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Research Article

Retrospective Analysis of Suspected Adverse Drug Reactions Reported in Tertiary Care Hospital

Saurabh K. Jain[1*], Amul Mishra[1], Vandana Goyal[2], Sunil K. Mathur[2]

[1]*Bhupal Noble's Institute of Pharmaceutical Sciences, Bhupal Nobel's University, Udaipur, Rajasthan, India .*
[2]*Department of Pharmacology, Jawaharlal Nehru Medical College and Associated Hospital, Ajmer, Rajasthan, India*

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ABSTRACT

In the past, pharmacovigilance happened 174 years back. In 1848, a little girl (Hannah Greener) died due to chloroform anesthetic before eliminating an infected toenail. The reason for death was investigated. Probably girl died of a lethal arrhythmia or pulmonary aspiration. 107 deaths occurred in the USA in 1937, due to the use of sulfanilamide elixir formulation prepared with the solvent used as a diethyl glycol. In 1961, happened the thalidomide disaster. Dr. McBride investigated this disaster; he investigated that the 1.5% incidence of congenital malformations in babies had greater than before up to 20% in women who had taken thalidomide medicine for medical treatment during pregnancy. The World Health Organization (WHO) Programme for International Drug Monitoring (PIDM) was launched by WHO in 1968, after the thalidomide disaster major changed the pharmacovigilance system globally, necessary to establish national systems for spontaneous Adverse Drug Reactions (ADR) monitoring and reporting after consumer use. To conduct a retrospective observational study of adverse drug reactions for inpatient and outpatient in the different clinical departments in a tertiary care hospital. In the present study, 749 adverse drug reaction reporting forms were reported, out of which 990 ADRs occurred in 749 patients (inpatients n=502,67.02% and outpatients n=247,32.97%). The overall incidence of ADR was found0.0194%. At least one ADR was recorded in 0.25% of the admitted patients (IPD) and in 0.0067% of the outdoor patients (OPD). In this study male to female ratio was (60.0%) & (40.0%). A total of (82.62%) of ADRs were found nonserious as compared to serious (17.37%). The majority of the ADRs were reported as gastrointestinal system disorders, type-A (60.40%), probable (86.0%), mild (52.72%), preventable (definitely 67.87% and probably 24.24%). Predisposing factors were associated with age (24.14%), polypharmacy (68.38%), and multiple and intercurrent diseases (15.75%). The studies concluded that most adverse drug reactions involved gastrointestinal system disorders and are mild, preventable, and have a probable causality relationship with the suspected drug. ADR monitoring systems monitor unlisted ADRs and other drug-associated problems that have not been recorded during a clinical trial and before regulatory authorities to identify signals of new and suspected unexpected unknown ADRs.

Introduction

Adverse drug reactions (ADR) is a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.[1] ADR occurs almost in hospitals and can harmfully affect a patient's safety, increasing morbidity and mortality rates. The epidemiological importance of ADR is justified by its high prevalence rate of 5% of all hospital admissions due to an ADR and approximately 10%-20% of the admitted patients will have at least one ADR during their hospitalization.[2] In that order, the prevalence of serious and fatal ADR in hospitalized patients is 6.7% and 0.32%.[3] When an ADR occurs, if serious in nature, a patient may need to relocate to a higher-level healthcare center for continuous monitoring and medical support, such as from a primary

***Corresponding Author:** Saurabh Kumar Jain

Address: Bhupal Noble's Institute of Pharmaceutical Sciences, Bhupal Nobel's University, Udaipur, Rajasthan, India.

Email ✉**:** saurabhpharma1983@gmail.com

Tel.: 9878681918

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healthcare center to the tertiary care hospital. The medical team, including doctors and nursing professionals, should evaluate every medicine prescribed during treatment to the patient to identify suspected drugs cause ADR.[4]

Hospital-based ADR monitoring and reporting system can provide scientific outcomes associated with medicines used in the hospital. Identifying the rare ADRs not listed in the Indian regulatory database and generating new signals, drug alerts, and changes in patient's information leaflet or package insert would improve a pharmacovigilance system on the ground level and by quality ADR monitoring and reporting under the pharmacovigilance program of India. However, healthcare professionals (physicians, pharmacists, nurses, dentists, etc.) are still less aware of ADR reporting, so many unlisted adverse incidents are unrecognized by the Indian population.[5]

A drug's safety is an essential part of a patient's safety and rational use of medicines. Benefit-risk assessment of pharmaceuticals product implemented throughout the life cycle of medicines from clinical trial to post-marketing stage. Pharmacovigilance data on adverse drug reactions were shared with WHO to strengthen drug safety globally; the WHO team took policy-level decisions for patients' safety and improved the quality of life.[6]

Developed countries like the USA, Japan, and the UK have a well-built pharmacovigilance research system as compared to India. In the current scenario, pharmaceutical and medical research institutions will focus on the research study about unlisted adverse drug reactions, drug alerts, and signals released from PvPI and emergency use approved drugs and newly approved drugs.

During the COVID-19 pandemic, unapproved drugs were used due to public health emergency. This allowed drug regulatory authority to approve unapproved medical products to be used in an urgent emergency to identify, treat or prevent COVID-19 infection. Emergency used drugs are needed to monitor closely to detect the possible adverse drug reaction. Therefore, continuous ADR monitoring (post-marketing surveillance) is essential throughout the drug's lifecycle to ensure medicine safety and patient safety.[30]

Materials and Methods

Study Design

This was a retrospective study. Which was carried out in the Department of Pharmacology, pharmacovigilance unit of Adverse Drug Monitoring Centre at Jawaharlal Nehru Medical College and Associated Hospital, Ajmer, Rajasthan (India).

Methodology

We utilized the spontaneously reported voluntary ADRs data of outpatients and inpatients from September 2017 to June 2020. This retrospective study was conducted after being approved by the Institutional Ethical Committee, letter No.1533Acad-III/MCA/2020 dated 30.07.2020, Jawaharlal Nehru Medical College and Associated Hospital, Ajmer, Rajasthan.

In the present study, all materials were used as patient's medical records including patient's medical history, laboratories reports of investigations, past adverse drug reactions, and medicines treatment charts along with dose, frequency, route and duration of treatment, follow-up information including disease course, development of new signs and symptoms, change in laboratory repeat investigation if any, consultation with the treating physician and other healthcare professional like nurses, pharmacists, laboratory technicians as per requirement.

Inclusion criteria

- The study included all the patients registered in Jawaharlal Nehru Hospital in the different departments.
- All suspected ADRs in patients following prescribed and self-medicated medications, either as inpatients or outpatients, were noted as per a voluntary, spontaneously ADR reporting system.
- Patients with ADR reports by healthcare professionals and themselves.

Exclusion criteria

- The ADRs due to other alternative systems of medicine such as ayurveda, homeopathy and unani were excluded.
- The ADRs due to medical devices & diagnostic kit etc. was excluded.
- The patients with known drug abuse and accidental poisoning with the drug or overdose.

Method of Collection of ADR Data

Healthcare staff was trained for ADR reporting through the suspected ADR reporting form and informed technical staff of proper documentation as per pharmacovigilance guidelines. Suspected ADR Reporting form was recorded for adverse reactions related to drugs with all the relevant data such as patient details including initials, age at the time of event or date of birth, sex, weight, reaction starting date and recovery date, description reaction details, suspected medications including dose, route, frequency, date of therapy started and stopped, indication, outcomes of event and reporter information.[7]

Evaluation of ADR Data

The collected suspected ADR form was verified by the committee members, analyzed, and evaluated to understand the ADR pattern with respect to patient demographics, reaction characteristics, characteristics or classification of the drugs involved, management, and outcome of reactions. Causality assessment, severity assessment, preventability, and the presence of predisposing factors for the reaction were analyzed.

Patient characteristics like age and sex were integrated for ADR evaluation. Patients are divided into the following age group: 0–4 years, 5–19 years, 20–44 years, 45–65 years, 66–74 years, and > 75 years.[8] We utilized the classification of drug reactions given by Rawlins and Thompson.[9] For system organ class as per the medical Dictionary for Regulatory Activities (MedDRA).[10] The seriousness of ADRs was divided according to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E2A guideline.[11] Drugs were classified according to the Anatomical Therapeutic Chemical [ATC] classification system as per WHO-ATC Index.[12] Regarding action taken due to ADRs, management was categorized as drug withdrawn, dose reduction, dose not changed, or additional treatment for ADR. The outcome was finalized after confirmation of dechallenge and rechallenge information.[7] Causality assessment was analyzed using the WHO-UMC assessment criteria.[13] The severity of ADRs was classified according to the modified Hartwig Siegel Scale.[14] The Preventability of ADRs was classified using the criteria of preventability assessment modified Schumock & Thornton Scale.[15,16] Predisposing factors were classified into age, gender, genetics, multiple and intercurrent disease state, and polypharmacy.[17,18] Polypharmacy was considered as three or more three drugs at the same time based on the characterization by Veehof *et al.*[19,20]

Statistical Analysis

This study used a descriptive statistical method to analyze ADR-related data.

Results

In the present study total of 749 adverse reactions were reported out of which 990 ADRs occurred in 749 patients reported in different clinical departments of the tertiary care hospital during the 34 months period. Most of the ADRs reported were from indoor patients (67.02%) and while only 32.97% were found from outpatients. Upon evaluation of the patient demographics male to female ratios were 446(60%) and 303(40%). The number of admitted patients and those who visited the hospitals as outpatients during the study period were 197,996 and 365,8041, respectively, making up a total of 385,60,37 (patients data collected from the hospital medical record department). On considering the incidence of ADRs among inpatients and outpatients, at least one ADR was recorded in 0.25% of the hospitalized patients and 0.0067% of outpatients. The frequency of ADRs in the patient population was found 0.0194%. Maximum numbers of ADRs 458 (46.26%) were reported in the adult age group between 20 to 44 years, compared to 17.57% children age group 0 to 19. The gender-wise ratio of ADRs among patients was male at 60.40% and female at 39.59% (Table1).

The total reaction reported majority have to type A reactions (60.40%) followed by type-B reactions (39.59%). As per WHO, causality assessment scale majority reports considered as probable were 86.26% followed by certain 7.57%, possible 5.35% and unlikely 0.8%. Reaction severity as per the modified hartwigsiegel scale accounted for mild 52.72%, moderate 43.33%, and only 3.93% of the reactions were severe. On the evaluation of the preventability of ADRs, it was evident that most of them were preventable 67.87% followed by probably preventable 24.24% and non-preventable 7.87% as per the modified Schumock and Thornton scale. The association of predisposing factors with adverse drug reactions had shown that at least one predisposing factor was present in (68.98%) of the reports. The most common predisposing factors were polypharmacy (68.38%), age (24.14%), Multiple and intercurrent diseases (15.75%) of reports, and 31.01% of ADRs were not associated with any predisposing factors (Table 2).

The organ system most commonly affected was gastrointestinal disorders (25.45%) followed by skin and subcutaneous tissue disorders (23.43%), general disorders & administration site conditions (16.16%) and nervous system disorders (8.48%). (Table 3)

The majority of ADRs were reported due to the suspect drug category of antituberculosis agents (40%) followed by the Anti HIV drugs (5.65%) while ceftriaxone sodium (4.1%) was the individual drug most frequently reported as the suspected drug in the reactions. (Table 4)

This shows that majority (89.85%) of the reports, the suspected drug was withdrawn for the management of the ADR followed by does not change (6%), not applicable (3.20%), dose reduced (0.8%) and unknown (0.13%). A total of (37.27%) of the ADRs were recovered, (0.6%) ADRs were recovered with sequelae, followed by not recovered (20.50%). After medical treatment, improvement in the adverse drug reaction was observed in a majority of the reports 40.90% at the ADR report time (Table 5).

The major share of the ADRs was reported from the department of respiratory medicine (43.39%), followed by the department of general medicine (24.03%), pediatric (9.07%) antiretroviral therapy Centre (7.34%), skin (6.40%), gastrointestinal (3.60%), psychiatry (2.67%), surgery (1.60%) (Table 6).

The distribution of ADRs based on seriousness was described in table no. 7(A) and 7(B). It is evident from this table that a total of 818 (82.62%) ADRs were found nonserious. We observed only 172 (17.37%) serious ADRs out of these serious reactions, and prolonged hospitalization was reported in 139(80.18%), followed by disability in 20 (11.76%) and life-threatening in 3 (1.74%) and other medically important conditions in 10 (5.81%) cases. No one was found death and with congenital

Table 1 A: Demographic distribution of ADRs according to hospital admission type including incidence rate (%)

Measure	*Number of patients associated with ADRs as per admission type*		*Total number of patients (%) associated with ADRsas per admission type*
	OPD	IPD	
Female	116	187	303(40)
Male	131	315	446(60)
Total number of patients with ADR	247	502	749
Number of patients	3658041	197996	3856037
Incidence rate (%)	0.0067	0.25	0.0194

Table 1 B: Age wise distribution of Patients with ADRs (i.e., ADRs 990)

Age Group	*(0-4)*	*(5-19)*	*(20-44)*	*(45-65)*	*(66-74)*	*Age>=75*
Number (%) of ADR reports	24 (2.42%)	150 (15.15%)	458(46.26%)	308(31.11%)	39 (3.93%)	11 (1.11%)

Table 1 C: Gender wise distribution of Patients with ADRs (i.e., ADRs 990)

Gender	*Number (%) of ADR reports*
Male	598 (60.40%)
Female	392(39.59%)
Total	990 (100%)

Table -2: Analysis of ADRs (Type of reaction, Causality assessment, Severity, Preventability and predisposing factors)

Reaction type	*Number of ADRs*	*Number of ADRs %*
Type-A (Augmented)	598	60.40
Type-B(Bizarre)	392	39.59
Grand Total	990	
Causality Assessment		
Probable	854	86.26
Certain	75	7.57
Possible	53	5.35
Unlikely	8	0.80
Grand Total	990	
Severity of ADRs		
Mild	522	52.72
Moderate	429	43.33
Severe	39	3.93
Grand Total	990	
Preventability		
Definitely preventable	672	67.87
Probably preventable	240	24.24
Non preventable	78	7.87
Grand Total	990	
Predisposing factors		
Age below 18 years age	138	
Age above 60 years age	101	24.14
Age Total	239	
Polypharmacy	677	68.38

Multiple and intercurrent disease	156	15.75
Gender	0	0
Genetics	0	0
Nil	307	31.01

Table 3: Organ Systems related disorder due to ADRs

Organ Systems	***Number of ADRs***	***(%) of ADRs***
Gastrointestinal disorders	252	25.45
Skin and Subcutaneous tissue disorders	232	23.43
General disorders and administration site conditions	160	16.16
Nervous system disorders	84	8.48
Investigations	65	6.56
Hepatobiliary disorders	61	6.16
Ear and labyrinth disorders	33	3.33
Blood and lymphatic system disorders	25	2.52
Musculoskeletal and connective tissue disorders	18	1.18
Psychiatric disorders	15	1.51
Immune system disorders	9	0.90
Eye disorders	9	0.90
Vascular disorders	7	0.70
Renal and urinary disorders	4	0.40
Cardiac disorders	4	0.40
Metabolism and nutrition disorders	3	0.30
Respiratory, thoracic and mediastinal disorders	3	0.30
Infections and infestations	3	0.30
Reproductive system and breast disorders	2	0.20
Injury, poisoning and procedural complications	1	0.10
Grand Total	990	100

Table: 4 Description of suspected drugs, individual reaction with frequency and total number of ADRs associated with drugs

Suspected drug/Active ingredient(s)	***ADRs(Frequency of occurrence)***	***Number of ADRs***
Pyrazinamide	Vomiting (60), Gastritis (19), Liver function tests abnormal (17), Joint pain (17), Nausea (6), Drug-induced hepatitis(5), Generalized itching (4), Renal function test abnormal (3), Raised serum uric acid (2), Epigastric pain (1), Generalized pruritus (1), Giddiness (1), Platelet dysfunction (1)	137
Rifampicin	Vomiting (75), Gastritis (24), Liver function tests abnormal (20), Nausea (9), Drug-induced hepatitis (5), Generalized itching (1), Hypotension (1), Pancytopenia (1), Renal function test abnormal (1)	137
Ethambutol+ Isoniazid+ Pyrazinamide+Rifampicin	Gastritis (16), Liver function tests abnormal (15), Vomiting (9), Renal function test abnormal (4), Drug-induced hepatitis (4), Raised serum uric acid (1), Itchy rash (1), Maculo-papular rash (1)	51
Ceftriaxone sodium	Generalized itching (8), Administration site swelling (7), Generalized rash (5), Generalized urticarial rash (4), Administration site induration (3), Administration site edema (2), Rigors (2), Vomiting (2), Administration site nodule (1), Itchy rash (1), Anaphylactic reaction (1), Localized itching (1), Burning sensation (1), Administration site rash (1), Burning sensation in eye (1), Erythematous Skin rash (1)	41

Isoniazid+ Pyrazinamide+ Rifampicin	Liver function tests abnormal (19), Drug-induced hepatitis (13), Vomiting (3), Renal function test abnormal (3), Dizziness (1), Generalized itching (1)	40
Efavirenz+ Lamivudine+ Tenofovir disoproxil fumarate	Generalized rash (14), Vertigo (9), Liver function tests abnormal (3), Renal function test abnormal (3), Breathlessness (1), Drug rash (1), Erythematous Skin rash (1), Abnormal dreams (1)	33
Kanamycin	Ototoxicity (18), Vertigo (2), Hearing impaired (1), Hypokalemia (1), Numbness of limbs (1)	23
Isoniazid	Generalized tonic-clonic seizure (5), Psychosis (3), Seizures (3), Drug-induced hepatitis (2), Liver function tests abnormal (3), Peripheral Neuropathy (1), Generalized pruritus (1), Peripheral nerve infection (1), Function liver abnormal (1), Generalized rash (1), Vomiting (1), Movements involuntary (1)	22
Cyanocobalamin+ Ferrous fumarate+ Folic acid	Administration site swelling (8), Administration site erythema (6), Injection site hyperpigmentation (1), Itchy rash (1), Injection site itching (1), Pustules on hand (1), Administration site rash (1), Administration site induration (1), Application site papules (1)	21
Blood, whole	Generalized rash (4), Generalized urticarial rash (4), Generalized itching (3), Itchy rash (2), Facial swelling (2), Febrile reaction (1), Rigors (1), Eye swelling (1), Hypersensitivity reaction (1)	19
Lamivudine+ Nevirapine+ Zidovudine	Deficiency anaemia (10), Haemolytic anaemia drug-induced (7), Generalized rash (1)	18
Diclofenac sodium+ Paracetamol	Fixed drug eruption (8), Vasculitis (2), Generalized urticarial rash (2), Toxic epidermal necrolysis (1), Facial swelling (1), Generalized rash (1), Glossitis (1), Generalized itching (1)	17
Vancomycin	Rash on face (3), Red man syndrome (3), Generalized itching (3), Itchy rash (2), Erythema (1), Generalized rash (1), Chills (1), Breath sounds decreased (1), Anaphylactic reaction (1), Facial swelling (1)	17
Tramadol	Administration site swelling (11), Administration site induration (2), Allergic rash (1), Haemolytic anaemia drug-induced (1), Abnormal eye movements (1)	16
Streptomycin	Giddiness (12), Tinnitus (1), Vertigo (1), Renal function test abnormal (1)	15
Haloperidol	Extrapyramidal syndrome (14), Generalized itching (1)	15
Linezolid	Peripheral Neuropathy (5), Blurring of vision (2),Numbness in leg (2), Optic neuritis (1), Peripheral nerve infection (1), Optic neuropathy (1), Deficiency anaemia (1), Anorexia (1),	14
Ofloxacin+ Ornidazole	Fixed drug eruption (9), Mouth ulcer (1), Stevens Johnson syndrome (1), Generalized rash (1), Laryngeal edema (1)	13
Diclofenac sodium	Administration site swelling (5), Fixed drug eruption (4), Stevens Johnson syndrome (1), Rash on leg (1), Administration site erythema (1), Generalized rash (1)	13
Atropine sulfate	Administration site swelling (8), Hypersensitivity reaction (1) Allergic rash (1), Administration site induration (1), Administration site erythema (1)	12
Metronidazole	Generalized itching (4), Fixed drug eruption (2), Drowsiness (1), Rash trunk (1), Small papule (1), Vomiting (1), Dizziness (1), Headache (1)	12
Albendazole	Chronic abdominal pain	12
Cycloserine	Psychosis (3), Suicidal tendency (2), Speech disorder (2), Pruritus (1), Burning feet syndrome (1), Depression (1), Abnormal behavior (1), Hallucinations (1)	12
Amoxicillin trihydrate+ Clavulanate potassium	Rigors (3), Fixed drug eruption (2), Antibiotic-associated diarrhea (2), Stevens Johnson syndrome (1), Facial swelling (1), Vesiculobullous rash (1), Generalized itching (1), Hypotension (1)	12
Metoclopramide	Extrapyramidal syndrome (10), Dystonia (1)	11

Ciprofloxacin	Generalized itching (2),Hand rash (1), Administration site swelling (1), Erythema (1), Injection site itching (1), Fixed drug eruption (1), Localized itching (1), Focal seizures (1)	9
Paracetamol	Fixed drug eruption (6), Administration site swelling (1), Maculo-papular rash (1), Generalized itching (1)	9
Snake venom antiserum	Shivering (3), Generalized urticarial rash (2), Generalized itching (1), Palpitation (1), Chills (1), Hypertension (1)	9
Ketamine	Administration site swelling (6), Administration site erythema (1), Hypersensitivity reaction (1), Application site redness (1)	9
Cefotaxime sodium	Generalized itching (3), Vomiting (2), Generalized urticarial rash (1), Urticaria localized (1), Administration site swelling (1), Generalized rash (1)	9
Ethambutol	Renal function test abnormal (2), Vitiligo (1), Burning feet syndrome (1), Generalized itching (1), Vomiting (1), Hair loss (1), Loss of vision (1)	8
Ibuprofen+ Paracetamol	Fixed drug eruption (4), Generalized rash (2), Generalized urticarial rash (1)	7
Phenytoin	Allergic rash, Gum hypertrophy, Generalized rash, Ataxia, Toxic epidermal necrolysis, Diplopia, Drug toxicity,	7
Ethionamide	Anorexia, Pruritus, Hallucinations, Breast pain, TSH increase, Burning feet syndrome, Depression	7
Diphtheria vaccine toxoid+ Pertussis vaccine+ Tetanus vaccine toxoid	Administration site induration (2), Seizure , Vomiting, Administration site swelling, Convulsion	6
Thiopentone	Administration site swelling (5), Hypersensitivity reaction	6
Iodine	Administration site swelling (4), Application site redness (2)	6
Folic acid+ Nicotinamide+ Vitamin B12	Administration site swelling (2), Localized itching, Generalized itching, Administration site erythema, Erythema	6
Glucose+ Sodium chloride	Rigors (2), Shivering, Chills, Generalized itching	5
Dicycloverine hydrochloride	Generalized urticarial rash (2), Generalized itching Administration site swelling	4
Carbamazepine	Generalized rash (2), Toxic epidermal necrolysis, DRESS syndrome	4
Aceclofenac+ Paracetamol	Toxic epidermal necrolysis, Stevens Johnson syndrome, Generalized urticarial rash, Skin peeling	4
Cefuroxime	Administration site induration (2), Localized itching, Administration site swelling	4
Ofloxacin	Fixed drug eruption (2), Toxic epidermal necrolysis, Facial swelling	4
Ibuprofen	Generalized itching, Hypotension, Fixed drug eruption, Generalized rash	4
Rabies antiserum	Administration site induration, Generalized rash, Facial swelling	3
Piperacillin sodium+ Tazobactam sodium	Administration site induration, Palpitation, Application site redness	3
Azithromycin	Administration site rash, Stevens Johnson syndrome, Generalized rash	3
Mecobalamin	Administration site swelling (2), Localized itching	3
Propofol	Administration site swelling (2), Erythema	3
Cefixime	Dyskinesia, Maculo-papular rash, Fixed drug eruption	3
Saccharated iron oxide	Administration site edema, Hypersensitivity reaction, Administration site swelling	3
Nevirapine	Facial swelling, Rash on leg, Generalized rash	3
Sodium lactate	Shivering (2), Rigors	3
Ondansetron	Administration site swelling (2), Generalized urticarial rash	3
Fluconazole	Fixed drug eruption (3)	3

Ethambutol dihydrochloride+Lomefl oxacinhydrochloride+ Protionamide+ Pyrazinamide	Hepatorenal failure, Gastritis	2
Ampicillin	Administration site swelling, Administration site erythema	2
Immunoglobulin human anti-rabies	Vertigo, Facial swelling	2
Vitamin b complex	Hypersensitivity reaction, Generalized rash	2
Amikacin sulfate	Generalized urticarial rash, Erythematous Skin rash	2
Bupivacain	Administration site swelling (2)	2
Ranitidine hydrochloride	Administration site swelling (2)	2
Gentamicin	Generalized itching, Drug-induced headache	2
Zidovudine	Deficiency anaemia (2)	2
Prochlorperazine maleate	Extrapyramidal syndrome, Dystonia	2
Metadoxine	Headache, Dizziness	2
Measles vaccine+ Rubella vaccine	Vomiting, Dizziness	2
Clomipramine	Drowsiness, Dizziness	2
Immunoglobulin anti-Corynebacterium diphtheriae	Erythematous Skin rash (2)	2
Pantoprazole	Hematoma, Administration site swelling	2
Fluoxetine	Drowsiness, Dizziness	2
Abacavir sulfate+ Lamivudine	Rash on leg, Haemolytic anaemia drug-induced	2
Glucose+ Potassium chloride+ Sodium chloride+ Sodium lactate	Rigors, Chills	2
Itraconazole	Function liver abnormal, Generalized rash	2
Glycopyrrolate	Administration site swelling (2)	2
Paclitaxel	Breathlessness	1
Cefoperazone sodium+ Sulbactam sodium	Hypersensitivity reaction	1
Cefalexin	Stevens Johnson syndrome	1
Ciprofloxacin hydrochloride+ Tinidazole	Fixed drug eruption	1
Ceftriaxone sodium+ Sulbactam sodium	Generalized urticarial rash	1
Thiopentone	Application site redness	1
Isoniazid+ Pyrazinamide+ Ethambutol	Vomiting	1
Rabeprazole	Pain in limb	1
Clindamycin	Administration site swelling	1
Glycopyrronium bromide	Administration site erythema	1
Chlorphenamine maleate+ Dextromethorphan hydrobromide	Toxic epidermal necrolysis	1
Clofazimine	Skin discoloration	1
Calcium chloride dihydrate+ Potassium chloride+Sodium chloride+ Sodium lactate	Skin peeling	1
Allopurinol	Cataract	1
Platelets	Itchy rash	1
Ketoconazole	Generalized rash	1
Pyridoxine	Itchy rash	1
Cefixime trihydrate+ Ofloxacin	Skin peeling	1
Levetiracetam	Mood depression	1
Salbutamol	Palpitation	1

Levofloxacin	Burning feet syndrome	1
Sulfa methoxazole+ Trimethoprim	Generalized rash	1
Amitriptyline hydrochloride	DRESS syndrome	1
Tranexamic acid	Injection site itching	1
Lopinavir + Ritonavir	Haemolytic anaemia drug-induced	1
Ornithine aspartate	Generalized itching	1
Measles vaccine	Administration site swelling	1
Paracetamol	Administration site swelling	1
Ibuprofen + Paracetamol	Fixed drug eruption	1
Pentazocine	Administration site swelling	1
Etoricoxib	Erythema multiforme	1
Levocetirizine	Generalized rash	1
Factor viii (antihaemophilic factor)	Genital itching	1
Levofloxacin	Pruritus	1
Folic acid+Iron	Generalized urticarial rash	1
Domperidone+Naproxen sodium	Fixed drug eruption	1
Quetiapine fumarate	Extrapyramidal syndrome	1
Multi B complex	Palpitation	1
Cyanocobalamin+Ferrous fumarate+ Folicacid+ Pyridoxine hydrochloride+ Zinc sulfate	Administration site swelling	1
Nalbuphine	Administration site swelling	1
Ranitidine hydrochloride +Domperidone	Fixed drug eruption	1
Domperidone+ Pantoprazole	Pruritus	1
Xantinol nicotinate	Nausea	1
Nimesulide	Fixed drug eruption	1
Atracurium	Administration site swelling	1
Nimesulide +Paracetamol	Fixed drug eruption	1
Acetylsalicylic acid	Drug-induced hypersensitivity syndrome	1
Norfloxacin+ Tinidazole	Fixed drug eruption	1
Thiamine hydrochloride	Administration site induration	1
Doxorubicin hydrochloride	Alopecia	1
Bupivacain	Application site redness	1
Doxycycline	Generalized urticarial rash	1
Chlorphenamine maleate	Generalized rash	1
Olanzapine	Extrapyramidal syndrome	1
Albumin human	Rigors	1
Ofloxacin	Administration site swelling	1
Dextrose and electrolyte	Erythematous Skin rash	1
Grand Total		990

anomaly due to serious ADRs in the present study (Table 7). In this study, stakeholders reporting the frequency of ADRs are depicted in Table 8. The majority of reporting was reported by physicians (88%) as compared with nursing staff (9%) and pharmacists (2%) and consumers (1%) (Table 8).

Discussion

Currently, adverse drug reaction is a major public health crisis globally. Drug safety monitoring is the accountability of all stakeholders of the healthcare system, including physicians, nursing professionals, pharmacists, and other paramedical staff. The joint responsibility of healthcare

Table 5: Management and outcome of the ADRs

Action taken	*Number*	*(%)*
Drug Withdrawn	673	89.85
Dose not Changed	45	6.00
Not Applicable	24	3.20
Dose Reduced	6	0.80
Unknown	1	0.13
Grand Total	749	
Final Outcome		
Recovered	369	37.27
Recovered with Sequelae	6	0.60
Recovering	405	40.90
Not Recovered	203	20.50
Unknown	7	0.70
Grand Total	990	

Table 6: Distribution of ADRs according to department-wise ADRs Reporting

	Number	*%*
Respiratory medicine	325	43.39
General Medicine	180	24.03
Pediatric	68	9.07
ART Centre	55	7.34
Skin & V.D.	48	6.40
Gastroenterology	27	3.60
Psychiatry	20	2.67
General Surgery	12	1.60
Community Medicine	8	1.06
Orthopedics	4	0.53
Oncology	2	0.26
Grand Total	749	

Table 7 A: Distribution of ADRs

Distribution of serious and non-serious ADRs	*Number*	*(%)*
Non-serious	818	82.62
Serious	172	17.37
Grand Total	990	

Table 7 B: Distribution of ADRs based on seriousness criteria as per ICH guideline

Caused/Prolonged hospitalization	139	80.81
Disabling/incapacitating	20	11.76
Life-threatening	3	1.74
Other medically important condition	10	5.81
Death	0	
Congenital anomaly	0	
Total	172	