IJPSR (2022), Volume 13, Issue 7 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 27 January 2021; received in revised form, 13 June 2022; accepted, 16 June 2022; published 01 July 2022

ADVERSE DRUG REACTION MONITORING IN A TERTIARY CARE HOSPITAL: A PRELIMINARY APPROACH TO ENHANCE REPORTING

Aswathi Elisabeth Philip [1], A. S. Ezhilarasi [1], V. R. Gautham [1], Mancy Jose Mattam [1], Babu Narayanan [2], Aarthi Prakasam [3] and S. Ramalakshmi [*1]

Department of Pharmacy Practice [1], K. K. College of Pharmacy, Chennai - 600122, Tamil Nadu, India.
Dr Mehta's Hospital [2], No.50, Poonamallee High Rd, Velappanchavadi, Thiruverkadu, Chennai - 60007, Tamil Nadu, India.
MGM Healthcare Pvt Ltd [3], New No 72, Old No 54 Nelson Manickam Road, Aminjikarai, Chennai - 600029, Tamil Nadu, India.

Keywords:

Pharmacovigilance, Adverse drug reaction, Causality assessment, Severity assessment, Preventability assessment

Correspondence to Author:
S. Ramalakshmi

Professor and Head ,
Department of Pharmacy Practice,
K. K. College of Pharmacy,
Chennai - 600122, Tamil Nadu, India.

E-mail: sramalakshmi@rediffmail.com

ABSTRACT: Background: Adverse drug reaction (ADR) evaluation and monitoring is key for safe medication use. This study aimed to initiate, enhance reporting and support the Pharmacovigilance program of India. **Methodology:** This prospective observational study on the evaluation of adverse drug reactions was carried out for 6 months with the approval of ethics committee. Using standard tools, data was collected in the Standard suspected ADR reporting form and assessed for causality, severity, and preventability. Complete data were collected until the discharge of the patient. **Results:** A total of 31 cases were recorded with 33 ADRs. The incidence of ADRs was predominant among the elderly (38.7%). ADRs were more prevalent in females (54.83%) than males. Hypertension was the commonly observed co-morbidity among the patients enrolled in the study. The most common suspected drug class was antibiotics (48.48%) followed by anti-hypertensive agents (12.12%). Type B adverse reactions were predominant (69.69%) with a higher incidence of cutaneous manifestations (51.61%). On Causality assessment using the WHO-UMC scale, the majority of the ADRs were Probable (83.87 %) and 6.45% were possible. Most of the ADRs were moderate (87.09%) in severity (Hartwig's scale), and the majority of ADRs were not Preventable (96.77%). **Conclusion:** This study provides a database of ADRs, which will help the healthcare professionals for optimum and safe use of the drugs.

INTRODUCTION: The World Health Organization (WHO) defines pharmacovigilance (PV) as the science and activities relating to detecting, understanding, and prevention of adverse effects or any other drug-related problems [1]. Medication safety monitoring is an essential element of healthcare system for high quality medical care.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.13(7).2787-93

This article can be accessed online on www.ijpsr.com

DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.13(7).2787-93

In view of it, nationwide Pharmacovigilance program of India (PvPI) was launched by the Ministry of Health and Family Welfare (MoHFW) in the year 2010. Indian Pharmacopeia Commission (IPC) under the MoHFW has been functioning as the National Coordination Centre (NCC) for PvPI since April 2011.Since then; PvPI regularly recommends the drug regulatory authorities and suggests the health care professionals (HCPs) towards safe use of the drugs.

Scenario of Reporting ADR in Hospitals: Three hundred and eleven ADR monitoring centers (AMCs) are established in various medical institutions/hospitals across India to monitor and collect ADR reports under NCC-PvPI [2].

Spontaneous reporting of ADRs is considered as the foundation of post-marketing drug safety surveillance [3]. The main function of spontaneous reporting is to detect early signals of new, rare, and serious ADRs. Under reporting of ADR's is a common problem in Indian PV system. There is an inadequate nationwide awareness and poor knowledge about PV among health care professionals [4].

Lack of knowledge of where and how ADRs should be reported also affects reporting. The reason for poor reporting includes no financial incentives, legal aspects, apprehension that the serious ADRs are already documented when a drug is introduced into the market and that a single report would make no difference, ignorance (that only serious ADRs are to be reported) and lack of time or overload [5].

Strategies Undertaken to Improve Reporting of ADR in Hospitals: The major drawback observed in India was poor reporting of ADRs. However, there is an improvement in reporting of ADR after regular training sessions and awareness programs conducted by IPC. A single countrywide specific reporting form should not only be used by the National Pharmacovigilance Centers but also by all registered hospitals, teaching hospitals, Primary health care centers, drug information centers, and pharmacies throughout India.

The Under reporting issues are resolved due to accessible reporting facilities like toll-free dial numbers, messages, mail, ADR forms with vernacular languages and outsourcing of PV activity by different multinational companies with awareness among the healthcare sector and public [6, 7]. In light of supporting PVPI, this study was undertaken to initiate and enhance ADR reporting in the hospital.

MATERIALS & METHODS: This prospective observational study was carried out at Vijaya Hospital for 6 months (March-August 2019), after getting approval from the Institutional Ethics Committee (IEC-VCMR)– EC/LTR/2019/049(F) of Vijaya Hospital. All inpatients greater than 18 years of age, of either sex with ADR, were enrolled with written informed consent. Outpatients, patients on chemotherapy, Pediatrics, History of drug abuse, Drug poisoning (intentional and unintentional), Materialistic reactions, and Reaction due to blood and its products were excluded from the study.

Complete data were collected from the case sheets individually, both by visiting the patients or by going through case sheets and consulting the treating clinicians. The data on demographics (age, sex, weight) details, co-morbidities, past and present medication, medical history, newly diagnosed disease, drug treatment regimens and all the lab parameters were collected.

Causality Assessment: Causality assessment (CA) is a method of evaluating the relationship between drugs exposed and reported adverse drug reactions. Causality assessment of ADRs was carried out by using the WHO-UMC scale [8]. Several criteria, as given below, were used to assess and categorize the identified ADRs in patients

- Time relationship between drug use and the adverse reaction.
- Absence of other competing causes.
- Response to drug on withdrawal or dose reduction (de-challenge).
- Response to drug on re-administration (re-challenge).

The ADRs were classified into Certain, Probable, Possible, Unlikely, Conditional (unclassified), and Unassessable.

Severity Assessment Scale - Hartwig's Scale: Seriousness of an ADR is related to its life-threatening nature. It defined as any untoward reaction to the medicinal product that may require inpatient hospitalization or may result in prolongation of existing hospitalization, or death. Hartwig's Severity Assessment Scale was used to evaluate the seriousness of reported ADR based on their life-threatening nature and were classified as Mild (level 1, level 2), Moderate (level 3, level 4), Severe (level 5, level 6, level 7) [9].

Preventability Scale - Schumock and Thornton: Modified Schumock and Thornton scale were used to identify the preventability of ADR, thereby improving drug use.

The preventability of the ADR was classified as Definitely Preventable, Probably Preventable, and not Preventable [10]. A regular follow-up of the patients until discharge was carried out.

The identified ADRs were documented in the Indian Pharmacopoeia Commission (IPC version 1.2) documentation form and were reported to the nearest Pharmacovigilance center. All the data collected was entered in Microsoft Excel. Descriptive data analysis was carried out and represented as percentage and frequency.

RESULTS: A total of 33 ADRs in 31 patients were recorded and assessed for 6 months. Among 31 patients, the incidence of ADRs was predominant among the elderly, i.e., > 60 years of age (38.70 %.) Adverse drug reaction observed with respect to age is depicted in **Fig. 1.**

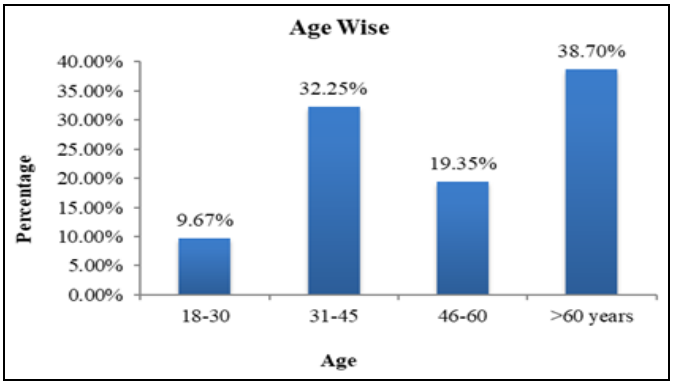

FIG. 1: AGE-WISE DISTRIBUTION OF THE STUDY POPULATION

Within the study population, female patients (54.83%) developed more ADR than Male (45.16%). Varied Comorbid condition is a risk factor for causing ADR. The distribution of co-morbidity among the study population is presented in **Table 1.**

TABLE 1: COMORBIDITIES AMONG THE STUDY POPULATION

Co- Morbidities	FREQ	Percentage (%)
Htn	10	32.25%
Type 2 DM	6	19.35%
Respiratory Disorder (Ba, Copd, Tb)	4	12.90%
Cad	3	9.67%
Hypo Thyroidism	3	9.67%
Malignancy	2	6.45%
Autoimmune Disease	2	6.45%
Cerebro Vascular Accident	1	3.22%
Renal Disease	1	3.22%

Polypharmacy adds on to the risk of causing ADRs. Among the study population, most patients had less than 5 medications (74.19%).

The distribution of concurrent medications with the suspected drug is depicted in **Fig. 2.**

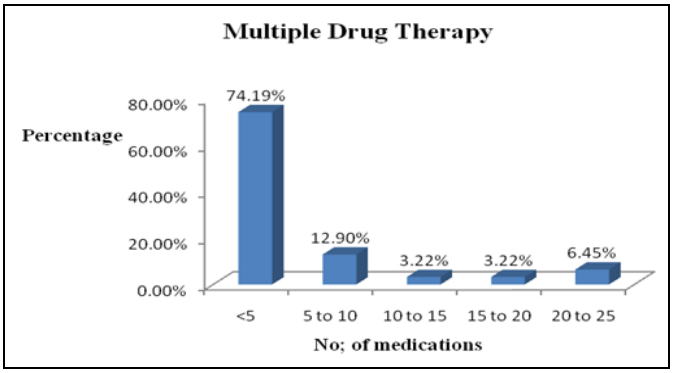

FIG. 2: NUMBER OF MEDICATIONS PRESCRIBED AMONG THE STUDY POPULATION

The ADRs were commonly observed in the department of general medicine (54.83%), followed by critical care (25.80%) and surgery (19.35%). Of the total (n=33) reactions observed, Type B ADR (69.69%) was predominant followed by Type A (21.21%).

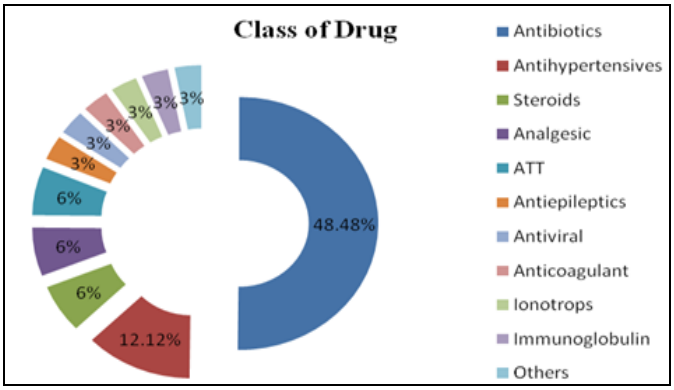

FIG. 3: CLASS OF THE DRUG INVOLVED WITH ADR

Incidences of Type C, D, and F were 3.03% each. Antibiotics were the major class of drug causing ADR, followed by other drug classes as shown in

Fig. 3. The distribution of various organs affected is depicted in **Fig. 4.**

Incidence of ADR was high in a patient receiving drug *via* the Intravenous route of administration (50%) followed by Oral (40.62%), Intradermal (6.25%), and nebulization (3.125%), Cutaneous Manifestations (n=16) was the commonly observed Adverse Drug Reaction followed by SJS (n=2) and Numbness (n=2).

The drugs involved in these reactions are depicted in **Table 2**.

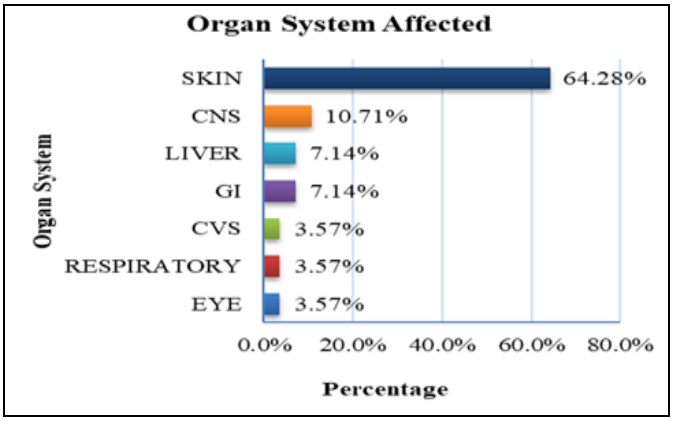

FIG. 4: ORGAN / SYSTEM AFFECTED BY ADR

TABLE 2: SPECTRUM OF REACTIONS AND THE DRUGS INVOLVED

Types of reaction	Drugs involved in reaction	Frequency (n= 26)
Cutaneous Manifestations	Cefoperazone+sulbactam (n=5), ofloxacin (n=1), clindamycin (n=1), tramadol(n=2), ciprofloxacin (n=2), immunoglobulin (n=1), rifampicin (n=1), piperacillin + tazobactam (n=1), iron (n=1), cefotaxime (n=1)	16
SJS	Phenytoin/Ofloxacin (n=1), cefuroxime (n=1)	2
Numbness	Polymyxin B	2
Obesity	Prednisolone	1
Insomnia	Tamiflu	1
Gingival hypertrophy	Amlodipine	1
Eye irritation and discharge	Phenytoin/Ofloxacin	1
Bronchospasm	Tobramycin	1
Acute gastroenteritis	Amoxicillin - clavulanate	1

Abnormal laboratory values were observed in 7 patients following drug administration. Hyperkalemia was observed with Aldactone-telmisartan, spironolactone (n=2), Hypernatremia with Amlodipine + indapamide (n=1), Elevated liver enzymes with ATT, warfarin (n=1), Elevated blood sugar with Methylprednisolone sodium succinate (n=1) and decreased BP with levosimendon (n=1).

Causality assessment of ADRs using the WHO-UMC scale indicated that most of the ADRs were probable, as illustrated in **Fig. 5.**

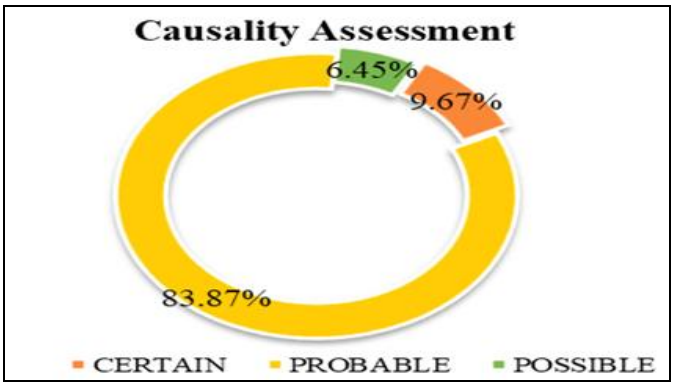

FIG. 5: CAUSALITY ASSESSMENT BASED ON (WHO-UMC SCALE)

The severity assessment of the ADRs indicated 85.29% as moderate, and 14,7% were mild. No severe cases were found during the study period. On the assessment of preventability, most of the ADRs that occurred were not Preventable (96.77%), followed by probably Preventable (3.22%), and none of ADRs were Preventable. About 75.75% of the patients with ADRs were managed by giving specific treatment, 12.12% required supportive care, and 12.12% required drug withdrawal. The fate of the suspected drug is shown in **Table 3.**

TABLE 3: FATE OF SUSPECTED DRUGS

Fate of suspected drug	Number of drugs (N=32)	Percentage (%)
De-challenged with treatment	**20**	**62.5%**
De-challenged only	9	28.12%
Substituted with same class of drug	1	3.125%
Re-challenged/ continued	2	6.25%

Upon follow-up of these patients, the outcome of the ADR was good, as 67.74% of the patients recovered from the ADR, 29.03% of the patients were recovering, and 3.22% does not recover

because of obesity. The duration of recovery from ADRs is represented in **Fig. 6.**

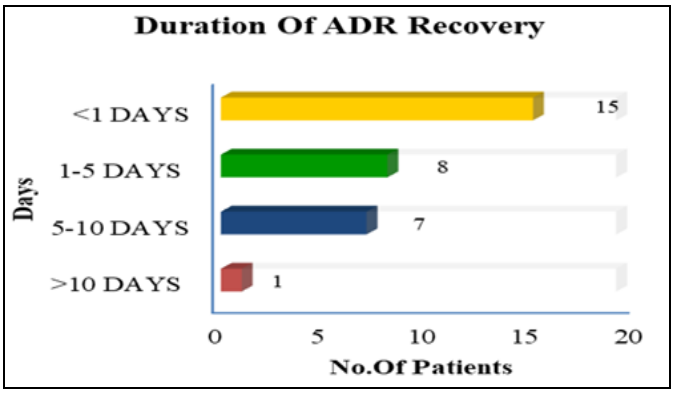

FIG. 6: DURATION INVOLVED FOR RECOVERY FROM THE ADR

DISCUSSION: This study identified and reported ADR among inpatients from various departments of a tertiary care hospital for 6 months. Age is a very important factor that affects the occurrence of ADRs. In our study, ADR incidence was predominant among the Elderly (38.7%). It is widely acknowledged that elderly patients are mainly at risk for ADRs [11-13], primarily due to increased chronic disease, polypharmacy (concomitant prescription of five or more drugs), and age-related physiological changes affecting the pharmacokinetics and pharmacodynamics of drugs. ADR incidences were more common among females (17(54.83%) than males. Interpretations of Global post-marketing surveillance data on spontaneous reports from individual case reports indicate that women, from puberty and onwards and especially in their reproductive years, report more ADRs than men [14].

The difference in susceptibility pattern of ADRs between male and female is due to the physiological characteristics, such as weight, intestinal transit velocity and fat percentage, and genetic/metabolic and hormonal differences [15]. Concomitant patient's disease may also influence susceptibility to ADRs. The commonly observed co-morbidities in our study population were HTN (32.25%), Type 2 DM (19.35%), Respiratory Disorder (12.9%), and CAD (19.67%). The was similar to a prospective cohort study done by Peter U Bassi *et al.,* 16 wherein 36% were hypertensive, 2.2% hypertensive with diabetes, 4.4% were diabetic, and 4.3% were asthmatic. Hypertension and diabetes are some of the factors responsible for causing drug-disease interaction [17]. Taking several drugs, whether prescription or over-the-counter, contributes to the risk of having an ADR. ADRs may occur due to drug interaction, synergism, and additive effect. Our study observed polypharmacy (>5 medications in a prescription) in only 8 patients. In a study by Marisa Rosimeire Ribeiro et al., higher number of medications used during their hospital stay showed a 10% increase in the rate of an overall adverse event indicating a positive correlation between the number of concomitant medications and ADR [18].

Alcohol affects the metabolism of many drugs, and it facilitates the development of ADRs. Smoking also affects the metabolic process by affecting liver enzymes acting as a potent inducer of the hepatic cytochrome P-450 (CYP) isoenzymes 1A1, 1A2, and, possibly, 2E1[19]. In our study, two patients were alcoholics, and one was a chronic smoker. Drug-independent cross-reactive antigens can induce sensitizations, manifesting as a drug allergy. The Frequent drugs involved were with sulfa antibiotics and β-lactams [20]. Among the 31 patients, 3 patients had a history of allergies to Diclofenac, Sulpha drugs & Penicillin, respectively. About 69.65% of the ADRs were Type B (69.649%), and one was Type F (telmisartan, aldactone), Type C (Amlodipine induced gingival hypertrophy) each. These findings were consistent with other studies that reported an increased incidence of Type B cutaneous manifestations [21, 22].

The adverse reaction can occur with any class of drugs. According to a study, the most troublesome class of drug contributing to Adverse Drug Reactions was antibiotics [23]. In our study, antibiotics (48.48%) were the most common class of drugs causing ADRs. A study by S. M. Shareef *et al.,* also showed a similar pattern. It is because of the routine practice of these drug groups for prophylactic or curative therapy [24]. In India, Cutaneous adverse drug reactions account for 2–5% of all inpatients and a common manifestation of allergic and non-allergic hypersensitivity [18]. In our study, cutaneous manifestations (51.61%) were prevalent, with a very low chance of prevention.

A study done by Pankaj Daulat *et al.* showed that 26% of the suspected ADRs reported during the study period were skin rashes with swelling [25].

Causality assessment is essential to confirm whether the reaction is because of the drug alone or other pre-disposing factors. Causality assessment was carried out using WHO-UMC scale, which showed a majority of the ADRs as Probable 26 (83.87 %) and (6.45%) were possible. Our study was consistent with a prospective observational study done by Meena Shrivastava *et al.,* which revealed that among 1475 ADRs, most of the ADRs belonged to probable (55.89%)followed by possible categories [26]. Among the suspected drug-causing ADR, about 93.75% of the patients were de-challenged with the drug, and 6.25% were re-challenged. Re-challenging in these cases was done based on the risk-benefit ratio. This was consistent with an observational study conducted by S.M. Shareef *et al.* [24] where 58.02% of the patients were de-challenged, and 38.80 were re-challenged.

Assessment of Severity is also essential to take action against the drug continuation. Most of the study population's ADRs were moderate 27 (87.09%). A study by Jamunarani R *et al.* reported moderate ADRs (66.7%), and no severe ADRs were found [27].

Assessment of Preventability helps In improving rational drug use. About 96.77% of the ADRs were not preventable. A prospective spontaneous reporting study by M. Shamma *et al.,* conducted in India, also reported that the incidence of ADRs was definitely preventable (55.10%) [28].

Altering a dosage regimen or withdrawing a medicine suspected of causing an ADR are common methods of managing ADRs in practice [29]. About 75.75% of patients with ADRs were managed with a specific treatment, mainly antihistamine and steroids, 12.12% of patients required supportive care treatment, followed by withdrawal of the drug (12.12%). Among the 33 ADRs, de-challenge of the suspected drug with specific treatment was given in 62.50% of the patients, de-challenge alone in 28.12%, and 3.125% were substituted with the same class of drug (diuretics- Dytor Plus was substituted with Dytor). This was consistent with the observational study by Jayanthi C R *et al.,* were the suspected drug was withdrawn, and medical treatment was given [30]. Among the study population, 67.74% of the patients recovered and managed well. This was consistent with a study by Meda Venkatasubbaiah *et al.,* which also reported a good outcome as most of the patients (67.74%) recovered after the drug withdrawal and/or with the treatment of ADRs [31].

As the majority of the patients (48.38%) had less severe hypersensitivity reactions, the duration of recovery was less than one day, and this was consistent with Brahadeesh Mayathevar *et al.*, which also reported improvement within 2-7 days (47.92%), indicating good recovery [32, 33].

CONCLUSION: Adverse reactions are a major inevitable risk factor associated with modern medicines. Identification, treatment, prevention, and reporting not only improve the patient's quality of life but will decrease hospitalization of patients due to ADR and the cost. With continuous awareness and motivation, reporting culture can be Improved through well organized and dedicated pharmacovigilance system in the hospital. Due to constraints in data collection and the short study period, this study was limited to inpatients. This study also affirms further research on possible intervention strategies to reduce ADR burdens among all patients.

ACKNOWLEDGEMENT: We are thankful to Dr. Shahjahan, O. M, Clinical Pharmacologist, Vijaya Hospital, for his clinical input during data collection.

CONFLICTS OF INTEREST: Authors declare no conflict of interest.

REFERENCES:

1. WHO. Definition of Pharmacovigilance. Geneva: WHO, 2002.
2. Kalaiselvan V, Mishra P and Singh GN: Helpline facility to assist reporting of adverse drug reactions in India. WHO South East Asia J Public Health 2014; 3(2): 194.
3. Rishi RK, Patel RK and Bhandari A: Under reporting of ADRs by medical practitioners in India—results of pilot study. Adv Pharmacoepidem Drug Saf 2012; 1(3): 112.
4. Güner MD and Ekmekci PE: Healthcare professionals' pharmacovigilance knowledge and adverse drug reaction reporting behaviour and factors determining the reporting rates. J Drug Assess 2019; 8(1): 13-20.
5. Kalaiselvan V, Kumar P, Mishra P and Singh GN: System of adverse drug reactions reporting: What, where, how, and whom to report? Indian J Crit Care Med 2015; 19(9): 564-6.
6. Amale PN, Deshpande SA, Nakhate YD and Arsod NA: Pharmacovigilance process in India: An overview. J Pharmacovigil 2018; 6(2): 259.

7. The use of the WHO–UMC system for standardised case causality assessment. Accessed from: http://www.who-umc.org/graphics/4409. pdf (last accessed on 2011 Feb 1)
8. Hartwig SC, Siegel J and Schneider PJ: Preventability and severity assessment in reporting adverse drug reactions: Am J Hosp Pharm 1992; 49(9): 2229-32.
9. Schumock GT and Thornton JP: Focusing on the preventability of adverse drug reactions. Hosp Pharm 1992; 27(6): 538.
10. Eric J. Thomas and Troyen A: Brennan. Incidence and types of preventable adverse events in elderly patients: population based review of medical records. British Medical Journal 2000; 320: 741-744.
11. Alessandro Oteri, GiampieroMazzaglia, Serena Pecchioli, Mariam Molokhia, Sinna PilgaardUlrichsen, Lars Pedersen, Elisabetta Poluzzi, Fabrizio DE Ponti, EdeltrautGarbe, Tania Schink, Ron Herings, Irene D. Bezemer, Miriam C.J.M. Stturkenboom and Gianluca Trifiro: Prescribing pattern of antipsychotic drugs during the years 1996–2010: A population based database study in Europe with a focus on torsadogenic drugs. British Journal of Clinical Pharmacology 2016; 82(2): 487-497.
12. Steinman MA and Hanlon JT: Managing Medications in Clinically Complex Elders: "There's Got to Be a Happy Medium". JAMA 2010; 304(14): 1592–1601.
13. Watson S, Caster O, Rochon PA and den Ruijter H: Reported adverse drug reactions in women and men: aggregated evidence from globally collected individual case reports during half a century. EClinical Medicine 2019; 17: 100188.
14. Soldin OP, Chung SH and Mattison DR: Sex differences in drug disposition. J Biomed Biotechnol 2011; 2011: 1-14.
15. Bassi PU, Osakwe AI, Ogar CK, Elagbaje C, Nwankwo BB,Balogun ST, Ntadom GN and Isah AO: Impact of co-morbidity on adverse drug reaction profile in a cohort of patients treated with Artemisinin combination therapies for uncomplicated malaria in Nigeria. Pharmacol Res Perspect 2017; 5(2): 1-8.
16. Nehad M Hamoudi: Does Hypertensive Patients are More Susceptible to the Risk of Drug-Drug Interactions? Edelweiss Pharma Analytic Acta 2019; 1(1): 27-30.
17. Ribeiro MR, Motta AA, Marcondes-Fonseca LA, Kalil-Filho J and Giavina-Bianchi P: Increase of 10% in the rate of adverse drug reactions for each drug administered in hospitalized patients. Clinics 2018; 73.
18. Alomar MJ: Factors affecting the development of adverse drug reactions (Review article). Saudi Pharm J 2014; 22(2): 83-94.
19. Stover KR, Barber KE and Wagner JL: Allergic Reactions and Cross-Reactivity Potential with Beta-Lactamase Inhibitors. Pharmacy (Basel) 2019; 7(3): 77. doi: 10.3390/pharmacy7030077.
20. Mammen SJ: A study of adverse drug reactions in a tertiary care Hospital of Pune. Pharma Tutor 2018; 6(8): 38-43.
21. Lihite RJ, Lahkar M, Das S, Hazarika D, Kotni M, Maqbool M and Phukan S: A study on adverse drug reactions in a tertiary care hospital of Northeast India. Alexandria Journal of Medicine 2017; 53(2): 151-6.
22. Sharma M, Baghel R, Thakur S and Adwal S: Surveillance of adverse drug reactions at an adverse drug reaction monitoring centre in Central India: a 7-year surveillance study. BMJ Open 2021; 11(10): e052737.
23. Shareef SM, Naidu CDM and Shreenivas R Raikar: Development, implementation and analysis of adverse drug reactions monitoring system in rural tertiary care teaching hospital in Narketiapally, Telangana. Interna J of Basic and Clinical Pharmacology 2015; 4(4): 757-760.
24. Pankaj Daulat, Ambika Abhishake V. J, Prabhakar Singh and Bhupendra Raj: A prospective study of adverse drug reactions in a tertiary care teaching hospital. IJBCP 2018; 7(10): 1965-1969.
25. Meena Shrivastava, Ganesh Uchit, AshishChakravarti, Gajanan Joshi, Mohini Mahatme and Harshaln Chaudhari: Adverse Drug Reactions Reported in Indira Gandhi Government Medical College and Hospital, Nagpur JAPI 2011; 59: 1-4.
26. Jamunarani R and Priya M: Analysis of Adverse Drug Reaction Related hospital admissions and Common Challenges Encountered in ADR reporting in a Tertiary Care Teaching Hospital. Asian Journal of Pharmaceutical and Clinical Research 2014; 7(1): 141-143.
27. Shamna M, Dilip C, Ajmal M, Linu Mohan P, Shinu C, Jafer CP and Mohammed YA: Prospective study on Adverse Drug Reactions of antibiotics in a tertiary care hospital. Saudi Pharm J 2014; 22(4): 303-8.
28. Coleman JJ and Pontefract SK: Adverse drug reactions. Clinical Med 2016; 16(5): 481.
29. Jayanthi CR, Debdipta Bose and Sushma M: Evaluation of pattern, predictability, severity and preventability of adverse drug reactions in the department of psychiatry at a tertiary care hospital in Bengaluru- a five years experience. International Journal of Research in Pharmacology and Pharmacotherapeutics 2017; 6(2): 182-190.
30. Meda Venkatasubbaiah, P. Dwarakanadha Reddy and Suggla V. Satyanarayana: Analysis and reporting of adverse drug reactions at a tertiary care teaching hospital. Alexandria Journal of Medicine 2018; 54: 599-603.
31. Brahadeesh Mayathevar, Dhivya Thiyagarajan, Thamilarasi Soundararajan, Vallish B. N and Rizwan S. A: A prospective study on adverse drug reactions reported in a tertiary referral hospital. IJBCP 2017; 6(1): 25-29.
32. Haripriya Simha, Syamalamarisarla and Mujeebuddin CS: Pharmacovigilance in India. IJPSR 2020; 63(1): 73-80.

How to cite this article:
Philip AE, Ezhilarasi AS, Rgautham V, Mattam MJ, Narayanan B, Prakasam A and Ramalakshmi S: Adverse drug reaction monitoring in a tertiary care hospital: a preliminary approach to enhance reporting. Int J Pharm Sci & Res 2022; 13(7): 2787-93. doi: 10.13040/IJPSR.0975-8232.13(7).2787-93.