KNOWLEDGE ON PRESCRIBED ARTEMETHER-LUMEFANTRINE AMONG OUTPATIENTS AND CARETAKERS ATTENDING TEMEKE HOSPITAL: PATIENTS FUNDAMENTAL RIGHTS

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Department of Bioethics and Health Professionalism



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A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the

Degree of Masters of Bioethics of

Muhimbili University of Health and Allied Sciences

October, 2017

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: "knowledge on prescribed artemether-lumefantrine among outpatients and caretakers attending Temeke hospital: Patients fundamental rights" in fulfillment of the requirements for the degree of Master science in bioethics of Muhimbili University of Health and Allied Sciences.

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DECLARATION AND COPYRIGHT

I, **Emmanuel John Msovela,** hereby declare that this dissertation is my own original work and it has not been presented nor will it be presented to any other University for similar or any other degree award.

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DEDICATION

This work is dedicated to my Mother Mrs. Magdalena Msovela and my Father Mr. John Msovela for their great care and support until I accomplish this study.

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T	IST	OF	FI	CI	IRE	C

LIST OF ABBREVIATIONS

ALU Artemether-Lumefantrine

CQ Chloroquine

CV Curriculum Vitae

EMEA European Medical Agency

HIV Human Immune Virus

ICCPR International Covenant on Civil and Political Rights

MCT Medical Council of Tanganyika

MUHAS Muhimbili University of Health and Allied Sciences

NCPIE National Council on Patient Information and Education

NQF National Quality Forum

OPD Out Patients Departments

PI Principal Investigator

SP Sulfadoxine-Pyrimethamine

TSH Tanzania Shilling

UDBHR Universal Declaration of Bioethics and Human Right

USA United State of America

UDHR Universal Declaration of Human Right

DEFINITIONS OF KEY TERMS

Anti-malaria; also known as anti-malarial drugs are designed to treat or prevent malaria disease, that occurs in tropical region, subtropical, and some temperate regions of the world. The disease is caused by a parasite, Plasmodium, which belongs to a group of one-celled organisms known as protozoa (medical dictionary).

Information; information refers to the prescribed drug and how it is used as instructed by health care professional (Free Dictionary).

ALu; is a combination of the two medications artemether and lumefantrine. It is used to treat malaria caused by Plasmodium falciparum that is not treatable with chloroquine. It is not typically used to prevent malaria.

Knowledge: understand of information about a subject that you get by experience or study ether known by one person or by people generally.

Participation in decision-making; Patient participation means involvement of the patient in decision making or expressing opinions about different treatment methods, which includes sharing information, feelings and signs and accepting health team instructions (1).

ABSTRACT

Background

Patients have fundamental rights and dignity of receiving adequate information regarding their illness and therapeutic management. Comprehension of information is essential for good adherence to the prescribed drugs and for participating in decision makingabout treatments as recommended in the International Covenant on Civil and Political Rights (ICCPR) article 19. In spite of existence of such covenants, Tanzania has recorded up to 85.1% of patients who do not adhere to prescribed ALU drugs; probably due to poor comprehension of instructions.

General Objective

The main objective of this study to assess the knowledge on prescribed ALu among outpatients and caretakers attending Temeke hospital.

Methodology

This was a cross sectional study involving 224 outpatients and caregivers who were attending at Temeke Hospital and received Artemether-lumefantrine(ALU) drugs. A self administered questionnaire was used. Data analysis was analyzed by using SPSS version 20.0. Frequency distributions were generated; then Chi-square was used to compare proportions of participants with high and low knowledge and the associated factors. P ≤0.05 was considered to be statistically significant.

Results

Majority of participants 172 (76.8%) of 224 received more than three types of drugs along with the prescribed ALu. Only 105 (46.9%) understood the Interval of hours required to take ALu pills; their knowledge did not vary with sex. However those with university/college education (74.1%) were more likely to be knowledgeable as compared to those with primary or lower education (45%). Fifty eight percent of participants did not understand the number of days required to complete ALu dosage, while only 114 (50.9%) understood the instructions written on the ALu package. When asked about the consequences associated with incomplete ALu dosage, 176 (78.6%) did not understand the

risks of not completing ALu dosage. More than half (58.5%) of participants were not satisfied with the information given by health workers about risks and benefits of the prescribed ALu. The Majority (84.8%) of participants did not discuss with care provider about managing the prescribed ALu. In this regard 198 (89.2%) of participants did not get an opportunity to ask any question about the prescribed ALu medication.

Conclusion

Finally this study revealed that, nearly half of patients neither knew the interval of hours required to take ALu nor did they know the number of days required to complete the ALu dosage. Those with higher education were more likely to be knowledgeable. Most patients did not get an opportunity to ask questions related to the prescribed medicine because there was little provision for discussion with the care provider.

Recommendation

It is recommended that; health care providers have to observe their moral obligation of spending sufficient time with their patients to ensure that their instructions are well comprehended by their patients

CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND

Patients have fundamental rights and dignity of receiving adequate information regarding their illness and therapeutic management (2). Principle of person autonomy emphasizes respect for the client's through informed choices and consent(3). Adequate information is essential for good adherence of the prescribed drugs and for participating in decisions about treatment(2). The International Covenant on Civil and Political Rights (ICCPR) article 19 (2) states that;

"Everyone shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, orally, in writing or in print, in the form of art, or through any other media of his choice ..." (4).

Furthermore; Universal Declaration of Bioethics and Human Right (UDBHR) of 2006 recognizes patients as autonomous agents who have innate right and dignity of receiving adequate information and participating in decision-making (5). Adherence to prescribed drug and self-determination springy from understanding of treatment information including details of prescribed drugs(6,7). Unfortunately, comprehension of information on prescribed anti-malaria drug predominantly ALu among outpatients and caretakers has not been well investigated (8,9). High health risks and least benefits are evident among patients with inadequate knowledge related on information of prescribed anti-malaria drugs (10). Majority of these patients are taking anti-malaria drugs in a way that is contrary to the provided instructions which reduces therapeutic benefits and increase health risks such as high health cost, drugs resistance, progression of disease and even death(2,11). However; laws and regulations emphasizing moral obligation among prescribers are in place in order to maximize health benefits and minimize possible risk or harm to their patients(5,12)

In developing countries misunderstanding of related information on prescribed anti malaria drugs are common and affects a large number of patients than developed ones (13). Whereby in sub-Saharan countries about 80% of the population live in risk of acquiring malaria fever (11). Majority of patients attending in the health care facilities for treating

malaria are prescribed anti-malaria drugs particularly ALu (14). In 2005 the government of Tanzania under the Ministry of Health and Social Welfare (MoHSW) made changes from using Sulfadoxine-Pyrimethamine (SP) to ALu due to high prevalence of drugs resistance (15), whereby in 2006 these changes were officially reinforced through national drugs policy (12). Since its initiation in Tanzania for more than 10 years, ALU has become popular anti-malaria drug prescribed in health care facilities for treating uncomplicated malaria(12,15). Despite all these efforts made by the government, a study conducted inTanzania rural revealed that 85.1% of the patients do not adhere to the prescribed ALu dosage, because majority of these patients fail to complete drug dosage and others do not follow the schedule as prescribed by heath care professionals (8).

Moreover ALu has complex instructions compared to the previous single dosage required for SP. Misunderstanding of prescribed drugs information may have a great impact on increasing non-adherence to the prescribed anti-malaria drugs, which may be in line with high health risks such as misuse of drugs, drugs resistance, increased rates of hospitalization, and unsuccessfully treatment results(9,10). As pointed earlier adherence to the prescribed anti-malaria drugs also depend on provision of adequate drug information (16). This information however is not comprehended by most of the patients. This study were focus on the comprehension of provided informationon prescribed anti-malaria drugs (ALu), as understood by the patients regarding the dosage, risks, benefits of prescribed ALu and barriers to decision-making on how to use them among patients/caretakers.

1.2 CONCEPTUAL FRAME WORK

The conceptual framework depicts how the dependent variable (knowledge of prescribed drugs information) is influenced by several variables such as poor communication between patients and doctors, low literacy among patients, ages of patients, sex of patients and multiple prescriptions of drugs.

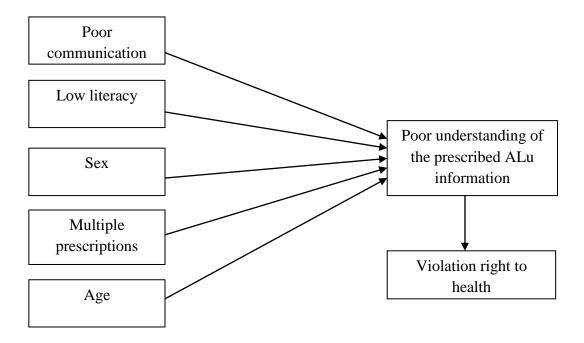


Figure 1: Source: Self invented to suit the purpose of this study

1.3 STATEMENT OF THE PROBLEM

Patients have fundamental rights and dignity on receiving adequate information regarding their illness and therapeutic management. Poor compression of information related to ALu is huge problem leading to poor adherence to the prescribed drugs, treatment failure and drug resistance; to mention a few. Poor comprehension which is expressed as low knowledge related to the prescribed drugs is associated inadequate time spent between patients and caretakers, complicated label information, and inadequate participation in decision making related to treatment. Majority of patients usually cannot comprehend information on drugs name, doses, risks and benefits. Thus this study will focus on assessing the knowledge related to the information on prescribed ALu drugs because majority of the patients fail to comprehend the information of the prescribed ALu drugs.

1.4 RATIONALE OF THE STUDY

The main focus of this study is to assess the knowledge related to information of the prescribed ALu among outpatients and caretakers attending Temeke Hospital. This study is worth at this time because majority of the patients do not adhere to prescribed anti-malaria drugs regime. Thus the findings of this study helping to formulate intervention plan which helping to facilitate comprehension of information on the prescribed anti-malaria drugs among patients and caregivers. This study will help to reduce risks and will maximize health benefits to the patients. This study will also help the patients to understand their rights of receiving adequate information and participating in decision making. Furthermore the study is also for partial fulfillment of Master of Bioethics.

1.5 RESEARCH QUESTION

- 1. What proportion of outpatients/caretakers attending Temeke Hospital understands the information related to prescribed ALu dosage?
- 2. Do outpatients/caretakers attending Temeke Hospital know the risks and benefits of prescribed ALu drugs?
- 3. Do patient/caregivers attending Temeke Hospital participate in decision-making related to the prescribed ALu drugs?

1. 6 OBJECTIVES

1.6.1 General Objective

To assess the Knowledge and related factors on prescribed ALu drugs among outpatients/caretakers attending Temeke hospital.

1.6.2 Specific Objectives

- 1. To determine proportion of outpatients/caretakers with knowledge related to the information of prescribed ALu dosage?
- 2. To determine proportion of outpatients/caretakers with knowledge related to the risks and benefits of prescribed ALu?
- 3. To assess proportion participants who participated in decision-making related to prescribed ALu?

CHAPTER TWO

LITERATURE REVIEW

2.1Knowledge related to the information on prescribed ALu

Astudyconducted disclosed that, patients fail to interpret the correct dosage of their prescribed drugs, do not understand the directives on how to take the medication, pictorial aid helped majority (95%) of patients to comprehend the information on prescribed drugs (9). Many drugs label instructions contains complex information in small font size which is difficult for the patients to interpret and understand (17). Pictorial aid is also adopted by ALu producers in order to improve the compression of information to the prescribed antimalaria drugs among patients and caretakers(9). Even though ALu blister pack employs pictorial aid still some patients do not understand the instructions related to the prescribed dosage. This suggests that; some patients may need more time in order to understand information related to prescribed anti-malaria dosage (ALu). In some instances, poor communications between care givers and patients can be a major source of non-adherence to the prescribed drugs (11,18). Singh et al reported that poor doctor-patients ratio in Thailand is highly associated with misunderstanding of prescribed drugs among outpatients (8). Large numbers of patients in health care facilities lead to imbalanced ratio between patients and health care professionals (19). These situations can influence the health care professionals to spend a little time per patient. Inadequate time leads to poor provision of information related to prescribe ALu dosage because patients fail to ask questions and healthcare professionals fail to make patients understand the prescribed drug instruction (20). In this regard; misunderstanding of prescribed drugs information is unethical and morally wrong and also is prohibited by the laws and regulations (21). In Tanzania, the Medical Council of Tanganyika (MCT) under the Ministry of Health and Social Welfare set off the code of ethics and professional conduct for medical and dental practitioner for the aim of regulating the immoral behaviors of the prescribers (3).

The studies revealed that misunderstanding of prescribed ALu dosage among outpatients and caregivers is associated with poor provision of information chronic disease, cognitive impaired disease and the use of multiple drugs (14,22). Likewise a study conducted in Tanzania also reported that, majority of malaria patients misunderstand the timing of

taking the second dose of anti-malaria drugs particular ALu and also majority of these patients are not completing the second dosage of prescribed ALu medication (22,23). This could be due failure to comprehend the information provided by health care provider, on how the drugs are to be taken. This is a serious concern which necessitated the Universal Declaration of Bioethics and Human right (UDBHR) to emphasize the right of patients to receive adequate information and understand the prescribed instruction (5,7).

A study by Minzi et al in Tanzania found out that, 85.1% of patients did not adhere to the prescribed ALu dosage due to low knowledge on information related to prescribed ALu drug (18). Another study conducted in Tanzania revealed that majority of vulnerable low literacy patients who are taking multiple drug are facing difficulties in understanding the related information of prescribed anti-malaria drugs (24). Majority of the patients misunderstand information of prescribed ALu dosage because they face difficulties in processing prescribed drug instructions (25). Similarly in a study conducted in the Malawi indicates a sizable proportion of patients (42%) patients do not understand the information on how their prescribed drugs are taken (16). This study further explores the extent to which the information on dosage of ALu is comprehended by users and caretakers.

2.2Knowledgetothe risks and benefits of prescribed ALu drugs

European Medical Agency (EMEA); emphasizes the provision of adequate information on benefits and risks of prescribed drugs (22). The study conducted in Sweden revealed that, only 6% of the patients were informed about the risks/adverse effects and warnings of the prescribed drugs (2). Inadequate information and poor knowledge on the risks and benefits of prescribed ALu drugs is the source of taking drugs incorrectly or not finishing the prescribed tablets (17,26). Although the Universal Declaration of Bioethics and Human rights emphasizes that the patients and caregivers to have fundamental right and freedom of understanding therapeutic information and participating in decision making (5,7). Many patients do not enjoy this freedom and hence make wrong decisions which put their health in jeopardy.

Another study revealed that, prescription of multiple drugs increase health risks and minimize benefits to the patients (18). About 67% of Patients who are taking multiple-drugs face difficulties in remembering prescribed drugs information (2). A study conducted

in Kenya found out that patients aged 65 years and above are taking average of 7.9 drugs per day (27). In this case; it becomes more complicated for patients to understand the benefit and risks of each of these multiple prescribed drugs. For that reason, more time is required for the risks and benefits of drugs to be discussed and understood to the patients. This concept is clearly emphasized by the Universal Declaration of Bioethics and Human Rights article 4 state that, medical practices must provide benefits directly or indirectly and any possible harm should be minimized (5).

2.3 Participating in decision-making related to the prescribed ALu drugs

Patients as the autonomous agents have the right to participate in decision making related to prescribed drugs (1,5). The study conducted in Tanzania revealed that patients are seen as passive participants in decision making while doctors and pharmacist act as evaluator and decision makers (10,27). Participating in decision-making among patients and caregivers reduce health risks such drugs resistance, hospitalization and health costs (28). Furthermore participating on decision making about treatment is essential because it improves the adherence of prescribed ALu drugs (29). This study will assess the ability of participating in decision making among patients and care givers.

CHAPTER THREE

MATERIAL AND METHODS

3.1 Types of the study

This study was a descriptive cross sectional hospital based study; designed to find out if patients understand the instructions provided when ALu is prescribed for them.

3.2 Study population

This study involved 224 patients and caretakers attending Temeke Hospital who had ALu drugs prescribed for them or the patients they take care of. Both patients/caretakers were supposed to be 18 years and over for better understanding of the questions that were posed to them by the researcher.

3.3 Inclusion and exclusion criteria

3.3.1 Inclusion criteria

This study will include outpatients and care takers who were received ALu medication in the currents hospital visit.

3.3.2 Exclusion criteria

This study will exclude inpatients and patients under 18 years old.

3.4 Sample size

Sample size was calculated by using the following formula.

N = Z2 P (100-P)/D2

Where;

Z = value for 95% confidence interval (1.96)

P = Expected period prevalence which is 84.9% (Minzi et al, 2014: Adherence to artemether-lumefantrine drugs combination: a rural community experience six years after change of malaria treatment policy in Tanzania).

D = Absolute precision (acceptable error = 5%) = 0.05

N = Desire sample size

10

Therefore, N = (1.96)2x 85.1(100-85.1)/(5) 2

N = 195

Addition of 15% was done to accommodate for the missing data.

Therefore, sample size N = 224.

3.5 Sampling Procedure

A systematic sampling technique was used to sample malaria patients and caretakers attending the outpatient departments throughout the period of the study. The patients were selected at the point of exit after receiving their drugs from the pharmacy.

3.6 Recruitment of study participants

Recruitment of study participants was done at Temeke hospitals from 9 am to 5 pm Monday to Friday with exception of public holidays as well as Saturday and Sunday. Identification of eligible individuals was being done after patients receiving ALu drug by the help of a pharmacist who dispensed the drugs.

3.7 Study area

This study was conducted at Temeke hospital. Temeke hospital was chosen because it is among of the three urban hospitals in Dar esSalaam region. Temeke hospital is the largest referral hospital in Temeke district and was upgraded to regional referral hospital in November 2010. Temeke municipal is an urban area with an area of 659 km square and a total population of 1,368,881 with an annual growth rate of 5.6%. Temeke hospital provides services to Temeke population and neighboring district of Rufiji, Mkuranga and Ilala. Also Temeke district is reported to have high prevalence of malaria cases compared to other districts in Dar es Salaam (12).

3.8 Data collection procedure

Before data collection, participants were informed about the objective of the study. Participants were informed that participation in the study is voluntary. Informed consent was obtained from participants before collection of data. Confidentiality was assured and attained by using codes rather than names. Data was collected using questionnaire with mainly closed ended questions, which were prepared in English and other translated in Swahili language. Data collection aimed at assessing the knowledge related to information

about prescribed ALu drugs among patients and caretakers at Temeke Hospital. Questionnaires were used to interview the patients after receiving drugs from health care professional.

3.8.1 The questioners was divided into two parts

Part A of the questionnaire aimed at obtaining the demographic information of the participants including age, gender, address, education, marital status and employment as shown in table 1. All these were coded as categorical variables. Names were not recorded to make the information anonymous.

Part B assessed Knowledge and other information related to prescribed ALu among outpatients and caretakers at Temeke Hospital. (Table 2)

3.9 Validity

This is the mechanism of insuring that the instrument in this case the questionnaire measure what is supposed to measure. The questionnaire was checked for its contents by going through the questions that they measure knowledge in terms of how patients comprehend the prescription information. The questionnaire was field tested to remove ambiguity questions and insure clarity.

3.10 Reliability

Is the process of checking consistency of the responses of the question are asked more than once. The questionnaire was supposed to be re-administered to 10% of participants in an interval of two weeks. However this was not possible because this was an exit interview and it was not practical to invite the patients for a second time to be interviewed.

3.11 Data analysis

The data collected from the participants was pre-coded to ensure easy entry and analysis of data using SPSS version 20. Knowledge question on frequency of daily intake was recoded to a category of those who indicated a correct frequency of intake (knowledgeable) and those who did not (not knowledgeable). Recoding was also done to a question on duration of the dosage i.e. a category of those who indicated a correct duration of intake (knowledgeable) and those who did not (not knowledgeable). Frequency distributions were

generated to get the proportion of people with knowledge. The relationship between knowledge and other association factors was examined by using Chi-square.

3.12 Variables:

3.12.1 Dependent variable:

Knowledge

3.12.2 Independent variable:

Age, sex, education, and informed about risks and benefits

3.13 Ethical Consideration

The ethical clearance to conduct this study was granted from Research and Publications Ethical Committee of Muhimbili University of Health and Allied Sciences (MUHAS). Also permission to conduct a study at Temeke hospital was granted by District Medical Officer (DMO) and the Temeke Hospital administration.

Before collection of data, all the participants were informed about the aim of the study in Swahili language. This study encouraged voluntary participation and confidentiality of information was assured before and after data collection. The subjects were informed about their right to participate, refuse or withdraw to participate in this study without penalty.

3.14 Limitation

Patients who spent a lot of time to receive treatments did not pay much attention in filling questionnaires because they were already tied and may not have attached enough importance to the survey.

3.15 Mitigation

The questions were few, short and clear just sufficient to capture their understanding of the instructions related to how ALu should be taken and for how long.

CHAPTER FOUR

RESULT

3.1 Part A:Socio-demographic factors of participants

The majority of the respondents 167 (74.6%) were females. The age of participants ranged from 18 to 67 years old. Regarding education of participants, 85 (37.9%) had primary/less, 112(50%) had secondary/vocation education, and 27 (12.1%) had college/university education. Majority 118 (52.7%) of participants were married and 84 (37.5%) were single. Employments status of participants included 82 (36.8%) businessman/women, 80 (35.9%), employed in governments institution and non-government organization and 61 (27.4%) were unemployed.

Table 1: Distribution of participants by social demographic factors (N=224)

Variables	n (%)
Sex	
Male	57 (25.4%)
Female	167 (74.6%)
Level of education	
Primary or less	85 (37.9%)
Secondary/vocational	112 (50%)
College/University	27 (12.1%)
Marital status	
Single	84 (37.5%)
Married	118 (52.7%)
Divorced/Separated	1 (0.4%)
Cohabiting	3 (1.3%)
Widowed	18 (8%)
Employment status	<u>I</u>
Employed	80 (35.9%)
Unemployed	61 (27.4%)
Businessman/woman	82 (36.8%)

3.2 Part B; Knowledge and other information related to prescribed ALu

3.2.1 Knowledgerelated to the information of prescribed ALumedication

The result show that, 179 (79.9%) of participants had malaria, 173 (77.2%) of participants knew they received anti-malarial drugs, more than half 120 (51.8%) of participants did understand the name of anti-malaria drugs which were prescribed for them. Majority of patients 172 (76.8%) received more than three types of drugs. Only 105 (46.9%) knew the interval of hours required to take ALu pills and 94 (58%) did not know the number of days required to complete ALu dosage. Only 114 (50.9%) of participants understood the instructions written on the ALu package. About 114 (50.9%) of participants were not supported to take prescribed medication. More than half 123 (54.9%) of participants did not forgotten to take prescribed ALu in their life time. 163 (72.8%) of participants agreed that adequate instruction helps patients to remember the prescription information of ALu. majority (78.6%) of participants did not understand the risk of not completing ALu dosage. 140 (62.5%) of participants did not understand the risks of the prescribed ALu. More than half 140 (62.5%) of participants understood the benefits of their prescribed ALu dosage and more than half 131 (58.5%) of participants were not satisfied with the information given about risks and benefits of the prescribed ALu. The Majority 190 (84.8%) of participants were not involved in the discussion about managing prescribed ALu dosage and 198 (89.2%) of participants not asked any question when their taking ALu medication (Table 3).

Table 2: Distribution of participants by Knowledge and other information related to PrescribedALu (n=224, frequency and percentages in parenthesis)

Responses	
Yes	No
n ((%)
179 (79.9%)	45 (20.1%)
173 (77.2%)	51 (22.8%)
104 (46.4%)	120 (53.6%)
172 (76.8%)	52 (23.2%)
114 (50.9%)	110 (49.1%)
105 (46.9%)	119 (53.1%)
94 (42%)	130 (58%)
98 (43.8%)	114 (56.2%)
101 (45.1%)	123 (54.9%)
163 (72.8%)	61 (27.2%)
107 (47.8%)	117 (52.2%)
34 (15.2%)	190 (84.8%)
140 (62.5%)	84 (37.5%)
93 (41.5%)	131 (58.5%)
34 (15.2%)	190 (84.8%)
26 (11.6%)	198 (88.4%)
	Yes 179 (79.9%) 173 (77.2%) 104 (46.4%) 172 (76.8%) 114 (50.9%) 105 (46.9%) 94 (42%) 98 (43.8%) 101 (45.1%) 163 (72.8%) 107 (47.8%) 34 (15.2%) 140 (62.5%) 93 (41.5%)

3.2.2 Association between knowledge related to interval of hours supposed to take the ALu and sex, education, risks and benefits related to ALu

In this study revealed that, (49.1%) males were more likely to know the interval of hours required to take ALu medication compared 90 (53.9%) female were not know the interval required to complete ALu dosage. Chi squire were not significant.

Those with college/University education (74.1%) were more likely to know the correct interval (hours) of taking ALu medication as compared to those with Secondary/vocation education (41.1%) and primary/less (45.9%) did not know the correct interval of taking ALu medication. The difference statistically is significant chi square = 11.6; p = 0.008 (Table 3).

Those who were knowledgeable (65.1%) were more likely to claim that they informed about the risk of prescribed ALu medication as compared to those who were not knowledgeable (39.8%) were not informed about the risk of prescribed ALu medication, The statistically difference is significant chi square = 11.6; p = 0.001 (Table 3).

Those who were informed about benefits of prescribed ALu medication (46.4%) were more likely to know the interval of hours required to take ALu medication as compared to those (39.8%) who were not informed about the benefits of prescribed ALu medication. The statistically difference is not significant (Table 3).

Table 3: Distribution of participants by knowledge related to interval of hours in a day required to take the ALu by sex, education, risks and benefits related to ALu (n=224, frequency and percentages in parenthesis)

		Knowledgeable	Not	P. value
			knowledgeable	
Sex		L	I	
	Male	28 (49.1%)	29 (50.9%)	n.s
	Female	77 (46.1%)	90 (53.9%)	-
Education	1	1	ı	1
	Primary/less	39 (45.9%)	46 (54.1%)	
	Secondary/vocation	56 (41.1%)	66 (58.9%)	0.008
	College/University	20 (74.1%)	7 (25.9%)	-
Have you info	ormed about the risks o	f ALu		
	Yes	41 (65.1%)	22 (34.8%)	0.001
	No	64 (39.8%)	97 (60.2%)	-
Have you info	ormed about the benefit	ts of ALu	I	ı
	Yes	65 (46.4%)	75 (53.6%)	n.s
	No	40 (47.6%)	44 (52.4%)	1

n.s=not sign

3.2.3 Association between knowledge related to interval of day supposed to take the ALu and sex, education, risks and benefits related to ALu

Table 4 shows that females (47.9%) were more likely than males (24.6%) to know the correct interval required to complete ALu dosage per day. The difference was statistically (p = 0.002). Those with college/University education (59.3%) were more likely to know the correct number of days required to complete ALu dosage as compared to those with Secondary/vocation education (48.2%) and primary/less (28.2%). The difference statistically is significant p =0.003. In addition; those who were knowledgeable (46%) were more likely to claim that they know the risks of prescribed ALu medication as compared to those who were knowledgeable (40.4%), but the difference statistically not significant. Those who were knowledgeable (43.6%) were more likely to claim that they know benefits of prescribed ALu medication as compared to those who not knowledgeable (40.4%), as shown in Table 4. The difference is not statistically significant

Table 4: Distribution of participants by knowledge related to interval of days supposed to complete ALu dosage by sex, education risks and benefits related to ALu (n=224, frequency and percentages in parenthesis)

		knowledgeable	Not	P. value
			knowledgeable	
Sex				
	Male	14 (24.6%)	43 (75.4%)	0.002
	Female	80 (47.9%)	87 (52.1%)	
Education	1	1	1	1
	Primary/less	24 (28.2%)	61 (71.8%)	
	Secondary/vocation	54 (48.2%)	58 (51.8%)	0.003
	University/collage	16 (59.3%)	11 (40.7%)	-
Have you info	ormed about the risks of pre	scribed ALu medica	ution	
	Yes	29 (46%)	34 (54%)	n.s
	No	65 (40.4%)	96 (59.6%)	-
Have you info	ormed about the benefits of p	prescribed ALu med	lication	l
	Yes	88 (52.7%)	79 (47.3%)	n.s
	No	6 (10.5%)	51 (89.5%)	-

CHAPTER FIVE

DISCUSSION

This study aimed at assessing the Knowledge related to the information of prescribed ALu among outpatients and caretakers attending Temeke hospital. Additionally, it measured knowledge related to information on risks and benefits of prescribed ALu as well as patients' participation in decision making during prescription of ALu medication.

4.1 Knowledge related to the information of prescribed ALu dosage

This study revealed about half of the patients did not have the right information regarding interval at which ALu can be taken in a day and for how many days the drugs are supposed to be taken. These findings are in contrary to the expectations of the Universal Declaration of Bioethics and Human right (UDBHR), the declarationis emphasizing the fundamental right of patients on receiving adequate information regarding their illness and therapeutic managements (3). Especially so because a sizable proportion of patients were not satisfied with the instructions provided by the health care providers and that the majority did not get the opportunity to ask questions. A similar scenario was reported in another study conducted in Tanzania by Mace in (2011) whereby 43.9% of exiting patients who received ALu were not given instructions to follow when using ALU(16). Thus, the prescribers must spend more time with their patients to ensure comprehension of the provided instructions. Significantly higher proportion of patients and caretakers who had college/university was more knowledgeable compared to those with of primary/less education. Thus those with low education should be given more time as reflected in the findings of this study. A small proportion of males knew the correct number of days required to complete the ALu as compared females suggesting that people of different sexes may require different approaches when being assisted to comprehend the instructions.

The majority (58.5%) of patients were not satisfied with the information of prescribed ALu medication. This is similar to findings of a study conducted by Luyinga in Tanzania (2013) which revealed that 62.9% of exist patients were not satisfied with instructions to prescribed ALU for treatment of uncomplicated malaria. The current study also found that education is an important factor to understand the interval of hours required to take the

ALu pills. Those who had college/university (74.1%) were more likely as compared to those with primary/less (49.9%) to mention the correct interval for taking ALu pills. Similar findings were also reported by Mwanje in a study conducted in Uganda (30). The main reasons for not completing ALu dosage in the Ugandan study was the complexity instructions compared to the previous single dosage required by SP. In the current study patients received three drugs or more along with ALu resulting in multiple instructions which could be hard to comprehend.

4.2 Knowledge related to the risks and benefits of prescribed ALu drugs

This study revealed that majority 84.8% of the participants have never been informed about the risk of prescribed ALu medication. Those (46%) who were informed about the risk of prescribed were more knowledgeable regarding interval and duration of treatment compare to those (40.4%) who were not informed the risk of prescribed ALu medication. Similar findings were reported by Massawe (2013) in a study conducted in Tanzania whereby 76.5% of participants were not told of any possible side effects of ALu medication (31).

In this study 62.5% of patients were informed about the benefits of prescribed ALu drugs. Thus, the Universal Declaration of Bioethics and human right (UDBHR) emphasizing on the fundamental right and freedom of patients in understanding all the prescription information prescribed by health care providers has been violated in almost one third of all participants who were left uniformed of the benefits (5).

Those (52.7%) who were informed about the benefits of prescribed ALu were more likely to know the days required to complete ALu dosage compared to those were not informed the benefits of prescribed ALu. This study is in line with the findings of study conducted in Uganda by Mwanje (2013), which revealed that 87.3% of participants did not received enough information related to malaria medication (30).

Furthermore study found nearly half of the participants did not understand written instructions on the medication package. In the America study failure to comprehend was associated with small font size letter in scientific terminology used to write the information

but in Tanzania majority of patients fail to understand instruction written on ALu package due to illiteracy.

4.3 Participating in decision-making related to prescribed ALu drugs

Majority of participants in this study neither were involved in decision making nor were given opportunity to ask question during prescription of their medication. Similar results can be found in the study conducted in Tanzania which revealed that patients are seen as passive participants in decision making while doctors and pharmacist act as evaluator and decision makers (10). Patients participating in decision-making reduces health risks such drugs resistance, hospitalization, health costs and furthermore it help to increase understanding of prescribed medication(28). Universal Declaration of Bioethics and Human Right (UDBHR) of 2006 recognizes patients as autonomous agents who have innate right and dignity of participating in decision making related to prescribed ALu medication (5).

4.4 Study Limitations

Patients spend a lot of time to receive treatments might not pay much attention because they were already tied and they may not have given their actual responses.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

Finally this study revealed that, nearly half of patients neither knew the interval of hours required to take ALu nor did they know the number of days required to complete the ALu dosage. Those with higher education were more likely to be knowledgeable. Most patients did not get an opportunity to ask questions related to the prescribed medicine because there was little provision for discussion with the care provider. Thus, the universal declaration of bioethics and human right (UDBHR) in 2006 emphasizing respectively authorities to improve the knowledge of patients in order to understand all information related to prescribed drugs and also participates in decision making is fulfilled as recommended.

5.2 Recommendations

Basing on the findings of this study the government under the ministry of health and social welfare is needed to organize educational programs to improve knowledge of patients on the use of ALu medication.

Doctors and pharmacist should improve technique on prescription of information to be understandable among the low literacy patients.

Health care providers should inform the patients and caretakers about the risk of prescribed ALu medication in order to reduce the number of patients who are not understand the information of prescribed ALu drugs.

Improvement of environments and health care services for instance building is too small to accommodate majority of patients who are receiving health care because majority of patents/caretakers spends more than 30 minute on waiting line to receiving medication.

Furthermore, ALu has complex instructions compared to the previous anti-malaria drugs, thus pharmacist needed to insure that patients understanding potential instruction before departure to the pharmacy.

5.3 Areas for Further Research

Since the study was conducted in urban setting rather than rural setting, more studies should be focus in rural areas so as to get the real picture in that type of scenario.

Further study also should focus on knowledge on prescription of ALu medication among pharmacist from government and private pharmacy.

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7.0 APPENDICES:

7.1 APPENDIX 1; QUESTIONNAIRE (ENGLISH VERSION):

My name is Emmanuel John Msovela a postgraduate student at Muhimbili University of Health and Allied Sciences (MUHAS) I am doing a study to the malaria patients/caretakers who have been prescribed anti-malaria drugs particular ALu.

Questionnaire No.:	
SECTION 1: SOCIAL DEMOGRAPH provided boxes)	RAPHIC (Write the number of correct answer in the
1.1 Your sex?	
 Male Female 	
1.2 Please indicate your age	
1.3 Your level of education	
 Primary or less Secondary/vocational College/University 	
 Single Married Divorced/Separated Cohabiting Widowed 	
1.5 Your employment status	
 Employed Unemployed Businessman/woman 	

SECTION 2: KNOWLEDGE ON UNDERSTANDING INFORMATION OF PRESCRIBED ALu DOSAGE (please write the number of the correct answer).

2.1 Ha	ive you been diagnosed	with malaria disease?
1)	Yes	
2)	No	
2.2 W	ere anti-malaria prescrib	ped to you?
1)	Yes	
2)	No	
2.3 Do	you understand name o	of anti-malaria drugs were prescribed to you?
1)	Yes	
2)	No	
2.4 Di	d you receive any other	drugs apart from ALu drugs?
3)	Yes	
4)	No	
2.5 Ho	ow many types of other of	drugs did you receive?
1)	One type	
2)	Two types	
3)	Three types	
4)	More than three types	
2.6 Do	you understand the inst	tructions written on the ALu package?
1)	Yes	
2)	No	
2.7 Do	you understand after he	ow many hours in a day you are supposed to take the ALu?
1)	5 hours	
2)	8 hours	
3)	7 hours	

4) I don't know
2.8 How many days are you supposed to take ALu dosage?
 One day Two day Three day Four day I don't know Do someone help you when taking your prescribed ALu?
1) Yes
2) No
2.10 Have you ever forgotten taking the ALu?
1) Yes
2) No
2.11 Provision of adequate instruction will help you to remembering the information on prescribed ALu?1) Yes
2) No
2.12 Have you ever failed to complete the prescribed ALu dosage?
1) Yes
2) No
2.13 What barriers hinder understanding of prescribed ALu dosage among outpatients and
caregivers?
1) Inadequate information2) Shame
3) Multiple drugs
4) I don't know

PATIENTS UNDERSTANDING OF INFORMATION ABOUT THE RISKS AND BENEFITS OF PRESCRIBED ANTI-MALARIA DRUGS (please write the number of the correct answer)

2.14 Do you know th	ne Disadvantages of not finishing the dosage of prescribed ALu?
 Yes No 	
2.15 Do you understa	and the risks of the prescribed ALu?
1) Yes	
2) No	
2.16 Do you understa	and the benefits of your prescribed ALu?
1) Yes	
2) No	
2.17 Have you ever prescribed ALu?	been satisfied with information about the risks and benefits of the
1) Yes	
2) No	

PARTICIPATING IN DECISION-MAKING ABOUT MANAGING PRESCRIBED ALU DRUGAMONG PATENTS (please write the number of the correct answer)

2.18 H ALu?	ave you ever be	een involved in discussion about managing dosage of the prescribed
,	Yes No	
2.19 H	lave you ever b	een asked question about your prescribed ALu?
ŕ	Yes No	

The end of the questions, thanks for your cooperation

7.2 KIAMBATISHO 2; DODOSO LA KISWAHILI

Mimi ni mwanafunzi wa shahada ya uzamili kutoka katika Chuo Kikuu cha Sayansi za Afya na Tiba Muhimbili. Nafanya utafiti kuhusu uwezo wa kuelewa maelezo yamatumizi ya dawa za malaria (ALU) kwa wagonjwa wenye umri kati ya miaka 0 na 75 waliopewa dawa ya kutibu ugonjwa wa malaria.

Dodoso namba:
KIPENGELE 1:
1.1 Jinsi yako ni?
1) Mwanaume2) Mwanamke
1.2 Umri wako ni miaka
1.3 Tafadhari ainisha kiwango chako cha elimu?
 Shule ya msingi/chini ya shule ya msingi Shule ya sekondari/ Chuo cha ufundistadi Chuo/chuo kikuu
1.4 Hali yako ya ndoa
 Sijaoa/Sijaolewa Nimeoa/Nimeolewa Nimeacha/Nimeachika
4) Nimewekwakinyumba5) Mjane/Mgani
1.5 Kazi yako
 Nimeajiriwa Sijaajiriwa Mfanyabiashara
4) Mwanafunzi

KIPENGELE 2: UELEWA KUHUSU MATUMIZI SAHIHI YA DOZI YA MALARIA KWA WAGONJWA NA WASAIDIZI WA WAGONJWA

2.1 Je u	ılishawahi kuumw	a ugonjwa wa malaria?
ĺ	Ndio Hapana	
2.2 Je u	ımewahi andikiwa	dawa yoyote ya malaria na mtoa huduma ya afya?
ŕ	Ndio Hapana	
2.3 Je u	ınajua jina la dawa	ya malaria uliyoandikiwa na mtoa huduma ya afya?
ŕ	Ndio Hapana	
2.4 Je u	ımeandikiwa dawa	nyingine tofauti na dawa yako ya malaria?
ŕ	Ndio Hapana	
2.5 Je n	ni aina ngapi za da	wa ulizoandikiwa na mtoa huduma ya afya?
2)	Aina moja Aina mbili Aina tatu Zaidi ya aina tatu	
2.6 Je, ¹	Unaelewa maelezo	kuhusu matumizi ya dawa yako ya mseto yaliyo andikiwa katika
kifunga	shio?	
	Ndio Hapana	
2.7 Je, ı	unaelewani baada	ya masaa mangapi kwa siku unatakiwa kutumia dawa zako za
mseto?		
1)	Masaa 5	
2)	Masaa 8	

3) Masaa 7
4) Sijui
2.8 Je unatakiwa kutumia dawa mseto kwa muda wa siku ngapi?
1) Siku moja
2) Siku mbili
3) Siku tatu
4) Siku nne
5) Sijui
2.9 Je, kuna mtu huwa anakusaidia kukupa maelezo jinsi kutumia dawa mseto unapokuwa nyumbani?
1) Ndio
2) Hapana
2.10 Je, ulishawahi kusahau kutumia dawa mseto?
1) Ndio
2) Hapana
2.11 Kupewa maelekezo ya kutosha kuhusu dawa mseto ulizoandikiwa itakusaidia kukumbuka dozi yako?
1) Ndio 2) Hapana
2.12 Je, ulishawahi kushindwa kumaliza dozi ya mseto?
1) Ndio 2) Hapana
2.13 Je, ni vikwazo vipi vinapelekea wagonjwa kushindwa kuelewa maelezo ya matumizi
sahihi ya dozi ya mseto?
1) Kutojitosheleza kwa maelekezo
2) Aibu ya mgonjwa
2) 1100 ju ingonjiru

3) Matumizi ya nyingi za dawa

4) Sijui
WAGONJWA WANAELEWA MADHARA NA FAIDA ZA DAWA ZA MALARIA (ALU) WALIZOPEWA NA WAHUDUMU WA AFYA.
2.14 Je, unajua madhara yakuacha kutumia dawa zako za mseto ulizoandikiwa na wahudumu wa afya?
1) Ndio 2) Hapana
2.15 Je, umeelewa kuhusu madhara ya dawaya mseto ulizoandikiwa?
3) Ndio 4) Hapana
2.16 Je, umeelewa kuhusu faida za dawa ya maseto uliyoandikiwa na wahudumu wa afya?
1) Ndio 2) Hapana
2.17 Je, umeridhishwa na maelezo yaliyotolewa kuhusu faida na hasara za dawa za mseto ulizoandikiwa?
1) Ndio 2) Hapana

VIKWAZO VYA USHIRIKI WA MGONJWA KATIKA KUTOA MAAMUZI KUHUSU MATUMIZI YA DAWA YA MALARIA

2.19 Je, umesnirikian	ia na watoa nuduma ya arya katika kutoa maoni yako kunusu
matumizi sahihi ya d	lawa zako za mseto ulizoandikiwa?
 Ndio Hapana 	
2.20 Je, umewahi uli: ulizopewa?	za maswali yoyote kuhusu matumizi ya dawa zako za mseto
 Ndio Hapana 	

Mwisho wa dodoso, asante sana kwa ushiriki wako.

7.3 APPENDIX 3; INFORMED CONSENT FORM (ENGLISH VERSION)

INFORMED CONSENT FORM: REGISTRATION NUMBER _

Greeting

My name is Emmanuel John Msovela a postgraduate student at Muhimbili University of

health and allied sciences (MUHAS) I doing a study to the malaria patients who have

prescribed anti-malaria drugs.

Purpose of this study

To assess the knowledge of patients in understanding information of prescribed anti-

malaria drugs particular ALu. This study will be conducted at Temeke Hospital, Dar es

Salaam.

Participation in this study

If you have accepted to participate in the study, you will get a form and answer few

questions which have main objective in this study.

Right to withdraw from the study

To participate in this study is completely voluntary. Anyone can choose not to participate

in this study and may withdraw at any point. There will be no penalty for withdrawing and

he/she will continue to receive the services that are normally provided in the hospital.

Risk

This study does not have any risk to the research subjects.

Benefits of the study

This study will be beneficial in patients who get services at Temeke municipal hospital.

Also this study will be beneficial to the other patients who get drugs services all over

Tanzania. As well as will support to improve prescribed ALU drugs information.

Confidentiality

All data collected will be treated with strict confidence and stored in locked cabinets and will not be revealed to anybody outside the research team.

Payment

If you have participating in this study you will not get any payments.

For further information contact with

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I,	, patients/care givers	have
read/been told of the conte	nts of this form and have understood its meaning. I ag	ree to
enroll	_ (patient's name in full) in this study	
Signature or thumbprint of p	patient/caregiver	
Signature of Researcher	Date	

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7.4KIAMBATISHO 4; FOMU YA RIDHAA (KWA KISWAHILI)

FOMU YA RIDHAA: NAMBA YA USAILI TAREHE..../..../2017

Salamu

Mimi naitwa Emmanuel John Msovela, ni mwanafunzi wa shahada ya uzamili kutoka katika Chuo Kikuu cha Sayansi za Afya na tiba Muhimbili. Nafanya utafiti kwa wagonjwa wenye umri kati ya miaka 0 na 75 wanao tumia dawa ya kutibu ugonjwa wa malaria aina

ya ALu.

Sababu ya kufanya utafiti

Utafiti huu unafanyika ili kujua kuhusu uelewa wako juu ya maelezo uliyopewa na madaktari au mfamasia jinsi ya kutumia dawa za malaria. Utafiti huu Utakafanyika katika hospitali ya Temeke, Dar es Salaam nauta washilikisha wa gonjwa wa malaria walioandikiwa dawa ya malaria aina ya ALu.

Jinsi ya kushiriki

Kama utakubali kushiriki katika utafiti huu, utapewa fomu yakujaza yenye maswali machache yanayo tokana na madhumuni ya utafiti huu.

Uhuru wa kutoshiriki katika utafiti

Kushiriki kwenye utafiti huu ni hiari. Unaweza kujitoa wakati wowote ukijisikia kufanya hivyo. Kama utachagua kutoshiriki ataendelea kupatahuduma katika kituo chako cha afya bila kupata usumbufu wowote.

Hatari

Uchunguzi huu hauna madhara yoyote kwa mgonjwa.

Faida za utafiti

Uchunguzi huu utamfaidisha mgonjwa pamoja na wagonjwa wengine watakaokuja kupata huduma ya dawa katika hospitali ya manispaa ya Temeke na hospitali nyinginezo Tanzania. Pia utafiti huu utasaidia kuboresha huduma za mawasiliano kati ya mgonjwa, daktari na mfamasia ilikuongeza uelewa kwa wagonjwa waliopewa dawa za ALU.

Usiri

Taarifa zote zitakazo kusanywa katika utafiti huu zitakuwa siri, hivyo ushiriki wako hautajulikana na mtu yeyote. Taarifa hizi zitajulikana kwenye timu ya watafiti tu.

Malipo

Kwa kushiliki kwenye utafiti huu, hautalipwa wala hautalipa kiasi chochote cha fedha.

Kama unahitaji maelezo zaidi wasiliana na wafuatao,

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Chuo kikuu cha afya cha muhimbili

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Mimi,, mg	gonjwa au	mlezi wa	a
nimesoma/nimesomewa maelezo yote yaliyomo kwenye fomu hii na nimeelewa. Nakubali			
kushiriki/mgonjwa wangu ashiriki katika utafiti huu.			
Sahihi au dole gumba ya mzazi/muguzi/n	mgonjwa		Гаrehe
Sahihi ya Mtafiti	Tarehe		