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A PROSPECTIVE OBSERVATIONAL STUDY ON DRUG-RELATED PROBLEMS AND POTENTIAL RISK FACTORS IN PEDIATRIC PATIENTS OF TERTIARY CARE HOSPITAL

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ABSTRACT: The aim and objective of the study are to determine the nature, frequency, and potential risk factors of drug-related problems in pediatric patients. For three months, a prospective observational study was carried on 56 pediatric patients at Niloufer Hospital, India. A data collection form was prepared, and DRPs were identified based on the classification criteria of PCNE for drug-related problems (V9.1). A one-tailed Fisher's exact test or Chi-square test was used wherever appropriate to find a significant association between potential risk factors and DRPs. Odds ratio and confidence interval of 95% were used to see the strength of association. $P < 0.05$ was considered to be statistically significant. SPSS version 22.0 (copyright IBM Corporation and other(s) 1989, 2013) was used for performing statistical analysis. A total of 80 DRPs were identified with 173 causes. A mean of 1.43 with a standard deviation of 0.97 DRPs per patient ranging from 0 to 4 DRPs per patient was found. Nearing half the sample size, [22 (39.29%)] had two DRPs per patient. This indicates that the prevalence of drug-related problems was substantially high in the study area. This study revealed that half of the sample size had two or greater than two DRPs each. The number of drugs prescribed, the presence of comorbidities, and the number of diseases diagnosed have been ascertained as important risk factors for the occurrence of DRPs. The clinical pharmacist plays a significant role in determining and preventing DRPs.

INTRODUCTION: A Drug-Related Problem (DRP) is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes. The classification of drug-related problems (DRPs) is based on the most recent version of PCNE (Pharmaceutical Care Network Europe) Classification for Drug-Related Problems (V9.1).

The basic classification is divided into problems and causes. The primary domains in situations include treatment effectiveness and safety; in causes include prescribing and drug selection, dispensing, drug use process and patient-related causes with sub-domains, respectively. The cause is usually the behavior that has caused (or will cause) the problem and most often, that is a medication error¹.

The prevalence of DRPs is common today and most of them are preventable and curable²⁻⁵. Pediatrics are those age groups less than 19 years, including premature (born before 37 weeks), neonates (from birth to 28 days), infants (1 month to 1 year), children (above 1 year to 12 years) and

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adolescent (13 to 18 years) ⁶. The medication-use process in pediatrics requires several steps such as calculation, verification, preparation, and administration of doses which is complex and error-prone. There is insufficient and limited data on pharmacokinetics, pharmacodynamics efficacy, and safety of drugs in infants and children ⁷.

A few studies were conducted in India, but studies on pediatric patients in India, particular and in the world, in general, remain scarce ^{2, 8, 9, 10}.

The role of clinical pharmacists in monitoring drug therapy, identifying and preventing DRPs is of prime significance. To prevent DRPs, it is important to identify potential risk factors that may lead to or cause DRPs ¹¹.

Therefore, this study focused on determining the nature, frequency and potential risk factors of DRPs in pediatric patients. Thereby decreasing drug-related mortality and morbidity of pediatric patients, expanding the existing body of data, emphasizing the valuable role of clinical pharmacists and leading to a better healthcare system.

Aims and Objectives:

- To determine the nature and frequency of drug-related problems in pediatric patients.
- To determine the potential risk factors for drug-related problems.
- To decrease and prevent drug-related mortality and morbidity in pediatric patients.

MATERIALS AND METHODS:

Study Design and Subjects: A prospective and observational study was conducted at Nilofar Hospital, Hyderabad, for three months. The source population included all the hospitalized pediatric patients; however, the study population was based on the inclusion and exclusion criteria.

Inclusion criteria included patients below 19 years, willing to participate, in-patient (IP) ward, with or without chronic illness, and with discharge summary. A total of 56 patients were included in the study.

Exclusion criteria included patients of out-patient (OP) and dermatology wards, admitted in Intensive Care Unit (ICU) and emergency ward, those not discharged or discharged before collecting or cross-checking the data,

Data Collection:

Data that was Collected Included:

- Sociodemographic details: age, gender, past medical history, past medication history
- Clinical details: diagnosis and comorbid conditions and with or without chronic illnesses.
- Drug therapy includes all the drugs prescribed with dose, dosage regimen, route of administration, duration of treatment.
- DRPs was classified based on the PCNE classification (V9.1)
- A questionnaire was prepared to identify DRPs related to drug use and medication compliance.

DRPs were identified using patient medical records and standard treatment guidelines for each disease or condition. The drug-drug interactions were recognized using a standard database like Micromedex 2.0.

Statistical Analysis: Descriptive statistics were used to summarize patients' demographic and clinical characteristics. Frequency tables along with their percentages, mean and standard deviation were calculated using MS excel.

A one-tailed Fisher's exact test or Chi-square test was used wherever appropriate to find a significant association between potential risk factors and DRPs. Odds ratio (OR) and confidence interval (CI) of 95% were used to see the strength of association. Haldane-Anscombe correction for odds ratio was applied wherever appropriate. A *p*-value of or lower than 0.05 was considered to be statistically significant. The collected data were checked and assessed every day for completeness and accuracy before processing. Data were entered, and statistical analysis was done using SPSS

version 22.0 (copyright IBM Corporation and other(s) 1989, 2013).

Ethical Approval: The study was approved by the Institutional Ethics Committee (IEC) of MESCO College of Pharmacy, Hyderabad, Telangana, with the IEC approval number MCP/IEC/PD/PR/37.

RESULTS AND DISCUSSION: As shown in **Table 1**, out of 56 pediatric patients, the maximum number of patients were in the age group of above 1 year to 12 years [31 (55.36%)].

The majority of the patients were males [41 (73.21%)]. 27 (48.21%), 25 (44.64%), 29 (51.79%) and 15 (26.79%) patients have a chronic illness, comorbidities, past medical history and past medication history, respectively.

A total of 31 (55.36%) pediatric patients had a single disease diagnosed. A majority of 34 (60.71%) pediatric patients were prescribed ≥ 6 drugs. 36 (64.29%) patients had no drug-drug

interactions and the remaining had ≥ 1 interaction. The mean \pm SD (standard deviation) for age and drug-drug interactions are 9.3 ± 5.8 and 0.93 ± 1.94 , respectively.

Potential risk factors for DRPs such as comorbidities ($p = 0.049$), number of diseases diagnosed per patient ($p = 0.049$) and number of drugs prescribed per patient ($p = 0.014$) were found to be statistically significant as shown in **Table 2**.

Types of diagnosis and the distribution of patients based on diagnosis done by the physician are shown in **Table 3**. The mean of diagnosis per patient with SD was 1.54 ± 0.69 .

Blood disorders were diagnosed with a maximum number of 30 (34.88%) in 22 pediatric patients (39.29%) followed by liver disorders with a frequency of 10 (11.63%) in 9 pediatric patients (16.07%).

TABLE 1: SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTIC

Variable	Frequency n=56 (%)
Age	
Neonates (from birth to 28 days)	2 (3.57%)
Infants (1 month to 1 year)	3 (5.36%)
Children (above 1 year to 12 years)	31 (55.36%)
Adolescent (13 to 18 years)	20 (35.71%)
Gender	
Male	41 (73.21%)
Female	15 (26.79%)
Chronic illness	
Yes	27 (48.21%)
No	29 (51.79%)
Co-morbidity	
Yes	25 (44.64%)
No	31 (55.36%)
Past medical history	
Yes	29 (51.79%)
No	27 (48.21%)
Past medication history	
Yes	15 (26.79%)
No	41 (73.21%)
Number of diseases diagnosed per patient	
1	31 (55.36%)
2	21 (37.50%)
3	3 (5.36%)
4	1 (1.79%)
Number of drugs prescribed per patient	
1 to 5 drugs	22 (39.28%)
≥ 6 drugs	34 (60.71%)
Number of drug-drug interactions	
0 interactions	36 (64.29%)
≥ 1 interaction	20 (35.71%)

TABLE 2: POTENTIAL RISK FACTORS OF DRUG-RELATED PROBLEMS

Factors	DRPs		OR (CI) ^a	P value ^b	Factors
	Yes	No			
Age					
1 – 18 years	3	2	0.32 (2.21 – 0.05)		0.251
1 - 18 years	42	9			
Gender					
Male	32	9	0.55 (2.88 – 0.10)		0.381
Female	13	2			
Chronic illness					
Yes	22	5	1.15 (4.31 – 0.31)		0.838 ^c
No	23	6			
Co-morbidity					
Yes	23	2	4.70 (24.25 – 0.91)		0.049*
No	22	9			
Past medical history					
Yes	25	4	2.19 (8.54 – 0.56)		0.253 ^c
No	20	7			
Past medication history					
Yes	12	3	0.97 (4.27 – 0.22)		0.619
No	33	8			
Number of diseases diagnosed per patient					
1 disease	22	9	0.21 (1.09 – 0.04)		0.049*
Number of drugs prescribed per patient					
Yes	15	7	0.13 (0.72 – 0.02)		0.014 ^{*c}
	32	2			
Number of drug-drug interactions					
0 interactions	28	8	0.62 (2.65 – 0.14)		0.390
≥1 interaction	17	3			
>1 disease	23	2			

^a OR – Odds ratio with a 95% confidence interval (CI) ^b Fisher's exact test ^c Chi-square test * statistically significant ($p \leq 0.05$).

TABLE 3: TYPES OF DISORDERS/DISEASES DIAGNOSED

Type of diagnosis	Frequency n = 86 (%)	Frequency n = 56 (%)	DRPs		OR (CI) ^a	P value ^b
			Yes	No		
Blood disorders (DVT, malaria, thrombocytopenia, pancytopenia, anaemia, septicaemia, haemophilia, sepsis, septic shock)	30 (34.88%)	22 (39.29%)	20	2	3.60 (18.58 – 0.70)	0.103
Liver disorders (hepatitis, jaundice)	10 (11.63%)	9 (16.07%)	7	2	0.83 (4.68 - 0.15)	0.570
Fever (viral haemorrhagic fever, viral pyrexia, dengue fever)	8 (9.30%)	8 (14.29%)	6	2	0.69 (4.01 – 0.12)	0.497
Infectious diseases (HIV, meningitis, UTI)	8 (9.30%)	7 (12.50%)	7	0	2.46 (21.72 – 0.28) ^c	0.196
CNS disorders (seizures)	7 (8.14%)	6 (10.71%)	6	0	2.1 (18.8 – 0.23) ^c	0.251
Diabetes(DM – 1, DKA)	6 (6.98%)	4 (7.14%)	3	1	0.71 (7.61 - 0.07)	0.594
Respiratory disorders (pneumonia, pleural effusion)	3 (3.49%)	3 (5.36%)	2	1	0.47 (5.65 – 0.04)	0.488
Nephrotic disease	2 (2.33%)	2 (3.57%)	1	1	0.23 (3.95 – 0.01)	0.357
Others ^d	12 (13.95%)	11 (19.64%)	9	2	1.13 (6.14 – 0.21)	0.631

^a OR – Odds ratio with a 95% confidence interval (CI) ^b Fisher's exact test ^c Haldane-Anscombe correction for odds ratio ^d menorrhagia, appendicitis, rickets, OP poisoning, grade 3 tonsillitis, global developmental delay (GDD), anxiety, retardation with nocturnal enuresis.

The total number of drugs prescribed was 339 ranging from 1–14 drugs. The mean of drugs prescribed per patient was 6.05, with an SD of 2.56. The maximum number of patients were prescribed six drugs per patient, as shown in **Fig. 1**.

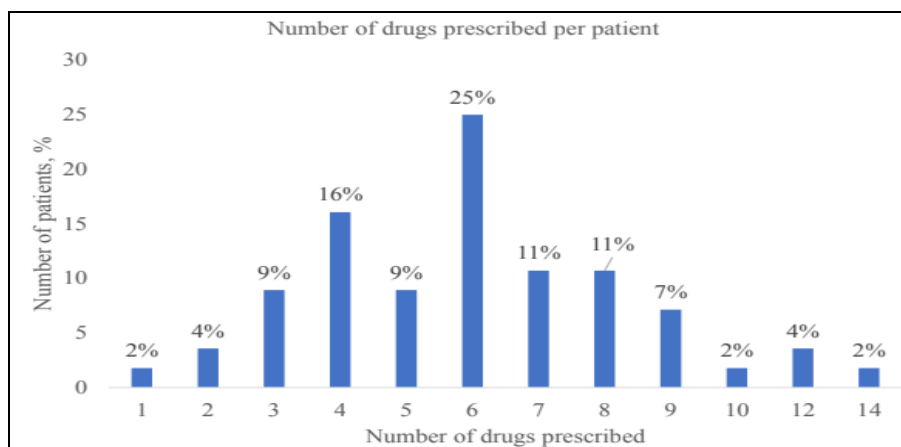


FIG. 1: DISTRIBUTION OF PATIENTS BASED ON NUMBER OF DRUGS PRESCRIBED PER PATIENT

Classes of drugs and distribution of patients based on classes of drugs prescribed are shown in **Table 4**. The most common class of drugs that was prescribed was vitamins/minerals/supplements (86 (25.37%)). Antibiotics were prescribed in a majority of patients (43 (76.79%)).

TABLE 4: CLASSES OF DRUGS PRESCRIBED

Classes of drugs prescribed	Frequency n = 339 (%)	Frequency n = 56 (%)	DRPs		OR (CI) ^a	P value ^b
			Yes	No		
Vitamins /minerals / supplements	86 (25.37%)	41 (73.21%)	33	8	1.03 (4.54 – 0.23)	0.619
Gastrointestinal drugs	69 (20.35%)	42 (75%)	36	6	3.33 (13.43 – 0.83)	0.091
Antibiotics	60 (17.70%)	43 (76.79%)	36	7	2.29 (9.54 – 0.55)	0.220
NSAIDs	43 (12.68%)	39 (69.64%)	33	6	2.29 (8.91 – 0.59)	0.196
CNS drugs	14 (4.13%)	9 (16.07%)	9	0	3.24 (28.01 – 0.37) ^c	0.117
Anti malarial drugs	8 (2.36%)	8 (14.29%)	7	1	1.84 (16.76 – 0.2)	0.503
Anti coagulant drugs	7 (2.06%)	6 (10.71%)	4	2	0.44 (2.78 – 0.07)	0.335
Corticosteroids	7 (2.06%)	7 (12.05%)	6	1	1.54 (14.28 - 0.17)	0.582
Anti histamines	6 (1.77%)	6 (10.71%)	6	0	2.1 (0.23 – 18.8) ^c	0.251
Anti diabetic drugs	5 (1.47%)	3 (5.36%)	2	1	0.47 (5.65 – 0.04)	0.488
ANS drugs	5 (1.47%)	4 (7.14%)	4	0	1.43 (13.43 – 0.15) ^c	0.406
Anti-fibrinolytics	3 (0.88%)	3 (5.36%)	3	0	1.12 (10.94 – 0.11) ^c	0.512
Other drugs	20 (5.90%)	15 (26.79%)	11	4	0.57 (2.31 – 0.14)	0.327

^a OR – Odds ratio with a 95% confidence interval (CI) ^b Fisher’s exact test ^c Haldane-Anscombe correction for odds ratio.

Distribution of drugs based on the route of administration showed that 188 drugs (55%) were administered intravenously (i.v) and 141 drugs (42%) were administered orally (p.o) whereas intramuscular (i.m), subcutaneous (s.c), rectal (p.r), and nasal (nas) route of administrations were in the minority **Fig. 2**.

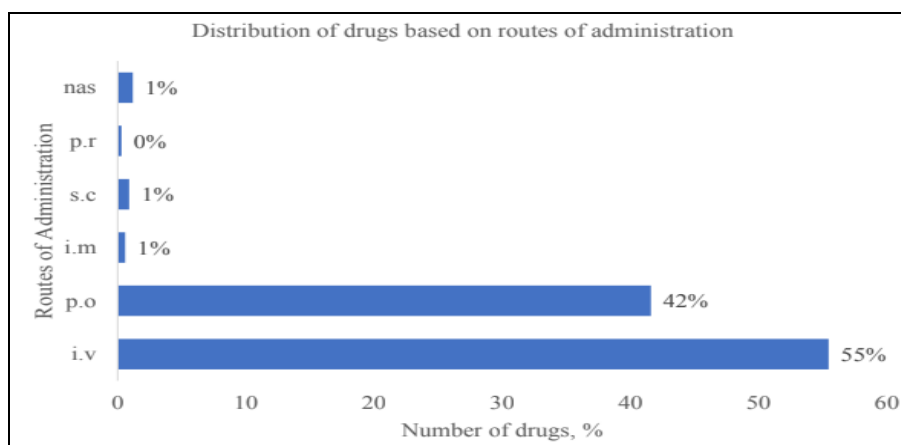


FIG. 2: DISTRIBUTION OF DRUGS BASED ON THE ROUTE OF ADMINISTRATION

DRPs were determined based on the classification criteria of PCNE for drug-related problems (V9.1). The primary domains of problems and causes of DRPs, their corresponding codes and sub-codes, and their frequencies and percentages are shown in **Table 5** and **Table 6** below.

The total number of problems associated with DRPs was found to be 80 and the causes of DRPs were found to be 173. The problem related to DRPs that was most prominent was the effect of treatment not optimal (P1.2) with a total of 34 (42.5%)

followed by equal frequencies [17 (21.25%)] of untreated symptoms or indication (P1.3) and unnecessary drug-treatment (P2.1).

The most prominent cause of DRPs was the inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements (C1.3) with a total of 53 (30.64%) followed by equal frequencies [19 (10.98%)] of inappropriate drug according to guidelines / formulary (C1.1) and no or incomplete drug treatment in spite of existing indication (C1.5).

TABLE 5: PCNE CLASSIFICATION FOR DRUG-RELATED PROBLEMS (V9.1)

	Code V9.1	Sub code	Sub domain	Frequency n = 80 (%)
Problems (also, potential)	P1	P1.1	No effect of drug treatment in spite of correct use	4 (5%)
		P1.2	Effect of drug treatment not optimal	34 (42.5%)
		P1.3	Untreated symptoms or indication	17 (21.25%)
	P2	P2.1	Adverse drug event (possibly) occurring	3 (3.75%)
	P3	P3.1	Unnecessary drug-treatment	17 (21.25%)
		P3.2	Unclear problem/complaint. Further clarification necessary (please use as escape only)	5 (6.25%)

TABLE 6: CAUSES OF DRPs AS PER PCNE CLASSIFICATION (V9.1)

	Code V9.1	Sub code	Sub domain	Frequency n = 173 (%)
Causes (including possible causes for potential problems)	C1	C1.1	Inappropriate drug according to guidelines / formulary	19 (10.98%)
		C1.2	No indication for drug	8 (4.62%)
		C1.3	Inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements	53 (30.64%)
		C1.4	Inappropriate duplication of therapeutic group or active ingredient	11 (6.36%)
		C1.5	No or incomplete drug treatment in spite of existing indication	19 (10.98%)
		C1.6	Too many different drugs/active ingredients prescribed for indication	1 (0.58%)
	C2	C2.1	Inappropriate drug form/formulation (for this patient)	2 (1.16%)
	C3	C3.1	Drug dose too low	4 (2.31%)
		C3.2	Drug dose of a single active ingredient too high	15 (8.67%)
		C3.3	Dosage regimen not frequent enough	4 (2.31%)
		C3.4	Dosage regimen too frequent	1 (0.58%)
	C4	C4.1	Duration of treatment too short	7 (4.05%)
		C4.2	Duration of treatment too long	2 (1.16%)
	C5	C5.2	Necessary information not provided or incorrect advice provided	7 (4.05%)
		C5.3	Wrong drug, strength or dosage advised (OTC)	4 (2.31%)
		C5.4	Wrong drug or strength dispensed	2 (1.16%)
	C6	C6.2	Drug under-administered by a health professional	1 (0.58%)
C6.4		Drug not administered at all by a health professional	1 (0.58%)	
C6.5		Wrong drug administered by a health professional	1 (0.58%)	
C7	C7.1	Patient intentionally uses/takes less drug than prescribed or does not take the drug at all for whatever reason	1 (0.58%)	
	C7.7	Inappropriate timing or dosing intervals	1 (0.58%)	
	C7.10	Patient unable to understand instructions properly	5 (2.89%)	
C8	C8.1	Medication reconciliation problem	1 (0.58%)	
C9	C9.1	No or inappropriate outcome monitoring (incl. TDM)	3 (1.73%)	

A mean of 1.43 with an SD of 0.97 DRPs per patient ranging from 0 to 4 DRPs per patient was found. Out of 56 patients, almost one-third of the sample size [17 (30%)] had at least one drug-related problem per patient. Nearing to half the sample size, [22 (39%)] had two DRPs per patient.

This indicates that the prevalence of drug-related problems was substantially high in the study area. The number of patients without any DRPs was 11 (20%), whereas patients with three and four DRPs per patient were in the minority **Fig. 3**.

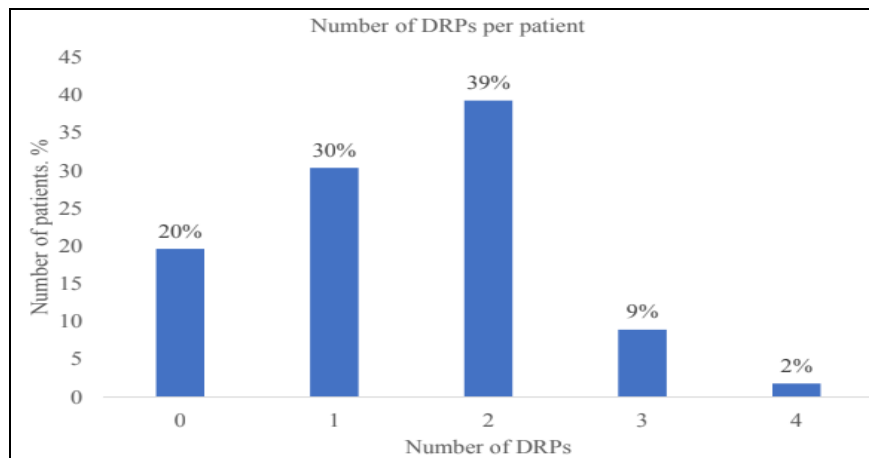


FIG. 3: NUMBER OF DRUG-RELATED PROBLEMS PER PATIENT

DISCUSSION: In our study, out of 56 patients majority of the patients were children in the age group of >1 year to 12 years which was similar to the data found in previous studies^{9, 10, 11}. The mean \pm SD (standard deviation) for age was 9.3 ± 5.8 , which differed from the studies conducted in Ethiopia^{9, 11}. The maximum number of patients were males whereas, in a study conducted in Ethiopia, the maximum number of patients were females¹¹. In other studies performed in northeastern Ethiopia and the U.K., and Saudi Arabia, this trend in the gender of patients was similar to our study⁹.

The clinical characteristics of the study population showed that most of the patients had no chronic illness with a slightly greater percentage (51.79%) than those who had a chronic illness which differed greatly in the study conducted in northeastern Ethiopia⁹. Most of the patients had a past medical history (51.79%) and also had no comorbidities (55.36%). Patients without any past medication history were in the majority (73.21%), which was almost similar to the study conducted in northeastern Ethiopia⁹. Each patient was diagnosed by a physician with diseases or disorders ranging from one to four. Most of the pediatric patients were diagnosed with a single disease or disorder with a percentage of 55.36%, which was similar to the data obtained in a study at a referral hospital in

Ethiopia¹¹. The number of drugs prescribed varied between ≤ 5 drugs or ≥ 6 drugs per patient, with the majority of the pediatric patients, prescribed with ≥ 6 drugs with a percentage of 60.71% differing from the study in Ethiopia¹¹ but similar to other studies performed in northeastern Ethiopia and Hong Kong^{9, 10}. Each prescription was evaluated to detect possible drug-drug interactions using an online database like Micromedex 2.0. The analysis showed no drug-drug interactions in the majority of the prescriptions accounting for about 64.29%, and the remaining had ≥ 1 interaction (35.71%).

The previous study at a referral hospital in Ethiopia showed differing results. In contrast, other studies in northeastern Ethiopia and Hong Kong showed a decreased percentage of drug-drug interactions similar to our study^{9, 10}. A total of 86 diagnoses were identified in our study. The most prominent type of diagnosis was blood disorders accounting for about 34.88% of the total number of diseases/disorders diagnosed and 39.29% of the total number of pediatric patients. These results varied from those in other studies^{9, 10, 11}. Three hundred thirty-nine drugs were the total number of prescribed drugs with a mean \pm SD of 6.05 ± 2.56 ranging from 1 – 14 drugs that differed from the results of studies in Ethiopia^{9, 11}. The most frequently prescribed class of drugs were vitamins/minerals/supplements with 25.37% of the

total number of drugs. Antibiotics were the most commonly prescribed drug class with 76.79% of the total number of pediatric patients, which was similar to the study in northeastern Ethiopia⁹. Antibiotics were also the most frequently involved class of drugs and gastrointestinal drugs [36 (64.2%)] with DRPs. Antibiotics were frequently involved in DRPs in other studies^{9, 11} and contrasting results were found in a study in Hong Kong¹⁰. The distribution of drugs based on the route of administration showed that the drugs were majorly administered intravenously (55.46%) followed by orally (41.59%). Patients without any DRPs to a maximum of four DRPs were identified, out of which 19.64% patients were without DRPs, 30.36% patients had only one DRP each and 39.29% patients had two DRPs each. This trend was less than that found in a former study⁹. The northeastern Ethiopia and Hong Kong studies showed varying results^{9, 10}.

The incidence of DRPs in this study was considerably high, with 80.35% in the study area, similar to the former study⁹ and comparable to other studies^{10, 11}. A mean of 1.43 DRPs per patient was identified, lower than the mean found in another study⁹. A total number of 80 DRPs were found similar to earlier study¹⁰ and higher in other studies^{9, 11}. The most common problem found was the effect of treatment not optimal, followed by untreated symptoms or indications and unnecessary drug treatment. One hundred seventy-three causes of DRPs were found greater than the causes found in a previous study¹⁰.

Inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements was the most common cause of DRP followed by the wrong drug according to guidelines/formulary and no or incomplete drug treatment despite existing indication. These results differed from almost all the previous studies evaluated in this study⁹⁻¹¹. Several reasons and risk factors are involved in the occurrence of DRPs among pediatric patients. To prevent and control DRPs in individual patients, it is important to detect these risk factors¹². Potential risk factors for the occurrence of DRPs, such as the number of drugs prescribed, were found statistically significant ($p = 0.014$), similar to the results in previous studies^{10, 11}.

The number of diseases diagnosed per patient was also a statistically significant potential risk factor ($p = 0.049$), similar to the findings shown in a prior study¹¹. Other potential risk factors such as comorbidities ($p = 0.049$) were also found statistically significant, comparable to former studies where certain infectious and parasitic diseases and type of admission were the potential risk factors for the occurrence of DRPs¹⁰. Several studies ascertained the important role of clinical pharmacists in determining and preventing DRPs and emphasized a need for a reporting system of DRPs and interventions to provide effective treatment in hospitals^{2, 4, 7, 11, 12, 13}.

CONCLUSION: The present study revealed that almost half of the sample size had two DRPs each, implying a significantly high incidence of DRPs in the study area. The number of drugs prescribed, the presence of comorbidities, and the number of diseases diagnosed per patient have been ascertained as important risk factors of DRPs. Pediatrics being a special population, requires mandatory checking of DRPs from time to time to avoid any detrimental effects/consequences. Therefore, it is the role and responsibility of clinical pharmacists to monitor and make necessary amendments to the therapeutic plan to provide quality patient care. Hence, a better understanding of DRPs in the study area was established, thereby facilitating a decrease in drug-related mortality and morbidity of pediatric patients, expanding the existing body of data and emphasizing a need for a mandatory system to report DRPs by the clinical pharmacists and thus determining the substantial role of clinical pharmacists.

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CONFLICTS OF INTEREST: The authors declare no conflicts of interest.

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