



IJPPR

INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals

ISSN 2349-7203





Human Journals

Research Article

August 2020 Vol.:19, Issue:1

© All rights are reserved by Kaushik Y N et al.

Assessment of Adverse Drug Reaction in Pediatric Department of Tertiary Care Hospital

	
Kaushik Y N* , Athira TK, Maryam Sheykhholeslami, Umesh M, Ravish S R, Mahendrakumar BJ	
<i>Department of clinical pharmacy, Farooqia College of Pharmacy, Mysore, Karnataka. India</i>	
Submission: 24 July 2020	
Accepted: 30 July 2020	
Published: 30 August 2020	



HUMAN JOURNALS

www.ijppr.humanjournals.com

Keywords: Adverse drug reactions, pediatric patient, tertiary care hospitals

ABSTRACT

The objective of the present study was to assess the adverse drug reaction in pediatric patients. A prospective, observational study was conducted at CSI Holdsworth Memorial. Hospital for 6 months. Study approved by the institutional ethics committee. Patients from, Pediatrics, ICU, OBG, and Surgery were enrolled. The data was collected in a well-designed data collection form. A total of 155 patients were enrolled in the study. Among these 155 pediatric patients, 97 were male and 58 were female. Male patients were 24 (68.57%) and female patients were 11 (31.42%). Out of all patients admitted 120 (77.4%) were diagnosed with no ADR's, type1 patients are 11 (7.09%) type 2 patients are 24 (15.48%), where type3 patients are 0 (0%) and type4 patients are 0(0%). 35 reports were vomiting 7 (20%), diarrhea, 5 (14.28%), rashes 4 (11.42%), pallor 4 (11.42%), fever 3 (8.57%), nausea 2 (5.71%), tachypnea, 2 ((5.71%), cough 1 (2.85%), irritation 1(2.85%), drowsiness 1 (2.85%), constipation 1 (2.85%), hematochezia, 1(2.85%), headache 1 (2.85%), mouth ulcer 1 (2.85%) and tachycardia 1 (2.85%). Among which antibiotic is the class of drug causing the more number of ADR's with 12 (34.3%), other drugs responsible for ADR's are H2-blockers 6 (17.14%), antiemetic 4 (11.42%), anticonvulsant 3 (8.57%), proton pump inhibitors 2 (5.71%), anthelmintic 2 (5.71%), corticosteroid 2 (5.71%), analgesic 1 (2.85%), antiviral 1 (2.85%), benzodiazepine 1 (2.85%) and metal 1 (2.85%). The demographic data shows that the incidence of adverse drug reaction was more in males when compared to females. Most of the adverse drug reaction was caused by the antibiotic class of drug. The maximum adverse drug reaction caused belonged to type2 class. It was classified based on the severity of the reaction occurred.

INTRODUCTION:

ADR:

ADRs, also known as 'side effects', 'adverse drug events', or 'drug misadventures', are frequent causes of morbidity in hospitals and the community. They have a significant cost both financially and in terms of quality of life. Few studies of ADRs have been carried out in the community so the effect on primary care is harder to assess, but studies in the hospital environment have shown the following: ADRs occur in 10–20% of patients in a hospital, ADRs are responsible for 5% of admissions to hospital, ADRs might be responsible for 1 in 1000 deaths in medical wards, ADRs are the most common cause of iatrogenic injury in hospital patients. Adverse reactions to drugs are as old as medicines themselves and there is no drug without iatrogenic condition (drug-induced disease state).

The World Health Organization (WHO) defines an ADR as follows:

A drug-related event that is noxious and unintended and occurs at doses used in humans for prophylaxis, diagnosis, or therapy of disease or the modification of physiological function.

However, this definition does not take into account the following scenarios, all of which can also cause ADRs: Overdose (including prescribing or administration errors), therapeutic failure, drug interactions, and Drug withdrawal.

Whereas according to FDA, An ADR is any undesired experience associated with the use of a drug, whether or not considered drug-related, and include any side effect, injury, toxicity or sensitivity reaction or significant failure of expected pharmacological action. The terms ADR and adverse drug effects can be used interchangeably.

MATERIALS AND METHODS:

Study Design and Setting

This was a Prospective cohort study. Conducted over 6 months of September 2018 – May 2019 in hospitalized patients of CSI Holds worth Memorial (Mission) Hospital, Mysore. The study was approved by the Institutional Ethics Committee of Farooqia College of Pharmacy, Mysore, and written consent was taken from parents.

A specially designed data collection form was devised for the study, The data collection form had provision for collecting key information like demographic details (name, age, and gender), clinical data like (the reason for admission, past medical history, diagnosis, comorbidities), treatment chart (name of the drug, dose, frequency, route, duration of administration). The treatment chart and all the prescriptions were reviewed to identify the ADRs of pediatrics in tertiary care hospitals.

The data collection and assessment form designed for use in this study was computerized using Microsoft word 2016 and Microsoft excel 2016 for easy storage, accessibility retrieval and analysis of data and excel has been used to generate graphs, tables, etc.

RESULTS AND DISCUSSION:

155 case sheet of pediatrics patients admitted to CSI Holdsworth Memorial Hospital, were analyzed. Among these 155 pediatrics patients, 97 were male and 58 were female.

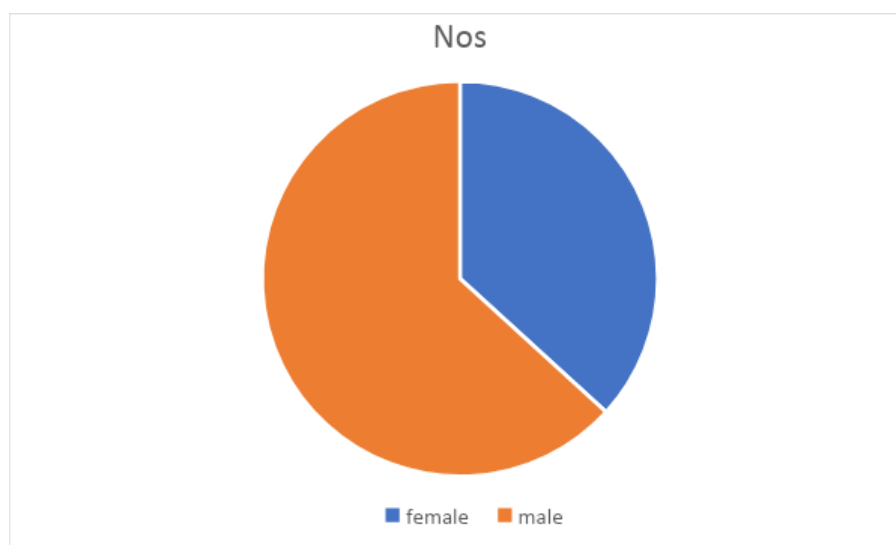


Figure No. 1: percentage of male and female pediatrics patients

GROUPING OF PEDIATRIC PATIENTS

Neonate 0 – 30 days

Infant: 1 month - 2 years

Young child: 2 years - 6 years

Child: 6 years - 12 years

Adolescent: 12 years - 18 years

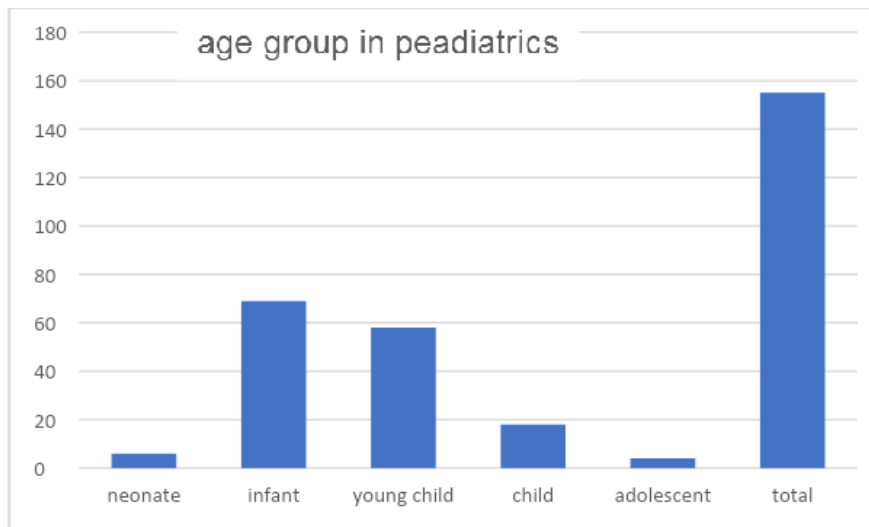
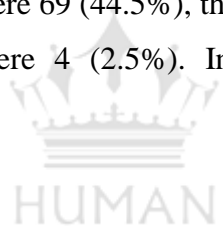


Figure No. 2: Age group in pediatrics

The 155 case sheets of pediatrics patients collected contained a different age group of people like neonates was 6 (3.8%), infants were 69 (44.5%), the young child was 58 (37.4%), a child was 18 (11.6%) and adolescent were 4 (2.5%). Infant and young children are more susceptible to disease.



Gender-based ADRs:

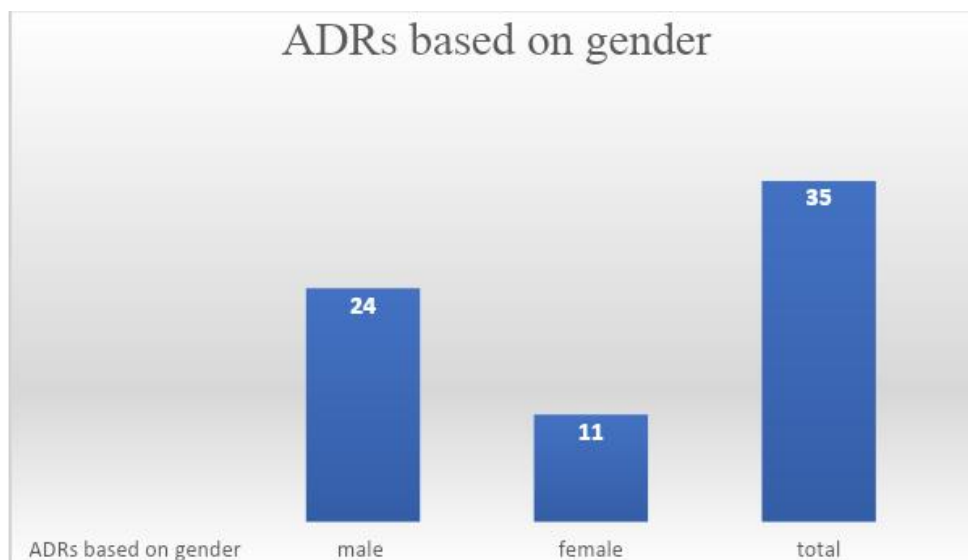


Figure No. 3: Gender-based ADRs

Out of 155 patients, 35 patients were diagnosed with ADR's (22.5%) which included both male and female patients. Male patients were 24 (68.57%) and female patients were 11 (31.42%) all patients were newly detected with ADR's.

Types of ADRs:

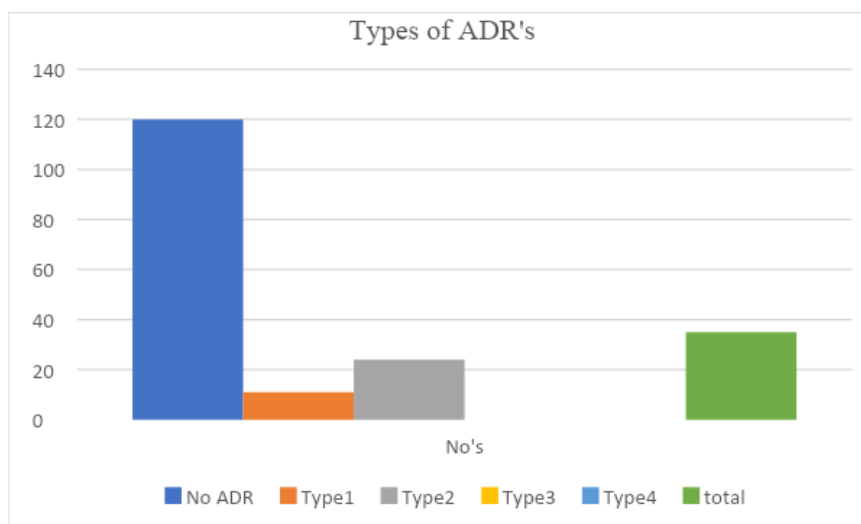


Figure No. 4: Types of ADRs

ADR's are classified into 4 groups based on their severity, minor, moderate, severe, and lethal ADR's. Out of 155 patients admitted 120 (77.4%) were diagnosed with no ADR's, type1 patients are 11(7.09%) type2 patients are 24 (15.48%), where type3 patients are 0 (0%) and type4 patients are 0(0%).

ADRs reported:

The ADR's reported from 155 case sheets which contained 35 reports were vomiting 7 (20%), diarrhea 5 (14.28%), rashes 4 (11.42%), pallor 4 (11.42%), fever 3 (8.57%), nausea 2 (5.71%), tachypnea 2 ((5.71%), cough 1 (2.85%), irritation 1(2.85%), drowsiness 1 (2.85%), constipation 1 (2.85%), hematochezia 1(2.85%), headache 1 (2.85%), mouth ulcer 1 (2.85%) and tachycardia 1 (2.85%). The ADR's reported are belonging to type1 and type2 class.

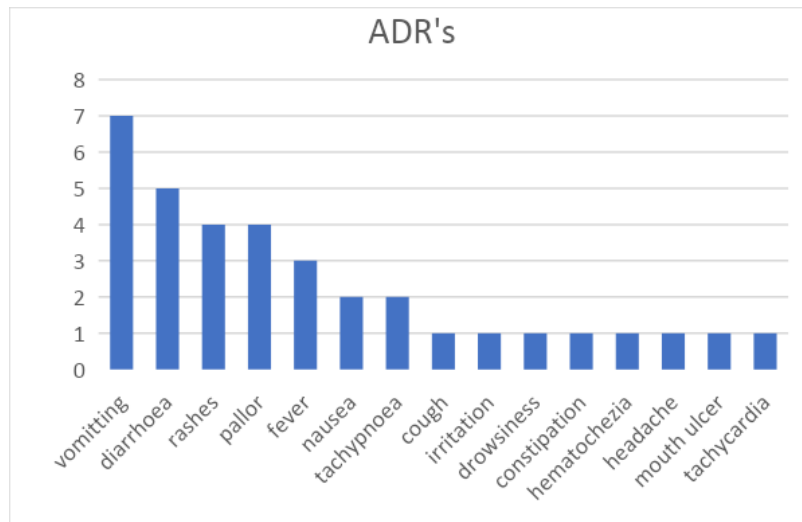


Figure No. 5: ADRs reported

Drugs involved in causing ADRs:

Among the 35 ADR's the drugs involved are ranitidine 8 (22.85%), Ondansetron 4 (11.42%), azithromycin 3 (8.57%), Doxycycline 3 (8.57%), Amikacin 2 (5.71%), ceftriaxone 2 (5.71%), hydrocortisone 2 (5.71%), Phenobarbitone 2 (5.71%), Vancomycin 2 (5.71%), Albendazole 2 (5.71%), folic acid 1 (2.85%), Fosphenytoin 1 (2.85%), Clobazam 1 (2.85%), Paracetamol 1 (2.85%) and oseltamivir 1 (2.85%).

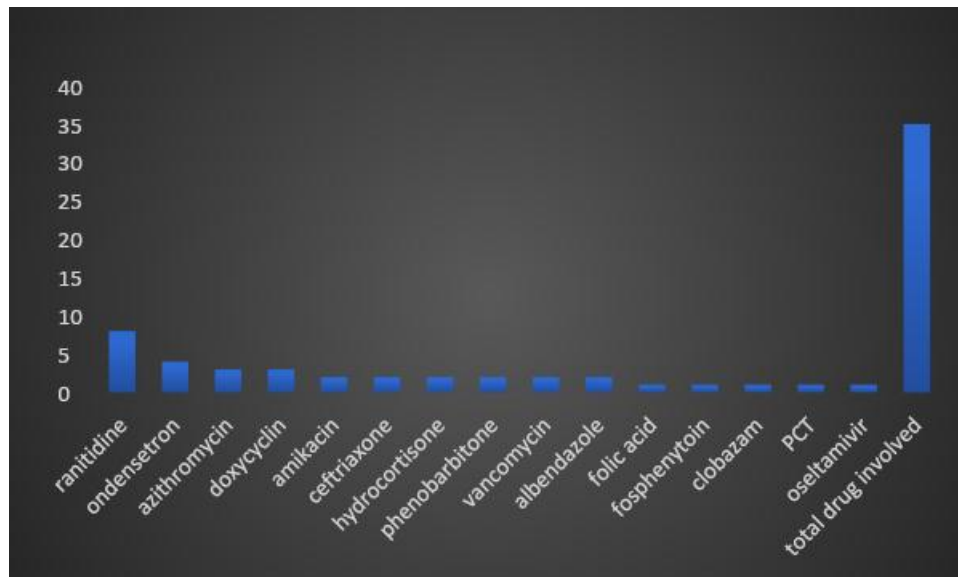


Figure No. 6: Drugs involved in causing ADR

Classes of drugs administered to patients

During the study of the ADR's the drugs therapy administered to the patients which included antibiotic 188 (26.4%), antiemetic 67 (9.41%), metal 37 (5.19%), probiotic 36 (5.05%), multivitamin 35 (4.91%), calcium supplement 20 (2.80%), NSAIDS 99 (13.90%), alpha beta adrenergic agonist 14 (1.96%), antiviral 12 (1.68%), bronchodilator 10 (1.40%), diuretic 7 (0.98%), antifungal 5 (0.70%), anticonvulsant 3 (0.42%), proton pump inhibitors 3 (0.42%), calcium channel blockers 2 (0.28%), sedative 2 (0.28%), anticholinergic 1 (0.14%), antiepileptic 1 (0.14%), electrolyte supplement 1 (0.14%), laxative 1 (0.14%), oxygen supplement 1 (0.14%) H2-blockers 43 (6.03%), anthelmintic 20 (2.80%), corticosteroid 17 (2.38%), nasal decongestants 17 (2.38%), analgesic 15 (2.10%), benzodiazepine 14 (1.96%), antihistamine 10 (1.40%), lactase supplement 10 (1.40%), beta blockers 6 (0.84%), mucolytic 4 (0.56%), ORS 3 (0.42%), antispasmodics 2 (0.28%), oral encephalinase inhibitor 2 (0.28%), 5HT3 receptor blocker 1 (0.14%), anti-diarrheal 1 (0.14%), antiprotozoal 1 (0.14%) and mineral supplement 1 (0.14%).

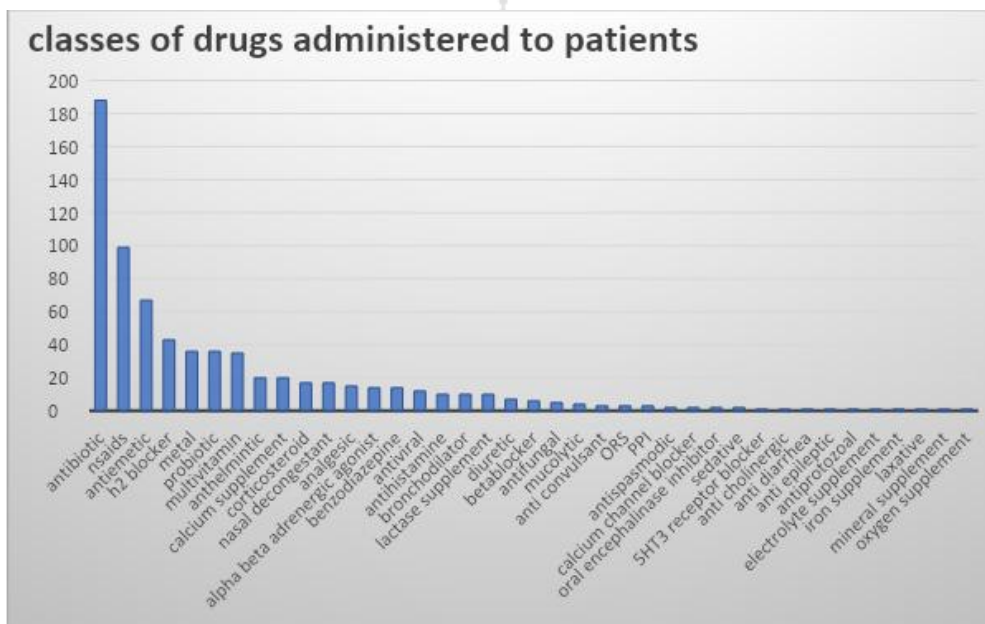


Figure No. 7: classes of drugs administered to patients

Classes of drugs causing ADRs:

Among the drug administered to the patient antibiotic is the class of drug causing the more number of ADR's with 12 (34.3%), other drugs responsible for ADR's are H2-blockers 6 (17.14%), antiemetic 4 (11.42%), anticonvulsant 3 (8.57%), proton pump inhibitors 2 (5.71%), anthelmintic 2 (5.71%), corticosteroid 2 (5.71%), analgesic 1 (2.85%), antiviral 1 (2.85%), benzodiazepine 1 (2.85%) and metal 1 (2.85%).

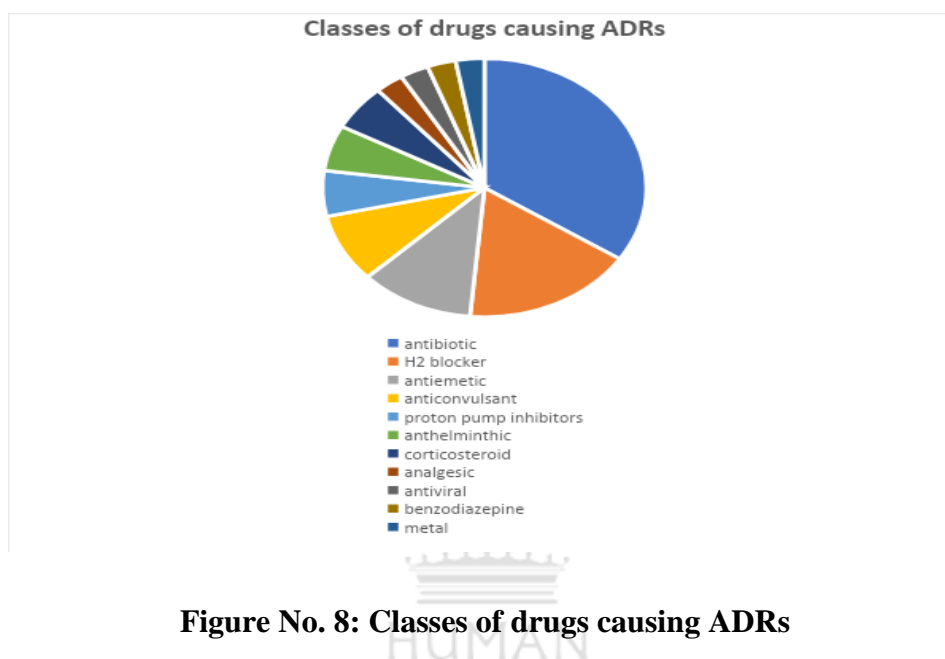


Figure No. 8: Classes of drugs causing ADRs

CONCLUSION:

Adverse Drug Reaction is a response to a drug which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function. The study was conducted in CSI Holdsworth Memorial Hospital concludes that among 155 patients, the demographic data shows that the incidence of adverse drug reaction was more in males when compared to females. Most of the adverse drug reaction was caused by the antibiotic class of drug. The maximum adverse drug reaction caused belonged to type 2 class. It was classified based on the severity of the reaction occurred. The drugs involved in causing adverse drug reactions are ranitidine, ondansetron, azithromycin, doxycycline, amikacin, ceftriaxone, hydrocortisone, phenobarbitone, vancomycin, albendazole, folic acid, fosphenytoin, clobazam, paracetamol, and oseltamivir. Vomiting is the adverse drug reaction reported in large numbers from the 35 patients who were analyzed out of 155 patients. Maximum adverse drug reaction is caused by the drug ranitidine.

REFERENCES:

1. Douglas W Strom et al. Continuous antibiotic prophylaxis in pediatrics urology 2018.
2. David R Nash et al. Antibiotic prescribing by primary care physicians for children with upper respiratory tract infection. Arch Pediatrics Adolescent hMed.2002; 156:1114-1119.
3. Matthew P Kronman et al. Ambulatory Visit rates and antibiotic prescribing for children with pneumonia, 1994-2007.
4. Joseph M Wiley MD Fungal infections in pediatric immune-compromised patients: Epidemiology, principles of treatment, and promising anti-fungal agents: S74-S80.
5. Brice Amadeo et al. European surveillance of antibiotic consumption (ESAC) POINT Prevalence survey2008: pediatrics antimicrobial prescribing in 32 hospitals of 21 European countries: 2247-2251.
6. M Shamna et al. A prospective study on adverse drug reactions of antibiotics in a tertiary care hospital.
7. Antonio Boccazi et al. The decision-making process in antibacterial treatment of pediatric upper respiratory infection: A national prospective office-based observational study.2002; 103-107.
8. Mathew p et al. Ambulatory visit rates and antibiotic prescribing for children with pneumonia, 1994-2007; 411-417.
9. Anita L et al. Evidence-based prescribing of antibiotics for children: role of socioeconomic status and physician characteristics. July 20, 2004; 139-145
10. Walter Alfredo Goycochea-Valdivia et al. identifying priorities to improve pediatrics in-hospital antimicrobial use by cross-section of prevalence and appropriateness' of prescription; 13 Sep. 2016.

