Galore International Journal of Health Sciences and Research
DOI: https://doi.org/10.52403/gijhsr.20211006
Vol.6; Issue: 4; Oct.-Dec. 2021
Website: www.gijhsr.com
Original Research Article *P-ISSN: 2456-9321*

A Study on Pharmacist Mediated Intervention in Identifying and Reporting of Adverse Drug Reactions at a Tertiary Care Hospital

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ABSTRACT

Background: Adverse drug reactions are major problem in health care system due to its consequences - morbidity, mortality and health care cost. Recent epidemiologic research reveals that the total incidence rate of ADRs was 6.7%, with an overall fatality rate of 0.32%.
Method: A prospective observational study was carried out for 6 months in a tertiary care hospital. Patients admitted to the department of medicine, Pediatrics, orthopedics & surgery were selected randomly and followed from date of admission to date of discharge by enrolling into the study by considering the study criteria.
Results: During the research about 27 ADRs were recognized & reported. Among them 14 (51.86%) patients were male and 13(48.14%) were female patients. The system or organ most commonly involved was Blood disorders were 8 (29.62%). Type A were 16(57.25%) reactions followed by Type B were 8 (29.62%); Type C were 3 (11.11%). Study depicts drug class usually implicated with ADRs was Antibiotics and antineoplastic drugs were 6 (22.22%) followed by Anti-Tubercular were 3 (11.11%); NSAIDS and Antidiabetic drugs were 2 (7.4%); The least implicated (3.7%) drug class are Anti-Pyretic, Diuretics and Antiretroviral. Causality was assessed for all the reported reactions are found to be PROBABLE according to WHO-UMC Scale.
Conclusion: The study report shows that incidence of ADRs is steadily increasing. Under reporting of ADR is a major problem in India. Clinical Pharmacist plays a vital role in surveillance and prevention of ADRs.

Key Words: Adverse Drug Reactions, Pharmacovigilance, Causality.

INTRODUCTION

Adverse Drug Reaction [ADR]; According to WHO ADR is defined as any response to a drug which is noxious and unintended, and which occurs at doses normally used in man.[1]

Medication errors are commonly seen in hospitals. These can be further subdivided as prescribing error, dispensing error and administrative error. In whole, medication errors include wrong medication, wrong dose, wrong strength, wrong formulation, expired medication. [2]

The reports reveal that the total burden of thyroid disorder in India is 42 million. In India, Iodine deficiency disorders account for 27 per 1000 where as Grave's disease accounts 5 per 10,0002. The

prevalence and pattern of Thyroid disorders depend on sex, age, ethnic and geographical factors and especially on iodine intake. Iodine deficiency can lead to mental retardation, still births, congenital anomalies and psychomotor defects. Research shows that hypothyroidism can contribute to morbidity from Osteoporosis, Hyperlipidemia, Hypercholesterolemia, Cardiovascular and Neuropsychiatry disease in the population.[3] The seriousness of thyroid disorders should not be underestimated as thyroid storm and myxedema can lead to death in a significant number of cases.[2]

Drugs are vital in the management of diseases. A Drug related problem (DRP) is defined as an any event or circumstance involving drug treatment that interferes or potentially interferes with the patient achieving an optimum outcome of medical care. Cipolle classified drug related problems in to eight types.

1. Untreated indication
2. Use of medication without an indication
3. Improper drug selection.
4. Sub therapeutic dosage.
5. Over dosage.
6. Medication error/non-compliance
7. Drug interactions, and
8. Adverse drug reactions [3]

Based on the profile of medications prescribed, the drug-drug interactions are identified and classified.

1) Major: The effects are potentially life threatening or capable of causing permanent damage.
2) Moderate: The effects may cause deterioration in patients' clinical status and additional treatment or extension of hospital stay.
3) Minor: The effects are usually mild.

Drug interactions may lead to adverse drug reactions that can be severe enough to necessitate hospitalization and increased health care costs. About 5% of all the adverse drug reactions in the hospitals are caused by Drug-Drug interaction, the majority of which are avoidable. Hence, this work is proposed to identify potential drug-drug interactions in the drug therapy by the clinical pharmacist and report the same to the physician so that adverse drug reactions can be prevented and patient outcome can be improved.[4,5]

As per WHO, Drug utilization studies and research information is the important part that helps in marketing, distribution and prescription pattern of drugs and helps to assess the impact of these on medical and socioeconomic status of patients. Thus, drug utilization studies are useful in understanding the prescription pattern along with the quality of prescription in terms of rationality, drug interactions and financial burden of disease to the individual. These information helps in improving the standards of treatment and identify the problems caused by polypharmacy, drug-drug interaction and adverse drug reactions. Periodically auditing of prescriptions in form of drug utilization studies are important tool to increase the efficacy of drug, to reduce the adverse effect, to optimize the cost of the treatment and to give better feedback to the medical practitioner. Previous studies conducted in Australia suggest that academic detailing improves the quality.[6]

The overuse and misuse of antibiotics has affected quality of life leading to larger side effects which caused financial burden to the patient, as well as over the health care system. Antibiotic use and antimicrobial resistance are increasing in India is reported by a “Community based Surveillance of Anti-microbial use and Resistance in the Resource constrained settings” by WHO based on the reports from 5 pilot projects three from India (Delhi, Mumbai, Vellore) and two from South Africa. [7,8,9]

It has been estimated that by 2050, 700,000 deaths per year occur inevitably to antimicrobial resistance and, there might be 10 million deaths per year. [10 ,11] Currently in India, even though most of medication errors remain unreported in many health care setups, we are still known to report 5.2

million injuries related to medication errors and adverse drug reactions.[12,13,14]

Pharmaco-epidemiological research is described as the study to estimate the utilization pattern and effect of drugs in any clinical populations and to understand the various therapeutic outcomes like adverse drug reactions, drug effects like drug-drug interactions, medication adherence. It is the study of drug-oriented safety and its effectiveness. Rational usage of drugs is required for an effective treatment to achieve the therapeutic goals and maintain standards as per the established protocol.[15]

Atopic dermatitis (AD) is an inflammatory dermatological condition that extensively affects almost all parts of the body (upper extremities, lower extremities) with clear exemption of the groin and axillary regions. The pathogenesis of AD depends on environmental factors as a result there are wide variations in epidemiology from country to country. AD is a complex genetic disease with underlying epithelial barrier defect involving skin as well as mucosa hence is often accompanied by other atopic disorders such as allergic rhino conjunctivitis and asthma. Genetics, barrier dysfunction, defects in adaptive and immune response genes, immune dysregulation and microbial colonization are some of the mechanisms of pathogenesis.[16,17]

The most commonly observed antiepileptic drugs (AEDs) induced cutaneous adverse drug reactions (cADRs) include maculopapular exanthema (MPE), Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).[1] There is an increased risk for Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN) among HLA-B*15:02 positive patients and CBZ induced reactions such as Hypersensitivity Syndrome (HSS) whereas MPE occurs in Human Leukocyte antigen (HLA-A*31:01) positive patients and SJS/TEN and acute generalized exanthemata's pustulosis rarely occure.[18]

Myasthenia gravis (MG) is an autoimmune disorder characterized by fatigue and muscular weakness. Around 15 percent of all cases of MG are graded as thymoma MG (T- MG).[1,2] In the United States, the prevalence of T-MG is around 0.15 per 100,000 person- years.[3,4] T-MG is categorized according to the histological classification of the World Health Organization (WHO) and graded according to the Masaoka staging system.[5,6] The severity of this disorder is determined through the Myasthenia Gravis Foundation of America (MGFA) clinical classification system.7T-MG is popular on both men and women alike. It occurs at any age, with a 50-year peak start. Asians, Pacific Islanders and African Americans are more likely to contract this disease. When thymoma diagnosis is identified in an MG patient, the neoplasm should be surgically removed and radical excision of the neoplasm is crucial. Most T-MG appears to have difficult clinical development and poor prognosis.[19]

Localized infection of Staphylococcus occurs in the skin, nose, mouth, throat, umbilicus and gastrointestinal tract (GIT). General malaise, irritability, fever, skin tenderness may be prominent. Other signs include facial edema, conjunctivitis and perioral crusting.[20]

Photosensitive eczema in combination with predominantly UVB sensitivity was identified as occurrence of eczema on photo exposed sites. Photo exposed site dermatitis and isolated UVA photosensitivity are also included in the concept of chronic actinic dermatitis in the absence of photoactive drugs, although much less common. Positive patch and/or photo patch results are found in the majority of identified patients. Photo testing and photo patch analysis facilities are not freely available and the histopathology is not comprehensive, the clinical characteristics remain the most important tool in chronic actinic dermatitis. The chronic actinic dermatitis treatment is generally divided into preventive, behavioral and environmental avoidance approaches to

restrict photo-sensitivity clinical manifestations and suppressive methods to reduce the immune and inflammatory nature of the disease.[21]

The coronavirus outbreak has caused a major interruption to education activities in colleges and universities worldwide. The worsening pandemic threatens to affect certain aspects of college life, from admission, tuition, extra learning activities, boarding and other school activities. Since the WHO declared the coronavirus outbreak, the number of infections has burgeoned to worrying levels. For this reason, educational stakeholders decided on implementing school closure policies in order to slow down the rate of infection. Social distancing rules were also introduced to reduce close contact as a countermeasure to coronavirus infections. Social distancing rules were felt hard by pharmaceutical and other health care graduate students who were restricted from visiting healthcare facilities where they can observe and learn from experienced practitioners. The making of a competent pharmaceutical practitioner demands a hands-on practice and a physical presence which is majorly undermined by the coronavirus crisis. This paper seeks to explore the various effects coronavirus has on pharmaceutical education and the different counter measures taken to facilitate education.[22]

The science dealing with detecting, assessing, understanding and preventing ADRs has been termed "pharmacovigilance". Pharmacovigilance plays an essential role in the reduction of ADRs, thus the evolution and growth of this science are critical for effective and safe clinical practice.[23]

As a result of thalidomide disaster, in 1968, the WHO started the Program for International Drug Monitoring (PIDM) for early detection of ADRs. This activity is now called as Pharmacovigilance. Ten members participated in this program (Australia, UK, USA, Germany, Canada, Ireland, Sweden, Denmark, New Zealand, and Netherlands). Italy participated in this program in 1975.[24]

WHO promotes PV at the country level by working in collaboration with the Monitoring centre at Uppsala. More than 135 countries are the part of this program. Uppsala Monitoring Centre (UMC) in Sweden is responsible to monitor and manage the WHO-PIDM activities. This program not only enhances patient safety for use of medicines but also gives information about safe use and prevention and treatment of any Adverse Drug Reactions (ADRs).[25]

In 1992, the European Society of Pharmacovigilance (ESoP) was funded, turned into the International Society of Pharmacovigilance (IsoP). The aims of this society were to promote Pharmacovigilance, and enhance all aspects of the safe and proper use of medicines.[26]

The Pediatric Rule for Labelling, which was came in to action in1994 by the FDA and its 1998 enactment requiring manufacturers of certain new and marketed drugs to conduct studies for pediatric labelling has increased the information available regarding drug safety for children.[27]

India accounts for around 10% of global intake of medicines; the reporting of ADRs of medicines is a meagre 2% of the global occurrence. This is largely due to the poor reporting of adverse drug reactions in India. Despite this, India was 7thin position amongst the top ten countries contributing to global drug safety database.[28]

The ADR form is available at any pharmacovigilance center. The completed form should be sent to the peripheral pharmacovigilance center or in case of doubts, it can be sent directly to CDSCO. The information provided is handled in strict confidence. The peripheral center forwards the submitted form to the regional center where causality analysis is carried out, after MC.[29]

A cohort study assessed the ADR incidence rate in ambulatory patients as 25%.[4] ADR incidence has been reported to range from 5.9 to 22.3% of all emergency

department admissions. ADRs are 4th-6th largest cause of death in USA.

A recent Swedish study has also implicated ADRs as 7th most common cause of death.5 The study of Bord et al indicated that, in patients who experience ADRs, death rates were 19.18% higher and the length of hospital stay is 8.25% higher.[30]

General Objectives:

A Study on Pharmacist Mediated Intervention in Identifying and Reporting Of Adverse Drug Reactions At A Tertiary Care Hospital

Specific Objectives:

- To Assess Demographic Characteristics.
- To Identify Types of Suspected ADRs.
- To Identify Predisposing factor contributing the ADRs.
- To Identify Drug Class and Medications involved in ADRs.
- To Assess Disease Category by System Organ Class.
- To Determine Seriousness of the ADRs.
- To assess causality and severity of ADR's detected
- To Determine the Outcome and Management of the suspected ADRs.

METHODOLOGY

STUDY SITE: Study was conducted at Tertiary Care Hospital.

SOURCE OF DATA: Case sheets of In-patients admitted to the department of Medicine, Pediatrics, orthopedics and surgery at Tertiary Care Hospital.

STUDY DURATION: Study was carried out over a period of 6 months.

STUDY DESIGN: "A prospective observational study".

STUDY CRITERIA: Patients were enrolled into the study by considering study criteria.

INCLUSION CRITERIA:

- Patients who are willing to participate in the study.
- Patients of either Gender.
- Patients admitted to the department of medicine, paediatrics, surgery & orthopaedics.

EXCLUSION RITERIA:

- Patients treated on out-patients basis were excluded from the study.
- Patients who were not willing to participate in the study.

ETHICAL COMMITTEE APPROVAL: The Human Ethical Clearance for the study was approved by Institutional Review Board (IRB).

MATERIALS:

The following study materials were prepared and used for the study. Informed Ascent/Consent Form

A Patient informed Ascent/Consent form was prepared and obtained from the patient before enrolling into the study by considering study criteria.

Patient Data Collection Form

A suitably designed Patient Data collection Form was prepared by referring standard textbooks, Journals and other relevant Sources which include information of Patient Demographic details such as Age, Gender, Duration of Disease, Hospital stay and Medication

History

- Yellow Card
- Red Alert Card
- Casualty Assessment Scale

STUDY PROCEDURE:

A Prospective observational study was carried out for a period of 6 months in a Tertiary care hospital. Patients admitted at Tertiary care hospital were selected randomly and enrolled into the study by considering the study criteria. Patient Informed Ascent/Consent proforma was taken from each patient at the time of enrollment into the study. Details regarding demography, laboratory investigations, past medical and medication history and current medication history was collected from the case sheets and noted in the suitably design

patient data collection proforma. The Patients who developed ADR were identified and reported. ADR identified was analyzed using causality assessment scales – Naranjo scale, WHO scale and Hartwig Severity Scale.

RESULT

In our study 27 suspected ADRs were identified and reported among 50 patients during six-month prospective observational study period. Accounting for an incidence of 32.05%. 24 (41.3%) patients were hospitalized due to ADRs, whereas 34 (58.6%) patients developed ADRs during their hospital stay. A maximum of 2 ADRs were reported among 12 patients (20.68%). It was observed that average length of the hospital stays for patients who developed ADRs was higher than patients without ADR.

Reported ADRs were evaluated for the following Parameters:

- Demographics – Age and Gender.
- Type of ADR reaction Mechanism.
- Predisposing factors.
- Drug class involved in ADRs.
- Individual Drug implicated.
- System Organ Effected.
- Frequency of ADRs in effected Organ.
- Characteristics of ADRs.
- Seriousness of the ADRs.
- Duration of the ADRs.
- Causality Assessment.
- Naranjo scale.
- WHO-UMC Scale.
- Hartwig severity scale.
- Outcomes of ADRs.
- Management of ADRs.

Demographic Characteristics of Patients:

Table 1: Details on Gender Distribution among the Patients with ADR in the study

S. No.	Description	Total	Percentage
1.	Male	14	51.86%
2.	Female	13	48.14%

During the study period, 27 patients were analysed, among them 14(51.86%) patients were male and 13 (48.14%) were female patients.

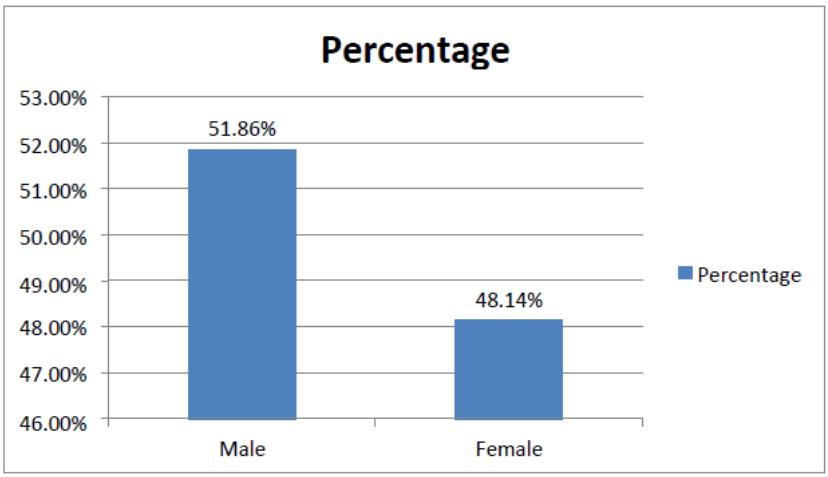

Figure 1: Details on Gender Distribution among the Patients with ADR in the study.

The Incidence of ADRs is higher in Males (50%) than in Females (50%).

Table 2: Details on age wise distribution among the patients with ADR in the study

Age	No. of ADRs	% ADRs
11 – 20	00	00%
21 – 30	08	29.62%
31 – 40	03	11.11%
41 – 50	08	29.62%
51 – 60	03	11.11%
61 – 70	03	11.11%
71 – 80	02	7.40%
Total	27	100%

In a total of 27 Patients, 00(00%) ADRs were found in the age group between 11-20 years followed by 08 (29.62%) ADRs were found in the age group between 21-30 years, 03 (11.11%) ADRs were found in the age group between 31-40years, 08(29.62%) ADRs were found in the age group between 41-50years, 03(11.11%) ADRs were found in the age group between 51-60 years, 03(11.11%) ADRs were found in the age

group between 61-70 years and 02(07.40%) ADRs were found in the age group of 71-80 Years.

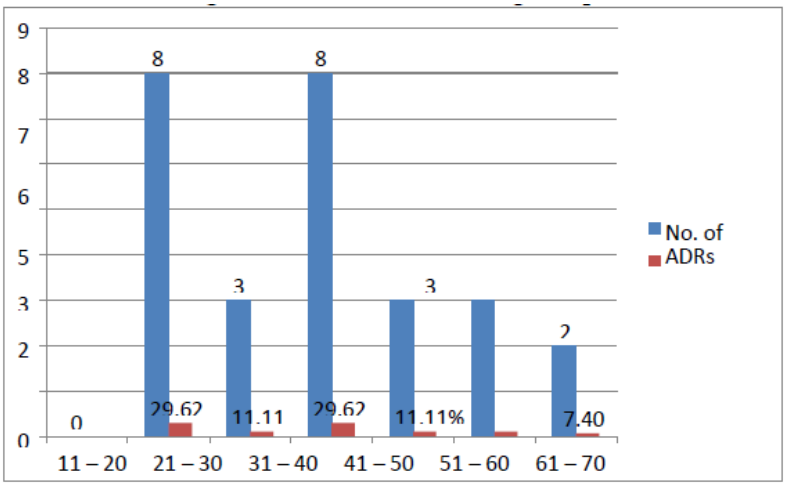

Figure 2: Details on age wise distribution among the patients with ADR in the study.

Table 3: Types of suspected ADR Reaction Mechanism

ADR Type	No. of ADR	Percentage
Type A	16	59.25%
Type B	08	29.62%
Type C	03	11.11%
Type D	00	0%
Type E	00	0%
Type F	00	0%
Type G	00	0%
Type H	00	0%
Type U	00	0%

Most (59.25%) of the reactions were Type A reactions followed by Type B (29.62%); Type C (11.11%). None of the reported ADR belonged to Type D, E, F, G, H, U.

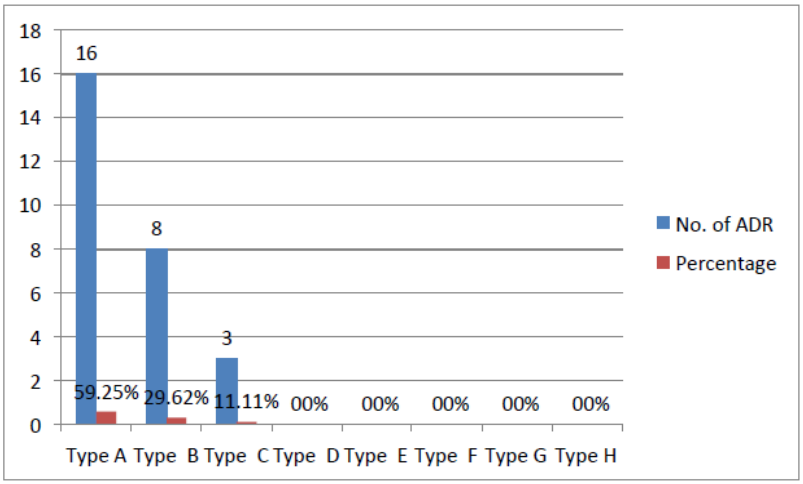

Figure 3: Types of suspected ADR Reaction Mechanism.

The Incidence of Type A ADR is higher than other types.

Table 4: Predisposing Factors.

Parameter	No. of ADRs	Percentage
Multi Drug Therapy	05	18.51%
Intercurrent Diseases	17	62.96%
Age (>60years)	05	18.51%

Most of the patients who developed ADRs were on multi drug therapy (Polypharmacy) and was the highest predisposing factors for most of the ADRs (05). Second predisposing factor of ADRs responsible was Age, 05 (18.51%) reactions were reported with age more than 60 years. Out of 27 ADRs 17(62.96%) reactions were due to intercurrent disease. The predisposing factors of the reported ADRs are

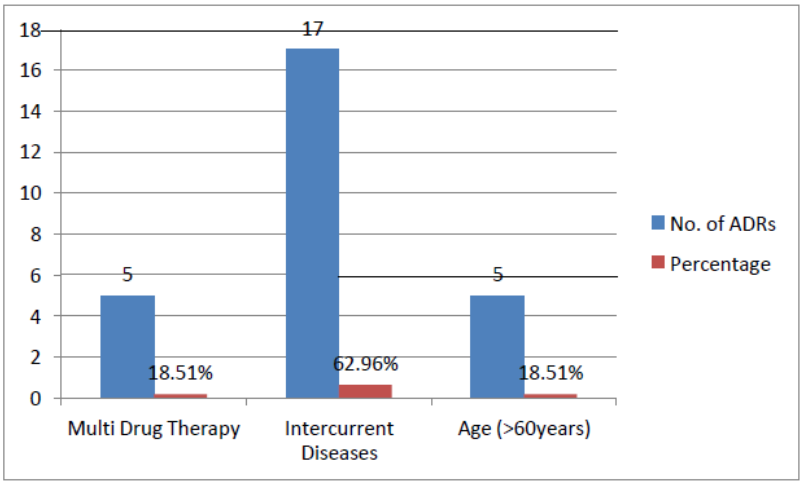

Figure 4: Predisposing Factors.

Table 5: Drug Class involved in ADRs

Drug Class	Number of ADRs	Percentage %
Anti-retroviral	01	3.7%
Antipyretic	01	3.7%
Antitubercular	03	11.11%
Diuretics	01	3.7%
Antineoplastic	06	22.22%
Antiepileptic	01	3.7%
NSAIDS	02	7.4%
Anti-biotics	06	22.22%
Anti-diabetics	02	7.4%
Anti enemia	01	3.7%
Anti-rheumatoid	01	3.7%
Anti-metabolite	01	3.7%
Anti-Coagulants	01	3.7%

The study shows the drug class most commonly implicated with ADRs was Antibiotics (16.66%) followed by NSAIDS (13.33%); Anti-Tubercular (10%); Antiretroviral, Anti-Convulsant, Anti-Coagulant and Anti-Psychotic are having equal Predominance (6.66%); The least implicated (3.33%) drug class are Anti-Pyretic, Diuretics, Anti-anginal, Multivitamins, Anti-Diabetics, Corticosteroids, Anti-Malarial, Anti-Parkinsonism, Analgesic and Iron supplements.

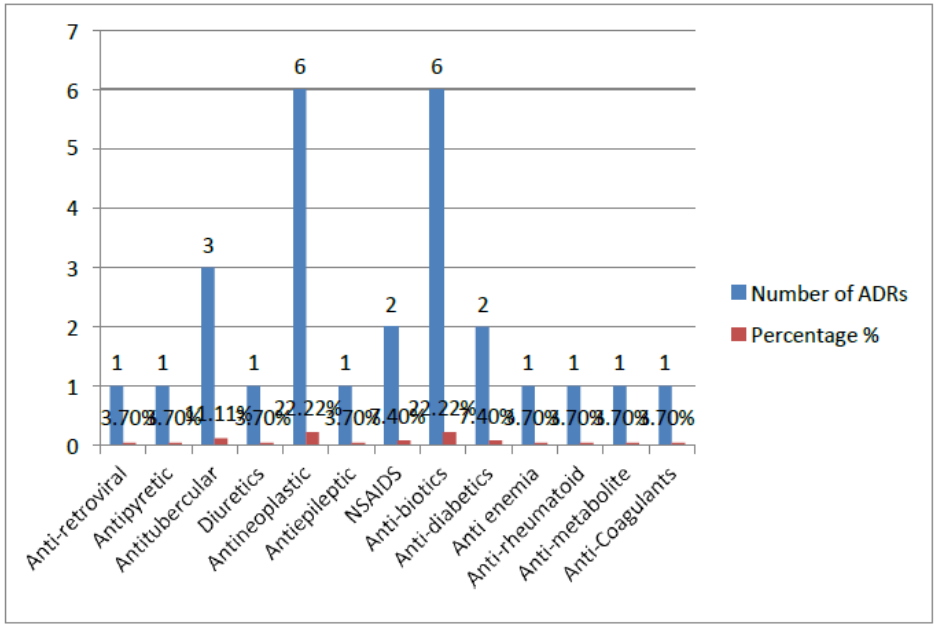

Figure 5: Drug Class Involved in ADRs.

The higher incidence of ADRs is associated with Antibiotics.

The least incidence of ADRs is associated with Anti-parkinsonism, Anti – Malarial and Anti-psychotics.

Table 6: Drugs Implicated in ADRs.

Individual Drug	Route	No. of ADRs	% of ADRs
Metformin 500mg	PO	01	3.7%
Methotrexate 2.5mg	PO	01	3.7%
Sodium valproate	PO	01	3.7%
Amikacin	PO	01	3.7%
Paracetamol 500mg	IV	01	3.7%
Cefotaxime 1mg	IV	01	3.7%
AkT4	PO	01	3.7%
Zidovudine	PO	01	3.7%
Carboplatin	PO	01	3.7%
Vincristine 2mg	PO	01	3.7%
Enoxaparin 100mg	PO	01	3.7%
AKT4+Forcox	PO	01	3.7%
Diclofenac 50mg+Paracetamol 325mg	PO	01	3.7%
Docetaxel 100mg	PO	01	3.7%
Gemcitabine 1.49mg	PO	01	3.7%
Rituximab	PO	01	3.7%
Docetaxel 60mg + leulovorin 300mg	IV	01	3.7%
Forcox	PO	01	3.7%
Lasix 20mg	PO	01	3.7%
Sulphamethoxazol	PO	01	3.7%
Paclitaxel	PO	01	3.7%
Mitomycin	IV	01	3.7%
Doxorubicin	IV	01	3.7%
Vintor 4000IV (Erythopectin)	IV	01	3.7%
OHA(Glemperide 2mg+Metformin500mg)	PO	01	3.7%
Ornindazole 200mg+Ofloxacin500mg	PO	01	3.7%
Etoricoxib 90mg	IV	01	3.7%

The drugs most commonly implicated in ADR were AKT4+ Forcox (11.11%), Metformin, Paracetamol, Diclofenac, Docetaxel, (7.4%), Methotrexate, sodium valproate, Amokacine, Cefotaxime, Zidovudine, Carboplatine, Vincristine, Enaxoprine, Gemicita bine, Rituximab, Lasix, Sulphamethaxazol, Paclitaxel, Mitomycine, Doxorubicin, Vintor, Ornindazole, Etoxicoxib (3.7).

Most commonly affected System Organ in the study was Blood (29.62%), followed by Other (22.22%) then Systems like renal (18.51%). Skin (11.11%). Hepatic and CNS (7.4%) Gastrointestinal (3.7%) were also found to be affected due to ADRs are least effected.

Table 7: System most commonly associated with ADRs

System Involved In ADR	No. of ADRs	Percentage%
Skin	03	11.11%
Renal	05	18.51%
Hepatic	02	7.40%
Gastrointestinal	01	3.7%
CNS	02	7.40%
Blood	08	29.62%
Others	06	22.22%

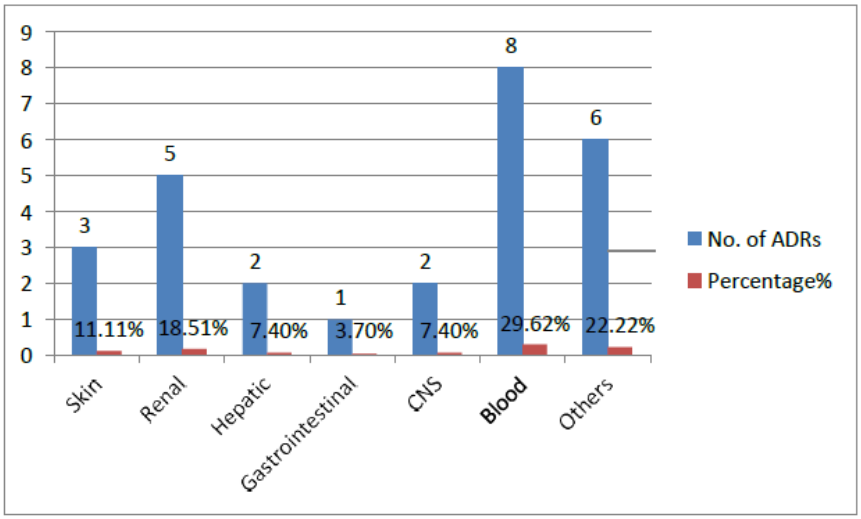

Figure 6: System most commonly associated with ADRs

The higher incidence of ADRs was seen in skin (20.78%), following by Blood and Renal system having equal Predominance (14.28%).

Table 8: Reported Reactions of System Organ Class.

Organ System	Symptoms/Complaint	Total Number
Skin	Steven Johnson Syndrome, Blister on hand	02(7.4%) 01(3.7%)
Gastrointestinal	Gastritis	01(3.7%)
Blood	Anemia, Leukopenia, Thrombocytopenia, Hemorrhage, Decreased platelet count, Thrombocytopenia Anemia Febrile neutropenia	01(3.7%) 01(3.7%) 02(7.4%) 01(3.7%) 01(3.7%) 02(7.4%)
Renal	Increase creatinine level Urinary tract infection, Nephropathy, Nephrotoxicity, Grade IV chronic kidney disease	01(3.7%) 01(3.7%) 01(3.7%) 01(3.7%) 01(3.7%)
Hepatic	Hepatitis	02(7.4%)
CNS	Neuropathy	02(7.4%)
Others	Infusion Reaction Hypokalemia Hypoglycemia, Hyponatremia Hypoglycemic attack	01(3.7%) 01(3.7%) 02(7.4%) 01(3.7%) 01(3.7%)

In the Current study, majority of the suspected reactions were Steven Johnson's syndrome, Febrile Neutropenia, Hemorrhage, Hepatitis, Neuropathy, Hypoglycemia (7.4%) which are fatal to the patients followed by Blister on hand, Grade IV chronic kidney disease, gastritis, Anemia, Leukopenia, Decreased platelets count, Thrombocytopenia Anemia, Increased creatinine level, UTI, Nephropathy, Nephrotoxicity, Infusion reaction, Hypokalemia, Hyponatremia, Hypoglycemic attack (3.7%).

Table 9: Seriousness of the Reaction.

Parameters	No. of ADRs	Percentage
Serious	04	7.40%
Life Threatening	04	7.40%
Death	00	00
Non-serious	23	42.59%
Required Intervention	20	37.03%
Hospitalization	03	5.55%

Among 30 ADRs, 13(43.33%) ADRs are found to be Non-serious and 07(23.33 %) ADRs are noticed as Serious. 07 serious reactions are found to be Life Threatening. None of the reported reactions led to death. Out of 13 non-serious reactions 1 is found to be hospitalized. Seriousness of the Reactions

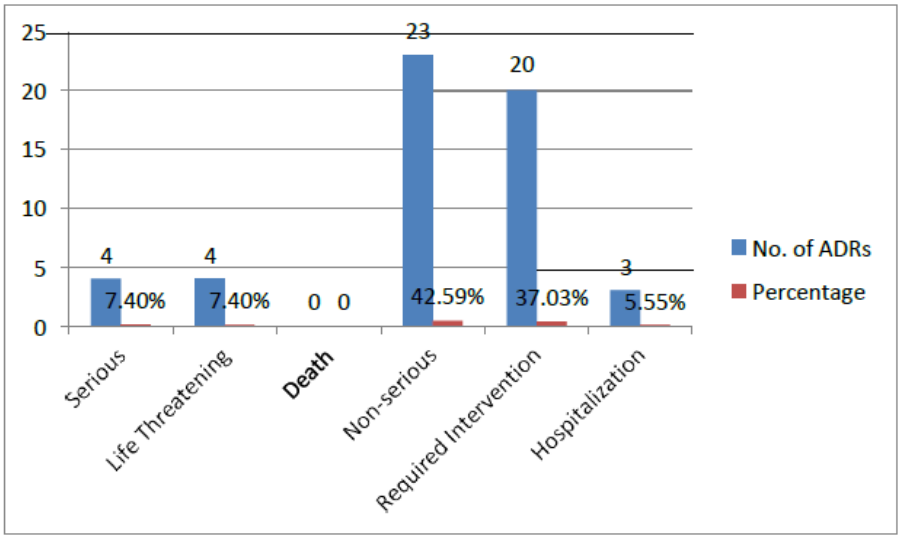

Figure 7: Seriousness of the Reaction.

Table 10: Duration of the Reaction.

Parameter	No. of ADRs	Percentage
<1day	03	11.11%
1 – 5 days	20	74.07%
>5days	04	14.81%

Majority of the ADRs (74.07%) are cured within 1-5 days, whereas 03(11.11%) ADRs took less than one day to cure and 04(14.81%) ADRs took more than 5 days to cure.

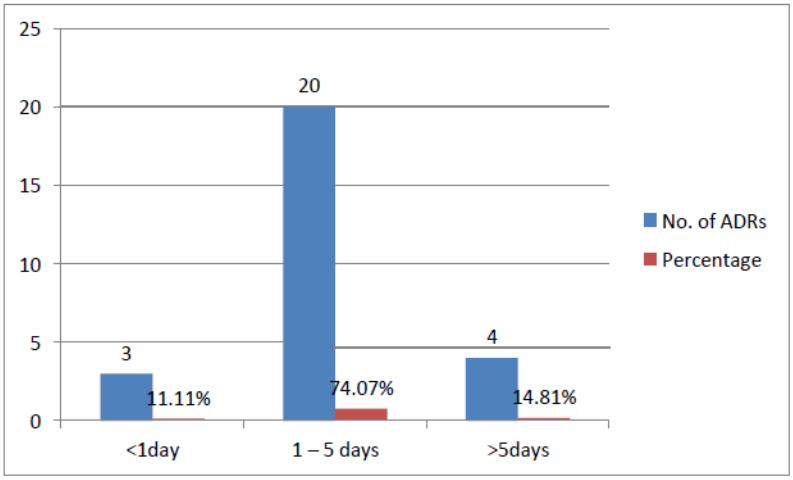

Figure 8: Duration of the Reaction.

Causality Assessment

Table 11: Naranjo Scale.

Parameter	No. of ADRs	Percentage
Certain/Definite	00	00
Probable	03	11.11%
Possible	24	88.88%
Unlikely	00	00

According to Naranjo Scale, 24(88.88%) reactions are found to be Possible and only 03(11.11%) are found to be Probable.

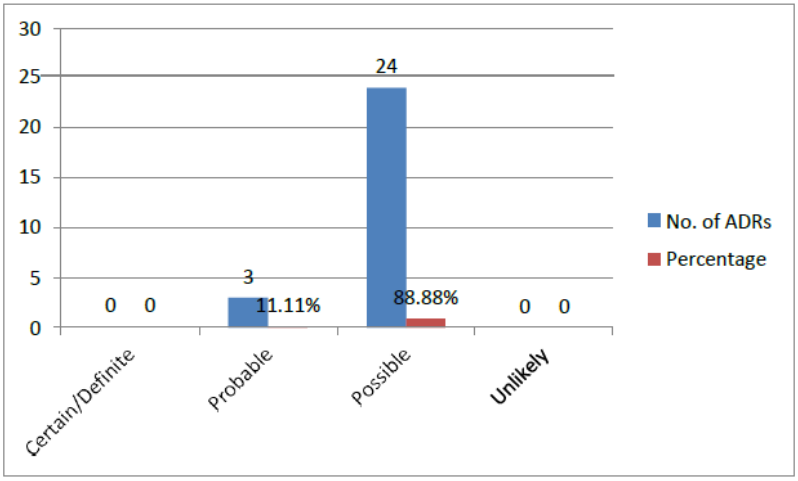

Figure 9: Naranjo Scale.

Table 12: WHO-UMC Scale.

Parameter	No. of ADRs	Percentage
Certain	00	0%
Probable/Likely	22	81.48%
Possible	05	18.51%

According to WHO scale, 22(81.48%) reactions are Probable/Likely and remaining 05(18.51%) reactions are possible.

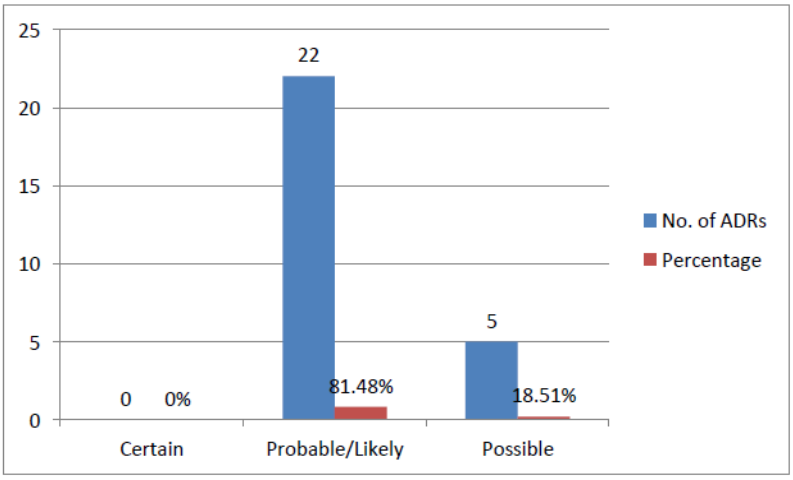

Figure 10: WHO-UMC Scale.

Table 13: Hartwig Severity Scale.

Parameter	No. of ADRs	Percentage
Mild	07	25.92%
Moderate	17	62.96%
Severe	03	11.11%

According to Hartwig Severity Scale, 17(62.96%) ADRs are moderate, 07(25.95%) ADRs are mild, 03(11.11%) ADRs are Severe.

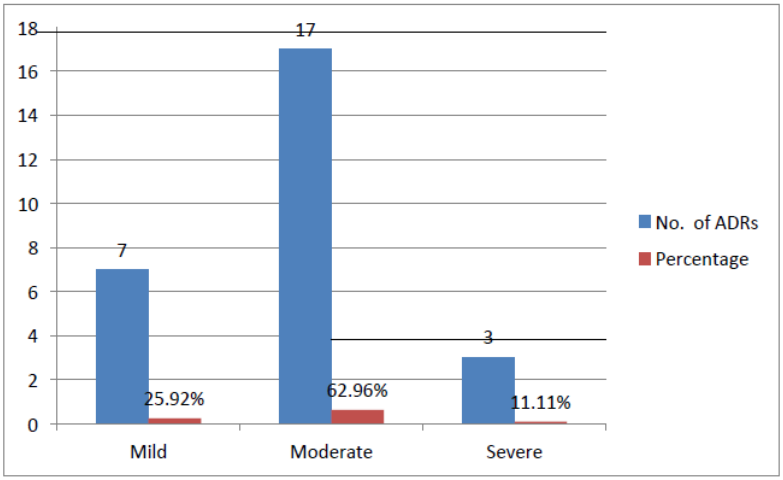

Figure 11: Hartwig Severity Scale.

Table 14: Outcomes of ADRs.

Parameter	No. of ADRs	Percentage
Unknown	01	3.7%
No recovery	02	7.4%
Recurrent of symptoms	04	14.81%
Recovered	17	62.96%
Continuing	02	7.4%
Fatal	01	3.7%

Among 27 ADRs, 17(62.96%) ADRs are recovered, 02 (7.4%) ADRs are Unrecovered, 02(7.4%) are remained as Continuing,01(3.7%) are unknown,01(3.7%) are fatal,04(14.81%).

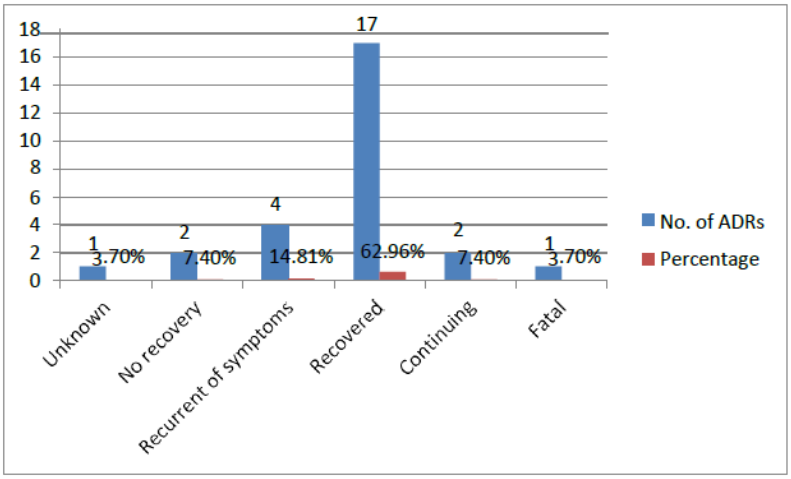

Figure 12: Outcomes of ADRs.

Table 15: Management of ADRs

Parameter	No. of ADRs	Percentage
Added Another Drug	00	0%
Stopped the Medication	19	70.37%
Substituted another Drug	05	18.51%
No Change	00	0%
Reduced Dose	03	11.11%
Reintroduction	00	0%
No Information	00	0%

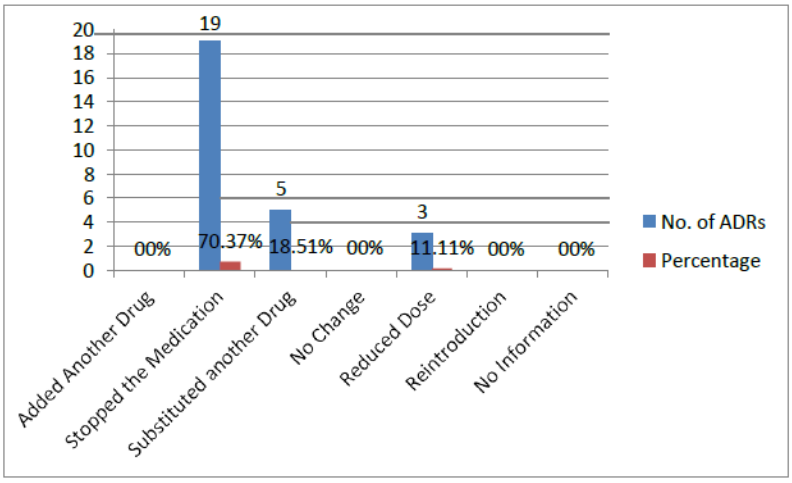

Figure 13: Management of ADRs.

DISCUSSION

In the pharmacotherapy of various diseases, most of the drugs are likely to have a dual effect- beneficial as well as adverse effect. So, the best way to control these adverse effects is to have a triple pronged approach of prevention, treatment and rehabilitation. Globally the incidences of adverse events were around 43 million each year and caused disability among 23 million. Among this two third occur in low income and middle-income countries. Adverse Drug Reactions were intensively monitored, documented and analyzed by Causality Assessment Scale. ADRs were evaluated by considering the Clinical investigations, Drug Dosing and Frequency. It was observed that average length of the hospital stay for patients who developed ADRs was higher than patients without ADR. Gender distribution of the patients showed that there were 14(51.86%) male and 13(48.14%) female Patients indicating male Preponderance. Age Distribution of the Patients showed that majority (29.62.%) of ADRs was seen in the Age group 21- 30 & 41-50years. Adult predominance (51.87%) is more than the pediatric (0%)

and geriatric (18.51%) patients. In the present study, the most common type of ADR is Type A with an incidence of 59.25%. As Type a Reactions are dose related in the development of ADR and can be almost preventable. Incidence of Type B is 29.62%; Type C is 11.11%. None of the reported reactions included in Type D, E, F, G, H and U. In our study, most of the patients who developed ADRs were on Intercurrent Disease 17(62.96%) and was the highest predisposing factors for most of the ADRs. Second predisposing factor of ADRs responsible was Age, 05 (18.51%) reactions were reported with age more than 60 years. Out of 27 ADRs only 5 (18.51%) reactions were due to Multi Drug Therapy. The study shows the drug class most commonly implicated with ADRs was Antibiotics & Antineoplastic (22.22%) followed by Antitubercular (11.11%); NSAIDS & Antidiabetic (7.4%); Antiretroviral, Anti-Coagulant, Anti pyretic, Diuretics, Anti-Epileptic, Anti-Anemia, Anti Rheumatoid, Anti Metabolite (3.7%). The drugs most commonly implicated in ADR were Amlodipine (6.45%), Diclofenac (5.17%), Combination Antitubercular drugs (5.47%), and Combination Anti-diabetic drugs (3.87%). Other Drugs like Carbamazepine (3.87%), Orofer, Phenytoin, has equal predominance (2.57%), Sodium Valproate, Cefuroxime, Cefotaxime, Ceftriaxone, Mitomycin, Omnocortisol and Fentanyl have an equal Predominance (1.27%). Most commonly affected System Organ in the study was blood (29.62%), followed by others (22.22%) then Systems like Renal (18.51%). Skin (11.11%). Hepatic and CNS (7.4%). and Gastrointestinal (3.7) were also found to be affected due to ADRs are least effected. In the Current study, majority of the suspected reactions were Anemia (11.11%) which are fatal to the patients followed by Steven Johnson Syndrome, Hepatitis, Neuropathy, Hemorrhage, Hypoglycemia, Febrile Neutropenia (7.4%) Blister on hand, Gastritis, Decreased platelet count, Increased creatinine level, Urinary tract infection, Nephropathy, Nephrotoxicity, Grad IV, chronic Kidney disease, Infusion reaction, Hypokalemia, Hyponatremia, Hypoglycemic attack (3.7%).

The Present study notify that Among 27 ADRs, 23(85.18%) ADRs are found to be Non-serious and 04(14.81%) ADRs are noticed as Serious, 04serious reactions are found to be Life Threatening, None of the reported reactions led to death, Out of 23 non-serious reactions 3 is found to be hospitalized. In this study, Majority of the ADRs20 (74.07%) were cured within 1-5 days, whereas 3(11.11%) ADRs took less than one day to cure and 4(14.81%) ADRs took more than 5 days to cure. Various Causality Assessment Scales revealed the following data:

According to Naranjo Causality Assessment Scale, 24(88.88%) reactions are found to be Possible and only 3(11.11%) reactions are found to be probable. According to WHO-UMC Causality Assessment scale, 22(81.48%) reactions are Probable/Likely and remaining 05(18.51%) reactions are possible. According to Hartwig Severity Assessment Scale, 07(25.92%) ADRs are found to be mild, 17(62.96%) ADRs are found to be moderate, 3(11.11%) ADRs are found to be Severe.

This study shows that 17(62.96%) ADRs are recovered, 02(7.4%) ADRs are Unrecovered, 02(7.4%) are remained as Continuing, 04(14.81%) are Recurrent of symptoms,01(3.7%) are fatal,01(3.7%) are Unknown.

In this study, 19(70.37%) ADRs were either managed by with drawl of the suspected Drug, 05(18.51%) ADRs by Substituted another Drug,03(11.11%) ADRs were reduced Dose. The duration of study was of short period and patients were randomly involved into the study. Hence the sample size was less, which is a major limitation of our study.

CONCLUSION

Pharmacovigilance is concerned with Identifying and Reporting of Adverse Drug Reaction associated with Medication

with Minimizing Hazardous Which Harms the Patient. At the study site there is an under reporting of Adverse Drug Reaction. Clinical Pharmacist in a Health Care Team Plays a vital role in usage of Medications appropriately and safely which in turn reduces Drug related problems. Systematic Approach toward Adverse Drug Reaction Identifying and Reporting will Help health care professionals in reducing Adverse Drug Reaction.

Acknowledgement: None

Conflict of Interest: None

Source of Funding: None

Ethical Approval: Approved

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How to cite this article: Mohsina F.P, Faheem I.P, Aquil-ur-Rahim Siddiuque et.al. A study on pharmacist mediated intervention in identifying and reporting of adverse drug reactions at a tertiary care hospital. *Gal Int J Health Sci Res.* 2021; 6(4): 26-41. *DOI: https://doi.org/10.52403/gijhsr.20211006*

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