

**Research Article****A retrospective study on adverse drug reactions monitoring and reporting in a quaternary care super speciality hospital in Karnataka**Jhoney Natasha<sup>1</sup>, Puneeth G.K.<sup>1\*</sup>, Sindhushree N.<sup>2</sup>, Kush Nimron<sup>3</sup><sup>1,2</sup>Sri Adichunchanagiri College of Pharmacy BG Nagara-571448, Karnataka<sup>1,3</sup>Clinical Pharmacologist, BGS Gleneagles global hospitals, Bangalore, Karnataka

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**Abstract**

**Background** The World Health Organization defines a "adverse drug reaction," which has been in use for about 30 years, as "a response to a drug that is toxic and unexpected and occurs at levels commonly employed in man for the prevention, diagnosis, or treatment of disease, or for altering physiological function." ADRs should be carefully considered and managed right away in order to shield patients from undesirable pharmacological side effects. **Objective:** To evaluate the degree of association between suspected ADR and pharmacological therapy, the WHO Probability assessment scale was applied. To establish the causative link between a drug and a suspected reaction, the Naranjo's causality assessment scale was applied. **Methodology:** The study was carried out at a quaternary care super speciality hospital. The study was carried out for a period of 2 month where the previous ADR reported forms were considered for the review from the year 2019-2022. **Results:** A total 106 ADR are reported from 2019 to 2021 in quaternary super speciality hospital in southern India. Among that majority were females 51.9% and males are 48.1%, maximum number of ADRs were reported from the general medicine 49(46.3%), followed by general surgery 16(15.2%), Orthopaedics 12(11.3%), Neurology 11(10.4%), Nephrology 8(7.5%), Oncology 5(4.7%), Gastroenterology 3(2.8%), Paediatrics 1(0.9%) and Cardiology 1(0.9%). 33% of the population experienced rashes and itching as the ADR. 80.2% of the ADR were minor and all were treated and recovered. **Conclusion:** The occurrence of adverse events, which raises healthcare expenditures, is influenced by adverse medication responses, which are a major cause of morbidity and mortality. Continuous encouragement is required for ADR reporting. It is crucial to foster a supportive attitude toward pharmacovigilance among medical practitioners, including pharmacists, so that reporting ADRs becomes a common and acknowledged practise.

**Keywords:** Adverse Drug Reactions, Self-medication, Causality, Severity, Clinical pharmacist

**Introduction**

The term "adverse drug reaction" has been in use for about 30 years and is defined by the World Health Organization as "a response to a drug that is noxious and unexpected and occurs at levels commonly employed in man for the prophylaxis, diagnosis, or therapy of disease, or for alteration of physiological function" (Edwards et al., 2000).

To prevent patients from experiencing unpleasant

pharmaceutical side effects, ADRs should be carefully evaluated and promptly handled. The earliest reports of infants being born with malformations in the early 1960s were traced to pregnant mothers taking the morning sickness drug thalidomide (Shamna et al., 2014). Providing patients with healthcare on a global scale is significantly hampered by drug toxicity. Impacted are both patient recovery and the healthcare industry's economy. Due to an increase in pharmaceutical product production, newer drugs are released every year. In order to get rid of the dangerous drugs that have made it onto the market, the WHO therefore clearly grasped the need for an active surveillance apparatus. The multinational programme of drug monitoring put forth by the WHO was built on this (Surendiran et al., 2010). India is still in the early stages of ADR reporting and monitoring.

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Establishing a dependable pharmacovigilance system for the country can be facilitated by programmes for reporting ADRs on an institutional level. Additionally, hospital-based ADRs programmes could provide crucial details about potential problems with drug usage at an institution (Palanisamy et al., 2013). Antibiotics continue to be the most commonly prescribed class of drugs by all clinical disciplines due to the enormous frequency of infectious infections, particularly in poor countries. Although this population also regularly receives illogical treatment, self-medication, over-the-counter use, and other serious forms of exploitation (Vijaishri et al., 2017). Antibiotics come in a variety of forms, including penicillins, cephalosporins, sulfonamides, and aminoglycosides, and they differ in terms of how they function and the potential harm they might cause. Antibiotics are frequently used in daily practise for the prevention and treatment of a wide range of medical issues (Tripathi, 2007). Age, sex, co-occurring diseases, genetics, and medication-related factors like drug type, administration technique, length of therapy, and dosage can all affect the frequency and severity of ADRs. In addition to ADRs, other important risk factors include gender, higher medication exposure, advanced age, length of hospital stay, and function of excreting organs (Beard and Lee, 2001). Especially in the scientific field of pharmacovigilance, which looks at medication safety, pharmacists are important players in the pharmaceutical industry (van Grootheest et al., 2004). Since doctors and nurses are the preferred sources of information, reporting an ADR is not only the pharmacist's responsibility; it is also everyone else's.

### Methodology

**Study site:** A super-specialty hospital offering quaternary care was the site of the study.

**Study design:** Retrospective study.

**Study period:** The study was carried out for a period of 2 month where the previous ADR reported forms were considered for the review from the year 2019-2022.

### ADR notification and documentation forms

A separate ADRs notification and documentation form was created, which contains all pertinent information, such as the patient's demographics, a list of all medications taken prior to the onset of the reaction, their route of administration, dosage, frequency, the date the reaction started, and whether or not the patient has any drug or food allergies. It also contains information about how ADRs are managed and the reporter's contact information. For convenient access by all medical staff, this form was made available in the hospital's nursing stations as well as the outpatient sections. It has two benefits, the first of which is that it acts as an official channel for relaying to the medical professional the pertinent details about the probable

ADRs recorded. Second, it serves as a means of encouraging their ongoing reporting of possible ADRs.

### Casualty, severity, and preventability data collection and assessment

Information about a particular suspected drug and reaction was obtained and recorded in an ADR documentation form that was properly created when a suspected drug was reported and met the inclusion and exclusion criteria. Data for the study were acquired from the patient's case sheet, treatment chart, investigation reports, personal interviews with the patient and any accompanying individuals, as well as personal interviews with the reporting persons and doctors. The ADRs documentation form, which was specifically designed for analysis, received the data transmission.

### Causality evaluation

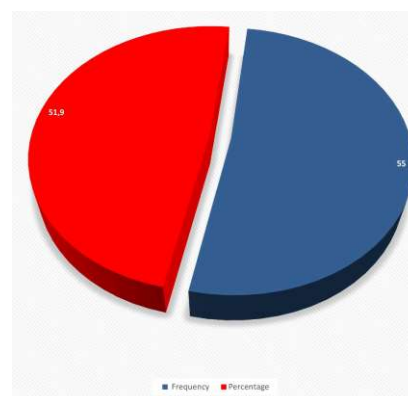
To evaluate the degree of association between suspected ADR and pharmacological therapy, the WHO Probability assessment scale was applied. The categories of Certain, Probable/Likely, Possible, Unlikely, Conditional/Unclassified, and Un-assessable/Unclassifiable were further subdivided. To establish the causative link between a drug and a suspected reaction, the Naranjo's causality assessment scale was applied. After that, the causal relationship was divided into four groups: certain, likely, plausible, and unlikely.

### Results

A total 106 ADR are reported from 2019 to 2021 in quaternary super speciality hospital in southern India. Among that majority were females 51.9% and males are 48.1% show in figure 1.

Among majority 47.2% were among 40 to 60 years of age groups. It is depicted in figure 2.

Figure 3 showed that maximum number of ADRs were reported from the general medicine 49(46.3%), followed by general surgery 16(15.2%), Orthopaedics 12(11.3%),



**Figure 1. Gender distribution**

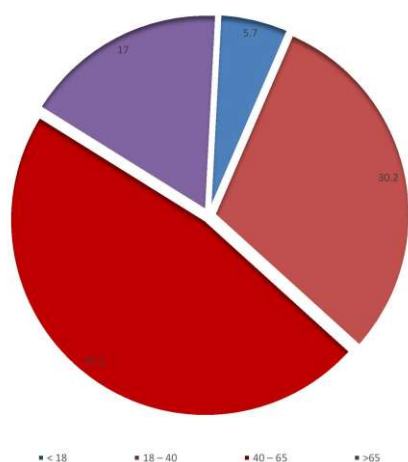


Figure 2. Age group distribution

Neurology 11(10.4%), Nephrology 8(7.5%), Oncology 5(4.7%), Gastroenterology 3(2.8%), Paediatrics 1(0.9%) and Cardiology 1(0.9%).

Among that Inj. Ciprofloxacin 15(14.3%) resulted maximum ADR in patients, Inj. Iohexol 13(12.4%), Inj. Piperacillin+ tazobactam 12(11.3%) and remaining are listed in Table 1.

Table 2 is listed on the complaints of ADR, among that maximum are itching & rashes 35(33%), rashes 17(16.1%) and itching 15(14.1%) are reported. Using Naranjo Algorithm -ADR Probability scale assessed causality of ADR among majority are probable 84(79.2%) followed by possible 21(19.9%) and unlike 1(0.9%) are reported and it is depicted in figure 4.

Figure 5 shows among the reported ADR most them are minor 85(80.2%) followed by major 11(10.4%) and moderate 10(9.4%).

Among the study population most them are admitted and treated in general ward 62(58.5%) followed by ICU

Table 1. List of drugs causing ADR

Drug names	Frequency	Percentage
Inj. Piperacillin + Tazobactam	12	11.3
Inj. Ciprofloxacin	15	14.3
Inj. Pantoprazole	5	4.9
Inj. Ceftriaxone	6	5.9
Inj. Iohexol	13	12.4
Inj. N- acetyl cystine	4	3.9
Inj. Streptokinase	2	1.9
Inj. Cefuroxime	2	1.9
Inj. Vancomycin	2	1.9
Inj. Cefixime	2	1.9
Inj. Paracetamol	2	1.9
Inj. Moxifloxacin	3	2.8
Tab. Azithromycin	1	0.9
Inj. Clarithromycin	2	1.9
Inj. Paclitaxel	3	2.8
Inj. Linezolid	1	0.9
Inj. Oxaliplatin	2	1.9
Inj. Cefoperazone + sulbactam	2	1.9
Inj. Tramadol	1	0.9
Tab. Amlodipine	1	0.9
Inj. Rituximab	1	0.9
Inj. Carboplatin	2	1.9
Inj. Meropenem	1	0.9
Tab. Cephalexin	1	0.9
Inj. Lefoperazone + sulbactam	1	0.9
Inj. Augmentin	1	0.9
Inj. Lignocaine	1	0.9
Inj. Diclofenac	1	0.9
Inj. Ofloxacin	1	0.9
Inj. Alteplase	1	0.9
Inj. Mucomix	1	0.9
Inj. Ferric carboxy maltose	4	3.9
Inj. Desferal	1	0.9
Inj. Dextrose 25%	1	0.9
Insulin aspart 10U	1	0.9
Inj. Fentanyl	1	0.9
Inj. Desram	1	0.9
Inj. Buscopan	1	0.9
Inj. MVI 1 ampule	1	0.9
Inj. Heamaccel	1	0.9
Inj. Albumax	1	0.9

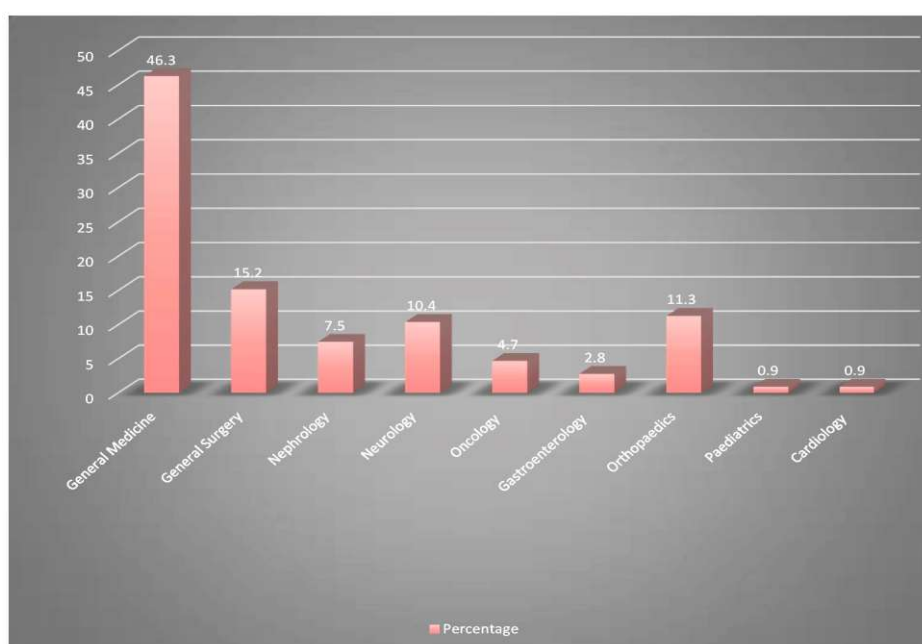
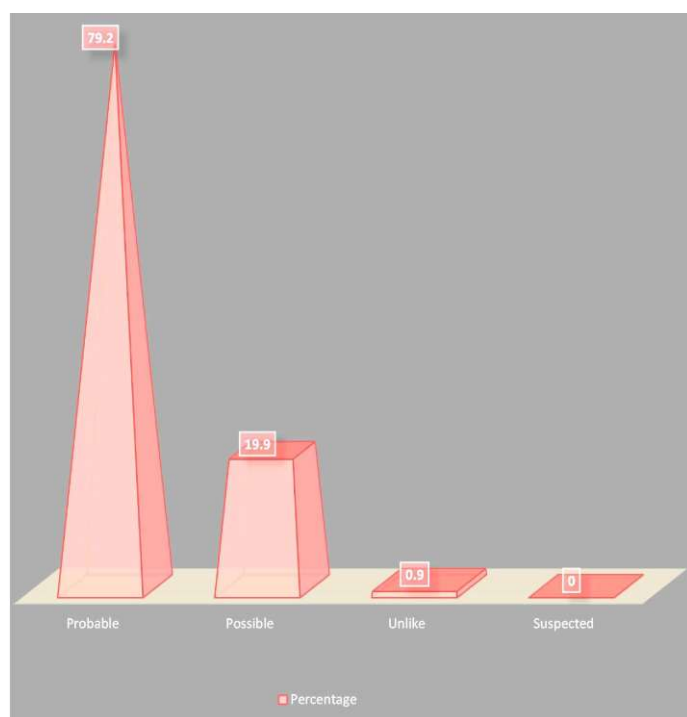
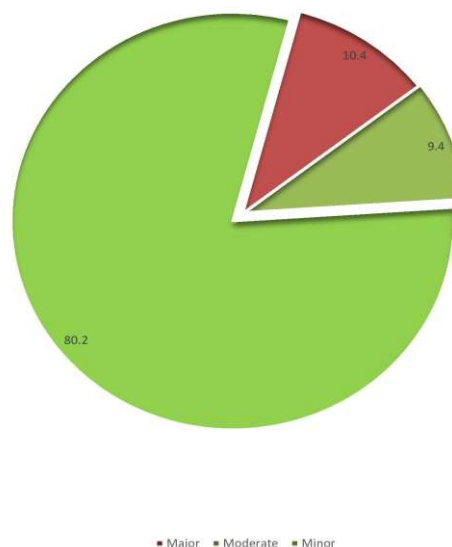


Figure 3. Number of ADRs received from different departments

**Table 2. List of complaints caused by ADR**

Complaints	Frequency	Percentage
Itching and rashes	35	33
Itching	15	14.1
Rashes	17	16.1
Rashes and swelling	4	3.8
Swelling, itching & fever	2	1.9
Urticaria	4	3.8
Itching, vomiting	4	3.8
Itching, breathless	3	2.8
Breathlessness	5	4.8
Itching, pain	2	1.9
Burning sensation	2	1.9
Fever and chills	2	1.9
Itching & dry mouth	1	0.9
Vomiting, headache & giddiness	2	1.9
Severe abdominal pain	1	0.9
Ulcerative colitis	1	0.9
Dizziness and hypotension	1	0.9
Bradycardia, hypotension, generalised edema	1	0.9
Itching, palpitations	2	1.9
Rashes and edema	2	1.9

37(34.9%) and emergency 7(6.6%) are shown in figure 6. Patients are treated and all patients are recovered from complaints of ADR.

**Figure 4. Causality assessment of ADR****Figure 5. Severity of ADR**

### Discussion

Since all medications have the potential to produce adverse drug reactions, ADR monitoring is absolutely necessary for the safe administration of medications, especially in patients who are very old, have two or more organ failures, have co morbid conditions, take multiple medications for chronic diseases, etc. Additionally, PvPI strongly advises all district, corporate, teaching, private, and non-profit hospitals to take part in India's drug safety programme for the patients' benefit. Specialized services are offered to patients by medical schools and hospitals. In comparison to other research, this study's incidence rate of antibiotic adverse responses was shown to be rather low. In comparison to other research, this study's incidence rate of antibiotic adverse responses was shown to be rather low. Few examples of the clinical pharmacist's successful intervention that contributed to this lower incidence rate in our hospital include the implementation of drop boxes in all nursing stations, the regular delivery of ADR awareness classes, the active involvement of clinical pharmacy and Pharm. D students in clinical activities, and the coordination of the hospital's quality control unit.

Our survey revealed that 51.9 percent of females and 48.1 percent of males reported having ADR as a result of medications, with the majority of these individuals being between the ages of 40 and 60. When compared to the study by Mukhtiar Singh et al., it shows that there were 66 male patients and 51 female patients, with respective percentages of 56.41 and 43.59, and that adult patients (those between the ages of 18 and 65) made up 1744 individuals and geriatric patients (those older than 65) 56. There were 6 elderly patients with ADR and 111 adult patients with the

condition. The prevalence of ADRs was found to be higher in female patients than in male patients in our study (Singh M et al., 2019). Comparing our study to that of M. Shamna et al., we found that the general medicine department reported the highest number of adverse drug reactions (ADRs). This may be because antibiotics are used more frequently in general medicine and paediatrics departments for the treatment and prevention of a variety of diseases (Shamna et al., 2014). In our study, the most common adverse drug reactions (ADRs) were recorded in patients taking Inj. Ciprofloxacin 15 (14.3%), Inj. Iohexol 13 (12.4%), Inj. Piperacillin+ tazobactam 12 (11.3%), and itching & rashes 35 (33%) and rashes 17 (16.1%). Cephalosporins and fluoroquinolones were the antibiotic classes that were most frequently used in inpatient settings, according to a study by M. Shamna et al., and as a result, these medication classes had the highest reported rates of adverse drug reactions (ADRs) (Shamna et al., 2014). Cephalosporin was also shown to be prevalent in a study by Stavreva et al., 2008. whereas Priyadharsini et al., 2011. found vancomycin and penicillins to be most common. (The complaints of patients due to adverse drug reactions (ADRs) of frequently prescribed medications in this institute are shown in a study by Mukhtiar Singh et al. There were 117 patients in total with ADRs. In comparison to our study, there are more of those that are skin-related (Singh et al., 2019). Our study demonstrates that the majority of ADRs with assessed causality are probable (84%), followed by possible (21%), and unlike one percent of ADRs that are reported, the majority of reported ADRs are mild (85%), major (10.4%), and moderate (10%). (9.4 percent) All patients who complained of ADR are treated and fully healed. This research's findings are comparable to those of (Singh et al., 2019) study. Our study demonstrates that the majority of patients are treated by being admitted to general wards, and this outcome is equivalent to that of the study done by (Vijaishri et al., 2017).

### Conclusion

Adverse drug reactions, a major contributor to morbidity and death, have an impact on the occurrence of adverse events, which increases healthcare costs. It is critical to inspire medical staff to comprehend their responsibilities for maximising patient safety through the identification, management, and reporting of suspected adverse drug reactions (ADRs). Continuous encouragement is required for ADR reporting. It is crucial to foster a supportive attitude toward pharmacovigilance among medical practitioners, including pharmacists, so that reporting ADRs becomes a common and acknowledged practise. The rate of hospitalisation attributable to ADRs was likely underestimated in the study due to underreporting or misclassification, since it was possible that not all ADRs were recognised. Because of the short length of stay at our hospital, the actual number of ADRs in our patients may have been higher

than what was found and recorded while they were there.

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