#### ORIGINAL RESEARCH

# Rational Dispensing of Oral Dosage Forms of Medicines to Children and Its Associated Factors in South West Ethiopia

Fikadu Ejeta 🕞, Diriba Feyisa 🕞, Temesgen Aferu 🕞, Jafer Siraj 🕞, Demeke Melkam, Ahmed Ali

School of Pharmacy, College of Medicine and Health Sciences, Mizan-Tepi University, Mizan-Aman, Ethiopia

Correspondence: Fikadu Ejeta, Tel +251910136034, Email fikaduejeta@gmail.com

**Introduction:** Obstacles encountered when maintaining excellent dispensing practices for children include a lack of age-appropriate dosage forms, a shortage of medications in appropriate strengths for children, a lack of appetizing drugs, and a lack of competence in pediatric pharmacy. These difficulties contribute to ineffective dispensing procedures and an urgent need to study whether oral dose forms of medications are dispensed to children in a rational way.

**Objective:** The purpose of this study is to evaluate the rational dispensing of oral dosage forms of medicines to children, as well as the factors that influence this practice.

**Methods:** Using validated indicators, a cross-sectional study design was utilized to analyze the rational dispensing practice of oral dosage forms of medicines administered to children under the age of 12 years in seven pharmacies and two drug stores over a one-month period.

**Results and discussions:** Out of 810 medicines, 11.7% and 4% were irrationally manipulated, 5.8% and 1.8% needed manipulation, 3.7% and 0.2% were alternatively dispensed, 8.8% and 7.5% of the medicines had correct advice on their label and also 745 medicines were adequately labeled in the hospital and the selected drug stores. In this study, 92% of medicines were adequately labeled and had sufficient advice on their labels, 15.3% of medicines were irrationally manipulated and around 7.7% of the dosage forms needed manipulation during dispensing. The type of medicine retail outlet had a significant effect on the percentage of instances where alternative solid oral dosage forms were dispensed (p = 0.003), the percentage of dosage forms were adequately labeled (p = 0.008), and the percentage of dosage forms were irrationally manipulated before dispensing (p = 0.001).

**Conclusion:** The rational dispensing practice of oral dosage forms of medicines was relatively poor and there is room for improvement.

Keywords: rational dispensing, oral dosage forms, rational drug use, children

# Introduction

Patients receive pharmaceuticals suited to their needs, in doses that match their own unique requirements, for an adequate duration of time, and at the lowest cost to them and their community.<sup>1</sup>

The key component in ensuring sensible use of medicine is good distribution procedures, the correct drug needs to be delivered to the correct patient in the correct way, in the correct amount and at the correct time, with clear instructions and in a way that preserves the drug's potency.<sup>2</sup>

Safe, effective, and cost-efficient medication is delivered through rational drug use. Prescribers, dispensers, and drug users are all working together to achieve this. Adherence to treatment is ensured through rational prescribing, and drug consumers are protected from unwanted drug side effects. On the other side, rational dispensing encourages the safe, effective, and cost-efficient use of medications.<sup>3</sup>

Pharmacists encounter many challenges in dispensing medicine to children in resource-constrained settings; particularly when dispensing to children, pharmacists confront two primary obstacles every day: There are no readily available formulations of the pharmaceutical that are both appropriate in size and potent enough to be taken by a child.<sup>4</sup> Because young children are unable to swallowsolid dosage forms designed for adults, these issues are magnified when dispensing oral dose forms (ODF) to them. Every day, pharmacists have to give pills or crushed tablets that parents must divide because not many medicines are available in appropriate sizes and dosage forms for young children. These altered adults dosage forms' bioavailability, efficacy, purity, safety, taste, and acceptability are all in question, and they are becoming a severe stumbling block to proper dispensing practice and rational drug use.<sup>5,6</sup>

Inappropriate drug usage has health and financial ramifications. From clinical considerations, ineffective therapy can lead to unnecessary death and suffering, as well as immune-mediated sickness and hospitalizations, as well as increased antibiotic-resistant microbes. Inappropriate drug usage also lowers trust of the public in the health-care system and reduces the number of people who use therapeutic and preventive therapies. Inappropriate medication use wastes a wealth of materials and makes vital pharmaceuticals unavailable in other sectors where they are required.<sup>4</sup>

To be deemed rational drug users, individuals need to acquire medicines that are suitable for particular healthcare needs, in quantities that meet their specific needs, for an appropriate duration, and also at the lowest cost possible to all of them and society.<sup>7</sup> Drug use that is rational improves high-quality treatment and is cost-effective treatment. It ensures that pharmaceuticals are only used when absolutely necessary, and that people will understand what they are for and what to utilize them for.<sup>7,8</sup> Over half of all drugs in the world are prescribed, given, or marketed wrongly, and half of the population does not take their medications as prescribed.<sup>9</sup> Furthermore, around one-third of the world's population lacks access to basic medicines.<sup>9,10</sup> Different studies have found that a lack of comprehension of drugs leads to non-adherence in Ethiopia.<sup>7,11–13</sup>

In developing countries, irrational dispensing practices such as dispensing prescription-only drugs at partial doses or even without a prescription, poor labeling of dispensed drugs, a lack of patient counseling, incomplete compiling and recording of prescriptions, and charging patients an unreasonably high price for dispensed items are common.<sup>14</sup> Because dispensing is such an important element of procedure for using drugs, improper practices during dispensing can have a negative impact on the health-care delivery system. Information presented during dispensing has a significant impact on patient compliance with prescription instructions. Mostly in impoverished countries, medication dispensing is typically performed by unskilled personnel. Risk of contamination is an issue that occurs when using a dispensing device to measure liquids or count tablets/capsules. Inadequate identification of supply containers can lead to incorrect preparation choices and raise the risk of accidents. Choosing a supply container during the dispensing procedure based on color or position while actively looking it up has serious consequences for the patient.<sup>15</sup> The manner in which pharmaceuticals are administered and the kind of information given to patients during the procedure have an influence on the efficiency and effectiveness of dispensing practices. The pharmacist has the final decision about whether or not to issue the medication.<sup>16</sup> The study's findings could be used to educate planning officials, health practitioners, medical training centers, and other health-related NGOs about the flaws in Aman's dispensing practices at health facilities so that healthcare practitioners can improve their methods by correcting flaws and malpractices. The study's goal is to enhance dispensing practices at various health-care facilities in the Aman town area. It provides pharmacists with information to help them identify primary causes of dispensing errors. It also serves as a baseline for future research because there is currently no study on good dispensing procedures in Aman and creates a chance for others to study about rational dispensing in Aman.

The goal of this study is to assess the rational dispensing of oral dose forms of medicines to children and assess the dispensing practice as well as the factors that influence this practice.

## Methods

#### Study Area and Period

The study was conducted in MTUTH and selected drug stores in Aman town from September, 2021 to October, 2021 G.C. Aman town is located 583 km from the capital city of Ethiopia in the south-west. It contains a teaching hospital which

provides service to a catchment population of 178,886. This hospital has five major wards, i.e. emergency, inpatient, pediatric, surgical and gynecology and obstetrics wards and each ward has their own pharmacy as a dispensing unit. The hospital delivers its services to the society under inpatient and outpatient case teams with different health-care professionals.

## Study Design

The rational dispensing practice of oral dose forms of medications in the MTUTH and selected drugstores was investigated in a cross-sectional study design.

## Population

#### Source of population

All children <12 years old who visited the hospital during data collection.

#### Study Population

All children who took oral dosage forms during the study period.

#### Inclusion and Exclusion

Inclusion Criteria All children <12 years old who visited the health facilities during the study period.

#### **Exclusion** Criteria

- Children greater than 12 years old.
- Children who take dosage forms other than oral dosage forms.

# Sample Size and Sampling Technique

At least 600 prescription interactions should be evaluated for evaluation of dispensing practice in a given health-care environment, according to the WHO guideline for assessing rational use of medications in outpatient departments of medical facilities.<sup>7,17</sup> There is only one hospital in the area and the drug stores were selected randomly.

Every other child was chosen through systematic sampling, but the first child was chosen at random, considering that a prescription contained at least one oral dosage form. Starting from the first child all the dispensing units data were collected accordingly.

## **Study Variables**

The variables to be included in the study are categorized as dependent and independent variables.

## Independent Variables

- Age
- Experience
- Monthly income
- Marital status
- Sex
- Types of dosage forms

## **Dependent Variables**

• Rational dispensing, dispensing practice.

# Data Quality Control Measure

The pre-test was done to check the feasibility of the study and suitability of data collection tool. The data collection tool was pre-tested to check whether it could enable an appropriate data collection process. It was done on seven prescriptions on a dispensary unit.

## Data Collection Instruments

Semi-structured questionnaires and structured observation checklist were used to collect the necessary information.

## Data Analysis and Interpretation

The data were collected, counted; Statistical Package for Social Sciences was used to classify and analyze data (SPSS version 20). A structured, pre-tested observation checklist and a semi-structured questionnaire were used to obtain the relevant data through observation. The association between the variables was investigated using the Chi square test and the one-way ANOVA post-hoc test. SPSS version 20 was used to analyze the data. It was considered to be significant if the p-value was less than 0.05. These results were interpreted and presented using tables.

# Ethical Clearance and Informed Consent

Mizan-Tepi University's School of Pharmacy, College of Medicine and Health Sciences provided ethical approval. Subsequently the formal letter with the reference number CP/562/2013 was received on July 26 and was given to MTUTH health administrative office in order to get permission to conduct the study collection in accordance with the Declaration of Helsinki. The data were collected after obtaining written informed consent from parents/guardians of children. Starting with the design of the data collection instrument, the confidentiality of the information acquired was guaranteed. The collected data were kept secure.

# Definition and Calculations of Indicators

Indicator 1: Instances where pharmaceutical alternatives were required; and it was calculated by dividing the total cases where replacement was done to the total number of prescribed medicines.

Indicator 2: This is defined under operational definition and the calculation was similar for all five indicators.

Indicator 3: Irrational manipulation of solid dosage forms occurs when patients do not receive pharmaceuticals that are appropriate to their clinical needs, in doses that satisfy their own specific requirements, for an adequate period of time, and at the lowest cost to them and their community.<sup>9</sup>

Indicator 4: Solid dosage forms which need manipulation before being taken by the patients with the aim of obtaining the required dose.

Indicator 5: Appropriate storage instructions of medicine is information delivered to patients on how they can appropriately store their medications.

# **Operational Definition**

- The age groups: have been derived mainly from physiological and pharmacokinetic differences from birth to adulthood:
  - Term newborn infants (0–27 days); infants and toddlers (28 days–23 months); children (2–11 years) and adolescents (12 to 16–18 years.<sup>18,19</sup>
- Adequate labeling and packaging: as per WHO it is "drug packages containing at least patient name, drug name and when the drug should be taken".<sup>7</sup>
- Rational dispensing: Patients receive pharmaceuticals suited to their needs, in doses that match their own unique requirements, for an adequate duration of time, and at the lowest cost to them and their community, according to the WHO definition.<sup>7</sup>
- Proper labeling (Indicator 2): finished drug products bearing at least the following information: name of the drug, list of the active ingredients, the batch number, the expiry date and the name and address of the manufacturer.<sup>20</sup>

# Results

# Socio-Demographic Characteristics of Pharmacy Professionals

A total of 22 dispensers participated in the study giving response rate of 100%. Of these 20 (90.90%) of respondents were from MTUTH and 2 (9.10%) were from DS in Aman town. Majority of the respondents were males 13 (2.2%) and

Variables	Category	Frequency	Percentage	
Age	<30	9	41%	
	31-40	11	50%	
	41–50	2	9%	
Sex	Male	13	59%	
	Female	9	41%	
Marital status	Married	14	63.6%	
	Single	8	36.4%	
Educational level	Pharmacy	16	72.7%	
	Pharmacy technician	2	9.1%	
	Druggist	4	18.2%	
Monthly income	4609–5358	2	9%	
	5358–7071	4	18.2%	
	7071–9056	12	54.5%	
	9056-1030	4	18.2%	
Experience of pharmacy	<3 yrs	9	40.9%	
professionals	3–5 yrs	9	40.9%	
	6-10 yrs	4	18.2%	

Table I Socio-Demographic Characteristics of Pharmacy Professionals	Table I	Socio-Demographic	Characteristics	of Pharmacy	Professionals
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within age group of 31-40 years. About 16 (72.7%), 2(9.1%), 4(18.2%), of respondents were pharmacist, pharmacy technician, druggist respectively. Meanwhile 14 (63.6%) and 8 (36.4%) were married and single respectively. Concerning training of rational dispensing, 14 (63.6%) dispensers had taken training of rational dispensing, 8 (36.4%) had not taken training on rational dispensing and also 20 (90.9%) had not dispensed drugs without prescription but 2 (9.1%) had dispensed drugs without prescription, as shown in Tables 1 and 2.

From the total of 600 patients, 12.3%, 26.5%, 30% and 31.2% were new-term, infant and toddler, preschool age and school age who had taken oral dosage forms of medicines respectively both in MTUTH and DS. Solid dosage forms accounted for 31.2% and 10.3%, liquid forms accounted for 34% and 14.7%, and other forms accounted for 5.5% and 4.3% in MTUTH and DS, respectively as shown in Tables 3 and 4.

Indicator 1: Percentage of cases where ODF replacements have been dispensed: The dosage forms details in the prescription were available for all 600 prescriptions from the ODF information obtained by the pharmacy and drug retailers. Alternative ODFs were dispensed only 22 (3.7%) and 1 (0.2%) of the instances at MTUTH and drug stores, respectively as shown in Table 5.

Indicator 2: The percentage of oral dose forms that are properly labeled.

All ODFs supplied in drug stores and pharmacies followed the label's frequency and duration recommendations. Adequate labeling was 94.7%. But 5.3% of dispensed drugs were inadequately labeled.

Indicator 3: Percentage of solid oral dosage forms (SODFs) irrationally manipulated by the pharmacist before dispensing.

Variables	Category	Frequency	Percentage
Training on rational dispensing	Yes	18	81.8%%
	No	4	18.2%
What would be your possible justification for dispensing drugs	Profitable	0	0%
without prescription?	Not enough HF	0	0%
	No regulations	0	0%
	Others	2	9.1%
What is type of medicine dispensed without prescription	Antibiotics	0	0%
	CNS	0	0%
	CVS	0	0%
	Others*	2	9.1%

Table 2 Questions Related to Practice of Rational Dispensing by Pharmacy Professionals

Note: \*Others: OTC drugs.

Table 3 Socio-Demographic Characteristics of Patients

Variables	Category	Frequency	Percentage
Age	New-term born	74	12.3%
	Infant and toddler	159	26.5%
	Preschool age	180	30%
	School age	187	31.2%
Sex	Male	270	45%
	Female	330	55%
Number of patient/	<3	1	0.2%
day	46	6	1%
	7–10	9	1.5%
	>10	6	1%
ODF/day	<10	6	1.5%
	11–20	10	1.7%
	21–30	4	0.7%

Abbreviation: ODF, oral dosage forms.

Results showed that 68 (11.7%) and 24 (4%) of the oral dosage forms had been manipulated inappropriately during dispensing by MTUTH pharmacy professionals and in drug stores, respectively. These manipulations consisted of broken down into pieces, powdered, and packaged in different packs.

Indicator 4: The proportion of solid dose units which must be manipulated for providing a single amount. In around 35 (5.8%) and 11 (1.8%) solid ODFs that were dispensed by MTUTH pharmacies and drug stores, respectively, when delivering a single entity, manipulating was required.

Dispensing Unit	Variables	Frequency	Percentage
Inpatient	Solid	6	1%
	Liquid	16	2.7%
	Others	2	0.3%
OPD	Solid	108	18%
	Liquid	122	20.3%
	Others	6	1%
ART	Solid	17	2.8%
	Liquid	7	1.2%
Emergency	Solid	35	5.8%
	Liquid	41	6.8%
	Others	18	3%
GYN	Solid	21	3.5%
	Liquid	19	3.2%
	Others	6	1%
DS	Solid	62	10.3%
	Liquid	88	14.7%
	Others	26	4.3%

 Table 4 Types of Oral Dosage Forms Dispensed to Pediatric Population

Abbreviations: Others, semi-solids; OPD, outpatient diagnosis; ART, antiretroviral therapy; GYN, gynecology; DS, drug store.

Indicators	ldeal (%)	Inpatient (%)	OPD (%)	ART (%)	EP (%)	GYN (%)	DS (%)	P value
Percentage of instance where alternative ODFS were dispensed	0	0.2	2.5	0	0.2	I	0.2	0.003
Percentage of ODFS adequately labeled	100	1.8	37.8	3.67	14.2	9.2	28	0.008
Percentage SODFS irrationally manipulated before dispensing	0	0.6	7.2	1.7	1.7	0.5	4	0.001
Percentage of SODFS need manipulation before dispensing	0	0.3	2	0.2	2	1.3	1.8	0.004
Percentage of ODFS dispensed with correct advice	100	0.5	21.8	0.8	5.8	1.5	7.5	0.001

Abbreviations: ART, antiretroviral therapy; OPD, outpatient diagnosis; EP, emergency pharmacy; GYN, gynecology & obstetrics pharmacy; DS, drug stores; SODFS, solid orla dosage forms.

Indicator 5: The percent of times oral medication formulations are supplied with appropriate storage instructions. Only 256 (42.7%) and 112 (18.7%) ODFs were given appropriate storing instructions in MTUTH and drug stores in Aman town as shown in Table 5.

Independent	Category	Indicators of Rational Dispensing					
Variables		Indicator I	Indicator 2	Indicator 3	Indicator 4	Indicator 5	
		p-value	p-value	p-value	p-value	p-value	
Age	<30	0.62	0.46	0.162	0.80	0.89	
	31-40	0.632	0.46	0.17	0.70	0.98	
	41–50	0.82	0.44	0.28	0.90	0.92	
Educational level	Pharmacy	0.62	0.44	0.90	0.90	0.90	
	Pharmacy technician	0.17	0.46	0.19	0.44	0.117	
	Druggist	0.85	0.16	0.049*	0.03*	0.112	
Monthly income	4609–5358	0.57	0.85	0.85	0.60	0.65	
	5358–7071	0.18	0.86	0.85	0.63	0.77	
	7071–9056	0.33	0.90	0.90	0.22	0.65	
	9056–1030	0.57	0.85	0.88	0.89	0.98	
Experience	<3 yrs	0.52	0.38	0.38	0.78	0.80	
	3-5 yrs	0.67	0.47	0.47	0.78	0.81	
	6-10 yrs	0.53	0.90	0.90	0.78	0.88	
Type of ODF	Solid	0.001*	0.93	0.001*	0.08	0.003*	
	Liquid	0.001*	0.81	0.001*	0.22	0.003*	
	Others	0.002*	0.91	0.001*	0.90	0.41	

Table 6 The Association	Between Sociodemographic	of Pharmacy Professiona	als and Indicators o	f Rational Dispensing

Note: \*Statistically significant figures.

The type of medicine retail outlets had significant effect on percentage of instances where alternative ODFs were dispensed (p = 0.003), percentage of ODFs adequately labeled (p = 0.008), percentage SODFs irrationally manipulated before dispensing (p = 0.001), percentage of SODFs which need manipulation before dispensing (p = 0.004) and percentage of ODFs dispensed with correct advice (p = 0.001).

The results of the one-way ANOVA test showed that being a druggist had significance on indicator 3 (p = 0.049) and indicator 4 ( $p = 0.03^*$ ); type of oral dosage forms as both solid and liquid dosage forms had significant association on indicator 1 (p = 0.001), indicator 3 (p = 0.001) and indicator 5 (p = 0.003); and semi-solid dosage forms on indicator 1 (p = 0.002). There was no association between independent variables (age, monthly income and experience) and indicators of rational dispensing, as shown in Table 6.

#### Discussion

In order to improve the effectiveness of the dispensing process, which is critical for clinical outcomes, the rational dispensing process of pharmaceuticals inside a health-care facility must be assessed.

A study conducted in pediatric hospital of Sri Lanka in 2020 indicated that an average number of 2.54 ODFs per children was reported.<sup>3</sup>

In our study, 515 children received 810 drugs, among these 690 ODFs were dispensed in MTUTH and also 120 medicines were dispensed to 85 at the drug stores in Aman town with an average number of 1.34 and 1.41 ODFs per

child, respectively. This could be due to the low number of patients per day and could also be attributed to the difference in sample size.

In our study only 22 (3.7) and 1 (0.2%) different oral dose formulations other than those prescribed were provided to the children in both MTUTH and drug stores, respectively in Aman town.

In another study, alternative ODF dispensed were only 0.9% of the instances. While 85% of the ODFs contained the dose forms in the prescriptions issued by the practitioners, alternate ODFS were actually given for only 0.7% of cases.<sup>3</sup> This might be due to unavailability of ODFs in the prescribed form in the study area.

In our study 68 (11.7%) and 24 (4%) ODFs were irrationally manipulated in MTUTH and DS, respectively. In another study, none of the oral dosage forms were modified inappropriately by the pharmacy professionals when the parents come to purchase a drug, while 2.8% were irrationally manipulated by clinical pharmacy. These oral dosage forms were broken, powdered, and packaged in different packages such as envelopes and given to parents/guardians for administration to children under the age of two years most frequently.<sup>3,10</sup> This might be justified as some professionals did not take training on rational dispensing in our case.

In our study 35 (5.8%) and 11 (1.8%) solid ODFs needed manipulation before administration in MTUTH and drug stores, respectively. In another study the amount of oral dosage forms which needed to be manipulated for administration as single entity was lower compared with our study.<sup>3,11</sup> This might be due to the fact that manipulation does affect therapeutic goals.

In our study 66.7% and 28% ODFs were adequately labeled in MTUTH and DS, respectively. A study was done in Ethiopia, to assess duration of labeling by dispensers,<sup>21</sup> to investigate the way information on drug use is communicated to patients and to evaluate the effectiveness of the information. The checklist on the dispensed packages revealed that 100% of the labels did not include the name of the patient while the name of the drug (product) was indicated on all of them. The strength of the preparations was on 92% and 84% of labels; the frequency of administration was given on 60% of the labels issued by hospital I (Black Lion) and Hospital II (St Paulo's) respectively.<sup>10</sup> This could be due to experience of pharmacy professionals i.e. governmental health facilities conform to the WHO standard compared with the private medicine retail outlets.

In our study 256 (42.7%) and 112 (18.7%) ODFs were dispensed with correct advice in MTUTH and DS in Aman town, respectively. This figure is higher compared with a study conducted in Sri Lanka.<sup>3</sup> This might be attributed to patient overload, absence of counseling area and a shortage of qualified staff available to inform the patient about their prescriptions.<sup>14</sup>

Associated factors were also identified in this study, as the level of dispenser certification was found to be substantially linked to indices of rational dispensing. The likelihood of rational dispensing was highest among druggists who dispensed irrationally manipulated solid oral dose forms in drug stores before dispensing, when before giving a single unit, ODFs must be manipulated. This could be because druggists' training programs (core competencies) place a greater emphasis on dispensing services. This research supports the findings of a previous study conducted in Ethiopia.<sup>22</sup> Besides types of dosage forms were significantly associated with rational dispensing indicators as indicator 1, indicator 3 and indicator 5 showed a significant relationship. This research supports the findings of a previous study in Sri Lanka.<sup>3</sup>

# Limitation of the Study

The study's main weakness was the risk of observer bias. The research team paid unannounced inspections, and no survey members of the team were there throughout counseling or dispensing, which reduced biases.

# **Conclusion and Recommendation**

#### Conclusion

The rational dispensing practice of oral dosage forms for children in Mizan Tepi University teaching hospital and drug stores was low. As a result, pharmacy practitioners must receive ongoing professional development in pediatric pharmacy skills such as anticipating needs, labeling, storage, communicating with parents, and giving details. The low rate of

rational dispensing shows there is need of more professional developments among the pharmacists. This shows there is still a gap to be improved by the medicine retail outlets from a rational dispensing point of view.

## Recommendation

Based on the study's findings, the following recommendations have been forwarded to the appropriate bodies. To ensure rational dispensing, pharmacy employees should have relevant and up-to-date drug information, and the drug should be given with the written indication, dose, strength, and instructions. Pharmacists should be trained in rational dispensing by health departments.

# Disclosure

The authors report no conflicts of interest in this work.

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