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REPORTING OF ADVERSE DRUG REACTION IN A TERITARY CARE HOSPITAL

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Abstract:
The main aim is to lay out the developing job of clinical drug specialist in checking and the board of ADRs. The objectives is distinguish ADR in all divisions of a tertiary consideration clinic, to screen and treat the ADR's. A total of 41 ADRs were reported during the one-year period of study. 41 patients reported 41 ADRs. Females 25 (60.97%) reported a greater number of ADRs compared to males 16 (39.02%). 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. 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%). A large portion of the thought drugs were obscure, the significant restriction was under-detailing of ADR which can be overwhelmed by making mindfulness and improving the way of life of ADR observing and revealing among medical services experts for safe utilization of medications.

Key words: *Adverse drug reactions, pharmacist, pharmacovigilance, Tertiary care hospital*

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INTRODUCTION:

Adverse drug reactions (ADRs) are defined as, "appreciably harmful or unpleasant reactions, resulting from an intervention related to the use of a medical product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product" [1]. ADRs due to medication errors ranked fourth among mortality causes in the US [2]. The number of deaths caused by ADRs and medication errors in breast cancer, acquired immune deficiency syndrome and accidents are highest [3], moreover, ADRs are responsible for approximately 7% of hospital admissions [2,4]. Clinical pharmacists' role has been evolved regarding caring for hospitalized patients with increased emphasis on patient interaction and collaborative care. The intervention of pharmacists includes ADRs, health-related quality of life, adverse drug events, economics, medication appropriateness, and patients' satisfaction [5]. The present review was conducted to overview ADRs and the role of clinical pharmacists to reduce them. Pharmacovigilance is an integral part of drug therapy. Still, it is not widely practiced in Indian hospitals. In various studies, adverse drug reactions have been implicated as a leading cause of considerable morbidity and mortality [6]. The incidence of adverse drug reactions (ADR) varies with studies which show incidences ranging from as low as 0.15% to as high as 30% [6-8]. Elderly and hospitalized patients are reported to be more susceptible to ADRs than the adult population (16.6% *vs.* 4.1%). Indian reports on ADR monitoring have been very few. This may be because ADR monitoring is still evolving here. After decades of hibernation, the need for an efficient pharmacovigilance programme was felt, the result of which was the institution of National Pharmacovigilance Programme in November 2004 [9]. Under this programme, the Central Drugs Standards Control Organization, New Delhi officiates as the central co-ordinating body under which two zonal, five regional and 24 peripheral centres have been established. The objective of this programme is to create awareness among the health professionals on ADR monitoring and to encourage a reporting culture.

Hospital-based ADR monitoring and reporting programmes aim to identify and quantify the risks associated with the use of drugs. This information may be useful in identifying and minimizing preventable ADRs while generally enhancing the knowledge of the prescribers to deal with ADRs more efficiently. The participation of pharmacists in national pharmacovigilance programmes is not a common feature. The pharmacists' involvement in such programmes is seen only in some countries. In India, clinical pharmacy is still evolving and hence, pharmacists' involvement in such activities has been low. The aim of the present study was to undertake ADR monitoring in a government hospital where a clinical pharmacy programme is well established.

The main aim is to lay out the developing job of clinical drug specialist in checking and the board of ADRs. The objectives are to distinguish ADR in all divisions of a tertiary consideration clinic, to screen and treat the ADR's caused because of prescription, sickness and food, to evaluate the loss and seriousness of ADR utilizing Naranjo Scale, to archive and report thought ADR

METHODOLOGY

STUDY POPULATION: patients from in patient of general medicine
DEPARTMENT: In patient, general medicine, Owaisi Hospital and Research center
SAMPLE SIZE:100 subjects.
STUDY PERIOD: 90 days
STUDY DESIGN: Prospective observational study
STUDY SITE: In understanding general medication office Owaisi Hospital and Research Center
CRITERIA:
INCLUSION FACTORS: All the thought ADR's that might be because of drugs in I patient general medication divisions.
EXCLUSION FACTORS:

- Pregnant and lactating ladies.
- Drug fiends.
- Use of elective arrangement of prescriptions.
- Patient conceded in basic consideration unit.

SOURCE OF DATA:

- Patient case sheet,
- Lab reports and patient guiding's.
- Treatment Charts

STUDY PROCEDURE:

• The patient information or details are recorded on a designed Profile form the outcomes of
the patient with ADRs were recorded.
• An observational study is carried out for 3 months in inpatient department of Owaisi
Hospital and Research Centre. ADRs were reported from inpatient department of the
hospital.
• The contact number and email id of study authors were circulated among the physicians of
respective departments to facilitate reporting of ADR.

• Those cases which were identified and reported by physicians of this hospital were
considered as an ADR and recorded.
• The collected information included patient's initial, age, gender, reporting department of
the hospital, description of the reaction, duration of reaction, name of the suspected drug
causing reaction, and outcomes.
• Drugs causality assessment was performed by Naranjo's probability assessment scale.

RESULTS:

A total of 41 ADRs were reported during the one-year period of study. 41 patients reported 41 ADRs. Females 25 (60.97%) reported a greater number of ADRs compared to males 16 (39.02%). 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. 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%). 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%). 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. Specific treatment was given in 27 (65.85%) while 8 (19.51%) cases required symptomatic treatment and 6 (14.63%) cases required no treatment. 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. 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. 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. Results are in. 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.

Fig: 1 Pie chart showing different age groups affected by ADRs

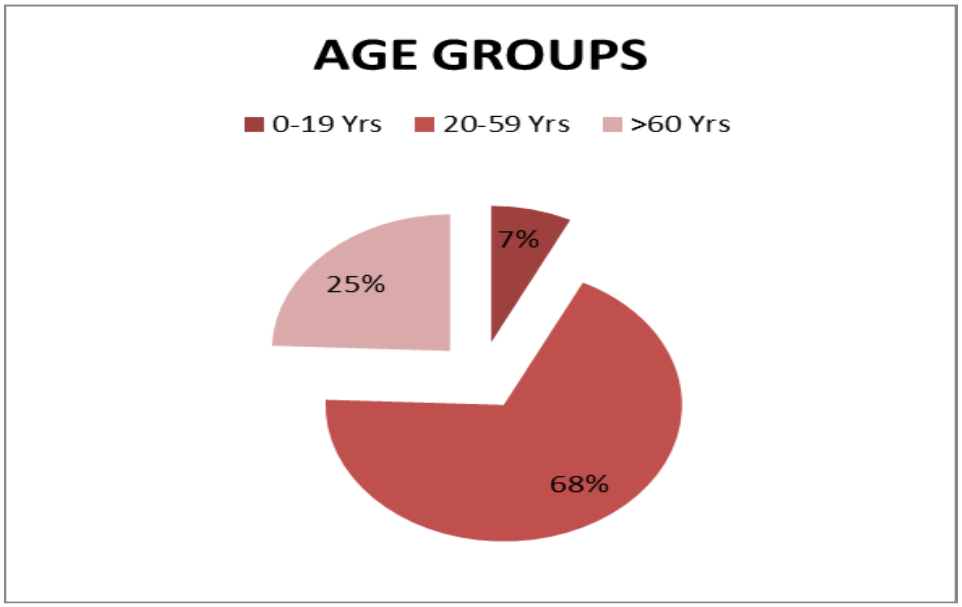

Fig: 2 Bar graph showing departments affected with ADRs

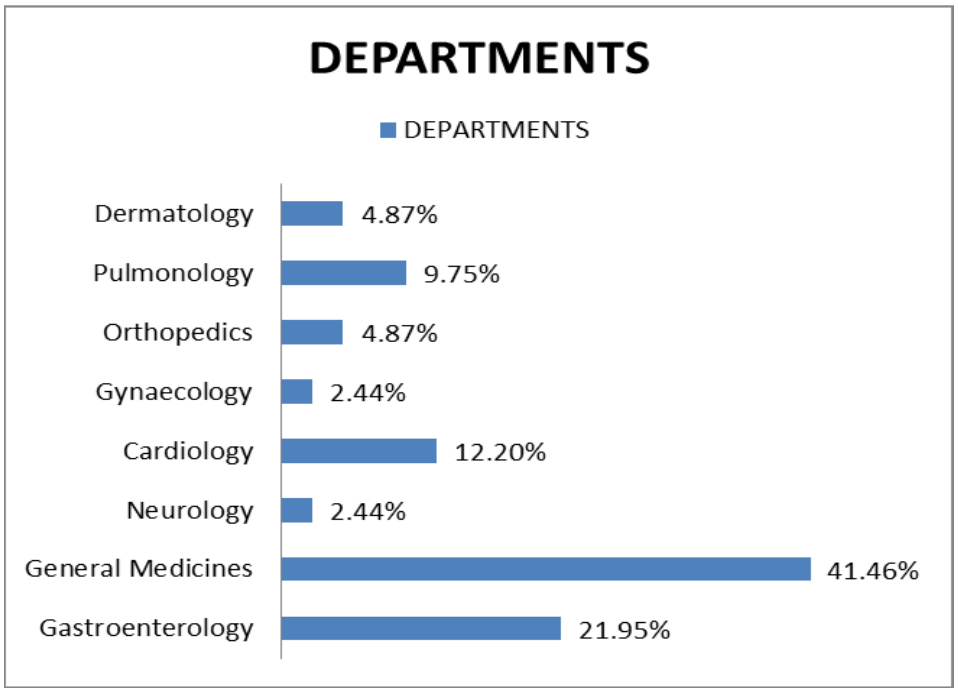

Table: 1 showing different age groups affected by ADRs

AGE GROUP	NO. OF PATIENTS
0 – 19	3
20 – 59	28
60 and above	10

Table: 2 showing departments affected by ADRs

DEPARTMENTS	NO. OF PATIENTS
Dermatalogy	2
Pulmonology	4
Orthopedics	2
Gynaecology	1
Cardiology	5
Neurology	1
General medicines	17
Gastroenterology	9

Fig: 3 Pie chart showing predisposing factors responsible for cause of ADRs

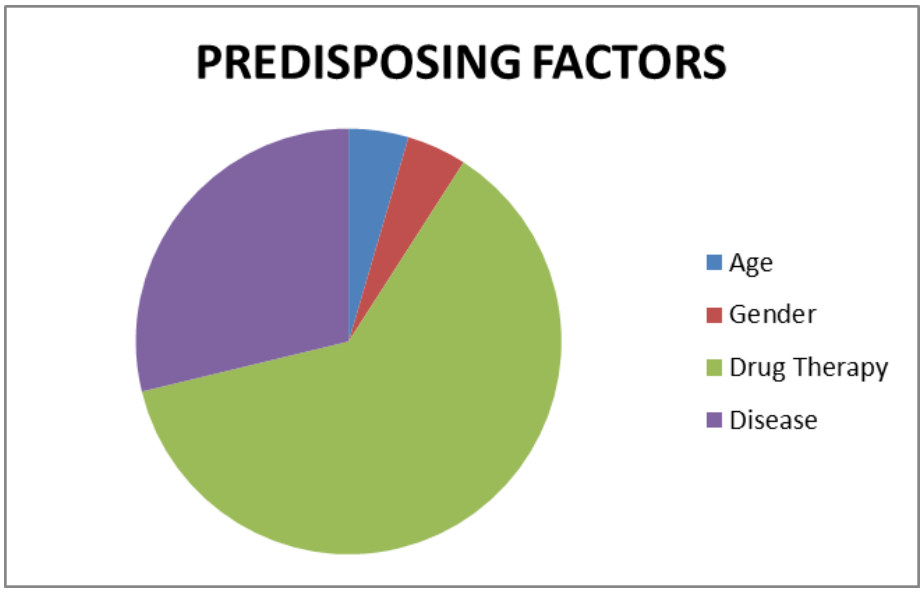

Fig: 4 Bar graph showing changes in the prescribed drug that are suspected to cause the ADRs

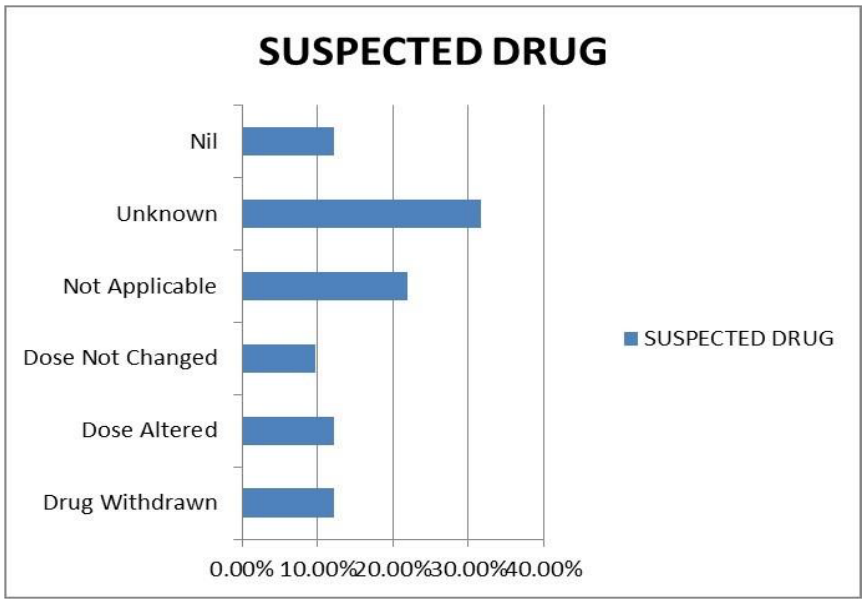

Table: 3 Showing changes in the prescribed drug that are suspected to cause the ADRs

SUSPECTED DRUG	NO. OF PATIENTS
Dose altered	5
Dose not changed	5
Drug withdrawn	5

Fig 5: Pie chart showing preventability of ADRs

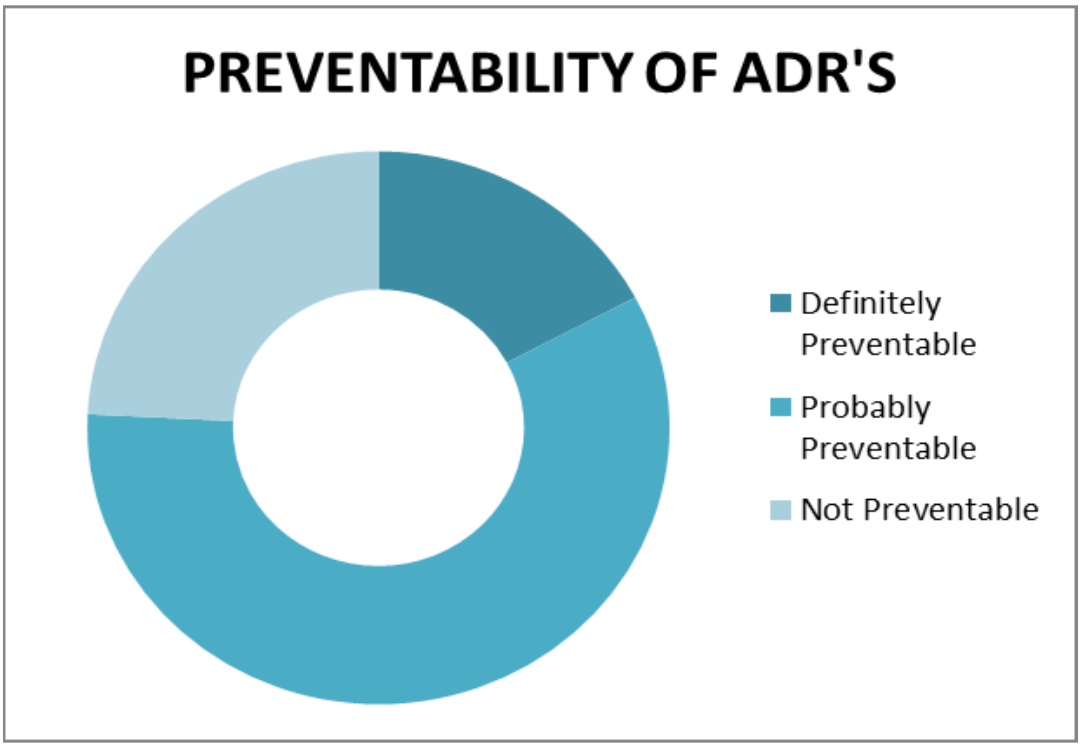

Table 4: Suspected drugs and their ADR'S:

S.NO	SUSPECTED DRUGS	ADVERSE EFFECTS
1	Injection tramadol	Nausea
2	Injection neomol	2-3 episodes of vomitings
3	Cefoperazone	Neutropenia
4	Injection metrogyl	Cough and expectoration
5	Injection metronidazole	Headache
6	Injection linezolid	Maculopapular rash all over the body
7	Injection linezolid	Rashes all over the body
8	Betnesol	Acne, dry skin and skin colouration
9	Tablet esclo plus	Restlessness and insomnia
10	Tablet scopolamine	Dry mouth and skin rashes
11	Nifidipine	Swelling ankles and feet
12	amikacin	Muscle twitching, convulsions
13	Ceftriaxone	Burning sensation in genital areas
14	Injection dynapar	Tachycardia
15	Zofer	Headache, constipation, diarrhoea
16	Medrol	Gastritis and osteoporosis

17	Injection PAN	Constipation
18	Injection metronidazole	Dizziness
19	Injection arachitol	constipation
20	Tab dynapar	Constipation
21	Injection zonomax	Neutropenia
22	Combutol	Jaundice
23	Pantoprazole	Constipation
24	metronidazole	Peripheral neuropathic symptoms with sensory disturbances
25	Tab atrova	Fibromyalgia
26	Injection enoxaparin sodium	Nausea and diarrhea
27	Disperzyme	Diarrhea
28	Injection hydrocortisone	Facial puffiness
29	Injection streptomycin	Rashes
30	Levosalbutanol	Restlessness
31	Clopitab	Dizziness
32	Tab azithromycon	Neck pain and sore throat
33	Injection ranitidine	Constipation and abdominal pain
34	Injection piptaz	Diarrhea
35	Rosuvaststin	Abdominal pain
36	Augmentin	Constipation
37	Injection cefriaxone	Induration, warmth and tightened skin
38	Injection lasix	Hyperuricemia
39	Clarithromycin	Skin rash and slight increase in blood pressure
40	Injection cefotaxime	Hard lump with inflammation at the site of administration
41	Injection clezane	Bleeding gums

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 more 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 more number of drugs than the males. This result is consistent with the results of the study carried out by Palanisamy. S S et.al [10] and which was something different from that observed from other study done by Subish.Pet.al. [11] 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. Paediatricians tend to use only a limited number of drugs for their patients, as paediatric patients rarely presented with multiple co-morbidities. This finding was consistent with the results of the study carried out by Ramesh.et.al [13] but different from the study carried out by Chuenjid Kongkaew et.al. [12] 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, [14] but different from the study carried out by Palanisamy.S et.al 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. [15] 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 detailing is a progressing and nonstop cycle.
- Studies from the organization assist with distinguishing and amending the issues connected with ADR announcing.
- According to the review performed, the vast majority of the ADRs were treatable right on time and with proper administration.
- Most of the ADRs were likely preventable and a large portion of the ADRs were referred to be unsurprising according to the given preventability and consistency scales.
- The seriousness of ADRs was gentle for a larger part of cases.
- The most incessant causality classification seen by the WHO-UMC standards, Naranjo scale as well as Algorithm techniques was "Likely".
- A large portion of the thought drugs were obscure, the significant restriction was under-detailing of ADR which can be overwhelmed by making mindfulness and improving the way of life of ADR observing and revealing among medical services experts for safe utilization of medications.

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