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# A prospective study of adverse drug reactions in a tertiary care hospital in patients

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**Abstract**
**Aim:** To study and report the adverse drug reactions in a tertiary care hospital in patients.
**Background:** Adverse drug reaction is an unwanted, undesirable effect of a medication that occurs during usual clinical use. Adverse drug reaction can effect a patient's quality of life, often causing considerable morbidity and mortality.
**Methodology:** A prospective spontaneous reporting study was carried out in all departments of MNR hospital Sangareddy for a period of 6 months. Data for the study was taken from case sheets, investigation reports of patients who had experienced an adverse drug reaction, past history of medication, personal interviews with patient. For the causality assessment and severity assessment Naranjo scale, Hartwig and Siegel scale and WHO-UMC scale were used. Collected adverse drug reactions were reported in Apollo adverse drug reaction monitoring centre using WHO-UMC Vigi flow form.
**Results:** Out of 65 patients included for the study, 28(43.07%) were males and 37(56.92%) were females. Out of 65, more number (38) of patients who experienced adverse drug reactions were within the age group of 30-60 years. During the period of study Antibiotics -11(16.92%) caused more adverse drug reactions. Out of different departments, in general medicine - 36 (55.3%), more adverse drug reactions were detected. During the study the most occurring adverse drug reaction was vomiting - 9(18.8%). Based on the causality assessment most of the cases were Probable according to Naranjo scale and Possible according to WHO- UMC scale. Severity assessment showed Moderate according to modified Hartwig and siegel scale.
**Conclusion:** This study suggests that there is a need of spontaneous ADR reporting from all the departments of this tertiary care hospital for monitoring and assessment of adverse drug reactions. This study is useful as a preliminary in initiating a culture of ADR reporting among the health care professionals in hospital. In addition, clinical pharmacists should interact with health care professionals to develop and implement an ADR reporting strategy to achieveoptimal care for patients.

**Keywords:** Adverse drug reactions, assessment, reporting

## Introduction
An Adverse Drug Reaction (ADR) is an unwanted, undesirable effect of a medication that occurs during usual clinical use. Adverse drug reactions occur almost daily in health care institutions and can adversely affect a patient's quality of life, often causing considerable morbidity and mortality. Much attention has been given to identifying the patient populations most at risk, the drugs most commonly responsible, and the potential causes of ADRs. An increase in the number of drugs on the market, an aging population, and an upward trend in polypharmacy are contributing factors to the prevalence of ADRs worldwide. Adverse drug reactions may cause patients to lose confidence in or have negative emotions toward their physicians and seek self-treatment options, which may consequently precipitate additional ADRs.

Around 5% of all hospital admissions are the result of an ADR, and around 10–20% of inpatients will have at least one ADR during their hospital stay. The actual incidence of ADRs may be even greater because some ADRs mimic natural disease states and may thus go undetected and/or unreported. Although some ADRs present as minor symptoms, others are serious and cause death in as many as 0.1%–0.3% of hospitalized patients. Pharmacovigilance involves the study of drug-related injuries and making warning or withdrawal recommendations for pharmaceutical agents; it encompasses the detection, assessment, understanding, and prevention of ADRs.

**Types of ADR'S [1]**

1. Type A: Dose related (augmented)
2. Type B: Non dose related (Bizarre)
3. Type C: Dose related and time related (chronic)
4. Type D: Time related (delayed)
5. Type E:Withdrawal (end of use)

**Causality Assessment of Suspected ADRs**

Although several methods for assigning ADR causality probability have been developed, no system has been able to produce a definitive estimation of relationship likelihood. Regardless, causality assessment is a routine practice in pharmacovigilance. Although causality assessment cannot change possibility into certainty, it can provide a degree of likelihood to the relationship between a drug and an adverse reaction. One scheme used in the United States is the World Health Organization - Uppsala Monitoring Centre (WHO-UMC) Causality Categories scheme. This scheme classifies the ADR into one of six category terms: certain, probable/likely, possible, unlikely, conditional/unclassified, and unassessable/unclassifiable (WHO 2014).

Determining the cause of a suspected ADR is a complex process. Because many patients take more than one drug, it can often be difficult to distinguish which agent caused the ADR. Furthermore, the suspected ADR may in fact be a manifestation of the patient's underlying disease state. An important step in identifying an ADR and determining causality is to obtain an accurate patient drug list. Not only is this an opportunity to screen for ADRs that could have led to the hospitalization, but maintaining an updated, accurate medication history for each patient can also help prevent future ADRs. If the inpatient prescriber is unaware of the patient's home drug regimen on admission, duplicate therapy may be prescribed. If admission and discharge reconciliation are not done, discharged patients may resume taking their home medication in addition to the newly prescribed therapy; this could result in an ADR might result or lead to re-hospitalization.

Assessing the timing between administration of the drug and development of the reaction is important. Does the reaction worsen with repeated or increased dosing? Does the reaction decrease in intensity when the dose of the drug is reduced or discontinued? Has the patient previously been exposed to the drug, in cases of allergic reaction? Is the reaction known to occur with long-term use of the medication? Did symptoms appear or worsen when a drug was discontinued? Answering such questions can help the pharmacist determine causality. The next step is to identify patterns in ADR symptoms. Do the symptoms fit the normal pharmacology or allergy profile of the drug? Is this a known adverse reaction associated with this drug, or is it unique? Have case reports been published on this reaction? Particularly with new medications, much of the information about associated adverse reactions is unknown. By the time a drug has been approved for marketing in the United States, only about 1500 people have been exposed to the drug [2].

**Materials and Methods**

**Study Site**

MNR hospital - Fasalwadi, Sangareddy.

**Study Design**

A Prospective, Cross sectional study.

**Study Population**

The study population includes 1055 In-patients. In the study the data is being collected in the data collection form.

**Study Duration**

Six months from December 2017 to May 2018.

**Selection of Study Subjects**

**Inclusion Criteria**

All the patients of either sex and of any age who developed an ADR during the period of study were included.

**Exclusion Criteria**

Patient who developed an ADR due to intentional or accidental poisoning.
ADR due to fresh blood/blood products.
ADR due to drug overdose.
Patients with drug abuse and intoxification
Outpatient**.**

**Methodology**

A prospective spontaneous reporting study involving, active methods (pharmacist actively looking for suspected ADRs) and passive methods (stimulating prescribers to report suspected ADRs) was carried out in all departments of "MNR Hospital, Sangareddy, Telangana" for a period of six months. Patients of all age groups who developed Adverse Drug Reactions to several drugs were included for the study.

The data for the study were taken from case sheets, investigation reports of patients who had experienced an ADR, personal interviews with reporting persons or clinicians, personal interviews with patient or patient's attendant, past history of medication use, which were generally obtained from, prescriptions from the past, reports of Medical and surgical interventions, referral letters, etc.

The causality assessment of the reported ADRs was carried out using the ''Naranjo causality assessment scale''. In the Naranjo Algorithm, the drug reaction can be classified as definite, probable, or possible.

The WHO-UMC scale classifies ADR as certain, probable, possible, unclassified and unclassifiable based on standard criteria.

The modified Hartwig and Siegel scale classifies severity of ADR as mild, moderate or 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.

Finally, all the collected ADRs were reported in Apollo ADR Monitoring Centre using
WHO-UMC Vigiflow.

**Causality and Severity Assessment Scales**

**Naranjo Causality Scale (adapted)**

1. Are there previous conclusive reports on this reaction?
   Yes (+1) No (0) Do not know or not done (0)
2. Did the adverse event appear after the suspected drug was given?
   Yes (+2) No (-1) Do not know or not done (0)
3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
   Yes (+1) No (0) Do not know or not done (0)
4. Did the adverse reaction appear when the drug was readministered?
   Yes (+2) No (-1) Do not know or not done (0)

5. Are there alternative causes that could have caused the reaction?
   Yes (-1) No (+2) Do not know or not done (0)
6. Did the reaction reappear when a placebo was given?
   Yes (-1) No (+1) Do not know or not done (0)
7. Was the drug detected in any body fluid in toxic concentrations?
   Yes (+1) No (0) Do not know or not done (0)
8. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?
   Yes (+1) No (0) Do not know or not done (0)
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?
   Yes (+1) No (0) Do not know or not done (0)
10. Was the adverse event confirmed by objective evidence?
    Yes (+1) No (0) Do not know or not done (0)

**Scoring**

- 9 = definite ADR
- 5-8 = probable ADR
- 1-4 = possible ADR
- 0 = doubtful ADR

WHO–UMC causality categories

| Causality term | Assessment criteria (all points should be reasonably complied) |
|---|---|
| Certain | Event or laboratory test abnormality, with plausible time relationship to drug intake cannot be explained by disease or other drugs.<br>Response to withdrawal plausible (pharmacologically, pathologically)<br>Event definitive pharmacologically or phenomenologically (ie, an objective and specific medical disorder or a recognized pharmacologic phenomenon) Rechallenge satisfactory, if necessary |
| Probable/likely | Event or laboratory test abnormality, with reasonable time relationship to drug intake unlikely to be attributed to disease or other drugs<br>Response to withdrawal clinically reasonable. Rechallenge not required |
| Possible | Event or laboratory test abnormality, with reasonable time relationship to drug intakecould also be explained by disease or other drugs information on drug withdrawal may be lacking or unclear |
| Unlikely | Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) disease or other drugs provide plausible explanation |
| Conditional/unclassified | Event or laboratory test abnormality more data for proper assessment needed, or additional data under examination |
| Unassessable/unclassifiable | Report suggesting an adverse reaction cannot be judged because information is insufficient or contradictory data cannot be supplemented or verified. |

**Modified Hartwig and Siegel Severity scale**

**Mild**

**Level 1:** The ADR requires no change in treatment with the suspected drug. OR

**Level 2:** The ADR requires that the suspected drug be withheld, discontinued otherwise changed. No antidote or other treatment is required, and there is no increase in length of stay.

**Moderate**

**Level 3:** The ADR requires that the suspected drug be withheld, discontinued Or otherwise changed, and/ or an antidote or other treatment is required. There is no increase in length of stay.

**OR**

**Level 4 (a):** Any level 3 ADR that increases length of stay by at least one day. OR

**Level 4 (b):** The ADR is the reason for admission.

**Severe**

**Level 5:** Any level 4 ADR that requires intensive medical care. OR

**Level 6:** The ADR causes permanent harm to the patient
OR

**Level 7:** The ADR either directly or indirectly leads to the death of the patient.

ADR Monitoring Card

**PATIENT DETAILS** Name : Sex : M / F Weight(Kg) : Age :
Ward : I.P No : DOA : DOD :

**SUSPECTED DRUG(S)** Please give following information if known

| Brand Name (Batch No if Known) | Route | Dosage | Date Started | Date Stopped | Prescribed for |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

**SUSPECTED REACTION(S)** Please describe the reaction(s) any treatment given.

Date Reaction(s) Started :
Date Reaction(s) Stopped :

**OUTCOME OF ADR**

Recovered ☐
Recovering ☐
Continuing ☐

Died due to reaction ☐
Died drug may be contributory ☐
Died, Unrelated to drug ☐
Unknown ☐

Do you consider the reaction to be serious? Yes / No
If 'Yes' please indicate why the reaction is considered to be serious
Patient Died due to reaction ☐
Life threatening ☐
Congenital abnormality ☐
Involved or prolonged in patient hospitalization ☐
Involved persistent or significant disability or incapacity ☐
Medically significant ; please give details

| Diagnosis | | | | | | | |
|---|---|---|---|---|---|---|---|
| Drugs | Dose | Started on | Stopped on | Drugs | Dose | Started on | Stopped on |
| | | | | | | | |

**OTHER DRUGS (including self-medication & herbal remedies)**

Did the patient take any other drugs in the last 3 months prior to the reaction Yes / No
If 'Yes' please give the following information if known :

| Drug (Brand if known) | Route | Dosage | Date Started | Date stopped | Prescribed for |
|---|---|---|---|---|---|
| _____ | _____ | _____ | _____ | _____ | _____ |
| _____ | _____ | _____ | _____ | _____ | _____ |

**Additional relevant information :** (e:g. medical history, investigation, known allergies, Suspected drug interactions)

**REPORTER DETAILS**

Name & Professional Address :

_____

_____Tele No : _____ Email Id :

_____

Specialty :

Signature : Date :

**DEPARTMENT OF PHARMACY PRACTICE**
**MNR COLLEGE OF PHARMACY**
**MNR HOSPITAL CAMPUS**

**ADVERSE DRUG REACTION ALERT CARD**

**PATIENT NAME :**

**AGE : SEX :**

**ADDRESS :**

***Please produce this card to your Doctor at the time of consultation***

**DEPARTMENT OF PHARMACY PRACTICE**
**MNR COLLEGE OF PHARMACY**
**MNR HOSPITAL CAMPUS**

**ADVERSE DRUG REACTION ALERT CARD**

**SUSPECTED DRUG(S):**

**DESCRIPTION OF REACTION:**

**DATE OF REACTION:**

**Demographic characteristics of the patients**

**Table 1:** Gender categorization of study population

| Gender | No. of patients |
|---|---|
| Male | 28 |
| Female | 37 |
| Total | 65 |

**Gender categorization**

Out of 65 patients included for the study 28 were males and 37 were females. This finding was similar to study done by Ratan J. Lihite *et al*. [7] with 101 males and 118 females.

**Table 2:** Age group distribution of study population

| Age Groups (yrs) | No. of patients |
|---|---|
| 1-30 | 15 |
| 31-60 | 38 |
| 61 and above | 12 |

**Age group distribution**

Out of all the 65 patients 12 patients were in the age group of 1-30 years, 38 patients were in the age group of 31-60 years and 12 patients were 61 and above. This findings were similar to study done by Ratan J. Lihite *et al*.,[7] in which the middle aged group patients experienced more adverse effects.

**Causality and Severity of ADR's in study population**

**Table 3:** Causality assessment of ADR' based on Naranjo scale

| Severity | No. of patients | Percentage (%) |
|---|---|---|
| Definite | 0 | 0 |
| Probable | 45 | 69.23 |
| Possible | 20 | 30.76 |
| Doubtful | 0 | 0 |

Out of 65 cases collected, ADR's were assessed according to Naranjo Scale, 69.23% of ADR' were Probable and 30.76% of ADR's were Possible differing from Ratan J. Lihite *et al*., (7) in which 94.1% of ADR's were Possible and 3.9% of ADR's were Probable.

**Table 4:** Causality assessment of ADR' s based on WHO-UMC Scale

| Severity | No. of patients | Percentage (%) |
|---|---|---|
| Certain | 03 | 4.6 |
| Probable | 19 | 29.23 |
| Possible | 43 | 66.15 |
| Unclassified | 0 | 0 |
| Unclassifiable | 0 | 0 |

Out of 65 cases collected the ADR's were assessed according to the WHO-UMC scale, 66.15% of the ADR's were Possible, 29.23% of the ADR's were Probable and 4.61% of the ADR's were Certain which is in accordance with Shanmugam Sri Ram *et al*.,[5] in which 42% of the ADR's were Possible.

**Table 5:** Severity assessment of ADR's based on modified Hartwig and Siegel scale

| Severity | No. of patients | Percentage (%) |
|---|---|---|
| Mild | 14 | 21.5 |
| Moderate | 48 | 73.8 |
| Severe | 03 | 4.61 |

Out of 65 patients included for study 36(55.3%) patients with ADR's were found in General Medicine followed by 9(13.3%) in Orthopaedics, 6(9.23%) in Dermatology, 5(7.69%) in Psychiatrty, 4(6.15%) in Pulmonology, 2(3.07%) in ENT, 1(1.53%) in General surgery, Ophtholmology, Paediatrics which is in accordance with M. Shamna *et al*., [6] in which highest number of ADR's were found in General Medicine (24.48%).

**Distribution of ADR's according to classes of drugs**

**Table 6:** Distribution of ADR's according to classes of drugs

| CLASS | No. of patients | Percentage (%) |
|---|---|---|
| Antibiotics | 11 | 16.92 |
| Anti hypertensives | 08 | 12.30 |
| Anticancer | 04 | 6.15 |
| Thyroid agents | 01 | 1.53 |
| Anti-tubercular drugs | 03 | 4.61 |
| Corticosteroids | 05 | 7.69 |
| Anti-malarial agents | 02 | 3.07 |
| NSAID'S | 10 | 15.38 |
| Anti-diabetic agents | 04 | 6.15 |
| GI agents | 01 | 1.53 |
| Anti-diarrhoeal | 01 | 1.53 |
| Opioid agents | 06 | 9.23 |
| Antiepileptic drugs | 01 | 1.53 |
| DMARDS | 01 | 1.53 |
| Antipsychotic agents | 04 | 6.15 |
| Diuretics | 01 | 1.53 |
| Leukotriene receptor antagonist | 01 | 1.53 |
| Analgesics | 01 | 1.53 |

Out of 65 patients included for the study, 11(16.92%) patients experienced ADR with Antibiotics followed by 10(15.38%) patients with NSAID'S, 6(9.23%) with Opioid agents and followed by other classes of drugs which is in accordance with Rohini Sharma *et al*.,[4] in which 60 patients experienced ADR's with Antibiotics followed by NSAID's.

**Types of ADR's in the study population**

**Table 7:** Types of ADR's in the study population

| ADR | No. of patients | Percentage (%) |
|---|---|---|
| Cough | 02 | 3.07 |
| Tardive dyskinesia | 01 | 1.53 |
| Vomiting | 09 | 13.8 |
| Nausea | 02 | 3.07 |
| Diarrhoea | 04 | 6.15 |
| Fainting | 01 | 1.53 |
| Rash | 08 | 12.3 |
| Swelling | 05 | 7.69 |
| Shortness of breath | 02 | 3.07 |
| Anaemia | 01 | 1.53 |
| Pleural effusion | 01 | 1.53 |
| Diabetes Mellitus | 02 | 3.07 |
| Constipation | 01 | 3.07 |
| Headache | 01 | 1.53 |
| Bell's Palsy | 01 | 1.53 |
| Cushing syndrome | 01 | 1.53 |
| Gastritis | 01 | 1.53 |
| Hypoglycaemia | 01 | 1.53 |
| Increased urination | 03 | 4.61 |
| Blackish discoloration | 01 | 1.53 |
| Weight gain | 03 | 4.61 |
| Spasm in legs | 01 | 1.53 |
| Oral Candidiasis | 01 | 1.53 |
| Abdominal pain | 03 | 4.61 |
| Muscle dystonia | 01 | 1.53 |
| Asthma | 01 | 1.53 |
| Chest pain | 01 | 1.53 |
| Hepatitis | 01 | 1.53 |
| Numbness of face and hands | 01 | 1.53 |
| Dysarthria | 01 | 1.53 |

Out of 65 patients in the study, vomitings were most commonly observed ADR during the study period followed by rashes and swelling differing from M. Palaniappan *et al*., [8] in which cough was most frequently observed ADR followed by gastritis and fatigue

**Percentage of ADR' based on risk factors**

**Table 8:** Percentage of ADR' based on risk factors

| Risk factors | No. of patients | Percentage (%) |
|---|---|---|
| Age | 14 | 21.53 |
| Comorbidity | 06 | 9.23 |
| Multiple drug therapy | 17 | 26.15 |
| Others | 28 | 43.07 |

Out of 65 patients in the study the major risk factor for the development of ADR was others like genetics, renal impairment, hepatic impairment, smoking, alcohol consumption followed by multiple drug therapy differing from Shanmugam Sriram *et al*., [5] in which the major risk factor for the development of ADR was cardiac problem followed by others.

**Discussion**

In our study, 35 suspected offending drugs were reported to induce various ADRs in a time period of 6 months and rechallenge was not performed in any patient. Majority of ADRs were reported from female patients (56.92%) than from male (43.07%). Paediatric and geriatric patients are vulnerable groups, supposed to experience ADR more often. However, in our study adult patients belonged to age group of 31–60 years were reported to experience maximum number of ADRs differing from previous study by Ratan J. lihite *et al*., [8] It is likely that this population is attending hospital more frequently and is a major population receiving drug therapy.

This study was conducted in MNR hospital, Sangareddy which is a tertiary care hospital and there is likely to be variation between different hospitals because of differences in the local population characteristics and the specialties within the hospitals. In this hospital, most of the ADRs were reported from General medicine department (55.3%) as opposed to the previous study by Ratan J. lihite *et al*. [8] From previous studies by Kinjal Prajapati *et al*., [4] and Ratan J. lihite *et al*., [8] commonly reported ADRs were skin and appendageal disorders like acne, itching, melasma, contact dermatitis, rashes, and erythematous rashes. In this study, vomiting, rashes, diarrhoea and abdominal pain were commonly reported ADRs.

In this study, majority of the ADRs were associated with oral intake of drugs and antibiotics were the major culprits. Paracetamol is also reported as one of the offending drugs to induce rashes.

According to Naranjo's scale, from south Indian studies by Shanmugam Sri Ram *et al*., [5] most of the reported ADRs were probable (63%), the same was observed in this study with most of the ADRs (69.23%) were classified as probable, and only 30.76% ADR reports were possible. As per modified Hartwig and siegel criteria most of the ADR reports were moderate (73.8%) in nature and recovered during study period. As per WHO scale 66.15% of ADRs were found to be possible.

The analysis of the fate of the suspected drugs showed that the drug was withdrawn in many of the cases and the dose altered in some while no change was made with the suspected drug in others because of considering the risk benefit ratio in specific patients. Antibiotics comprise the major volume of the drug family and inpatient prescriptions and thus are the most irrationally prescribed drug class. So implementation of antibiotic guidelines for the hospital scenario and strict adherence should be ensured to promote the rational use.

**Conclusion**

In conclusion of our study, occurrence of ADRs were found in every department we covered especially in general medicine with more number of occurrences The Antibiotics were reported to cause majority of ADRs and the commonly reported ADR in this study were vomiting. Female cases pre-dominated males and age group of 31-60 years were more susceptible. Based on the causality assessment most of the cases were Probable according to Naranjo scale and Possible according to WHO-UMC scale. Severity assessment showed Moderate according to modified Hartwig and siegel scale.

This study suggests that there is a need of spontaneous ADR reporting from all the departments of this tertiary care hospital for monitoring and assessment of ADRs. In the study various general risk factors lead to the development of ADR like genetics, renal impairment, hepatic impairment, smoking, alcohol consumption followed by multiple drug therapy.

This study is useful as a preliminary in initiating a culture of ADR reporting among the health care professionals in hospital. This study also warrants further research in this hospital for the development of possible intervention strategies to reduce burden of ADRs. In addition, clinical pharmacists should interact with health care professionals to develop and implement an ADR reporting strategy to achieve optimal care for patients. The results provided an insight to the health care providers on the importance of monitoring and reporting of adverse drug reactions.

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