International Journal of Pharmaceutical Science Invention
ISSN (Online): 2319 – 6718, ISSN (Print): 2319 – 670X
www.ijpsi.org Volume 8 Issue II ǁ Feb 2019 ǁ PP.18-39

Survey on Role of Healthcare Professionals in Reporting Adverse Drug Reactions & Monitoring and Documentation of Suspected Adverse Drug Reactions

*Sriram S[1], Dinu C[2], Jambulingam P[3]
[1]*Professor and HOD, Department of Pharmacy Practice, College of Pharmacy- Sri Ramakrishna Institute of Paramedical Sciences;Coimbatore.*
[2]*M..Pharm student, Department of Pharmacy Practice, College of Pharmacy- Sri Ramakrishna Institute of Paramedical Sciences;Coimbatore.*
[3]*Consultant Physician,Sri Ramakrishna Hospital,Coimbatore*
**Corresponding author: Sriram S*

ABSTRACT: *Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality worldwide.The objective of the study is to implement the culture of reporting ADR in the study hospital and also to detect, document, assess and report the suspected ADRs. A prospective-observational study was conducted. A self-administered Questionnaire Survey was conducted to know the attitude, knowledge and practice oriented issues prevailing among the study site and among the healthcare professionals. A total of 86 ADRs were included in the study. Severity of the suspected ADRs assessed using Modified Hartwig and Siegel Scale, revealed that 7(8%) suspected ADRs were severe, 46(53%) moderate and 33(39%) severity. The assessment by Naranjo scale showed that 26(30.2%) ADRs were possibly and 59(68.6%) probably drug-related. The assessment done by using WHO scale reveals that 36(42%) ADRs were possibly, 27(31%) probably and 19(22%) certain. 3 patients (3.5%) were admitted due to an ADR compared to 83(96.5%) who were affected by ADR after hospital admission.45% of patients who suffered from ADRs were above 60 years. System most commonly affected were Dermatological in 20(23%) patients. The drug class mostly associated with ADR was Antibiotics in 36(42%) cases. Adverse reactions encountered were treated and the final outcome was measured. About 81(94%) patients recovered, while in 5(6%) cases the ADRs decreased. Preventability of suspected ADRs were assessed by Modified Schumock and Thornton scale revealed that 67(78%) ADRs were definitely preventable and 9(10%) probably preventable. Our study documented an increased risk of suspected ADRs in elderly patients, and 88% of reactions were preventable.*

Date of Submission: 02-09-2019 Date of acceptance: 19-09-2019

I. INTRODUCTION

Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality worldwide. During last few years, pharmacovigilance science has evolved to recognize the importance for monitoring and improving the safe use of medicines. According to WHO, Pharmacovigilance is "The science and activities which are related to the detection, assessment, understanding and the prevention of adverse effects or any other drug related problems" .[1]

Inadequate awareness about the pharmacovigilance system among the health care professionals is the leading cause of under reporting of ADRs. There is a lack of studies that address the awareness of healthcare professionals toward the pharmacovigilance system and ADRs reporting. Till now only few studies had been carried out in different countries to assess the knowledge of pharmacovigilance among the healthcare professionals.[2]

The scope of PV to improve patients' safety includes detection and reporting ofADR events, medication errors, counterfeit and substandard medicines, lack of efficacy of medicines, misuse and/or abuse of medicines, and drug–drug interactions. However, ADRs remain the prime focus of PV activities.[3]

ADR monitoring is important so that medicines can be used rationally. All healthcare professionals can better use their experiences (both positive and negative) with their patients so as to better understand disease pattern and medical treatment. Most likely health professionals report ADR and therapeutic dilemmas to familiar academic unit. The Central Drugs Standard Control Organisation (CDSCO), New Delhi, under the aegis of Ministry of Health & Family Welfare, Government of India has initiated a nation-wide pharmacovigilance programme in July, 2010 [4].

Not all ADRs can be identified in clinical trials, and so post-marketing surveillance is imperative in identifying and evaluating those risks associated with medication use [5].

Spontaneous ADR reporting is a widespread method for post-marketing surveillance and is the best recognised method for rapidly detecting serious and unexpected ADRs. However, under-reporting is the major limitation of spontaneous ADR reporting [7].The potential value of patients as potential reporters into pharmacovigilance systems is increasingly acknowledged worldwide. Direct patient reporting to regulatory authorities is viewed as important and a large numbers of countries now permit and encourage patients to report ADRs. Patient reporting may enable earlier detection of unexpected ADRs and increase the overall rate of spontaneous reporting [6].

ADR reporting is the cornerstone of drug safety after the release of a drug into the market. It has been shown over the years that ADR reporting has provided early warning in drug safety. It is a formal or informal process whereby verbal or written accounts of health care related adverse events are shared with others either internally within an organization or externally with other interested parties. The purpose of a reporting system is often to provide a medium for sharing lessons learned and opportunities for improvement, and to prevent recurrence of similar incidents in future. It is a reporting system whereby accounts of health care related adverse events are compelled by law, policy, or by any other formal means. A reporting system whereby verbal or written accounts of health care related adverse events are shared without the inclusion of any identifiable details of the patient or care providers involved. The information contained in anonymous reporting systems is often less complete than information contained in confidential reporting system.[7]

India, with 1.3 billion population - 2nd largest in the world, developing rapidly and holds third in terms of production of pharmaceuticals in the world with more than one lakh branded formulations and over 6,000 licensed drugs. She also forms a major consumer of drugs too. A country being the clinical trial hub of the world where larger population is being exposed to newer drug treatments definitely needs to identify ADRs as early as possible in order to ensure the safety of the patient by preventing it at a reasonable cost.[8]

Currently, lot of attention is being received by the field of drug safety. Every week, articles regarding unexpected adverse drug reactions due to certain drugs are getting published in various tabloids as well as scientific journals. Unfortunately these articles are evoking apprehensions in drug users as well as health professionals regarding its use, leading to even more serious consequences- nonadherence among patients. This crisis can be solved only by Pharmacovigilance. As per the definition of WHO, pharmacovigilance is 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. It provides enough information to both doctors as well as patients and thereby help them to make an educated decision while using a drug, thus ensures the safety

Being the most common iatrogenic illness worldwide, morbidity and mortality due to ADRs are mainly caused because of immune and non-immune mechanisms. It complicates 5 to15 percentages of therapeutic drug courses leading to more than 100,000 deaths annually in United States. Adverse drug reaction is responsible for 3-6% of hospital admissions. The risk for hypersensitivity drug reactions increases with conditions like Asthma, Systemic lupus erythematous and use of beta blockers. Adverse drug reactions can results in hospitalization, permanent or persistent and significant disabilities, congenital anomalies, adversely affecting the quality of life, and can result even in death. Added to this it results in higher health care costs. "ADR" differs from "side effect", as later may also result to be a beneficial effect and former happens only at normal doses.[9]

Adverse drug reactions can also make patients to lose their confidence in Health Care Professionals. So, it is the responsibility of the HCP to identify, resolve and to prevent potential drug‐related problems. HCPs need to take initiative in developing Adverse Drug Reaction Monitoring and Reporting Programs which can enhance the awareness of ADRs thereby reducing its underreporting. Frequent illnesses, multiple diseases and exposure to numerous medications not only puts a patient at higher risk for ADR but also makes it difficult to detect an ADR. A method which is efficient, practical, feasible and less expensive to identify and predict those patients who are at higher risk for an ADR must be developed. Adverse drug reaction, being a curse of modern medicine is the price a patient have to pay despite its greater benefits and is anticipated to occur in the future with much higher frequency. Thus regulatory agencies of many countries have made it mandatory to track adverse drug reactions. In short, pharmacovigilance is concerned with the study of ADRs.[10]

Voluntary adverse drug reaction (ADR) reporting was on operation since the early sixties in many Western countries. It enables the health care professionals to report suspected ADRs and there by helps to identify new ADRs and risk factors responsible for recognized ADRs. Still, only a small proportion of ADRS is reported to the concerned National monitoring centres. On a survey conducted in The Netherlands showed that the lack of time and poor access to reporting forms were major reasons for underreporting whereas a survey done among general practitioners (GPs) reported that lack of knowledge with the Dutch national reporting centre was the prominent reason for poor reporting of an ADR.[11]

One year study conducted in UK, reports that despite the 6.5% hospital admission due to ADR and 15% experiencing ADR during hospital stay, one fifth patients getting re-admitted to hospital within 1 year of discharge are exclusively due to a suspected ADR in which half of those are definitely or possibly preventable.

The study says out of 40% of patients getting re-admitted to the study hospital within one year, 18% were due to ADRs.[12]

Present Methods of Practice :

The reporting of suspected adverse events determines the success or failure of any pharmacovigilance programme.

- Spontaneous reporting
- Other methods of collecting safety data
- National Pharmacovigilance centres
- WHO programme for International Drug Monitoring

Spontaneous Reporting

Spontaneous reporting is defined as,"a system whereby case reports of adverse drug events are voluntarily submitted by health professionals and pharmaceutical companies to the National Pharmacovigilance centre". The reporting of suspected adverse drug reactions determines the success or failure of any Pharmacovigilance programme. Spontaneous reporting by health professionals is the pulse of pharmacovigilance programme. All sectors of health care professionals must be involved to detect the entire complications of a therapeutic treatment. This includes both private and public hospitals as well as nursing homes, clinics, pharmacies, retail dispensaries and providers of traditional medicines. In all conditions which demand the use of medicine, a keen observation and reporting of unintended and unwanted medical events must be followed. A health care professional can report based on direct observation of a medicine or by interpreting the information provided directly by a patient who was actually subjected to harmful experience of medicine or medicinal products. Patients must be encouraged to report any adverse effects which would enable a health care professional to report it to the respective pharmacovigilance centre. Only a few countries provide with the opportunity to patients for direct reporting of adverse drug effects.

Other methods of collecting data:

Safety information can also be collected using various other pharmacoepidemiological methods. The limitations of spontaneous reporting must be taken in to account to establish a more systematic and robust method of collecting safety data. This has to be incorporated into the post marketing surveillance programmes. Some countries are using other methods to complement drawbacks of spontaneous reporting system. They are:-

- Record linkage
- Case control studies
- Prescription event monitoring (UK and New Zealand)

Functions of National Pharmacovigilance Centres are:-

- Promotion of adverse drug reaction reporting
- Collection of individual case safety reports
- Evaluation of reported cases
- Collating, analysing and evaluating patterns of adverse reactions.
- Identifying signals of adverse reactions
- Performing regulatory actions based on generated signals.
- Alerting the HCPs, manufactures and public about newer identified risks.
- Sending reports to WHO programme for International Drug Monitoring.

International Drug Monitoring Programme by WHO

WHO programme for International Drug Monitoring Programme coordinates the international network of National Pharmacovigilance Centres. The same programme has helped immensely to improve activities and functioning of member National Pharmacovigilance Centres[18]. The WH0-UMC, Sweden manages the international database of adverse reaction reports send by the national centres. An internet based information exchange system called VIGIMED is used to exchange the information's between national centres, UMC and WHO. It supplies the tools for the management of clinical information which includes the individual case safety reports. The major products are the WHO Adverse Reaction Terminology and WHO Drug Dictionary. The programme conducts methodological research for developing pharmacovigilance as a science[19].

II. METHODOLOGY

The study was conducted at a Private corporate Hospital in Coimbatore. It is a 750 bedded multi-specialty medical institution and one of the largest hospitals in Coimbatore. The hospital is unique and well known for its service to the people who come from various parts of the country.

Study design

The present study involves a multidisciplinary spontaneous (voluntary) reporting program that relies on both the prospective and concurrent detection of suspected adverse drug reactions and drug interactions. The voluntary component of the ADR reporting and monitoring system involved reporting by physicians, nurses, pharmacists and postgraduate students of pharmacy. Reports of suspected adverse drug reactions were accepted from different type of services and specialties.

Study Setting

The hospital identified for the purpose of this study is Sri Ramakrishna Hospital, which is a 750 bedded hospital situated in Coimbatore. This hospital provide both inpatient and outpatient health care services to people in and around Coimbatore district in all fields of medical sciences such as Medicine, Surgery, Obstetrics and Gynecology, Pediatrics, Neurology, Nephrology, Orthopedics, oncology etc.

Consent From Hospital Authorities:

Every project work carried out in the hospital by the Pharmacy Practice department students has to be approved by the Ethics committee of the hospital and should be informed to all the physicians and other healthcare professionals of the hospital. A protocol of the study which includes the objectives, methodology etc was presented to the Ethics committee of the hospital. The authorization from the Ethics committee was procured .The study was conducted with the expert guidance of junior and senior physicians of the study departments. The authority was permitted to utilize the hospital facilities to make a follow up of the cases, in the selected departments. All the health care professionals were well informed through Dean's official circular.

Source of Data

Whenever an adverse drug event was identified, it was assessed as to whether it could be drug-related. All the relevant and necessary data were collected from medical records of patients including case notes, treatment charts, ADR notification form and laboratory reports, and also where appropriate by interviewing patients and healthcare professionals. All the relevant and necessary details of any likely ADRs were recorded and documented.

Inclusion and Exclusion Criteria

i) Inclusion Criteria

Patients of either sex of any age who developed an ADR.

ii) Exclusion Criteria

- Patients who developed an ADR due to intentional or accidental poisoning
- ADR to fresh blood/blood products
- ADR due to overdose
- Patients with drug abuse and intoxication

Method

A self-administered Questionnaire Survey was conducted to know the attitude, knowledge and practice oriented issues prevailing among the study site and among the healthcare professionals. After ascertaining the need of the study through questionnaire survey, the CDSCO's Adverse Drug Reaction reporting forms were made available with various departments of the hospital. Adverse drug reaction reports were accepted from all the healthcare professionals of different specialties irrespective of their status and types of services offered. The reporter was not required to prove cause and effect prior to the reporting of 'suspected' adverse drug reaction. However, healthcare professionals were requested to report a 'suspected' ADR by using any of the modes of reporting. We adopted various modes of reporting system including use of ADR notification form, telephone reporting, direct access, referral of patients and personal meeting so as to ease the reporting of 'suspected' adverse drug reactions.

When an ADR was suspected, the involved healthcare professional first reported the suspected adverse drug reaction to department of pharmacy practice. Once the suspected ADR was reported, we reviewed patients' medical records and also interviewed patients and or healthcare professionals as appropriate to collect all the necessary and relevant data pertaining to the 'suspected' adverse drug reaction.

The details of data collected pertaining to the reported ADR include: description of event, suspected medication, other medications including over the counter medicines and medication on admissions, presenting complaints, past medical history, allergic status, possible involvement of risk factors of an ADR and previous exposure . Later all the collected data were further reviewed and documented in a suitably designed ADR documentation form. Then the reported event was subjected to evaluation, and analyzed to indicate how likely it was that the implicated drug caused the 'suspected' adverse reaction.

Collection of Reports

All those reported ADRs detected from the patients treated in any of the study site and met the study criteria were received either through ADR notification form, direct contact, telephonically or as a referred case. Each reported adverse drug reaction was scrutinized based on the 'criteria for reportable ADR', to identify whether the suspected ADR was a reportable ADR.

Criteria for Reportable ADR

In our study, we have adopted the World Health Organization (WHO) definition of an ADR as a criterion for reporting any suspected reaction. The WHO defines an adverse drug reaction as "one which is noxious and unintended, and which occurs at doses used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function".

Collection of Data

Where an event was identified and reported all the relevant and necessary data pertaining to event such as nature of event, onset of reaction, its severity; medications used including suspected drug and other drugs used prior to an event such as dose, route, frequency, method of administration, duration; patient history such as presenting complaints, past medical history, co-morbidities, allergic status, previous exposure, risk factors; laboratory findings as appropriate for the suspected reaction were collected from the patient case notes and other relevant data sources as mentioned previously. Also, where appropriate or necessary, further information pertaining to reported ADR was sought by interviewing the patient who experienced an ADR and or healthcare professional who reported an ADR.

Assessment of ADR Reports

All the reported events were evaluated, after collecting adequate data from appropriate sources, as to explore the likely involvement of suspected drug in causing the reported event. In assessing the causality, concerned clinician and or unit chief opinion was obtained. After having assessed the causal relationship between the suspected drug and the adverse reaction, irrespective of their causality category, the reports were subjected to further analysis including their severity, predictability and preventability of reported reactions.

Causality Assessment

The causality relationship between suspected drug and reaction was established by using WHO and Naranjo's causality assessment scales. The causality of reported reactions was categorized to any one of the following categories based on the scale used.

WHO assessment scale:

- Certain, Probable, Possible, Unassessable / Unclassifiable,
- Unlikely, Conditional /Unclassified

Naranjo's scale:

- Definite, Probable, Possible and Unlikely

Severity

The severity of reported reactions was assessed by using Hartwig scale and was categorized to any one of the following categories:

- Mild, Moderate and Severe.

Predictability

The predictability of the reported ADRs was assessed by using developed criterion for determining predictability of an ADR and was categorised to any one of the following based on the incidence rate of reported adverse drug reaction.

- Predictable
- Not predictable

Preventability

The preventability of reported ADRs was assessed by using Modified Schumock and Thornton scale and was categorised into any one of the following:

- Definitely preventable
- Probably preventable
- Not preventable

When an event was reported, all patients who experienced an ADR were followed from the day of reporting of an ADR until the discharge of patients to gather updated information regarding the changes and the progress in the patients' condition and management.

III. RESULTS AND DISCUSSION

A prospective-observational study was conducted on**"Survey on role of Healthcare professionals in reporting Adverse Drug Reactions & Monitoring and documentation of Suspected Adverse Drug Reactions"**at a 750 bedded multi-specialty hospital in the Department of General Medicine over a period of 10 months &cases were assessed for ADRs through a daily ward visit by the pharmacist. Suspected ADRs were analyzed for causality, severity and preventability using appropriate validated scales. ADR alert card was prepared and given to patients

A questionnaire survey was conducted among health care professionals of Sri Ramakrishna hospital to understand the role of Health Care Professionals (HCPs) in reporting ADRs and to check the feasibility of implementing an ADR monitoring centre in the hospital.

A questionnaire containing 20 questions were circulated to doctors, nurses and pharmacists personally explaining the purpose of the study. One week time was given to return back the filled questionnaire. Out of 572 questionnaires issued to health care professionals, 34 doctors, 460 nurses and 31 pharmacists responded generating a total of 91.78% response.

77% of HCPs were aware that all ADRs can't be fund out during the first three phases of clinical trials. Even though 53% have come across an ADR in their professional life only 48% have ever reported it.

The major factors that discourages one from reporting are,difficult to decide whether an ADR has occurred or not (46%), lack of time (21%), not being aware of how and where to report (18%), and false perception that a single unreported case may not affect ADR database (15%) respectively.

70% of HCPs responded that they have enough time to fill ADR monitoring form and 82 % demands the assistance of pharmacy PGs/interns to retrieve the fullest possible data to ensure effective Pharmacovigilance program.

Majority of health care professionals (98%) think that ADR reporting is necessary and that it can ensure patient safety and improve rational drug use. The need for education and training on ADR reporting is felt by 98% of health professionals and 94% agreed to have a Pharmacovigilance center at their hospital.

99% of HCPs felt that it is important to foster a culture of reporting ADRs in hospital and 95% reported that they are aware of the term Pharmacovigilance .

97% of HCPs felt that an ADR database is required and 90% demands the easy access of CDSCO form. Only 47% knows that IPC Ghaziabad as National Coordinating Centre (NCC) for ADR monitoring in India which clearly indicates the need of awareness of National Pharmacovigilance Programme among HCPs.

64% of HCPs are aware that all health care professionals can report an ADR. Eventhough 99% of the HCPs felt that it is important to foster a culture of reporting ADRs, 39% releaved that ADR reporting will create a negative impact on the quality of treatment.

Regarding CME of ADR, 98% of HCPs documented that, discussion of ADR cases on clinical meeting will help to improve quality of patient care and 77% of HCPs felt that circulation of identified ADR through newsletters, is essential.

A total of 86 suspected ADRs were identified in 4097 general medicine department admissions during the study period. The incidence of suspected ADRs was found to be 2.09 % and is comparable with the study done by Padma GM Rao

(2006)[20]**,** which evaluated the reports of ADRs in the inpatients at a south Indian hospital for their incidence and pattern and found that the incidence of ADRs was 2.8% in hospitalized patients. Another study conducted by Munir Pirmohamed et al (2004)[21] concluded from a prospective analysis of about 18,820 patients in UK in which about 1225 admissions were related to adverse drug reactions giving a prevalence of 6.5%.

The results of the age categorization revealed that the patients of 60 years and above age group experienced maximum Adverse Drug Reaction i.e.,45%, followed by 37% in age group between 30-59 years old and 18% in 18-29 years age group. A study done by Munir Pirmohamed et al (2004) have shown a greater percentage of geriatric population suffering from adverse reactions as compared to the patients with the age group 60 years and above in our study.

Of the patients who experienced ADR during the study period 45(52%) were male and 41(48%) were female. Male population was more compared to female which was something different from the studies done by Joene Hendry (2004).[22]

Severity of the suspected ADRs assessed using Modified Hartwig and Siegel Scale, revealed that 7(8%) suspected ADRs were severe, 46 (53%) ADRs were moderate and 33 (39%) ADRs were mild in severity. This comparable with the review conducted by Sivanandy Palanisamy (2013)[23] in reporting of ADR from an 800 bedded private corporate multi-specialty tertiary care hospital, during the month of July 2011and June 2012 reported 583 distinct admissions due to ADRs, with 5.79% of the cases categorized as severe, and 61.3% of the events were regarded as moderate.

Causality assessment was done by using WHO and Naranjo scale. The assessment by Naranjo scale showed that 26 (30.2%) ADRs were possibly drug-related, whereas 59 (68.6%) were classified as probable and 1 (1.2%) definitely related to the drug while the assessment done by using WHO scale revealed that

36(42%) ADRs were possibly drug-related, 27(31%) ADRs were probably drug-related, whereas 19(22%) were classified as certainly related to drug and this is comparable with a study by Davies EC et al., (2006)[24] which assessed the feasibility, and established the methodology for conducting a large prospective study to fully assess the impact of ADRs on inpatients. In their study, Patients admitted to five wards of university teaching hospital over a 2 week period were assessed for ADRs through daily ward visit by pharmacist. Suspected ADRs were analyzed for causality, severity and avoidability using Naranjo algorithm, Hartwig scale and the criteria outlined by Halla set al.(2006)**[25]** , respectively. Causality assessment showed that 29(56.8%) ADR were possibly drug- related whereas 17(33.33%) were classified as probably or definitely related to the drug and almost two- third of reaction were potentially avoidable.

3 patients (3.5%) were admitted due to an Adverse Drug Reaction compared to 83 (96.5%) who were affected by ADR after hospital admission.

The majority (45%) of patients who suffered from ADRs were above 60 years. System most commonly affected were Dermatological in 20(23%) patients, Gastrointestinal in 17 (19%) patients, CNS in 6(7%) patients, followed by Cardiovascular in 4 (5%) patients and the results are comparable matches with an international study conducted by Suh et al 2000,[26] which revealed that the system most badly affected was the dermatological and gastrointestinal system.

The drug class mostly associated with ADR was Antibiotics in 36(42%) cases, followed by anticonvulsants in 5(6%).Barbara M et al(1993)**[27]** developed and implemented an ADR reporting program in Loyola University Medical Center, a 563-bed tertiary care teaching hospital located in the western suburbs of Chicago. This study revealed that the most common adverse reactions were rash; and antibiotics were the most commonly implicated drug class.

This is comparable with other studies like those done by Classen DC et al and Cooper JW et al (1991)[28]which indicated that NSAIDs have caused extensive damage to human health.

In 83 (97%) cases the drug was withdrawn, dose altered in 3(3%) patients.Adverse reactions encountered were treated and the final outcome was measured. About 81(94%) patients recovered, while in 5(6%) cases the ADRs decreased. No fatal case was reported.

Preventability of suspected ADRs were assessed by using Modified Schumock and Thornton scale and the results revealed that 67(78%) ADRs were definitely preventable while 9(10%) ADRs were probably preventable. Our study documented an increased risk of suspected ADRs in elderly patients and 88% of reactions were preventable. Knowledge of pharmacological principles and how aging affects drug kinetics and response is essential if we are to promote safe prescribing.

Intervention was required in all ADRs indirectly contributed to affect the patient's Quality Of Life. A study conducted by Li Qing et al (2004)[29] showed that the main reasons for under reporting by health care professionals were lack of basic knowledge about ADRs and the voluntary reporting procedure. They concluded that education and training of healthcare professionals is needed to improve the current ADR reporting systems.

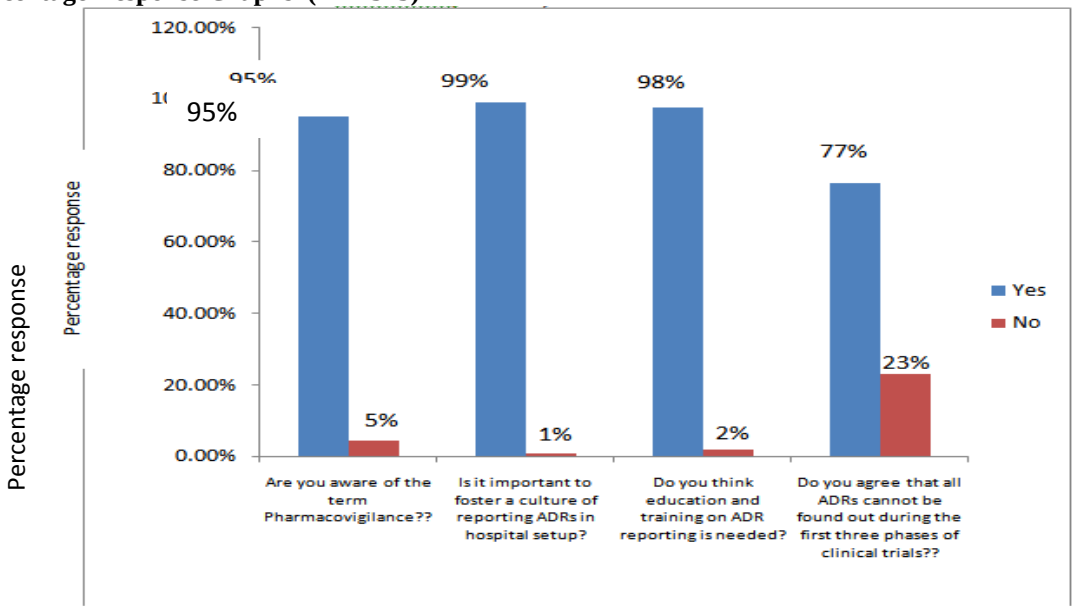
Our ability to anticipate and prevent such ADRs can be facilitated by the establishment of standardized approaches and active reporting of suspected ADRs by all healthcare professionals including physicians, dentists, nurses and pharmacists.

Backstrom M et al., (2007)[30] investigated whether nurses could be a useful tool for improving the reporting rate of Adverse Drug Reactions (ADRs). Fifty four nurses with special drug responsibilities were invited to participate in the study. During the study period, a total number of 23 reports with 39 ADRs were sent to the regional centres by the nurses. Seventeen (74%) of the reports were assessed as serious. Eight of the 39 ADR were unlabelled and all reports were considered appropriate. The reporting rate from the physicians during the study period was similar to the previous year, indicating that the nurses contributed with additional reports.

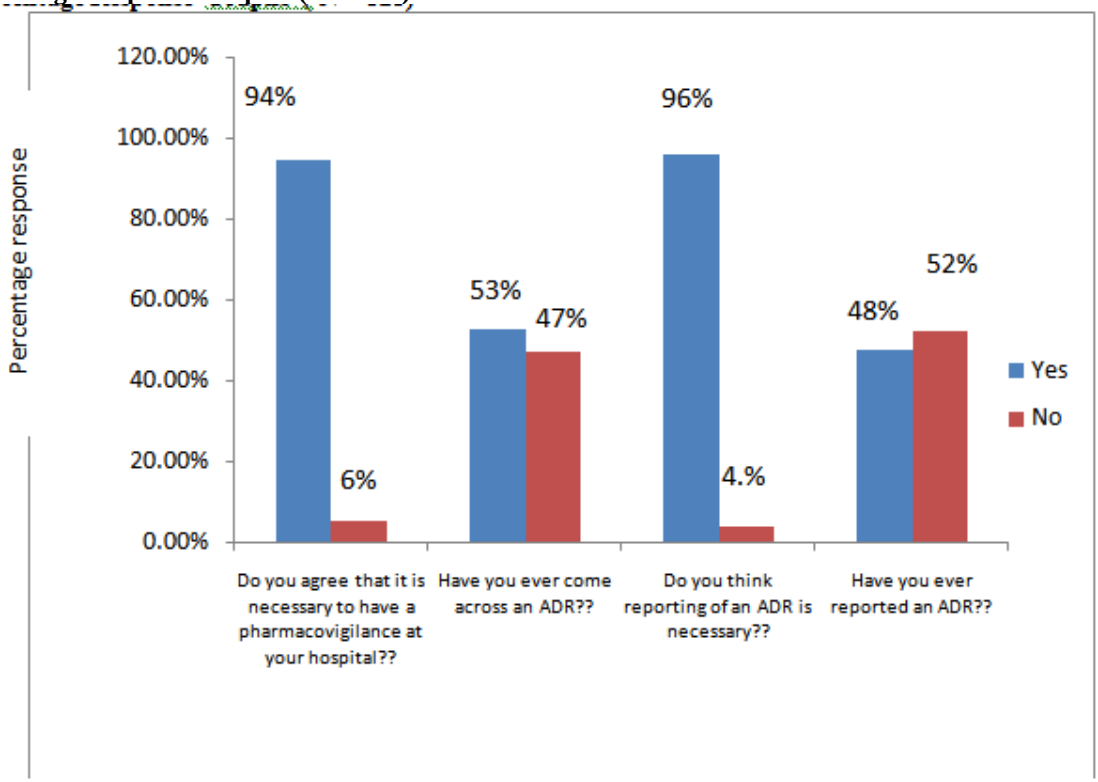
Under- reporting is a major problem even in western countries where the pharmacovigilance system is well established. In India the major problem is a lack of proper system of pharmacovigilance. In this study physician have reported majority of the cases which is encouraging.

Reporting by other healthcare professionals could be further improved by encouraging nurses through conducting educational programme on Pharmacovigilance, lectures, newsletters, slogans, banners, personalized letters etc. to aid and increase reporting of adverse reactions. Road side play and posters on importance of Adverse Drug Reaction reporting may further improve the reporting culture, which will add upto strengthen the Pharmacovigilance Program of India.

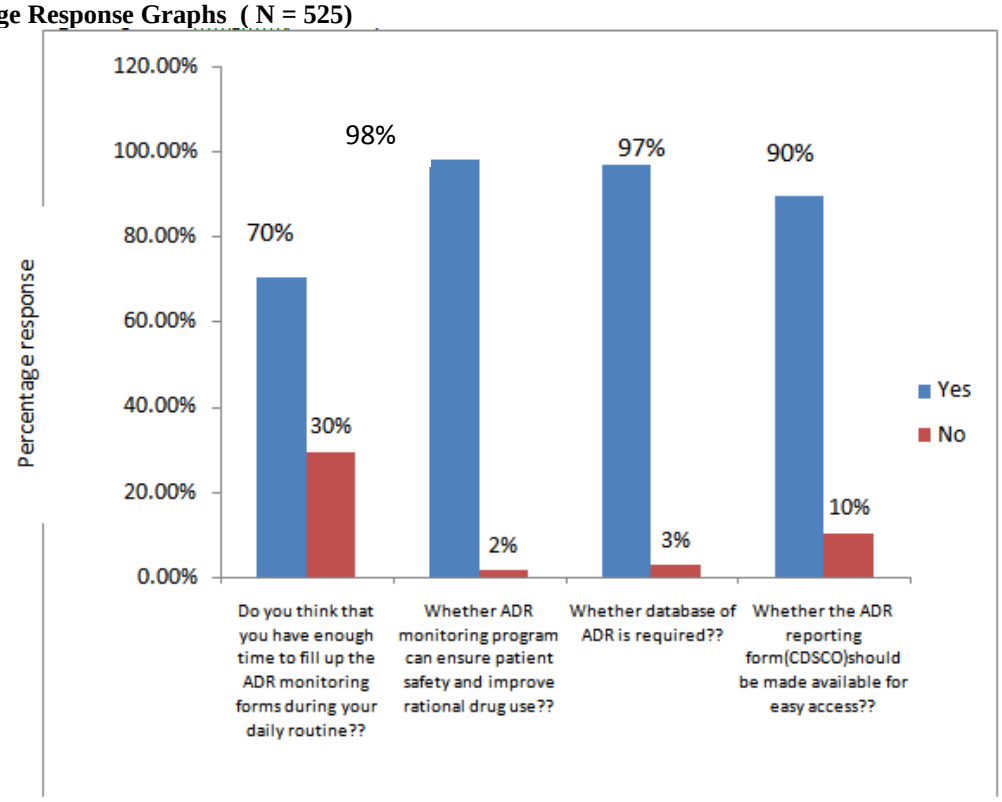
Percentage Response Graphs (N = 525)



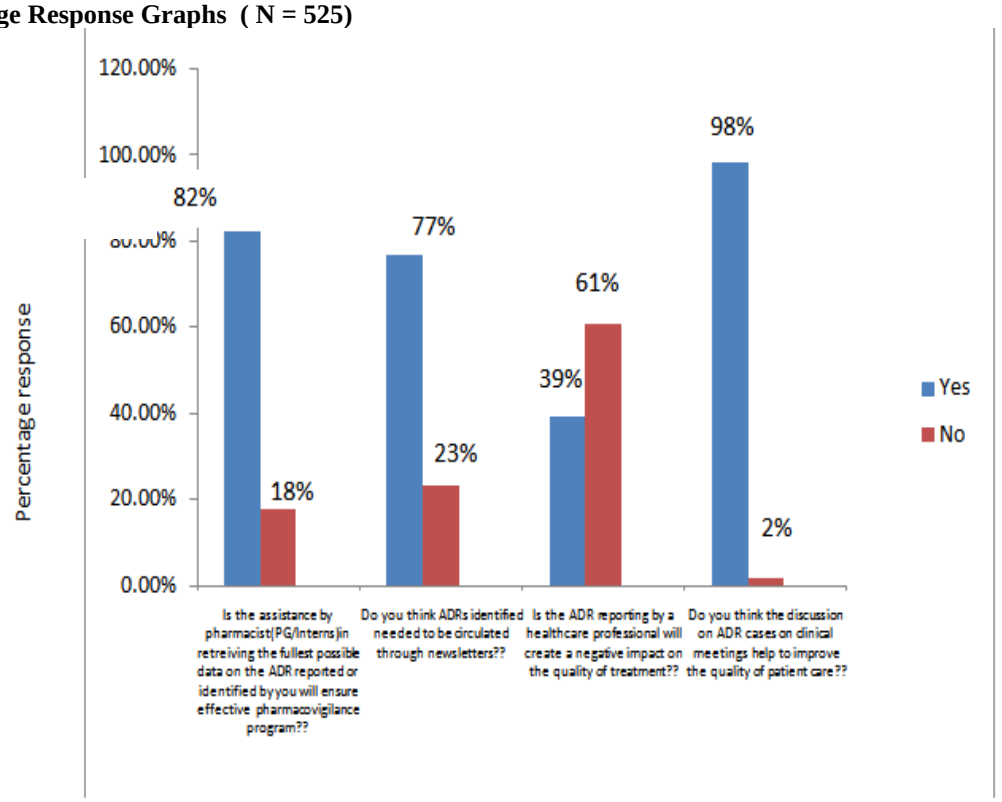
Percentage Response Graphs (N = 525)

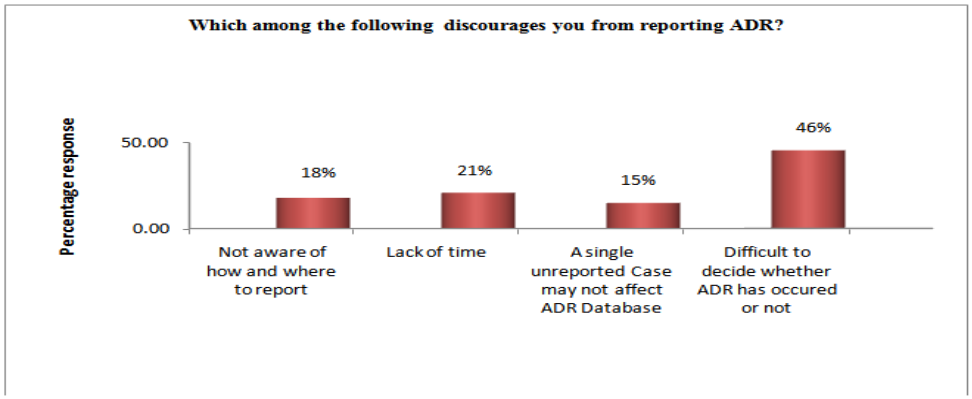


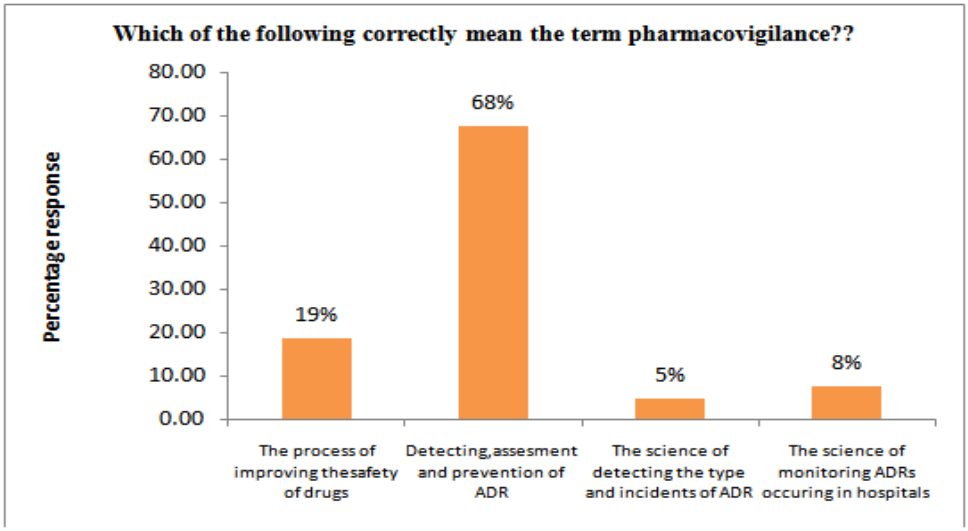
Percentage Response Graphs (N = 525)

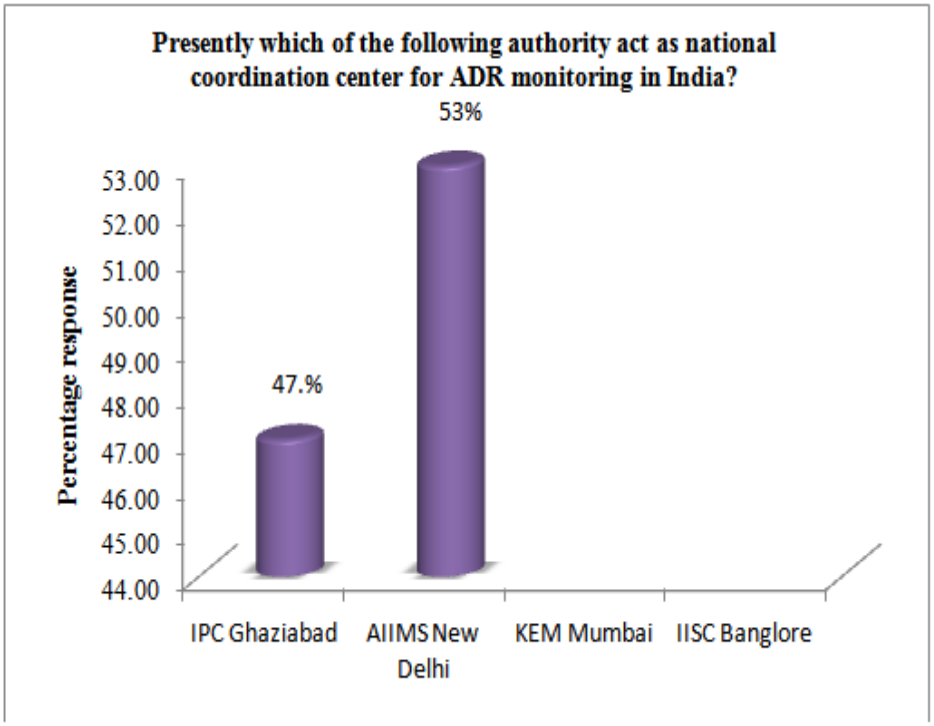


Percentage Response Graphs (N = 525)




Which among the following discourages you from reporting ADR?
Percentage response
50.00
0.00
18%
21%
15%
46%
Not aware of how and where to report
Lack of time
A single unreported Case may not affect ADR Database
Difficult to decide whether ADR has occured or not


Which of the following correctly mean the term pharmacovigilance??
Percentage response
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
19%
68%
5%
8%
The process of improving thesafety of drugs
Detecting,assesment and prevention of ADR
The science of detecting the type and incidents of ADR
The science of monitoring ADRs occuring in hospitals


Presently which of the following authority act as national coordination center for ADR monitoring in India?
53%
Percentage response
53.00
52.00
51.00
50.00
49.00
48.00
47.00
46.00
45.00
44.00
47.%
IPC Ghaziabad
AIIMS New Delhi
KEM Mumbai
IISC Banglore

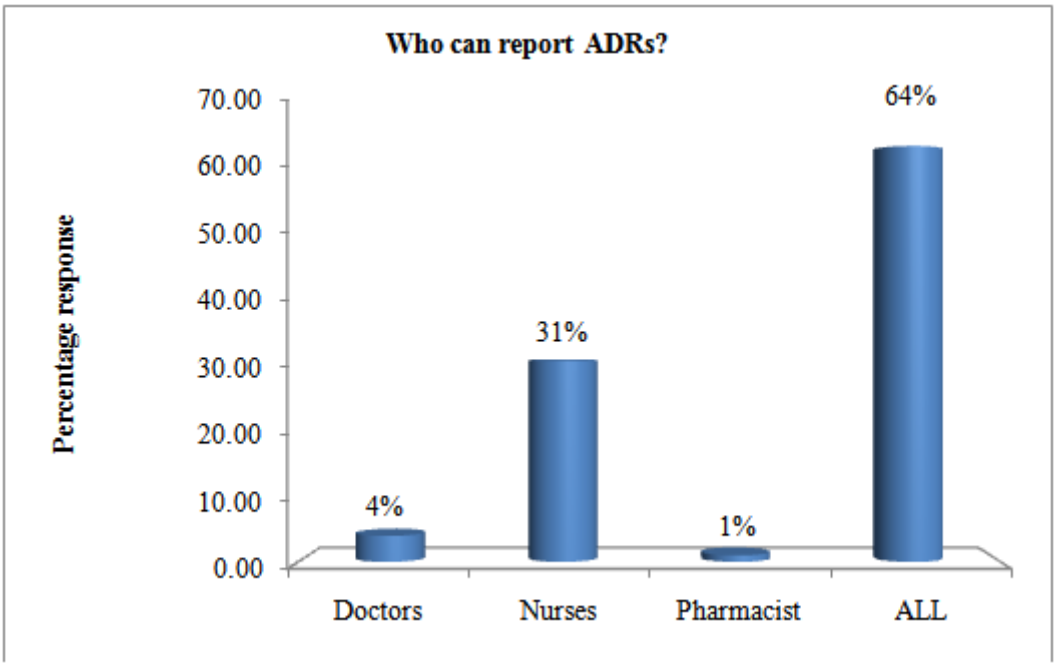


Table 1
Age Distribution of Patients (n= 86)

Age (in years)	No of patients	Percentage (%)
18-29	15	18
30-59	32	37
60 and above	39	45

Chart 1 Age distribution of patients (n=86)

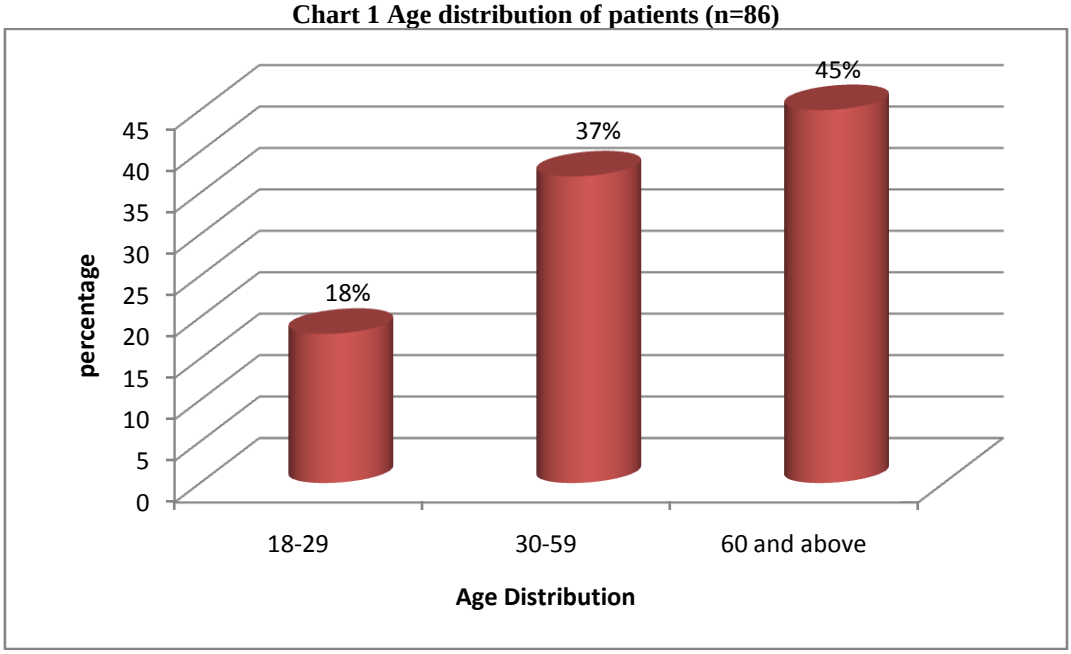


Table 2 Sex Distribution of Patients (n= 86)

Sex	No of patients	Percentage (%)
Male	45	52
Female	41	48

Chart 2 Sex Distribution of Patients (n= 86)

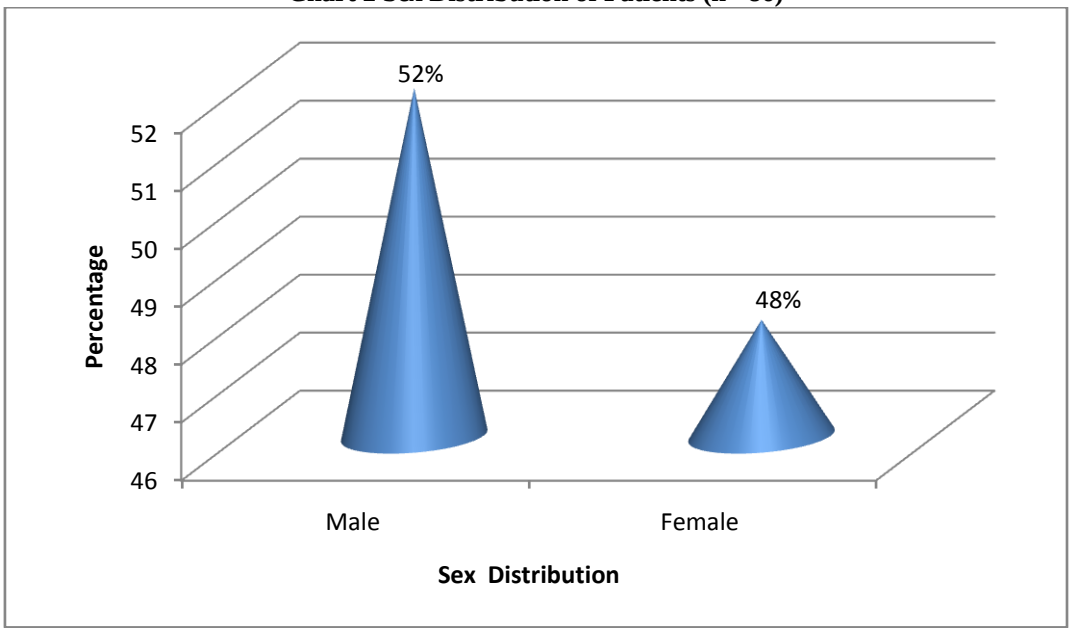


Table 3
ADR before admission and ADR after admission (n= 86)

Admission	No of patients	Percentage (%)
ADR before admission	3	3.5
ADR after admission	83	96.5

Chart 3 ADR before admission and ADR after admission (n= 86)

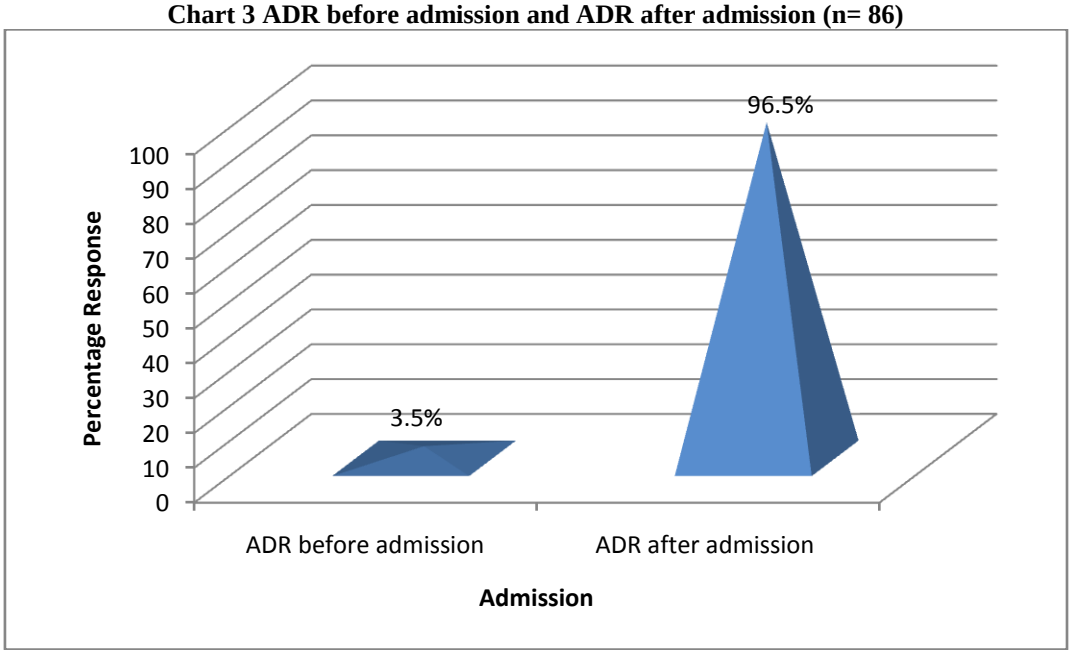


Table 4 System commonly affected (n= 86)

System	Number of Patients	Percentage (%)
Gastro Intestinal	17	19
Dermatological	35	41
Central nervous	6	7
Cardio vascular	4	5
Respiratory	4	5
Others	20	23

Chart 4 System commonly affected (n= 86)

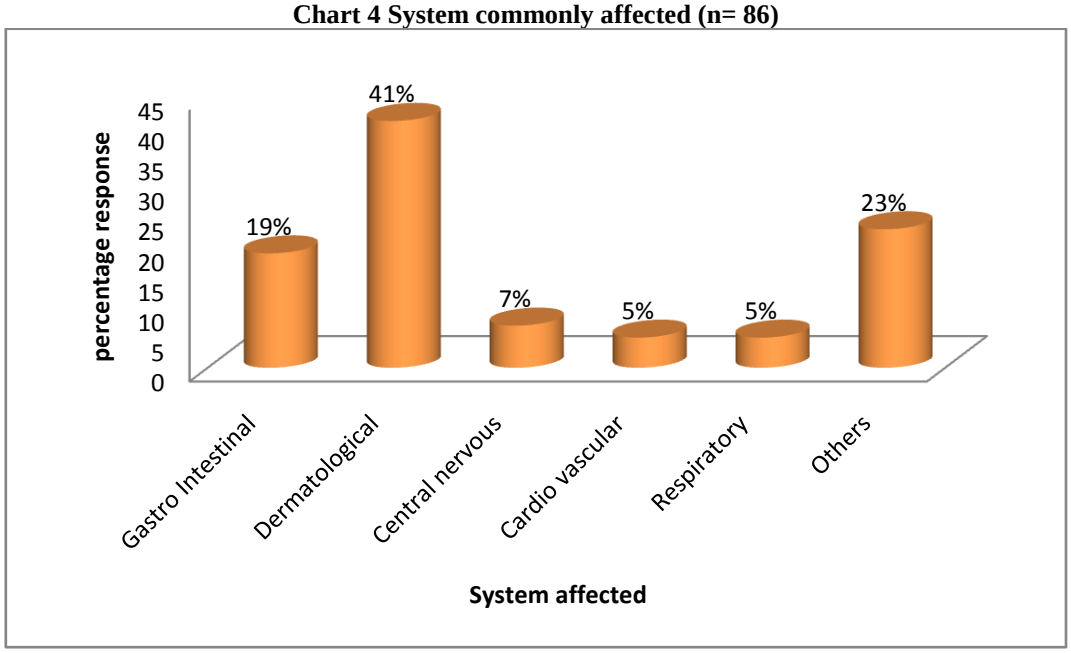


Table 5 Common drug category Causing ADR (n= 86)

Drug	Number of Patients	Percentage(%)
Antibiotics	36	42
NSAIDs	4	5
Anti diabetic	2	2
Anti convulsants	5	6
Anti tubercular	4	5
Others	35	40

Chart 5 Common drug category Causing ADR (n= 86)

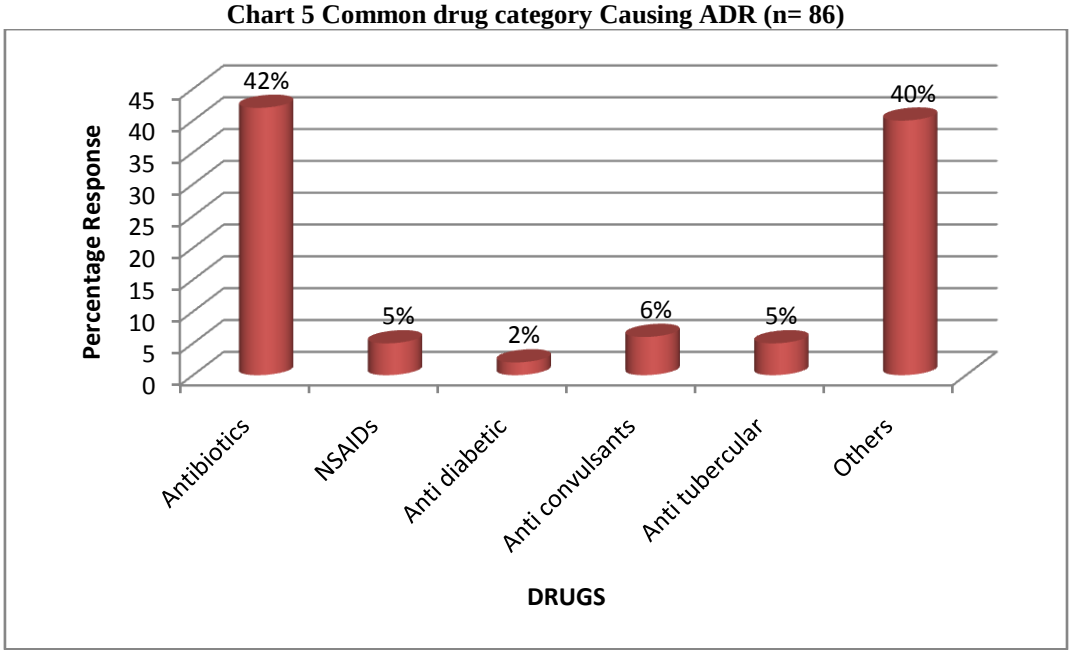


Table 6 Causality assessment of suspected ADRs -by WHO scale (n= 86)

WHO scale	Number of Patients	Percentage(%)
Certain	19	22
Probable	27	31
Possible	36	42
Unlikely	0	0
Unclassified	2	2
Unclassifiable	2	2

Chart: 6 Causality assessment of suspected ADRs -by WHO scale (n= 86)

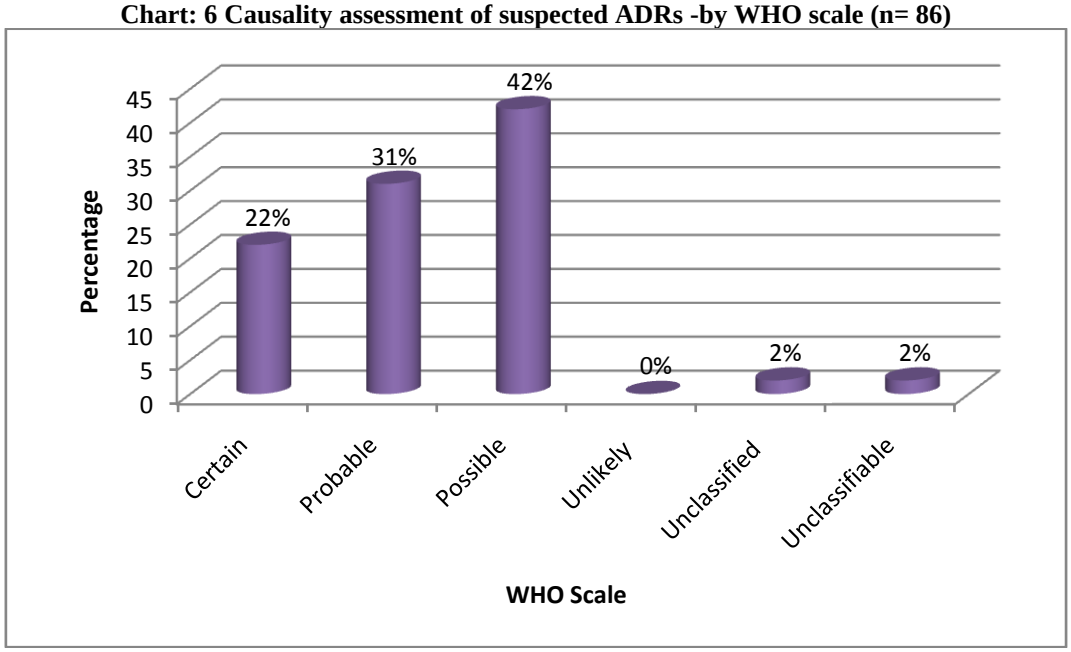


Table 7 Causality assessment of suspected ADRs by Naranjo's scale (n= 86)

Naranjo scale	Number of Patients	Percentage
Definite	1	1.2
Probable	59	68.6
Possible	26	30.2

Chart: 7 Causality assessment of suspected ADRs by Naranjo's scale (n= 86)

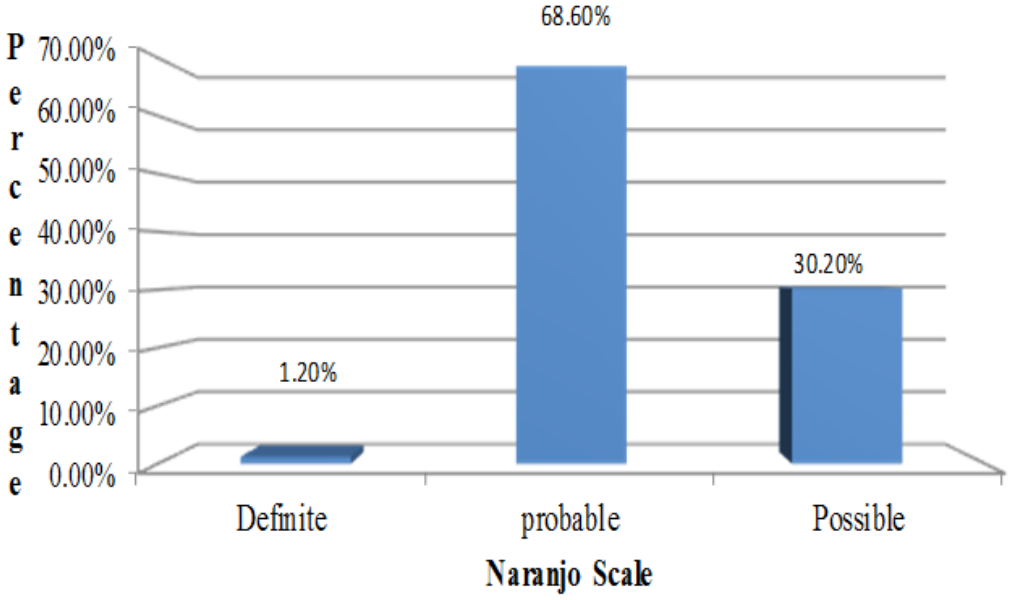


Table 8 Severity of suspected ADRs (n= 86)

Severity	No. of Patients	Percentage (%)
Mild	33	39
Moderate	46	53
Severe	7	8

Chart: 8 Severity of suspected ADRs (n= 86)

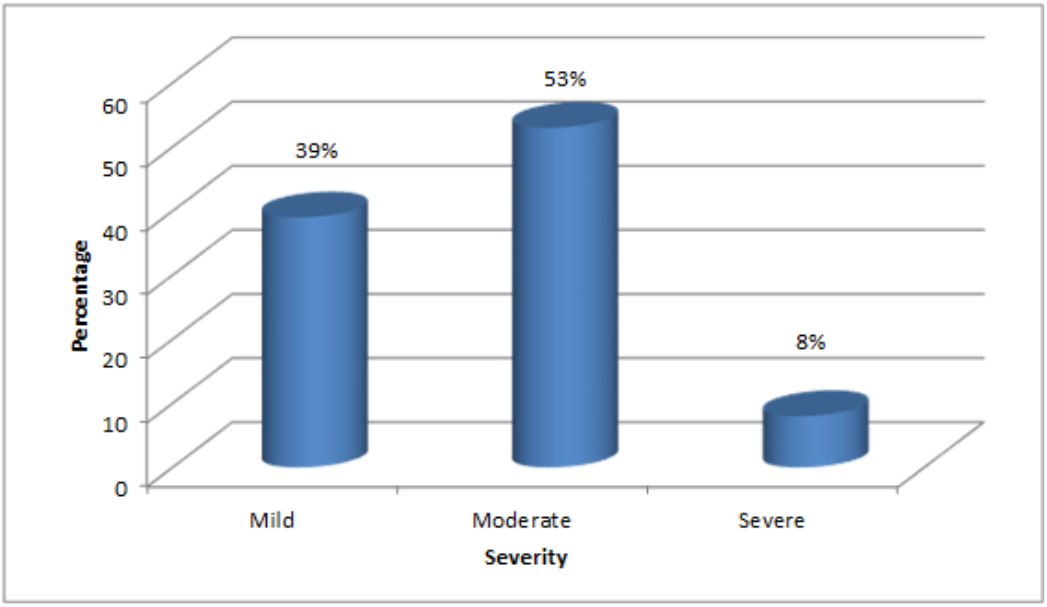


Table 9
Preventability of suspected ADRs (n= 86)

Preventability	No. of Patients	Percentage
Definite	67	78
Probable	9	10
Not preventable	10	12

Chart: 9 Preventability of suspected ADRs (n= 86)

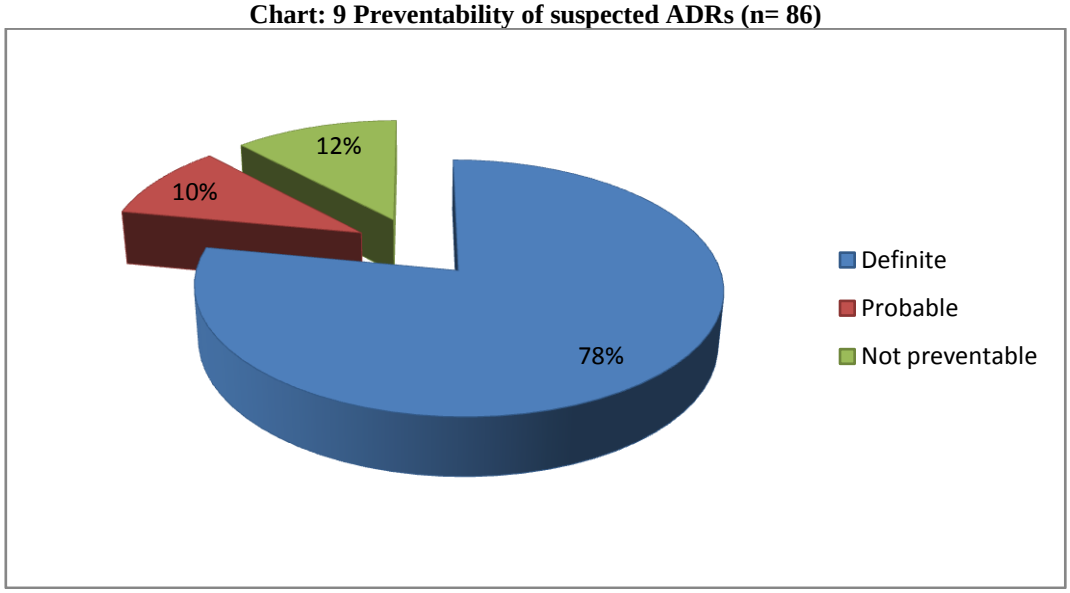


Table 10 Management of suspected ADRs (n= 86)

Management	No. of Patients	Percentage (%)
Drug withdrawn	83	97
Dose Altered	3	3
No Changes	0	0

Chart: 10 Management of suspected ADRs (n=86)

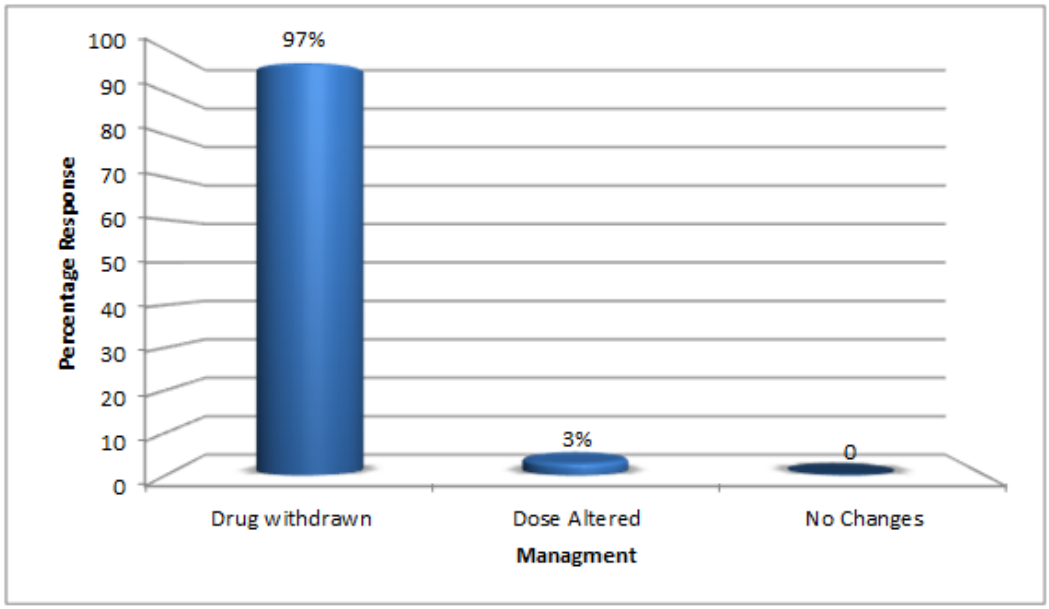


Table 11
Outcome (n= 86)

Outcome	No. of Patients	Percentage(%)
Recovered	81	94
Decreased	5	6
Fatal	0	0

Chart: 11 Outcome (n= 86)

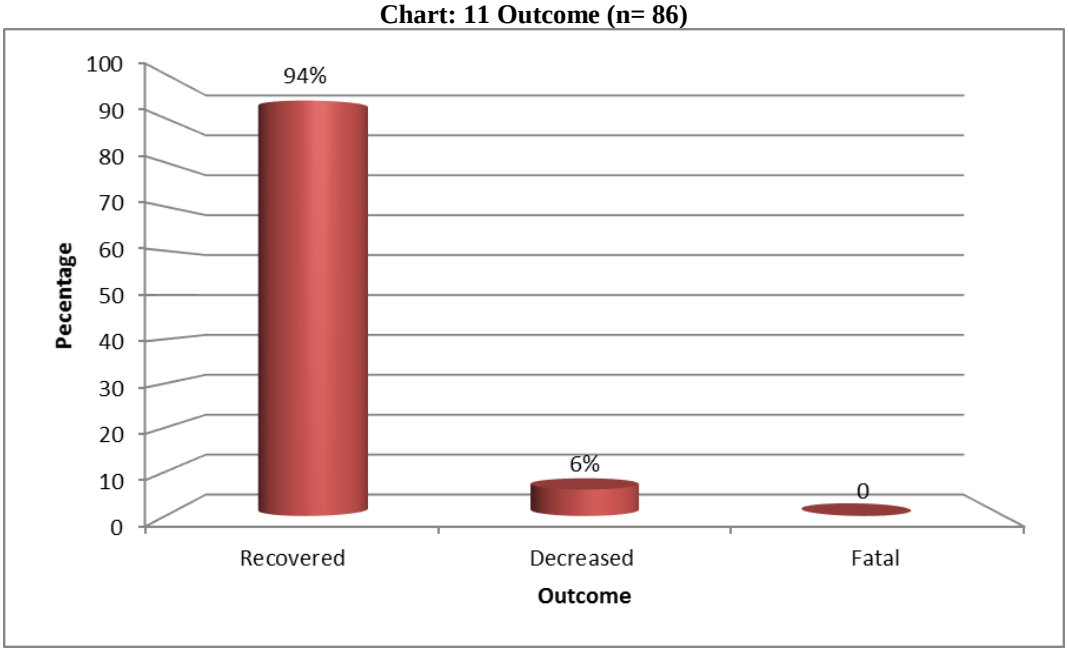


Table 12
Dechallenge and Rechallenge (n= 86)

	No. of Patients	Percentage (%)
Dechallenge	72	84
Rechallenge	0	00

Chart: 12 Dechallenge and Rechallenge (n= 86)

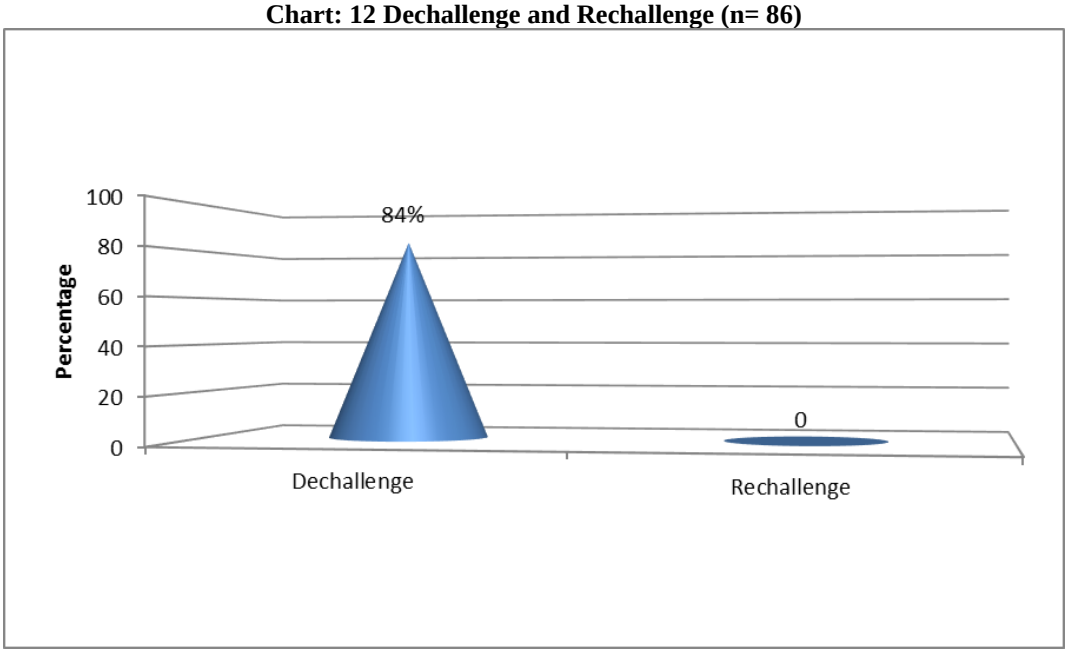


Table 13
Predisposing factors (n= 86)

Predisposing Factors	No. of Patients	Percentage (%)
Age	40	47
Genetic	5	6
Intercurrent diseases	27	32
Multiple drugs	28	38
Others	23	27

Chart: 13 Predisposing factors (n= 86)

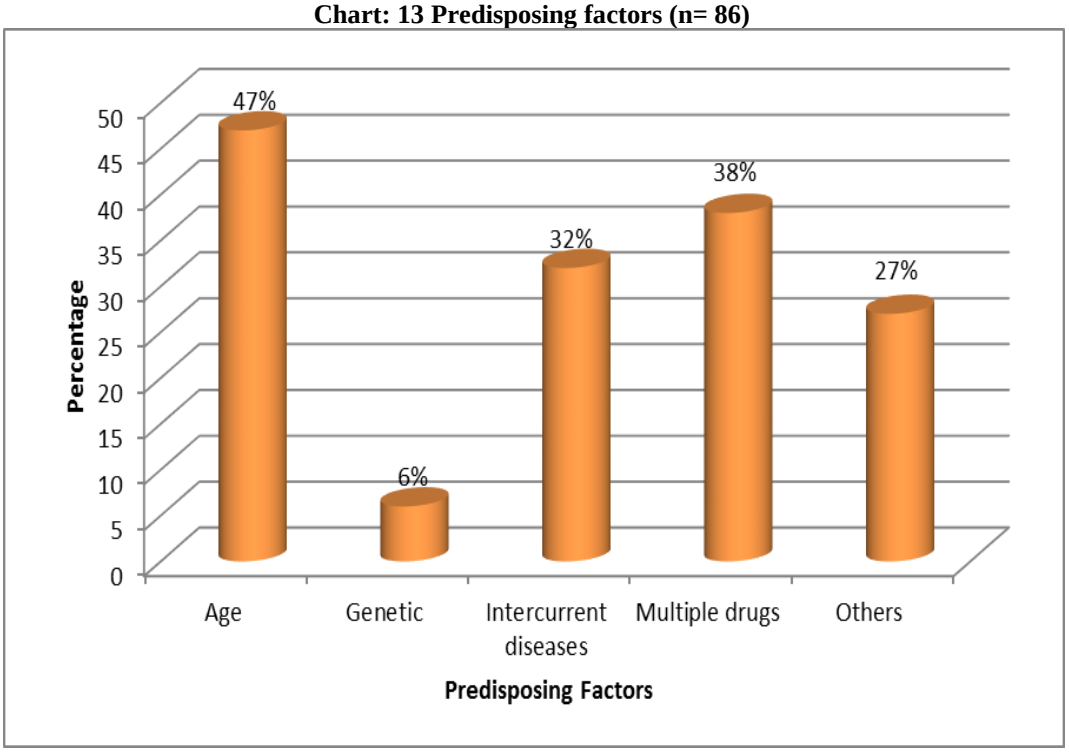


Table 14 Risk Factors (n= 86)

Risk Factors	No. of Patients	Percentage (%)
Renal insufficiency	12	14
Cardiac problem	22	25
Hepatic insufficiency	15	17
Previous allergy	8	9
Smoking	29	34
Alcohol	25	29
Drug addict	0	0.0
Others	19	22

Chart: 14 Risk Factors (n= 86)

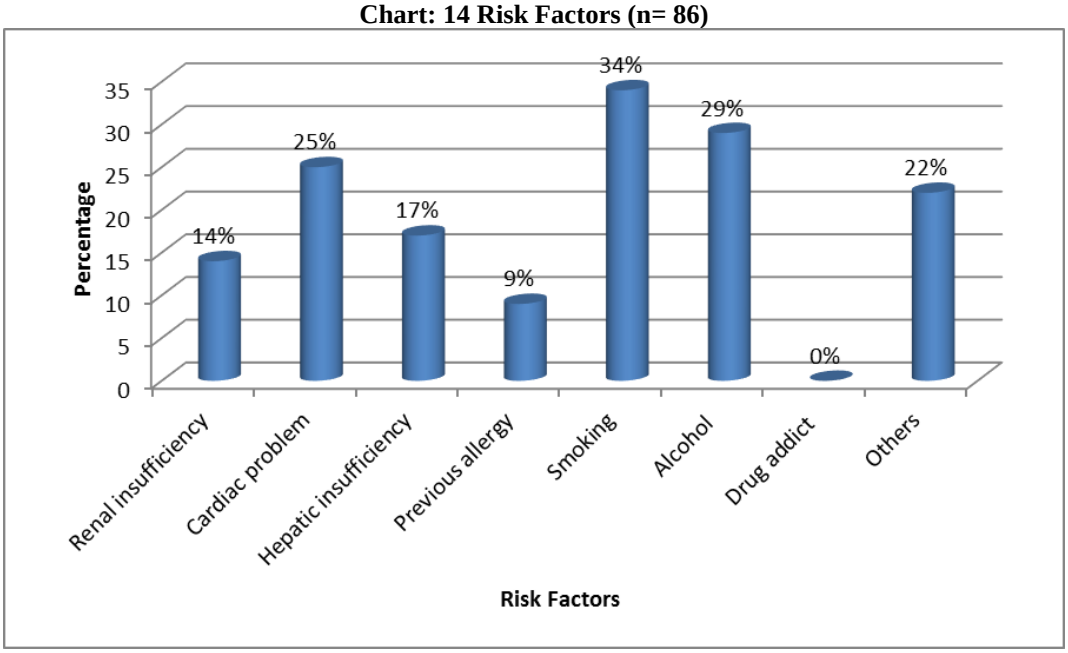


Table No: 15
LIST OF SUSPECTED ADRs

S.N	Suspected drug	Adverse Drug Reaction (s)
01	Furosemide	Hypokalemia
02	Ceftriaxone	Reddish Rashes
03	Vancomycin	Redman Syndrome
04	Nifedipine	Pedal edema
05	Atorovastatin+ Clopidogrel	Blackish Stool and abdominal Pain
06	Betamethasone	Increased FBS level
07	Baclofen	Insomnia
08	Ceftriaxone	Diarrhea
09	Cefditoren	Loose stools
10	Ceftriaxone	Hypersensitivity Reactions

11	Clindamycin	Diarrhea
12	Ceftriaxone	Sludge within Gallbladder
13	Phenytion	Ataxia
14	Methylprednisolone	Hyperglycemia
15	Silymarin	Constipation
16	Tramadol+Acetaminophen	Constipation
17	Atorvastatin	Reduced HDL
18	Ofloxacin	Headache
19	Tramadol	Constipation
20	Ceftriaxone	Loose stools
21	Amiodarone	Acute Respiratory Distrress Syndrome
22	Piperacillin + Tazobactum	Eosinophilia and systemic symptoms
23	Valproic acid	Diahorrea
24	Tramadol	Constipation
25	Phenytoin	Diskinesia
26	Methyl prednisolone	Hyperglycemia
27	Roxithromycin	Elevated Liver Enzymes
28	Furosemide	Hepatomegaly
29	Linezolid	Vomiting
30	Tranexamic acid+ Mefenamic acid	Anemia
31	Soduium Valproate,Phenobarbitone, Lorazepam	Choreoathetosis
32	Folic acid	Itching, rashes
33	Ringer lactate	Edema
34	Atorvastatin	Low HDL, LDL, Cholesterol
35	Betamethasone	Hyperglycemia
36	Tramadol	Constipation
37	MetaprololTartarate	Pedal edema
38	Aspirin + Dexamethasone	Melena
39	Montelukast + Levocetrizine	Xerostomia
40	Metformin	Loose stools
41	Rifamoicin + Isoniazid	Elevated liver enzymes
42	Piperacillin + Tazobactam	Thrombophelibitis
43	Amiodarone	Constipation

44	Metoclopramide	Facial swelling
45	Telmisartan	Drug induced Hyperkalemia
46	Mannitol	Metabolic acidosis
47	Ceftriaxone	Rashes
48	Methyl prednisolone	Elevated FBS
49	Warfarin	Hematuria
50	Linezolid	Lactic acidosis
51	Metoprolol	Altered Bladder habits
52	Rifampicin + Isoniazid + Ethambutol + Pyrizinamide	Erythema all over the body
53	Furosemide	Hyponatremia
54	Meropenem	Loose stools
55	Warfarin	Drug induced Hematuria
56	Methyl prednisolone	Hiccups
57	Furosemide	Hypotension
58	Betamethasone	Increased FBS
59	Rifampicin + Isoniazid + Ethambutol + Pyrizinamide	Decreased bicarbonate levels
60	Alphacalcidol	Constipation
61	Rifampicin + Isoniazid + Ethambutol + Pyrizinamide	Dark colored urine
62	Rifampicin + Isoniazid + Ethambutol + Pyrizinamide	Hemetemesis
63	Enaxoparin	Hematuria
64	Clopidogrel + Aspirin	Hematuria
65	Piperacillin + Tazobactam	Hypokalemia
66	Sodium Valproate	Hyper Ammonemia
67	Amikacin	Nephrotoxicaty
68	Clobazam	Drowsy
69	Prednisolone	Increased FBS level
70	Torsemide	Hypokalemia
71	Amikacin	Nephrotoxicity
72	Aspirin	Dyspepsia
73	Ceftriaxone	Itching
74	Levodopa + Cabidopa	Dyskinesia
75	Cilnidipine	Hypertension

76	Piperacillin + Tazobactam	Itching
77	Enoxaparin	Hematuria
78	Piperacillin + Tazobactam	Purpura
80	Torsemide	Hypokalemia
81	Levocetirizine	Throat pain or pharyngitis
82	Zolpidem	Hyponatremia
83	Carvedilol	Pedal edema
84	Hydrocortisone	Increased FBS level
85	Cilnidipine	Increased SGOT level
86	Cefotaxime	Allergic skin reactions

ACKNOWLEDGEMENT

We are very much delighted to connote our vehement indebtedness to Thiru. R.Vijayakumhar, our Managing Trustee, Dr.P.Sukumaran, Dean, Sri Ramakrishna Hospital & Dr. T.K. Ravi, Principal, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences and all the teaching staff of the Department of Pharmacy Practice, College of Pharmacy, SRIPMS for the support, guidance and encouragement throughout the study.

REFERENCES

[1]. Kilbridge PM, Campbell UC, CozartHB, Mojarrad MG. Automated drug events at a community hospital and an academic medical center. Am Med Inform Assoc. 2006; 13(4): 372-377.
[2]. Kamal NN, KamelEG, Mahfouz EM. Adverse drug reactions reporting, knowledge, attitude and practice of physicians towards it in El Minia University Hospitals. InInternational Public Health Forum 2014 (Vol. 1, No. 4, pp. 13-17).
[3]. Hadi MA, Neoh CF, ZinRM, Elrggal ME, Cheema E. Pharmacovigilance: pharmacists' perspective on spontaneous adverse drug reaction reporting. INTEGRATED PHARMACY RESEARCH AND PRACTICE. 2017 Jan 1;6:91-8.
[4]. Khattri S, Balamuralidhara V, PramodKT, Valluru R, Venkatesh MP. Pharmacovigilance regulations in India: A Step forward. Clinical Research and Regulatory Affairs. 2012 Jun 1;29(2):41-5.
[5]. Alshakka M, Bassalim H, Alsakkaf K, Mokhtar M, Alshagga M, Sami AL, Jha N, Abdoraboo A, Shanker PR. Knowledge and perception towards pharmacovigilance among healthcare professionals in tertiary care teaching hospital in Aden, Yemen. J Pharm Pract Community Med. 2016;2(1):21-8.
[6]. Hazell L, Shakir SA. Under-reporting of adverse drug reactions. Drug safety. 2006 May 1;29(5):385-96.
[7]. Ghulam Mustafa, Saeed-ur-Rasheed, Muhammad Tahir Aziz. Adverse drug reaction reporting system at different hospitals of lahore, pakistan - an evaluation and patient outcome analysis.2013jan, J App Pharm 04(01): 713-719.
[8]. Hema NG, Bhuvana KB, Sangeetha. Pharmacovigilance: the extent of the awareness among the final year students, interns and postgraduates (PGs) in a government teaching hospital. Journal of Clinical and Diagnostic Research. 2012 September [cited: 2013 Apr 3]; 6: 1248-1253.
[9]. Mariam Molokhia, ShivaniTanna, Derek Bell. Improving reporting of adverse drug reactions: systemic review. Clinical Epidemiology. 2009; 1: 75-92.
[10]. Amrita P, SimarP.S, Vineet K. Status of adverse drug reaction reporting by health care professionals of Delhi. Indian Journal of Pharmacy Practice. 2012; volume 5(4): 42-50.
[11]. The World Bank [Internet]. GDP per capita current US$ [cited 2013 Jan 14]. Available from: http://data.worldbank.org/
[12]. Mckinsey [Internet]. India pharma 2020: Propelling access and acceptance, realizing true potential: 2009 May 06 [cited 2009 Jun 16].
[13]. Rawlins M D, Thompson JW, Davies DM. Pathogenesis of adverse drug reactions. Textbook of adverse drug reactions. Oxford university press: 1977.p.10.
[14]. Wills S, Brown DA. A proposed new means of allergic reactions responsible for clinical hypersensitivity and disease. Clinical Aspects of Immunology ,Oxford: Oxford University. 1968; 575-96.
[15]. The use of the WHO-UMC system for standardised case causality assessment: Accessed at http://www.who-umc.org?graphics/ 4409.pdf on February 28,2009
[16]. Shah A, YadavPP, Chaudhari M, Vataliya A, Kantharia ND, Mehta R. A Prospective Study of Adverse Drug Reactions in Patients with Bipolar Disorder in Psychiatry Outpatient Department of a Tertiary Care Hospital. Journal of clinical and diagnostic research: JCDR. 2017 May;11(5):FC24.
[17]. Harmark LA, Van Grootheest et al. Pharmacovigilance: methods, recent development and future perspectives. European Journal of Clinical Pharmacology. 2008; 64: 743-752.
[18]. Availablefrom:http://www.mackinsey.com/locations/India/mckinseyonindia.pdf.
[19]. Ditto AM. Drug allergy. In: Grammer LC, Greenberger PA, eds. Patterson's Allergic diseases. 6th ed. Philadelphia: Lippincott Williams & Wilkins 2002; 295.
[20]. Rao PG, Archana B, Jose J. Implementation and results of an adverse drug reaction reporting programme at an Indian teaching hospital. Indian journal of pharmacology. 2006 Jul 1;38(4):293.

[21]. Pirmohammed M, James S et al. Adverse drug reactions as a cause of admissions to hospital: prospective analysis of 18820 patients. British Medical Journal. 2004; 329: 15-9.
[22]. Hendry J. Diagnostic problems in drug-induced diseases, Have More Complications. DOC News. 2004 Oct 1;1(2):14.
[23]. Sivanandy P, KotturSG Arul Kumaran, AiyaluRajasekaran. A study on assessment, monitoring and reporting of adverse drug reactions In Indian hospital. Asian J Pharm Clin Res. 2011; Vol 4(3): 112-116.
[24]. Davies EC, Green CF, MottramDR, Pirmohamed M. Emergency re-admissions to hospital due to adverse drug reactions within 1year of the index admission. British Journal of Clinical Pharmacology. 2010; 70:5: 749-755.
[25]. Hazell L, Shaki SA. Under reporting of adverse drug reactions: a systemic review. Drug Saf. 2006; 29:385-6.
[26]. SuhCP, Orr DB, Van DuynJW. T Detection of new adverse drug reactions. 5thEdn, Chichester: Journal of economic entomology. 2000 Aug;93(4):1137-45.
[27]. Peña BM, Krauss B. Adverse events of procedural sedation and analgesia in a pediatric emergency department. Annals of emergency medicine. 1993 Oct 1;34(4):483-91.
[28]. Lazarou J, Bruce HP, Paul NC. Incidence of adverse drug reactions in hospitalized patients - a meta-analysis of prospective studies. JAMA 1998 April 15;279(15):1200-5, 40.
[29]. Li Q, Zhang SM, Chen HT, Fang SP, Yu X, Liu D, Shi LY, Zeng FD. Awareness and attitudes of healthcare professionals in Wuhan, China to the reporting of adverse drug reactions. Chinese medical journal. 2004 Jun;117(6):856-61..
[30]. Bäckström M, Ekman E, Mjörndal T. Adverse drug reaction reporting by nurses in Sweden. European journal of clinical pharmacology. 2007 Jun 1;63(6):613-8.

Sriram S" Survey on Role of Healthcare Professionals in Reporting Adverse Drug Reactions & Monitoring and Documentation of Suspected Adverse Drug Reactions" International Journal of Pharmaceutical Science Invention(IJPSI), vol. 08, no. 02, 2019, pp. 18-39