IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Human Journals
Research Article
August 2022 Vol.:25, Issue:1

Assessment of Drugs Used in Paediatric Department for Their Off-Label Use in a Private Tertiary Care Teaching Hospital

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Submitted: 22 July 2022
Accepted: 28 July 2022
Published: 30 August 2022

Keywords: Off-label, Paediatrics, Clinical trials, Evidence.

ABSTRACT

Pediatrics is a branch of medicine dealing with the development, of diseases, and disorders in children. Off-label use is the use of pharmaceutical drugs outside the product license for an unapproved indication, unapproved age group, unapproved dosage, or unapproved form of administration. Off-label prescribing is the most common problem in pediatrics due to a lack of clinical trials in children and sometimes leads to ADR, morbidity, or mortality. The objective was to identify and assess the off-label drug use in the selected patients and to create evidence of off-label drug use patterns based on references like MICROMEDEX and SmPC. During the study, a total of 60 patients were enrolled based on inclusion and exclusion criteria. A total of 76 different drugs were prescribed and out of them, 14 different drugs were prescribed for off-label use. The results show that nearly 18.4% of drugs were prescribed as off-label drugs. Antibiotics were prescribed in the highest proportion (21.73%) followed by antipyretics (15.34%). Off-label drugs were prescribed more in children (2-12 years) (50%). The off-label drugs identified were categorized for off-label category based on the age, dose, frequency, indication, and safety and efficacy not established. The most common off-label category was found to be dose (36.95%). The study concluded that there is a need for strict drug regulation for the pediatric population to ensure the safety and effectiveness of pharmacotherapy. The study also emphasizes the necessary role of clinical pharmacists in creating pieces of evidence and substituting the therapy which might be useful for health care professionals.

INTRODUCTION:

The off-label use of medicines is more common in children because clinical trials are conducted to a lesser extent in children due to their ethical challenges and vulnerability. Off-label prescription of medication can lead to medication errors since dose calculation must be individualized for each child[1]. Off-label marketing by the pharmaceutical industry is regarded as an offense under the drug and magic remedies Act, 1954[2,3]. Off-label drugs are commonly used in sick neonates and pediatric practice[4]. Syed et al. conducted a study on 320 patients in the pediatric ward of a general hospital. Of the 1,645 prescriptions, 310 (19%) received at least one off-label drug. Studies have reported that 70% of off-label drug use, is mainly due to higher doses and age restrictions[5]. In one study, they found that 50.3% of 75% of prescriptions were not FDA-approved for neonatal use[6]. Bavedkar et al (2009) reported that anti-infectives were the most common among off-label drug[5,6.] The most common reason for off-label use was dose change, followed by age and indication from S.Jain et al. study[7.] In a policy statement submitted to the Ministry of Health, the association stated that doctors in India should be able to prescribe off-label medicines if there is scientific evidence to justify off-label treatment [8].

Off-label use allows unregulated experimental use of drugs. Research standards are lacking because there is no standard drug design, documentation, and statistical analysis. Studies have shown a significant association between off-label medication and adverse drug reactions [9,10,11]. Topical off-label use of drugs has been associated with adverse drug reactions but had less impact than systemically administered drugs [12] incorrect medication beyond its Summary of Product Characteristics (SmPC) has also been associated with adverse drug reactions[13]. The Significance of the study is to find out the list of off-label drug use with their reason and to create evidence in the future to avoid medication errors and adverse drug events in the pediatric population.

MATERIALS AND METHODS:

A prospective observational study was carried out in the pediatric department of a multispecialty teaching hospital, located in Siddhapudur Coimbatore. The study was conducted for six months (December 2020 – June 2021). Ethical committee permission (EC/2021/0501/CR/15) was taken before initiating the study.

Inclusion criteria: All the patients getting admitted to NICU, PICU, and pediatric ward, aged 12 years or less than 12 years of either gender, or willing to participate in the study were included.

Exclusion criteria: Patients aged above 12 years, outpatients, patients with insufficient data in their records, and patients who were not willing to participate in the study were excluded.

Data collection: A specially designed data entry form was prepared to document patient details such as age, gender, disease conditions, and drug therapy details with dose, frequency, off-label uses, and off-label categories. The details were collected after informing the patient (Patient Information Format) and obtaining their written consent (Patient Consent Format). The procured data were analyzed to identify medication off-label use of drugs. To identify the off-label drugs, we used Micromedex, SmPC, and the National Formulary of India 2011 according to Table 2. A total of 132 patient case sheets, out of which 60 patients matched our inclusion and exclusion criteria were examined to assess off-label drugs.

RESULTS:

Demographic Profile:

The total number of patients included in the study was 60 of which 27(45.0%) were males and 33(55.0%) were females. The results on gender categorization revealed that the male population was higher than the female population. (Table no:1, figure no: 1)

Table no: 1- Gender distribution

GENDER	NO.OF PATIENTS	PERCENTAGE
MALE	33	55%
FEMALE	27	45%
TOTAL	60	100%

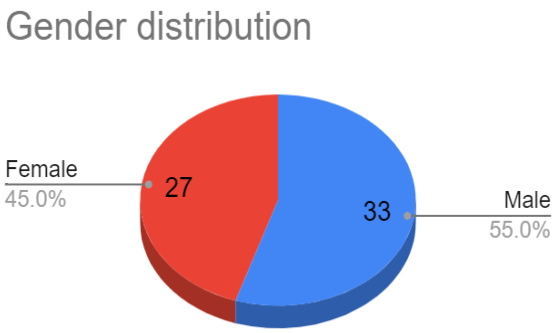

Figure no 1: Gender distribution

The study population was categorized based on their age as per development through life. The most predominant group was children who account for 61.7% of the overall population. This was followed by infants (Table no:2, Figure no: 2).

Table no:2- Age distribution

Age Groups (Years)	Frequency	Percentage
Neonates(0-28 days)	1	1.7%
Infants(>28days-2years)	20	33.3%
Children(2years-12years)	37	61.7%
Adolescents(12years-18years)	2	3.3%
Total	60	100

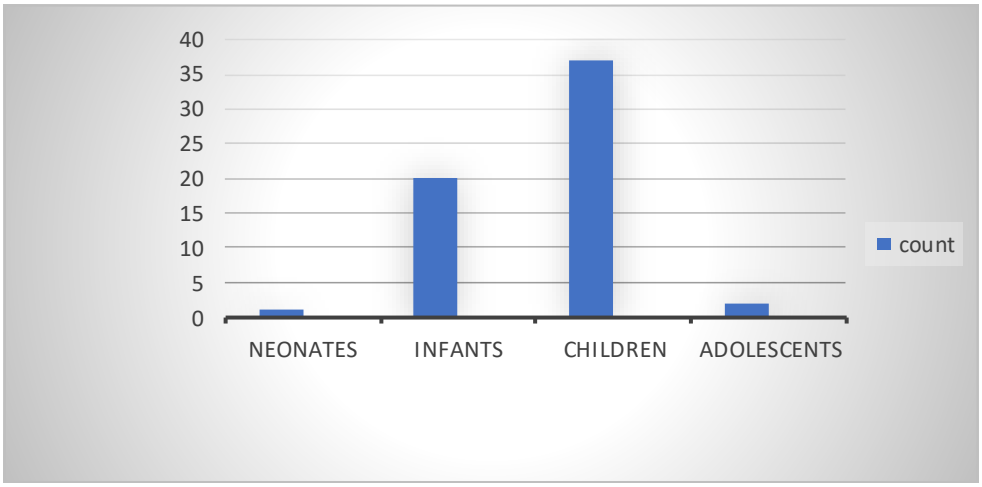

Figure no: 2 Age distribution

Table no 3: off-label use reference Reasons for admission:

S.NO	OFF-LABEL DRUGS	OFF-LABEL CATEGORY	OFF-LABEL USE	FDA-APPROVED USE
1	Pantoprazole	Indication	1)Acute gastroenteritis 2)Drug-Induced gastrointestinal prophylaxis 3)GERD 4)Helicobacter pylori gastrointestinal tract infection 5) Ulcer of the duodenum	1)Errosive esophagitis, maintenance therapy-gastroesophageal reflux disease 2)Erosive esophagitis-Gastroesophageal reflux disease 3)Gastric hypertension, pathological 4)Zollinger-Ellison syndrome
		Safety and efficacy not established	safety and efficacy not established in infants	safety and efficacy not established in infants
		Frequency	Given for more than once daily	20mg OD, 40mg OD
		Age	Prescribed for patients less than 5 years	Recommended for patients 5 years and older
2	Ceftriaxone	Dose	Increased dose	50-75 mg/kg/day IV/IM in divided doses every 12 hours
3	Propranolol	Indication	1)Anxiety 2)Burn, Post-event hypermetabolism 3)Congenital long QT syndrome 4)Congenital heart failure 5)Gastrointestinal hemorrhage 6)Percutaneous Coronary intervention 7)Portal hypertension 8)Retinopathy of prematurity 9)Supraventricular tachycardia, Prophylaxis, and	1)Angina pectoris 2)Cardiac dysrhythmia 3)Essential tremor 4)Hypertension 5)Migraine 6)Pheochromocytoma 7)Postmyocardial infarction syndrome

			treatment in infants 10)Thyroid storm 11)Thyrotoxicosis	
4	Tramadol	Safety and efficacy not established	Safety and efficacy have not been established in pediatric patients	Safety and efficacy have not been established in pediatric patients
5	Ondansetron	Age	Prescribed at 2 years of age	Approved for 4-11 years of age
6	Paracetamol	Dose	A lesser dose is given	15mg/kg
		Frequency	Once daily dose	15mg/kg/q6h
7	Clobazam	frequency	5mg PO BD	5mg PO once daily
8	Spironolactone	Safety and efficacy not established	Safety and efficacy not established in pediatric patients	Safety and efficacy not established in pediatric patients
9	Ofloxacin	Safety and efficacy not established	Given in age less than 18 years	Safety and efficacy not established in the oral dosage form in patients less than 18 years of age
10	Silymarin	Safety and efficacy not established	Safety and efficacy not established in pediatric patients	Safety and efficacy not established in pediatric patients
11	Lansoprazole	Safety and efficacy not established	Safety and efficacy not established	Safety and efficacy not established, No more effective than placebo in 1months-1years
12	Levetiracetam	Dose	Higher than the required dose is given	10mg/kg/day orally in 2 divided doses
13	Amikacin	frequency	OD daily dose is given	15mg/kg/day IV/IM divided every 8 hours
14	Metronidazole	Safety and efficacy not established	Safety and efficacy not established	Safety and efficacy not established

It was found that chief complaints were fever, fatigue, vomiting, and headache (Figure no:3).

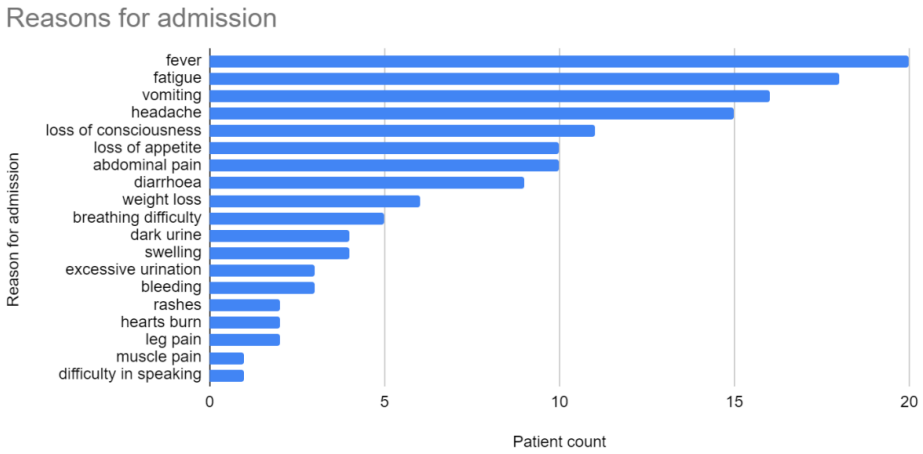

Figure No 3: Reasons for admission

Diagnosis:

The provisional diagnosis of the study population was also analyzed and the common diagnosis was found to be viral fever, febrile seizure, acute gastroenteritis, and UTI (Figure no:4).

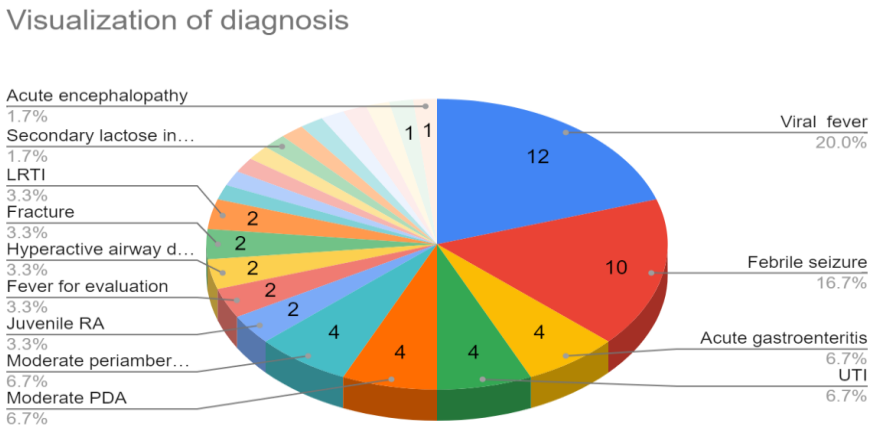

Figure no:4 – Diagnosis

LIST OF ALL DRUGS PRESCRIBED:

A total of 76 different drugs were prescribed to the study population. Analysis revealed that the majority of the study population had received antibiotics (21.73%) and antipyretics (15.34%). It was also found that ceftriaxone, paracetamol, pantoprazole, and ondansetron were prescribed in the highest proportion (Figure no:5).

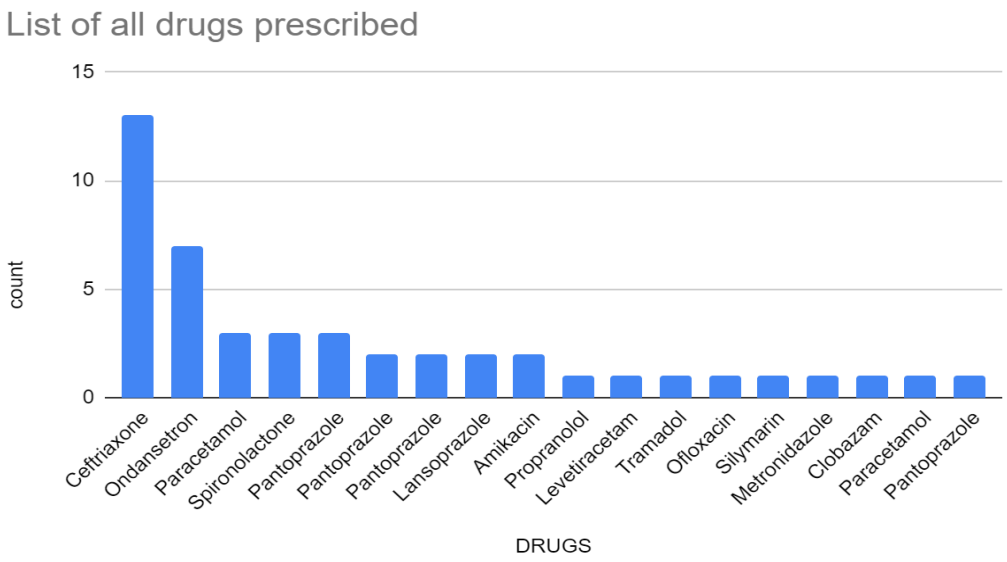

Figure no: 5- list of all drugs prescribed

ROUTES OF ADMINISTRATION:

Routes of administration of prescribed drugs were also analyzed. The results revealed that the most commonly used route of administration was injectables (49.5%) followed by syrups (30.5%) (Figure no:6).

OFF-LABEL DRUGS ANALYSED:

Drug use was analyzed in the study population. It was found that out of 76 different drugs used in the population 14 drugs have been given for off-label use. The details are given in Table no:4, Figure no:7

Table no 4: off-label use analyzed

Drugs administered	Count	Percentage
Off-label drug use	14	18.4%
FDA approved uses	62	81.5%
FDA + off-label	76	100%

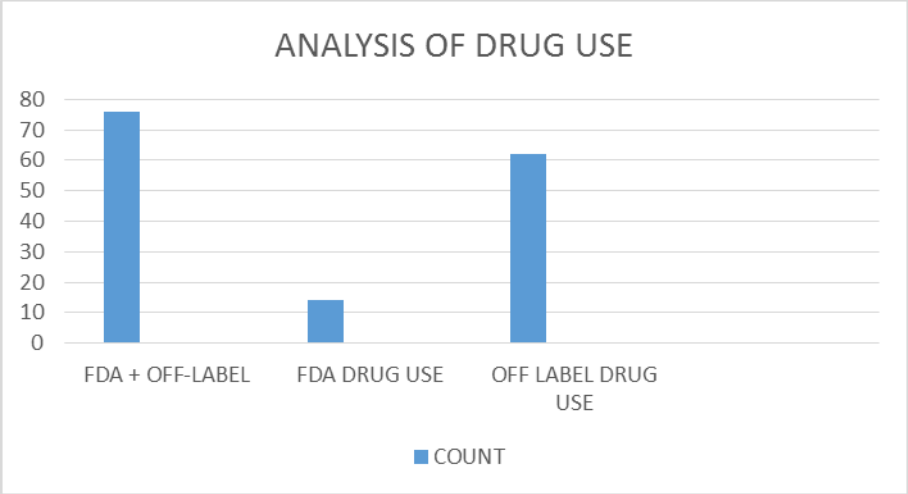

Figure no:6- Analysis of drug use

Among the off-label drugs analyzed, antibiotics were prescribed in the highest proportion (34.78%) followed by anti-ulcers(21.73%). The most common antibiotic prescribed as an off-label is ceftriaxone and the most common antiulcer off-label is pantoprazole (Figure no:8).

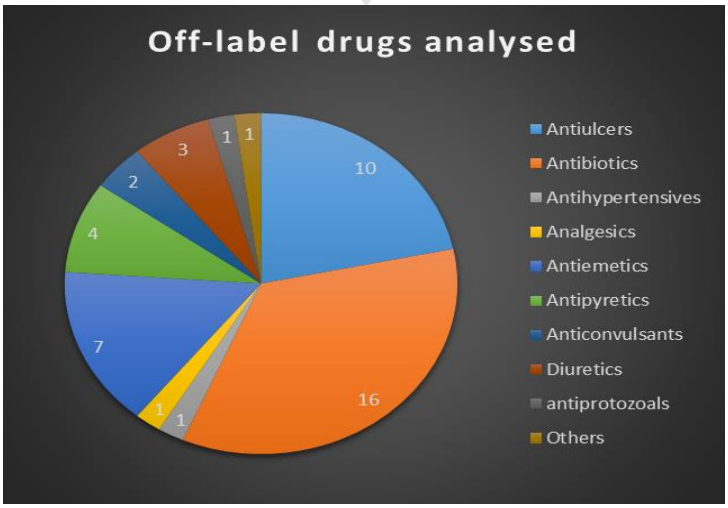

Figure no:7- Off-label drugs analyzed

OFF-LABEL CATEGORY:

The off-label drugs have been analyzed for the category for which they are used other than the intended FDA use and outside the terms of SmPC. The report shows that drugs were used off-label in the dose category in the highest proportion followed by age. Out of 46 times as off-label use, nearly 17 times the drugs were prescribed in a dose other than the intended

FDA use, and 10 times the drugs were prescribed in an age group outside the FDA intended use and the terms of SmPC (Table no:5, Figure no:9).

In our, study Pantoprazole is given to patients below the age of 5 years but its actual recommendation is 5 years and above. Ondansetron is approved for patients 4-11 years of age but it has been prescribed for 2 years of age. (Table no:3)

Paracetamol's usual dose is 15mg/kg body weight but a lesser dose has been prescribed. Levetiracetam should be given in the dose of 10mg/kg/day in 2 divided doses but a higher dose than the recommended dose has been prescribed. Ceftriaxone 50-75mg/kg in a divided dose can be given but it has been prescribed higher than the recommended dose. (Table no:3)

Amikacin has to be given with the frequency of every 8 hours but it has been given once daily dosing. Clobazam has to be given in once-daily dosing but it has been prescribed twice daily. Paracetamol has to be given every 6 hours but it has been prescribed as once daily dose. Pantoprazole should be given once daily frequency but it has been given more than once. (Table no:3)

For Spironolactone, tramadol, silymarin, lansoprazole, and metronidazole safety and efficacy have not been established in the pediatric population. Pantoprazole safety is not established in infants but it has been prescribed. For ofloxacin safety and efficacy are not established in the oral dosage form in patients less than 18 years but it has been prescribed in patients less than 18 years. (Table no:3)

Table no: 5- off-label category

S.NO	OFF-LABEL CATEGORY	OFF-LABEL DRUG USE	COUNT	PERCENTAGE
1	Age	Pantoprazole	3	21.7%(10)
		Ondansetron	7	
2	Dose	Paracetamol	3	36.95%(17)
		levetiracetam	1	
		Ceftriaxone	13	
3	Frequency	Amikacin	2	10.86%(5)
		Clobazam	1	
		Paracetamol	1	
		Pantoprazole	1	
4	Safety and efficacy not established	spironolactone	3	23.91%(11)
		Pantoprazole	2	
		Lansoprazole	2	
		Tramadol	1	
		Ofloxacin	1	
		Silymarin	1	
		Metronidazole	1	
5	Indication	Pantoprazole	2	6.81%(3)
		Propranolol	1	
TOTAL			46	100%

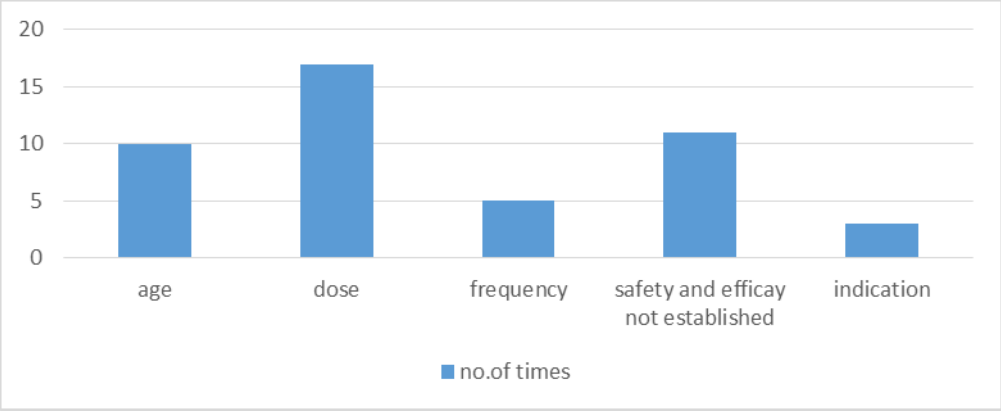

Figure no: 8 off-label category

DISCUSSION:

Unlike the developed world, the importance of drug safety and efficacy in the pediatric population in developing countries such as India receives less attention, despite the widespread use of unregistered and unlicensed drugs. To our knowledge, this is the second study conducted in India on off-label drug use in a pediatric population. According to the findings of our study, the overall prevalence of off-label drug use is 18.4%. The high rate of off-label use could be due to the lack of harmonization between the pediatric documentation in the existing literature and the approved drug label, which affects the prescribing practice of physicians. Within the organization of the Medicines and Therapeutics Commission, there is a need for expert groups dedicated to pediatric drug treatment, which could continuously process new literary data and pass on relevant information to prescribing physicians. Only such focused and coordinated actions would ensure that children's right to safe, cost-effective, and quality medicines will be realized. The therapeutic drug categories most commonly used off-label in our hospital were general antibiotics and antiulcer, which is comparable to this study. [5,14]

Ceftriaxone, ondansetron, and pantoprazole were the top three medications used frequently in an off-label manner. This finding was the same as the study by Shah S et al[14] which shows ceftriaxone as one of the top medications frequently used in an off-label manner.

Ondansetron is the next highly prescribed off-label drug under the age off-label category. Similarly, clinical studies conducted by BajceticMet al[15], Pandolfini C et al[16] show that ondansetron and lorazepam were widely prescribed for an off-label indication. Paracetamol is the most commonly prescribed substance as on-label and is also prescribed as off-label. It also has been reported by Conroy S et al[17], Jong GW et al[18], Cras A et al [19], Jonville-Bera AP et al[20.]

The most common reason for off-label drug prescribing is dose followed by safety and efficacy not established (absence of pediatric information in the SmPC) is in agreement with other studies conducted by Turner S et al[73.]

Several studies have shown that off-label use is more often associated with pediatric adverse drug reactions (ADRs) than on-label use [9,11,]74-76. Drug companies are unlikely to conduct trials to confirm the pediatric use of drugs already on the market and used in children, although in a non-standard way, the situation can be improved if prescribers report their

pediatric experience with various off-label drugs preparations in the form of research articles or discussions on scientific platforms. When medicines are used off-label, each patient is unique and the risk-benefit ratio that applies to them should be assessed based on high-quality evidence. The doctor needs to be updated with the latest evidence which could be achieved by using several useful drug compendiums like MICROMEDEX, National Formulary of India, and so on. Only such focused and coordinated actions would ensure that children's right to safe, cost-effective, and quality medicines will be realized.

LIMITATIONS

• A limitation of this study is the small sample size because of the pandemic.

• It should be noted that the definition of off-label drug use is sometimes perceived differently by different researchers, leading to difficulties in comparing studies.

• The study approach was descriptive and therefore did not analyze associations between off-label drug use and underlying conditions.

CONCLUSION

Based on our data it may be suggested that the magnitude of off-label prescribing in pediatric inpatients is common in India. Dose discrepancy and safety and efficacy not established were identified as the main contributor to off-label prescribing. There is a need for strict drug regulation for the pediatric population to ensure the safety and effectiveness of pharmacotherapy. Further studies are needed to examine why there are inadequate dosing guidelines and the generation of more clinical data, especially in antibiotics. For antibiotics, the development of resistances is fostered when low doses/sub-therapeutic doses are given. Understanding various risk factors and the spectrum of off-label medicine use can assist in developing prevention strategies. Off-label prescribing is a reality and will not go soon. Implementing an evidence-based approach can significantly improve the rationality of pediatric pharmacotherapy. The finding of our study revealed that the magnitude of off-label prescribing in pediatric inpatients is considerably high in children. Implementing an evidence-based approach to prescribing drugs by generating more quality literature on the safety profile and effectiveness of off-label would improve the injudicious use of drugs in the pediatric population. Further studies are needed to examine the situation at a national level. The study also emphasizes the necessary role of clinical pharmacists in creating evidence and substituting the therapy which might be useful for health care professionals. In future studies

the researchers can monitor the adverse events associated with off-label drugs in pediatric patients and create an evidence so that morbidity and mortality due to the off-label drugs can be prevented.

ACKNOWLEDGEMENT:

We acknowledge the management, S.N.R. Sons charitable trust, Sri Ramakrishna Hospital, and Principal Dr. T.K Ravi, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore, for providing the facilities to carry out the study.

DECLARATION OF CONFLICTING INTERESTS:

The author(s) declared no potential conflicts of interest concerning the research, authorship, and/or publication of this article.

FUNDING:

No funding was received for the presented work.

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