

Research Article

Assessment of Patients Misunderstanding Regarding Dosage Regimen Instructions at Nekemte Referral Hospita, Ethiopia

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***Corresponding author:** Gedamu M, Department of Pharmacology and Clinical Pharmacy, School of Pharmacy, College of Health Sciences, Addis Ababa University, PO box: 9086, Ethiopia**Received:** October 23, 2018; **Accepted:** November 28, 2018; **Published:** December 05, 2018**Abstract**

Patient misunderstanding of dosage regimen instructions is common and a potential root cause for medication error, poor medication adherence and treatment outcome. The aim of this study was therefore to assess the extent of misunderstanding of dosage regimen instructions among ambulatory patients from June-August, 2017. Cross sectional study was utilized. Study subjects were selected by random sampling technique and interviewed face to face at exit site of the outpatient pharmacy using structured questionnaire. Direct observations of the medication label were also done to evaluate the drug labeling practices of pharmacy professionals. Descriptive analysis was used to describe the percentages and number of distributions of variables. Chi square test of independence was used to assess association of outcome variables with independent variables with a significance value of less than 0.05.

A total of 398 patients were included in the study of which 62.8% were females. About 34% of the respondents were found to be in the age range of 25 to 34 years. This study revealed that 288(72.36%) of the study participants misunderstood one or more dosage regimen instructions, and 269(67.59%) of the subjects had also misunderstood the frequency of drug administration. Moreover, from medication label observations, 270(67.84%), were dispensed without a medication label. Misunderstanding of dosage regimen instructions was significantly associated with age, educational level and residence.

The extent of patients misunderstanding of dosage regimen instructions is relatively higher. Health care providers should work on advising the patient related to rational use of medication.

Keywords: Misunderstanding; Dosage regimen; Instruction; Outpatients; Ethiopia**Abbreviations**

NRH: Nekemte Referral Hospital; AOR: Adjusted Odd Ratio; ART: Antiretroviral therapy; CI: Confidence Interval; DNP: Doctorates of Nursing Practice; EFMHACA: Ethiopian Food, Medicine and Health care Administration and Control Authority; ICS: Inhaled Corticosteroids; NAAL: National Assessment of Adult Literacy; RCT: Randomized Control Trial; NSAIDs: Non-steroidal Anti-inflammatory Drugs; GIT: Gastro Intestinal Tract; WHO: World Health Organization.

Introduction

Appropriate use of medications has been promoted to be the cornerstone for medication therapy concentrating mainly on ensuring rational prescription habits and quality of dispensing though patient knowledge of dispensed drugs has been overlooked. It is agreed that the name and purposes of the medication use, the dose, frequency of dosing, and duration of treatment be included in patients' knowledge of medication use [1,2]. Dispensing practice plays a central role in the provision of rational drug therapy. Good dispensing practice ensures that the correct drugs delivered to the right patient in the

required dosage and quantities with clear instructions and a package that maintains an acceptable standard and quality of drug. Drug information on labels and inserts is a major source of knowledge for patients as they attempt to balance the risks and benefits of drugs [3,4].

Counseling during dispensing can significantly improve medication safety and patient compliance though improving patient knowledge of dispensed drugs. Moreover, each dispensed drug must be appropriately labeled to comply with legal and professional requirements to uniquely identify the content of container and to ensure that the patients have clear and concise information about the use of the drug. Communication between pharmacist and patient regarding the use of medication should involve both oral and written information [3,5,6].

It is estimated that a large share of outpatient medication errors occurs as a result of noncompliance on the patient's side that might be due to confusion in medication names and sounds. At primary care in Botswana, nearly half of patients were unable to understand one or more of the label instructions on five common prescription drugs [2-4]. Problems with prescription drug labeling were specifically cited

as a leading root cause of a large proportion of outpatient medication errors and adverse events, as patients may unintentionally misuse a prescribed medicine due to improper understanding of instructions. The size of commonly used paper envelopes for labeling in Ethiopia do not even allow writing the required drug information on it [7,8].

American journal health system pharma study showed that nearly half of patients misunderstand one or more dosage instructions. Those patients will obviously take their medications incorrectly which results in so many consequences including adverse drug reaction, drug resistance, increased health care costs, and decreased work productivity [6,9]. Although many patients rely on medication labels and instruction leaflets, these patient education materials are often difficult to understand. Medication labels and instruction leaflets are in small print size, making them hard to read, especially for geriatric patients, pictorial aids have played an important role in enhancing recall, comprehension and understanding of medication instructions. Problems with properly adhering to medication are associated with many factors: health system issues, individual factors related to medical conditions, physical disability, socioeconomic status, the complexity of the medication therapy and low health literacy [10].

Materials and Methods

Cross sectional study design and random sampling was conducted in Nekemte Referral Hospital outpatient pharmacy from June 15, 2017 to August 25, 2017. The hospital was situated in Nekemte town, East Wollega zone, Oromia region, Ethiopia to assess patients misunderstanding of dosage regimen instructions among adolescent and adult outpatients who received dispensed drugs in the outpatient pharmacy of NRH from June 15, 2017 to August 25, 2017. The source population were All patients who visited the outpatient pharmacy of NRH to fill for prescribed medications and the Study participants were adolescent and adult patients who visited the outpatient pharmacy of NRH to fill for prescribed medications were recruited for face to face interview and also for direct observation of the dispensed medication label who were volunteer to participate by excluding outpatients whose medications were administered by health professionals, pediatric patients, mentally ill patient and patients with hearing disability [11].

The required sample size was determined by using single population proportion formula considering 50% proportion of outpatients served in hospitals outpatient pharmacy due to on the paucity of pertinent literature [12].

$$N = \frac{Z^2 \times p(1-p)}{(d)^2}$$

where; n= the minimum sample size; Z= confidence interval; Z= 95% = 1.96.

p = the proportion of outpatients served in hospitals outpatient pharmacy to be 0.5 as p=0.5 gives a maximum sample size for the desired 95% confidence interval and degree of precision. With value of q= 1-P =0.5, d= Margin of sampling error tolerated (5%) = 0.05

$$\text{Then } n = \frac{(1.96)^2 \times (0.5)^2}{(0.05)^2} = 384,$$

since the numbers of outpatients served in hospital outpatient pharmacy in average is 50,000 patients per year which is above

Table 1: Socio-demographic characteristics of outpatients at NRH, from June 15, 2017 to August 25, 2017.

Socio-demographic characteristics	Variables	Frequency
Age	15-24	80 (20.10 %)
	25-34	137 (34.42%)
	35-44	72 (18.10%)
	45-54	60 (15.08%)
	55-64	41 (10.30%)
	65	8 (2.01%)
	Total	398 (100%)
Sex	F	250 (62.81%)
	M	148 (37.2%)
	Total	398(100%)
Educational status	Cannot read / write	61 (15.33%)
	Can read / write	45 (11.31%)
	Grade 1-6	66 (16.58%)
	Grade 7-12	150 (37.69%)
	Diploma and above	76 (19.10%)
	Total	398 (100%)
Residence	Urban	150 (37.69%)
	Rural	248(62.31%)
	Total	398(100%)
Ethnic group	Oromo	158(39.71%)
	Amhara	105(26.40%)
	Gurage	40 (10.05%)
	Others	95 (23.87%)
	Total	398 (100%)
Religion	Protestants	68(17.09%)
	Orthodox	95(23.87%)
	Muslim	103(25.88%)
	Wakefata	72(18.09%)
	Others	60(15.08%)
	Total	398(100%)

Table 2: Percentage of patients misunderstanding dosage regimen instructions among outpatients in NRH, from June 15, 2017 to August 25, 2017.

Misunderstanding of dosage regimen instructions	Frequency	
	N	%
Amount of dose administration vs. misunderstanding	Incorrect	62 15.58
	Correct	336 84.42
Frequency of drug administration vs. Misunderstanding	Incorrect	269 67.59
	Correct	129 32.41
Duration of treatment vs. Misunderstanding	Incorrect	170 42.71
	Correct	228 57.29
One or more dosage regimen instruction vs. Misunderstanding	Incorrect	288 72.36
	Correct	110 27.64

10,000. To compensate for non-response rate and errors, 5% of the sample size was added and a total of 403 outpatients were selected

Table 3: Percentage of patients misunderstanding dosage regimen instructions among outpatients stratified by characteristics in NRH, from June 15, 2017 to August 25, 2017.

General characteristics		Misunderstanding dosage regimen instructions		
		Dose N (%)	Frequency of administration N (%)	Duration of treatment N (%)
Age	15-24	3(4.84%)	28(10.41%)	15(8.82%)
	25-34	10(16.13%)	80(29.74%)	38(22.35%)
	35-44	6(9.68%)	70 (26.02%)	32(18.82%)
	45-54	23(37.17%)	59 (21.93%)	60(35.30%)
	55-64	16(25.81%)	26(9.67%)	20(11.76%)
	65	4(6.45%)	6(2.23%)	5(2.94%)
	Association	$X^2 = 66.469, p=0.000$	$X^2 = 99.348, p=0.000$	$X^2 = 113.788, p=0.000$
Education Status	Cannot read and write	52(83.87%)	60(22.30%)	53(31.18%)
	Can read and write	4(6.45%)	44(16.36%)	35(20.59%)
	Grade 1 – 6	2(3.23%)	58(21.56%)	48(28.24%)
	Grade 7-12	4(6.45%)	59(21.93%)	34(20.59%)
	Diploma and above	(0.00%)	48(17.84%)	(0.00%)
	Association	$X^2 = 267.599, p=0.000$	$X^2 = 112.839, p=0.000$	$X^2 = 176.852, p=0.000$
Sex	Male	28(45.16%)	12(4.47%)	78(45.88%)
	Female	34(54.84%)	144(53.53%)	92(54.12%)
	Association	$X^2 = 2.000, p=0.157$	$X^2 = 95.546, p=0.000$	$X^2 = 9.608, p=0.002$
Residence	Rural	50(80.65%)	198(73.61%)	148(87.06%)
	Urban	12(19.35%)	71(26.39%)	22(12.94%)
	Association	$X^2 = 10.511, p=0.001$	$X^2 = 45.081, p=0.000$	$X^2 = 77.388, p=0.000$

from source population.

The dependent variable was misunderstanding of dosage regimen instruction.

Where as, the independent variables were age, sex, education status, religion, residence and ethnicity.

Face to face interview and direct observation of dispensed medications were used during data collection with structured questionnaire for interview composed of both closed and open ended questions addressing socio-demographic and variables that address patients understanding of dosage regimen instructions.

The collected data were cleared, categorized and analyzed using SPSS VERSION 20 and the results were presented in tables and figures as necessary. Chi-square test was employed to look for any association between outcome variables and independent variables with a significance level (α) of 0.05. When $p < 0.05$, it was stated that there is an evidence of association between outcome variables and independent variables. Ethical clearance was obtained from Wollega University, College of Medicine and Health Sciences, Department of pharmacy. Then, letter of permission was presented to NRH. Verbal informed consent was obtained from each study subject prior to the interview after the purpose of the study is explained to them. Confidentiality of the information was assured.

Results and Discussion

From a total of 403 out patients approached, 398 of them were voluntary and agreed to conduct the interview, with a 98.76% %

of response rate. Therefore, the response of 398 outpatients were analyzed and reported. From the total respondents, 158(39.71%) of them were Oromo in ethnicity followed by Amhara 105(26.40%), Gurage 40(10.05%) and others 95(23.87%). The majority of the patients, i.e. 248(62.31%) were residing in rural area. Regarding respondent's religion, Muslim were 103(25.88%), Orthodox were 95(23.87%), Wakefata were 72(18.09%), Protestants constituted 68 (17.09%) and others were 60(15.08%). Two hundred fifty of the respondents (62.8%) were females, about 150 (37.69%) were from grade 7-12 and about 137 of the patients (34.42%) were in the age range of 25 to 34 years (Table 1).

From the total 398 respondents, 288(72.36%) patients misunderstood one or more dosage regimen instructions and 269(67.59%) misunderstood frequency of drug administration. One hundred seventy (42.71%) of the patients misunderstood duration of treatment and about 62(15.58%) misunderstood amount of dose to be administered (Table 2).

Regarding the number of medications dispensed to the study participants, 212(53.27%) respondents had received two medications followed by 142(35.68%) who received one medication (Figure 1).

During direct observation of medication packages for medication labeling, 270(67.84%) of patients' medications were dispensed without any label and only 128(32.16%) were labeled. Twenty three (37.17%), 34(54.84%), and 52(83.87%) of patients who misunderstood dosage regimen instructions were in the age range of 45- 54 years, females, and those who cannot read and write, respectively. From the patients characteristics education status has

Table 4: Percentage of medications according to their pharmacological classification misunderstood by patients for their dosage regimen instructions among outpatients in NRH, from June 15, 2017 to August 25, 2017.

Class of drugs	Number of medication misunderstood		
	Dose N (%)	Frequency of administration N (%)	Duration of treatment N (%)
Antibiotics	25(40.32%)	125(46.47%)	80(47.06%)
Antiprotozoal	3(4.84%)	28(10.41%)	8(4.71%)
Drug acting on GIT	5(8.06%)	30(11.15%)	14(8.24%)
Cardiovascular drugs	4(6.45%)	18(6.69%)	20(11.76%)
NSAIDS	7(11.29%)	22(8.18%)	16(9.41%)
Antifungal	3(4.84%)	8(2.97%)	9(5.29%)
CNS drugs	0(0.00)	4(1.49%)	3(1.76%)
Anthelmintic	4(6.45%)	7(2.60%)	6(3.53%)
Antidiabetics	1(1.61%)	5(1.86%)	0(0.00)
Vitamins	2(3.23%)	4(1.49%)	5(2.94%)
Respiratory drugs	3(4.84%)	10(3.72%)	7(4.12%)
Ophthalmologic drugs	5(8.06%)	8(2.97%)	2(1.18%)

great extent of association with misunderstanding of dose i.e., $X^2=267.599$, $P=0.000$, misunderstanding of frequency has $X^2=112.839$, $P=0.000$ and duration of treatment has, $X^2=176.852$, $P=0.000$ and sex characteristics has no relation with misunderstanding of dose i.e., $X^2=2.000$, $P=0.157$ which shows p-value >0.05 . This study also revealed that, misunderstanding of dosage regimen instruction is higher for those medications which were dispensed without any label (Table 3).

From a total of 695 dispensed drugs, 501 drugs were misunderstood by study participants. From these, the majority accounted for misunderstanding of frequency of drug administration (269) and the least was misunderstanding of the dose of drug therapy, 62. The major classes of drugs associated with misunderstanding of dosage regimen instructions were antibiotics (Table 4).

Patients' misunderstanding of dosage regimen instructions to dispensed drugs in the outpatient pharmacy of NRH was assessed. Pharmacy professionals may assume that patients can and are able to understand most medication counseling provided to them. However, in this study, 72.36% of patients misunderstood one or more dosage regimen instructions given by pharmacy professionals. This is significantly higher when compared to a study done in USA, where 46.3% of patients had misunderstood one or more dosing instructions [10]. The difference might be due to differences in medication counseling policy between these two countries as well as might be due to differences in the health literacy status of the study populations. The other possible explanation might be due to the reason that most patients visit outpatient pharmacy tired after waiting and spending long hours in the physician's office for history taking and physical examination; in the laboratory for laboratory tests and diagnostic procedures in NRH. This makes patients to be less attentive for medication counseling provided by pharmacy professionals that can ultimately lead them to misunderstand the instructions [11].

In this study, 67.59% of respondents misunderstood the

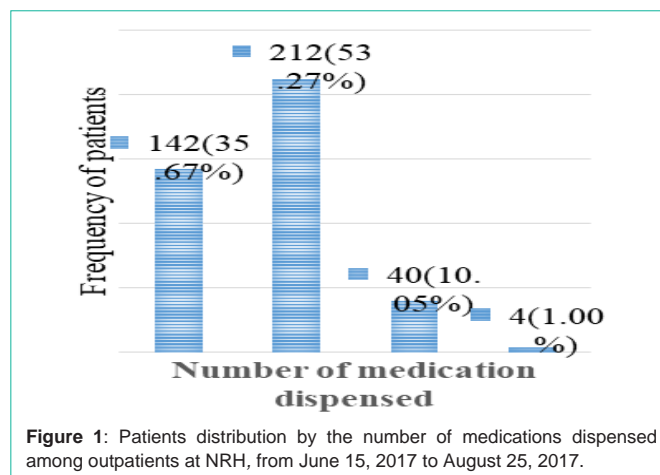


Figure 1: Patients distribution by the number of medications dispensed among outpatients at NRH, from June 15, 2017 to August 25, 2017.

frequency of drug administration which is slightly lower than a study done in USA which revealed that 79% of patients reported taking all TID doses within twelve hours [6]. This may be due to the reason that the American study was done only on medications prescribed in three times in frequency of drug administration, but the present study included all on as needed prescription, two times, three times and four time per day.

The extent of misunderstanding of dose of dispensed medications among respondents was 15.58%. Those patients who are illiterate and with low literacy were less able to state the correct number of pills taken daily compared to those with adequate literacy. In this study also, from 61 patients who cannot read and write, close to 84% misunderstood dose instructions. Similarly, a study conducted in USA, showed that, 65.3% of patients with low literacy could not demonstrate the number of pills to be taken daily [10].

Regarding the rate of misunderstanding of duration of treatment, it was found that close to 43% of the respondents misunderstood the instruction given. This result is almost similar to a cross sectional study conducted in Jimma, Ethiopia on assessment of knowledge and practice on appropriate use of drugs in rural and urban community. In the above mentioned study, it was found that 39.9% of patients discontinued taking drug when the symptoms of disease disappeared [12,13].

In this study, the majority of respondents, 67.84%, received the prescribed medication from dispensary without any medication label written in appropriate local language. Almost all medications were packed in blisters, strips, bottles and tubes which were dispensed for the patients without label and the drug information was given only verbally. This study showed that the frequency of misunderstanding of dosing instruction is higher among patients receiving unlabeled medications. During direct observation of the label, dosing instructions labeled on the container were not enough, simply, morning, evening, etc. rather than the exact time intervals and duration of treatment. Studies also documented that patient misunderstanding can be minimized through additional efforts by healthcare professionals by improving the clarity and comprehensibility of labeling on prescription drugs [10,14].

From the results of present study, such high extent of patient misunderstanding of dosage regimen instructions observed clearly

alert us that, the health care professionals, the hospital administrators, and policy makers should design an effective medication counseling policy and procedures so as to minimize the negative consequence of patient misunderstanding in medication use which will have a significant impact on the health care. For instance, if we look at the data for those medication classes, most commonly involved in misunderstanding were antibiotics at the top. This kind of problem will contribute to the rising burden of antimicrobial resistance as well as sub therapeutic treatment outcomes.

Reports from both developed and developing countries indicated that, incorrect dispensing and use of sub therapeutic doses are the major causes of irrational drug use. It is pharmacy professional's responsibility to provide pharmaceutical care that meets the medication needs of the patient and also must provide the patient with necessary information and guidance to ensure the patient's compliance in taking the medication properly. Pharmacists can help patient to avoid medication misuse and latent errors at home by providing them adequate information on medication safety [5].

Pharmacy professionals should confirm patients understanding through the "teach-me back" method, in which patients are asked to repeat instructions to demonstrate their understanding, especially for those vulnerable groups of the population, like patients with low health literacy [13]. There should also be a mechanism that addresses the legal requirement for medication labeling by dispensers in local language for patients to refer at home in case of confusions.

Conclusion

Generally, in this study, the prevalence of misunderstanding of dosage regimen instructions were relatively higher in the outpatient pharmacy of the NRH. Some patients might presume the task of reviewing the instruction regarding dose, frequency, and duration of treatment as it was simple. As a result, they may not have allocated adequate time to process and understand the information. Some misunderstandings appeared to be the result of container label organization. Pharmacists, physicians and pharmacy technicians should effectively communicate the direction for the drug therapy to the patients. Establishing drug information system to health care professionals and through increasing patients' awareness about the appropriate use of drugs using posters on the walls of health institutions will help to reduce this significant percentage of misunderstanding.

Responsible bodies should also effect an extensive public advocacy towards the population to contact nearby health professionals whenever patients have confusion later at home in drug dosage regimen instructions rather than guessing the probable instructions. Further extensive studies should be done to understand clearly the ranges of possible reasons that lead patients to have misunderstanding of dosage regime instructions.

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