Assessment of Patients Misunderstanding of Dosage Regimen Instructions among Adolescent and Adult Outpatients in Ethiopia: The Case of a Primary Hospital

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Abstract

Purpose: Patient misunderstanding of dosage regimen instructions is common and a potential root cause for medication error, poor medication adherence and treatment outcome. We assessed patient misunderstanding of dosage regimen instructions among outpatients in Shambu Primary Hospital.

Methods and materials: A facility based cross sectional study was conducted from February 10 to 30, 2013 at Shambu primary hospital, Southwest Ethiopia. Study subjects were selected by random sampling technique and were interviewed face to face at exit site of the outpatient pharmacy using semi structured questionnaire translated into local languages. Direct observations of the medication label were also done to evaluate the drug labeling practices of dispensing pharmacy professionals. Descriptive analysis was used to describe the percentages and number distributions of variables. Chi square test was used to assess association of variables with primary outcome with a significance level (α) of 0.05.

Results: A total of 400 patients were included in the study and 52.3% were female in gender. Around 37% of respondents were found to be in the age range of 25 to 34 years. Present study revealed that 293 (73.3%) of the study participants misunderstood one or more dosage regimen instructions, and 264 (66%) of the subjects had also misunderstood the frequency of drug administration. Moreover, from medication label observations, 273 (68.25%) were dispensed without a medication label. Misunderstanding of dosage regimen instructions was significantly associated with age, educational level and residence.

Conclusion: The extent of patients misunderstanding of dosage regimen instructions is relatively higher. Effective targeted interventions are highly warranted to resolve these significant patient safety problems.

Keywords: Misunderstanding, dosage regimen, instructions, outpatients, Ethiopia

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 policy 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 occur as a result of noncompliance on the patient's side that might be due to confusion in medication names and sounds. In a study, 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 envelops for labeling in Ethiopia don't not even allow writing the required drug information on it [7, 8].

Studies 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 [6-11].

Aim of the study

Thus, this study was aimed to assess patient misunderstanding of dosage regimen instructions provided on dispensed drugs in the outpatient pharmacy of Shambu primary hospital, a hospital proving primary level health care services in Shambu town, South west Ethiopia. We also studied the extent and appropriateness of medication labeling among outpatients receiving medications from the pharmacy.

Subjects and Methods:

Study area and period

This descriptive cross sectional study was conducted in Shambu Hospital outpatient pharmacy from February 10 to 30, 2013. The hospital is situated in Shambu town, Horro Guduru Wollega, Oromia region, South west Ethiopia which is located at 365km west from Addis Ababa. The Hospital provides different primary level health care services for inpatient and outpatient in the surrounding area and nearby woredas. There are three pharmacies in the hospital, in which pharmacy professionals provide service to patient (Outpatient pharmacy, Inpatient pharmacy and ART pharmacy).

Study participants

 All patients who visited the outpatient pharmacy of Shambu primary hospital to fill for prescribed medications were recruited for face to face interview and also for direct observation of the dispensed medication label.

Patients and Eligibility Criteria

Inclusion criteria

- Outpatients who received their medication from Shambu primary hospital outpatient pharmacy
- Outpatient who are adult and receive their medication and dosing instruction from outpatient pharmacy

Exclusion Criteria

- Outpatient whose medications were administered by health professionals
- Pediatric patients who receive their medication with the help of their family/care giver
- Mentally ill patient and patients with hearing disability

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

$$n= \frac{Z^2 pq}{d^2}$$

Where; n= the minimum sample size, 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

Then n= $\dfrac{(1.96)^2 (0.5)^2}{(0.05)^2}$ = 384, since the numbers of outpatients served in hospital outpatient pharmacy in average are 30,000 patients per year which is above 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 from study population. Random sampling technique was used to select study subject to be interviewed and observed.

Data collection process

Before data collection, data collection instrument was developed in English and was translated to local languages, i.e. Amharic and Afan Oromo. The instrument was a structured questionnaire composed of both closed and open ended questions addressing socio-demographic & economic variables, and variables that address patients understanding of dosage regimen instructions. Data were collected by the principal investigator. Data collection method was both face to face interview and direct observation. The data collection instrument was checked for face validity by experts of the study team and rectified as suggested. The collected data were cleared, categorized, tallied and analyzed and the results were presented in tables and figures as necessary. All data were then analyzed using descriptive statistics to describe the percentages and number distributions of variables. Chi-square test was employed to look for any association between outcome variables and independent variables with a significance level (α) of 0.05.

Ethical consideration

Ethical clearance was obtained from the Jimma University, College of Public Health and Medical Science. Then officials at different levels in the study area were communicated through letters from Jimma University. Letters of permission was presented to Shambu Primary hospital. Verbal informed consent was obtained from each study subject prior to the interview after the purpose of the study is explained to respondents. Confidentiality of the information was assured.

Results

From a total of 403 out patients approached, 400 of them were voluntary and agreed to conduct the interview with a 99.3% response rate. Therefore, the response of 400 outpatients were analyzed and reported. From the total respondents, 325 (81.25%) of them were Oromo in ethnicity followed by Amhara, and the majority i.e. 263 (65.75%) were residing in rural. Regarding respondents religion, protestant were 217 (54.25%), Orthodox 147(36.75%), Wakefata 25(6.25%) and Muslim 11(2.75%). Two hundred nine (52.25%) were female, about 151 (43.75%) were from grade 7-12 and about 149 (37.25%) belongs to 25-34 years age group [**Table 1**].

Of the total 400 respondents, 293 (73.25%) patients misunderstood one or more dosage regimen instructions and 264 (66%) misunderstood frequency of drug administration. One hundred sixty eight (42%) patients misunderstood duration of treatment and about 68 (17%) misunderstood amount of dose to administered [**Table 2**].

Regarding number of medications dispensed to study participants, 215 (53.75%) respondents had received two medications followed by 137 (34.25%) respondents for one medication **[Figure1]**.

During direct observation of medication packages for medication label, 273 (68.25%) patients medications were dispensed without any label and only 127(31.75%) were labeled. Eleven (47.82%), 39 (18.66%), and 51 (79.68%) of patients who misunderstood dosage regimen instructions were in the age range of 55- 64 years, females, and those who cannot read and write respectively. This study also revealed that, misunderstanding of dosage regimen instruction is higher for those medications which were dispensed without any label. Fifty five (20.15%), 199 (72.90 %), and 121 (44.30%) of patients misunderstood the dose, frequency, and duration of drug therapy respectively from those who received unlabeled medications [**Table 3**].

From a total of 715 dispensed drugs, 516 drugs were misunderstood by study participants. From these, the majority accounted for misunderstanding of frequency of drug administration (273) and the least was misunderstanding of the dose of drug therapy, 71. The major class of drugs associated with misunderstanding of dosage regimen instructions was antibiotics [**Table 4**].

Discussion

We assessed patients misunderstanding of dosage regimen instructions to dispensed drugs in the outpatient pharmacy of a primary hospital in southwest Ethiopia. Pharmacy professionals may assume that patients can and are able to understand most medication counselling provided. However, in this study, 73% of patients misunderstood one or more dosage regimen instructions given by pharmacy professionals. This was significantly high when compared from a study done in USA, 46.3% of patients had misunderstood one or more dosing instructions [13]. The difference might be due to difference in medication counseling policy between these two countries as well as might be due difference in the health literacy status of the study population. 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. This makes patients to be less attentive for medication counselling provided by pharmacy professionals that can ultimately lead them to misunderstand the instructions given as a study showed that lack of attention to the warning labels has been recognized as a problem [15].

In this study, 66% of study subjects misunderstood the frequency of drug administration which is slightly lower than when compared with earlier study 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 TID frequency of drug administration, but the present study included all medications prescribed on PRN, BID, TID and QID basis.

The extent of misunderstanding dose of dispensed medications among respondents was 17%; 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 again, from 64 patients who cannot read and write, close to 80% of them misunderstood dose instructions. Similar study conducted in USA showed that 65.3% of patients with low literacy could not demonstrate the number of pill to be taken daily [13]. Regarding the rate of misunderstanding of duration of treatment, it was found that 42% of the respondents misunderstood the instruction given. This result is almost similar with a cross sectional study conducted in Jimma, Ethiopia on assessment of knowledge and practice on appropriate use of drugs in rural and urban community. It was found that 39.9% discontinued drug administration when the symptoms of disease disappeared [14].

The majority of respondents, 68.3%, received the prescribed medication from dispensary without any medication labeling by pharmacy professionals using appropriate local language. Almost all medications packed in blisters, strips, bottles and tubes were dispensed for the patients without labeling and the drug information was given verbally. This study showed that 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 done mainly in elderly population, a population especially vulnerable to misunderstanding prescription labels and instructions, showed that poor comprehension of prescription labels were a significant predictors factor for misunderstanding not alone a medication without totally a label [17, 18]. Studies also documented that patient misunderstanding can be minimized through additional efforts by health care professionals by improving the clarity and comprehensibility of labeling on prescription drugs [19, 20].

When we see the implications of these study results, such high extent of patient misunderstanding of dosage regimen instructions observed here clearly alert us the health care professionals, the hospital administrators and policy makers to design an effective medication counselling 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 class most commonly involved in misunderstanding, antibiotics were the top ones, this problem will contribute to the rising burden of antimicrobial resistance as well sub therapeutic treatment outcome. If this scenario is replicated in disease like tuberculosis, definitely it will contribute to the rising number of MDR TB cases.

Several 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 not only must be precise in the manual aspects of filling the prescription order but also must provide the patient with necessary information and guidance to ensure that the patient's compliance in taking the medication is proper. Pharmacist can help patient 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 those vulnerable groups of the population, like patients with low health literacy [16]. There should also be a mechanism that addresses the legal requirement for medication labelling by dispensers in local language for patients to refer at home in case of confusions. The authors also would like to recommend effective reinforcement of the prepared manual for medicine good dispensing practice of the government of Ethiopia among pharmacy professionals. This manual addresses good dispensing practices to be followed by pharmacy professionals in Ethiopia. The manual puts minimum drug label information that should be available in any medication label by pharmacy professionals dispensing medications in the country. It has contained critical steps that should be followed in order to minimize confusion and misunderstanding among patients whom medicines have been dispensed for [21].

The limitations to our study should be also noted. First, we investigated patient misunderstanding of dosage regimen instructions based on the information found in the original physician direction for prescription medications only. We did not examine whether pharmacy professionals dispensing the medications provided appropriate dosage regimen instructions or not, we assumed that the information found in the physician prescription is clearly instructed to the patients. The association between misunderstandings of these instructions and medication error and the patients' actual medication taking behavior was not also studied. We did not also study the root cause that lead patients to misunderstand the given information.

In conclusion, generally in this particular study the prevalence of misunderstanding of dosage regimen instructions were relatively higher in the outpatient pharmacy of the primary hospital. 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 allot adequate time to process and understand the information. Some misunderstandings appeared to be the result of container label organization. Pharmacy professionals should counsel and educate patients on the frequency and duration of drug administration and using words like "morning, day time and "evening" by correlating it with figures like sunset during dispensing and telling the exact time interval of the drug administration. 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. We should also effect an extensive public advocacy towards the population to contact nearby health professional whenever patients have a 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 for a focused intervention.

Authors' contributions

AT was involved in the design of the study, data analysis, and interpretation of the findings, report writing. TC was involved in the design of the study, data analysis and interpretation of the findings as well as writing and review of the report. All authors read and approved the final manuscript.

Conflict of Interest: None declared.

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Tables and Figures:

Table 1: General characteristics of outpatients in Shambu Hospital from February 10 - 30, 2013.

Variables		Frequency, N (%)
Age (year)	15-24	75 (18.75)
	25-34	149 (37.25)
	35-44	72 (18)
	45-54	69 (17.25)
	55-64	23 (5.75)
	65+	12 (3)
	Total	400 (100)
Sex	Male	191 (47.75)
	Female	209 (52.25)
	Total	400 (100)
Educational status	Cannot read and write	64 (16)
	Can read and write	45 (11.25)
	Grade 1 – 6	65 (16.25)
	Grade 7 – 12	151 (37.75)
	Diploma and above	75 (18.75)
	Total	400 (100)
Residence	Rural	137 (34.25)
	Urban	263 (65.75)
	Total	400 (100)
Ethnic group	Oromo	325 (81.25)
	Amhara	75 (18.75)
	Total	400 (100)

Table 2: Percentage of patients misunderstanding dosage regimen instructions among outpatients in Shambu Hospital from February 10-30, 2013.

Misunderstanding of dosage regimen instructions	Frequency, N (%)
Amount of dose administration vs. misunderstanding	
Incorrect	68 (17)
Correct	332 (83)
Frequency of drug administration vs. misunderstanding	
Incorrect	264 (66)
Correct	136 (34)
Duration of treatment vs. Misunderstanding	
Incorrect	168 (42)
Correct	232 (58)
One or more dosage regimen instruction Vs. misunderstanding	
Incorrect	292 (73.25)
Correct	108 (26.75)

Table 3: Percentage of patients misunderstanding dosage regimen instructions among outpatients stratified by characteristics in Shambu hospital, from Feb10 - 30, 2013.

General characteristics		Misunderstanding dosage regimen instructions			Association
		Dose	Frequency admin	Duration	
		N (%)	N (%)	N (%)	
Age	15-24	4 (5.33)	32 (42.60)	17 (22.67)	X^2=33.00
	25-34	12 (8.05)	83 (55.70)	43 (28.85)	P=0.000
	35-44	5 (6.94)	64 (88.90)	31 (43.05)	
	45-54	31 (44.92)	56 (81.16)	53 (76.81)	
	55-64	11 (47.82)	20 (86.96)	17 (73.91)	
	65+	5 (41.66)	9 (75	7 (58.30)	
Educational level	Cannot read and write	51 (79.68)	60 (93.75)	54 (84.37)	X^2=93.6
	Can read and write	9 (20.00)	35 (77.78)	34 (75.55)	P=0.000
	Grade 1 – 6	8 (12.30)	57 (87.76)	45 (69.23)	
	Grade 7 – 12	0	109 (72.18)	35 (32.11)	
	Diploma and above	0	3 (4)	0	
Sex	Male	29 (15.18)	120 (62.80)	79 (41.36)	X^2=0.379
	Female	39 (18.66)	144 (68.89)	89 (42.58)	P=0.828,
Residence	Rural	60 (22.81)	197 (74.90)	147 (55.89)	X^2=13.8
	Urban	8 (5.84)	67 (48.90)	21 (15.33)	P=0.001
Ethnic group	Oromo	60 (18.46)	219 (67.38)	139 (63.47)	X^2=1.24
	Amhara	8 (10.67)	45 (60)	29 (38.60)	P=0.539

Table 4: Percentage of medications according to their pharmacological classification misunderstood by patients for their dosage regimen instructions among outpatients in Shambu Hospital, from Feb. 10- 30, 2013

Class of drugs	Number of medication misunderstood		
	Dose	Frequency of admin	Duration of treatment
	N (%)	N (%)	N (%)
Antibiotic	32 (45.07)	133 (48.89)	88 (50.87)
Antiprotozoal	8 (11.27)	51 (18.75)	37 (21.39)
Drug acting on GIT	7 (9.86)	26 (9.56)	23 (13.29)
Cardiovascular drugs	0	2 (0.74)	0
NSAIDS	14 (19.72)	18 (6.62)	13 (7.51)
Antifungal	2 (2.82)	5 (1.84)	3 (1.73)
CNS drugs	0	9 (3.31)	2 (1.16)
Antihelmentics	6 (8.45)	13 (4.78)	4 (2.31)
Antidiabetic	1 (1.41)	8 (2.94)	0
Vitamin	1 (1.41)	7 (2.57)	3 (1.73)

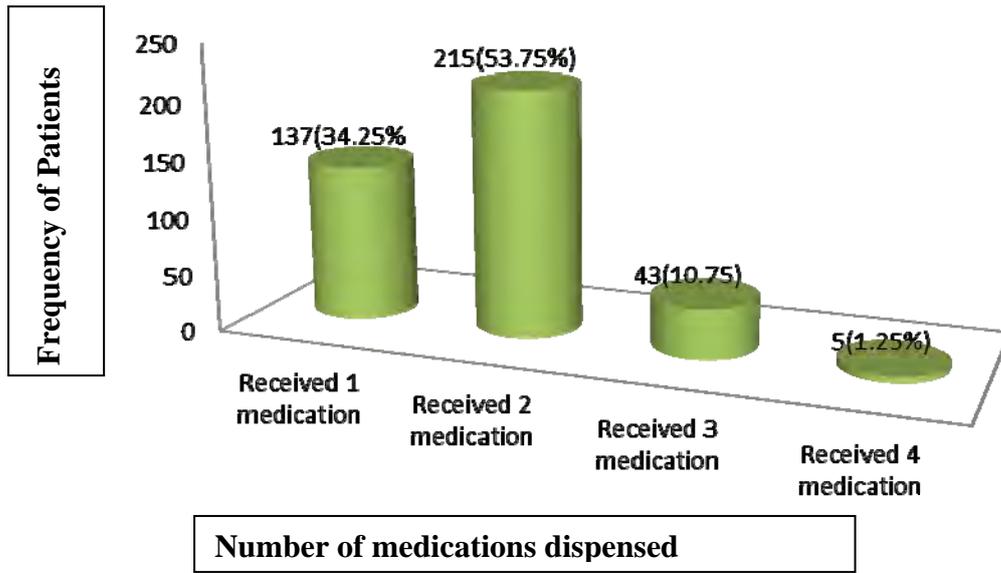#only for those medications where misunderstanding of dosage regimen instruction has occurred

Figure 1: Patients distribution by the number of medications dispensed among outpatients in Shambu Hospital, from February 10 - 30, 2013.