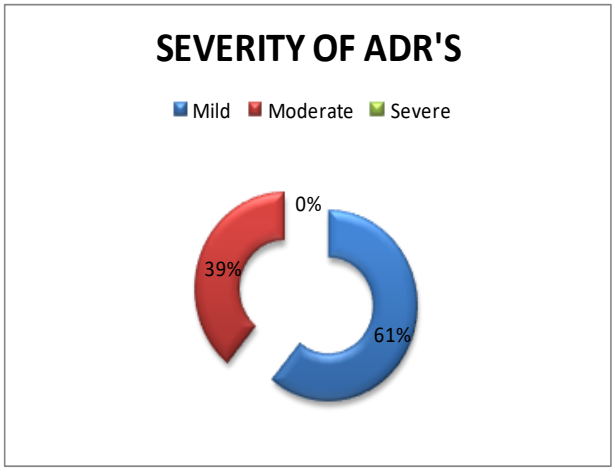


Figure 9: Percentage of Severity of ADR's

Severity assessment

SEVERITY	NUMBER OF ADR's
Mild	25(60.97%)
Moderate	16(39.02%)
Severe	0

- Preventability of reported ADRs was assessed using modified Shumock and Thornton method. Using this scale results revealed that 7 (17.1%) of the ADRs were definitely preventable, while 24(58.3%) were probably preventable and 10 (24%) were not preventable.

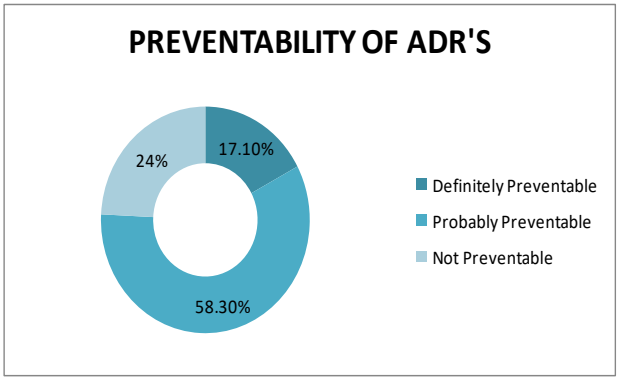


Figure 10: Percentage of Preventability of ADR's

- The causality assessment of ADRs had been done using Naranjo scale. As per Naranjo scale 23 (56.9%) were probable, 16 (39.02%) were possible, 2 (4.8%) were definite and 0% were unlikely.

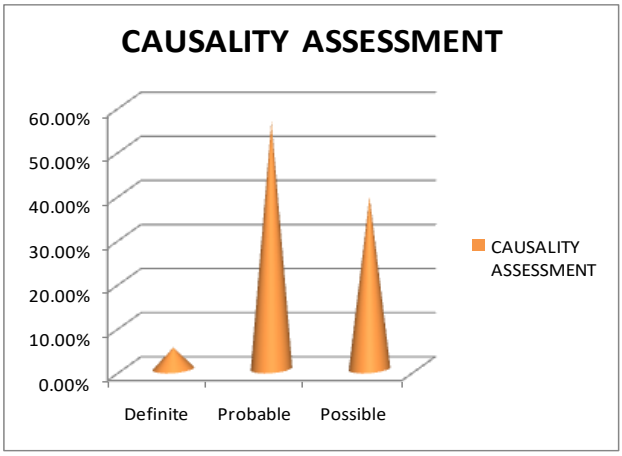


Figure 11: Percentage of Causality assessment of ADR's

Causality assessment

CAUSALITY	NUMBER OF ADR's
Doubtful: ≤0	0
Possible: 1-4	16 (39.02%)
Probable: 4-8	23 (56.9%)
Definite: ≥9	2 (4.8%)

DISCUSSION

The study was conducted in Owaisi Hospital with more than 60 consultants of national reputations and about 85% patients in the hospital were prescribed with more than two drugs every day. In this study, we followed the spontaneous reporting method. We received a total of 41 ADRs from our hospital during one year study. From this study we found out that, females 25 (60.97%) reported a greater number of ADRs compared to males 16 (39.02%). This may be due to fact that compared to males, females have a tendency to use a greater number of drugs than the males. This result is consistent with the results of the study carried out by Palanisamy. S S et.al [5] and which was something different from that observed from other study done by Subish.Pet.al. [6] The study revealed that Maximum number of ADRs were reported from adults (20-59) – 28(68.29%) followed by geriatrics (>60) - 10 (24.39%) and children (0-19) – 3(7.317%). This may be due to the fact that the number of hospital admissions of adults was more in our hospital when compared to Paediatrics. Pediatricians tend to use only a limited number of drugs for their patients, as pediatrics patients rarely presented with multiple co-morbidities. This finding was consistent with the results of the study carried out by Ramesh.et.al[8] but different from the study carried out by Chuenjid Kongkaew et.al.[7] It was reported that drug related hospitalizations were significantly higher in the geriatric population. Before the starting of study, an awareness lecture was given to the doctors of all the departments about the importance of reporting ADRs. With effect to this, maximum number of ADRs were reported from General medicine department 17(41.46%) compared to other departments. This is because in our hospital the patients were primarily consulted by general medicine department and then referred to the other specialists. So, this department uses more drugs than other departments. This result was consistent with the study carried out by S.ASamuel et.al, [9] but different from the study carried out by Palanisamy. S et.al [5] wherein highest percentages of ADRs were reported from neurology department. Majority of patients who developed ADR were receiving more than 2-4 drugs at the time of experiencing an ADR. Drug therapy 41 (100%) and diseases 19 (46.34%) were the most prominent predisposing factors of ADRs. Majority of the patients who developed ADRs were having co-morbidities like Diabetes, Tuberculosis, Bronchial Asthma, renal failure, Coronary artery disease, Hypertension, Depression, Rheumatoid arthritis, hepatitis, cirrhosis, anaemia, seizures etc. necessitating them to receive multiple drugs. This result was consistent with the study carried out by Rajesh et.al.[10] When ADRs were identified, all the necessary and relevant data were collected from the various sources like patient case sheets. Treatment charts, laboratory reports, patient interview and filled in the ADR card and ADR Reporting and Documentation Form. Through patient interview and interaction with doctors and healthcare professionals, causality was assessed as per Naranjo Scale. According to Naranjo scale 23(56.9%) were probable, 16(39.02%) were possible, 2(4.8%) were definite and 0% were unlikely. The severities of the reactions were done using Hart Wig Scale. Study reveals majority of ADRs were mild reactions 25(60.97%) followed by moderate

reactions 16(39.02%) and none of the reactions was severe. No fatal cases reported. This indicates the good health status of our hospital. Withdrawal of the Drug 5 (12.19%) was the main line of management of ADRs, while no change was made with the suspected drug in 5 (12.19%) and the dose was altered in 5 (12.19%)) cases. During the study Specific treatment was given in 27 (65.85%) while 8 (19.51%) cases required symptomatic treatment and 6(14.63%) cases required no treatment. There was a complete recovery from ADRs in 41 cases (100%). No fatal cases reported. This indicates the good health status of the hospital. Reported ADRs were assessed for their preventability by using modified Shumock and Thornton method. We concluded that 07(17.07%) of the ADRs were definitely preventable, while 24(58.53%) were probably preventable and 10(24.39%) were not preventable. Predictability of ADRs was assessed based on the incidence of the reactions and literature reports. Results revealed that most of ADRs were predictable 31(75.609%) while, 10 (24%) were not predictable.

CONCLUSION

- ADR reporting is an ongoing and continuous process.
- Studies from the institute helps to identify and rectify the problems related to ADR reporting.
- As per the study performed, most of the ADR's were treatable by early and appropriate management.
- The majority of the ADR's were probably preventable and most of the ADR's were known to be predictable as per the given preventability and predictability scales.
- The severity of ADR's was mild for majority of cases.
- The most frequent causality category observed by the WHO-UMC criteria, Naranjo scale as well as Algorithm methods was "Probable".
- Most of the suspected drugs were unknown, the major limitation was under-reporting of ADR's which can be overcome by creating awareness & enhancing the culture of ADR monitoring & reporting among health care professionals for safe use of drugs.

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