COMPREHENSION IN DOUBT: AN INFORMED CONSENT TOWARDS TREATMENT AMONG PEOPLE LIVING WITH HIV AND AIDS AT MWANANYAMALA HOSPITAL

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MSc (Bioethics) Dissertation
Muhimbili University of Health and Allied Sciences
October, 2017

Muhimbili University of Health and Allied Sciences

Department of Bioethics and Health Professionalism

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By

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A Dissertation Submitted in (partial) Fulfillment of the Requirements for the Degree of Master of Science in Bioethics of

Muhimbili University of Health and Allied Sciences
October, 2017

CERTIFICATION

The undersigned certify that she has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: *"**Comprehension in doubt: an informed consent towards treatment among people living with HIV and AIDS at Mwananyamala hospital"*** in (partial) fulfillment of requirement for the degree of Master of Bioethics of Muhimbili University of Health and Allied Sciences.

_____

Dr. Renatha Joseph

(Supervisor)

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Date

DECLARATION AND COPYRIGHT

I, **Shukran Harun** declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University or institution for a similar or any other degree award.

Signature: …… **Date…….**

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ACKNOWLEDGMENTS

Completion of this work would not have been possible above all without the blessings from the Almighty God, Amen. As I moved along this path, there have been many people who prayed for me and believed in me and in my ability to finish the race. I thank each and every one who has helped me reach my goal.

I would also like to thank the Fogarty Global Health through the management of the Muhimbili University of Health and Allied Science, under the Department of Bioethics and Health Professionalism for the financial support from Dartmouth/Muhas Research Ethics Training (DMRET) grant No.5R25TW007693-07 which contributed to the accomplishment of this research.

To my supervisor, Dr. Renatha Joseph, I express my appreciation for your guidance, hours of assistance and dedication. You willingly gave your time to ensure that true learning and a quality document will result from this endeavor. Thank you.
I thank each study participant for sharing with me their knowledge about the study topic. I learned more than I could put on the pages of this document. The shared experiences will always be remembered and treasured.

To all my MBE2015 colleagues, most especially Sia Malekia, Tausi Haruna, Pacras Katunzi and Sikudhani Luambo, many of you have served as role models, even though you may not know it. I appreciated the support, time, and tolerance that you afforded me from day one until the end.

Lastly, to my loving husband Isaack Mukungu, My son Darwin, My daughter Jolene and My twin Cranley and Clarice, for being my constant companion and inspiration.

ABSTRACT

Background: Comprehension is one of the essential elements in truly informed consent. Maximizing comprehension is a major challenge for informed consent processes within an education difference and resource-limited settings. Comprehension with the informed consent process was found to be markedly lower among persons with lower educational levels. Tanzania is one among the underdeveloped countries, challenged by low education and poverty. So these make a doubt on Comprehension of informed consent process of treatment among HIV and AIDS patients.

Objective: This study aimed at assessing level of comprehension of informed consent process for treatment among people living with HIV and AIDS.

Methodology: This was a cross-sectional study carried out from March to June 2017 at Mwananyamala hospital. Random sampling technique was employed to select 75participants among people living with HIV and AIDS. Data was collected using a questionnaire. Data analysis was done using SPSS version 20+ to analyze dependent and independent variables which included descriptive statistics for frequency and tables. Fishers' exact test used for showing associations between study variables during statistical analysis. P-value of < 0.05 was considered statistically significant.

Results: Out of the 75 patients 50.7% have good comprehension while 38.7% had poor comprehension of treatment preliminary information of informed consent. Of the 75 patients 96% comprehended the purpose(s) of their treatment. More than half (61.3%) of patients did not know the risk while 54.7% did not know voluntariness of their treatment. A significant association between level of education, sources of information and gender with patients' comprehension was observed ($p<0.05$). There was no association between patients' comprehension with age.

Conclusion

The study clearly indicated that, level of comprehension of informed consent towards treatment preliminary information among People living with HIV and AIDS is poor, especially for female. Their lack of adequate sources of information towards treatment on informed consent was associated with lower level of formal education. All above factors affect greatly 51.2% of female comprehension of informed consent towards treatment. Therefore, more than half of female consent is not meaningful.

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LIST OF ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
CIOMS	Council for International Organizations of Medical Sciences
CTC	Care and Treatment Clinic
DMO	District Medical Officer
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and counseling
MUHAS	Muhimbili University of Health and Allied Sciences
PLWHIV	People Living with HIV
REA	Rapid Ethical Assessment
UNAIDS	United Nations AIDS
WHO	World Health Organization

DEFINITION OF KEY TERMS

Consent: Permission or agreement (1).

Comprehension: Capability of understanding something complete and be familiar with a situation (2).

Informed consent: The process by which a patient learns about and understands the purpose, benefits, and potential risks of a medical or surgical intervention, including clinical trials, and then agrees to receive the treatment or participate in the trial. Informed consent generally requires the patient or responsible party to sign a statement confirming that they understand the risks and benefits of the procedure or treatment (3).

Informed consent process: Involve all element of informed consent that needs to fulfill, information, comprehension and consent (4).

Doubt: Mean lack of sureness about someone or something (5).

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Informed consent is a cornerstone of modern medical practice (6,7). It is seen as not only a matter of signing a form but a collaborative procedure between healthcare provider and patient (8,9). Informed consent is the process that results to interaction between health provider and patient. Informed consent protects patients' autonomy, which is one of the four important principles of biomedical ethics (10). Physician should disclose information to patient and discuss the diagnosis if known, nature and purpose of proposed treatment and procedure, alternative, risk and benefits of alternative and if not receiving treatments or undergoing procedures. A patient's informed consent process requires adequate information, capacity to make informed decision and the absence of any coercion (11). Informed Consent is a doctrine that helps patients to protect themselves from unwanted interventions and allow patients to take their own responsibility.

Obtaining informed consent is an essential ethical obligation and legal requirement. A physician has moral duty to respect patients' human dignity with explicit attention to human rights so as to enhance the treatment process (12).

In a truly informed consent, comprehension is one of the essential elements to be considered in order to reach informed decision (13). According to the International guidelines, informed consent must be given in a comprehensive manner to a competent person who has the ability to understand and freely decide to participate in understanding information (13). However, the quantity and quality of information required can cause comprehension unclear.

The National Health Act of South Africa Section7 (1) state that, "any health service may not be provided to a user without user's informed consent." In most African settings, the majority of patients have low literacy as a result comprehension is seen as a challenge for most participants due to the informed consent design and its delivery which is seen to be complex (14). In ensuring that the information is properly understood, Informed consent may either be

transmitted orally or in written form. A valid consent can be obtained only from an informed person (15). The patient can consent expressly to a treatment either orally or in written or tacitly by conduct.

The World Health Organization (WHO), through Joint United Nations on HIV/AIDS (UNAIDS), mention that consent is one of the five key component which must be respected and adhered to in HIV testing and counseling. People being tested for HIV must give their informed consent to be tested (16).

In accordance with the Tanzanian HIV and AIDS Prevention and Control Act No.28, each client must sign an informed consent form, for client unable to write, a thumb print shall be substitute of the signature. Therefore, this imply that in HIV, informed consent treatment sessions involve two basic demands: informing the patient and obtaining his or her agreement. (17). The duty of counselor is to cover a given number of points about HIV and make a patient understand them before expressing a choice

A doubt to comprehension of informed consent was raised in a study in Northern Ghana, which involved parents who gave consent for their children to participate in a prospective cohort study that evaluated immune correlates to trial in protection against childhood malaria (18). Within the similar cohort, another study was done to assess understanding and retention of informed consent process to parents who consented, the study confirmed the fact that understanding of informed consent in underdeveloped countries was low (18).

Another study conducted by Fitzgerald et al. in Haiti, on HIV-1 transmission involve poorly educated volunteers, before they enrolled in the study, participants were assessed if they understood the informed consent information. The results showed that first meeting research participants from developing countries are unable to understand more than 80% of a complex Informed Consent (19).

In most of underdeveloped countries like Tanzania, individuals including PLWHIV experiences difficulties in processing information due to low education level (20), which may lead to raise some doubt on comprehension of informed consent process towards treatment.

Some scholars have urged that individuals who best understand the texts are those with higher educational levels, with reading habits, internet access and with a higher income (21), but other scholars argued against this point.

Moreover, the multiple randomized controlled trials demonstrated that providing patients with supplemental written materials, in simplified language, results in higher patient recall of informed consent information (15). In this study 192 patients underwent intraperitoneal, intrathoracic or vascular surgery at a large teaching hospital, half of the participants were given “information cards” which explained in a simplified manner the procedure and what the patient could expect during and after the surgery. Both groups had the same level of knowledge, one hour after signing the consent form, those who received the information cards had better information recall on the day of hospital discharge (15).

A study in India, about informed consent in clinical practice in Bangalore, physicians reported that it was difficult to obtain consent from illiterate patients. The study also found that nearly one third of the 148 patients and 60 doctors interviewed believed that provision of information could sometimes be harmful. Although investigators are encouraged to use simplified forms with clear language (22), but another study found that, use of simplified informed consent forms can make the comprehension process to be low. The lower illiteracy level alone does not necessarily result in increased comprehension. However, in resource-poor countries, higher rates of illiteracy may contribute to the challenges associated with comprehension of informed consent document (23).

A study in Botswana, assessed comprehension of informed consent using a 20-questions true or false, quiz administered in 6-months intervals in the context of a placebo-controlled randomized trial for the prevention of tuberculosis among HIV-infected adults revealed that, participants with low comprehension of informed consent were those with low education and language problems (24).

Another study in Mwanza Tanzania, investigated the effectiveness of a continuous informed consent process during the MDP301 phase III vaginal microbicide trial showed that comprehension of informed consent was low due to several factors such as poor resources, low education and illiteracy, but provision of continuous informed consent framework resulted to high level of comprehension (25).

1.2 Statement of the problem.

It is clearly agreed that comprehension is an essential element of the informed consent process globally. This is a source of valid consent to patients, it must be respected and adhered too during HIV testing and counseling, care and treatment of HIV and AIDS patients (8,26).

According to Tanzania national counseling and testing for HIV and AIDS guideline ; Physicians have a duty to provide sufficient information to patient who are receiving CTC services in order to give their informed consent and to make sure patients comprehend the information (17).

However in most of underdeveloped countries like Tanzania, Individuals including People living with HIV and AIDS experiences low comprehension of medical information toward treatment due to low education level and resources setting (20). This low comprehension leads to poor adherences of treatment including improper attendance to clinic and drugs misuse (27).

Different findings indicate that comprehension of informed consent to PLWHIV is poor. For instance a study done in 2002 by Fitzgerald show 80% of PLWHIV has poor comprehension of the information given during the first meeting with physician and this was so due to low education and inequality in access to health care information from different sources of information. The information given in a rapid manner in the busy clinic setting lead to poor retention and low level of understanding (19).

Therefore this proposed seeks to assess comprehension of informed consent process towards treatment among people living with HIV and AIDS at Mwananyamala Hospital.

1.3 Conceptual Framework

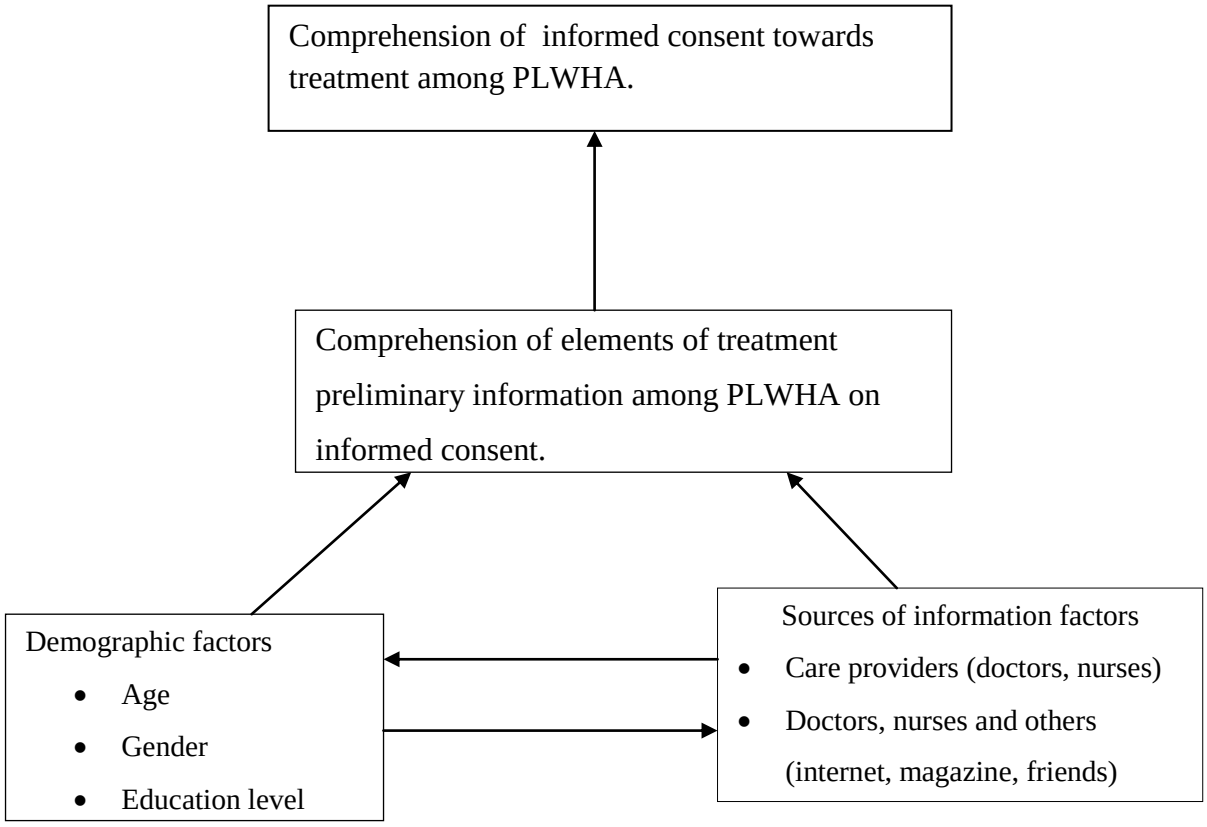


FIGURE.1.1 Source: (30), **Conceptual framework that illustrates factors associated with comprehension of informed consent towards treatment**.

Comprehension of informed consent towards treatment among PLWHA based on Comprehension of seven specific elements of treatment preliminary information. Comprehension of elements of treatment preliminary information is an outcome of several related factors. Comprehension is direct to socio-demographic such as education level, Age and sex. Doctors, Nurses, Magazine, network reflect to sources of information factors.

Therefore diagram reflects relationships among factors and their influences on PLWHA Comprehension of informed consent towards treatment.

1.4 Rationale

In Tanzania, the number of the people living with HIV and AIDS who are attending to Care and Treatment Clinics is increasing for the purpose of testing and treatment. So people who attending CTC need to consent, after being informed about testing and later on treatment in case they are HIV positive. For HIV negative they are informed about prevention and retesting. Detail and clear information together with understanding of that information are very important for valid consent**.** The study will uncover the extent to which the consent obtained in daily practice, requires improvement.

1.5 Research questions

1. What do patients understand from seven elements of treatment preliminary information's given on informed consent process?

2. What is association between comprehension of elements of treatment preliminary information given to people living with HIV and AIDS on informed consent process with age, gender and education level?

3. What is association between comprehension of elements of treatment preliminary information with the sources of information to people living with HIV and AIDS on informed consent process?

1.6 Objectives

1.6.1 Broad Objectives

To assess level of comprehension of informed consent towards treatment among people living with HIV and AIDS.

1.6.2 Specifics Objectives

1. To assess comprehension of seven elements of treatment preliminary information to people living with HIV and AIDS on informed consent process.
2. To determine association between comprehension of element of treatment preliminary information given to people living with HIV and AIDS on informed consent process with gender, age and education level.
3. To determine association between comprehension of elements of preliminary treatment information with the sources of information to PLWHIV on informed consent process

CHAPTER TWO

2.0 LITERATURE REVIEW

Studies on comprehension of informed consent process have been conducted in Tanzania and worldwide. The studies show that comprehension of informed consent is very important. Obtaining higher comprehension of informed consent is beneficial to both the patient and health care provider and researcher. Comprehension enables patient participation in decision making process, which is a matter of concern for ethics committees on research trials but also in clinical practice. Comprehension is related to factors such as age, education and ability to access information from different sources (31). Within informed consent for clinical treatment, factors like young age, old age and illiteracy create a doubt in understanding of informed consent process to people living with HIV and AIDS, because services for HIV and AIDS treatment is provided equally for all HIV and AIDS patients (31).

Understanding of informed consent process.

Informed consent process includes health care provider and patients engage in dialogue about a proposed medical treatment's nature, harms, benefits, risks and alternative (15). The CTC health care provider provides information about treatment in which purpose, procedure, risks, benefits, voluntariness, harms and time duration for treatment are explain to the patient (17). People living with HIV and AIDS need to understand the information provided on informed consent process so as to enable them to give free consent. However, patient understand only some of the aspects within the informed consent process (18), this is thus doubtful, because a truly informed consent process requires understanding of all aspects within informed consent process before treatment.

A study conducted in Botswana on repeated assessments of informed consent comprehension among HIV infected adult participants in randomized trial for the prevention of tuberculosis after examination of specific quiz items, revealed that participants would tend to answer questions correctly that were related to study purpose and procedures, while some questions related to randomization, placebos, risks, and voluntariness were answered less correctly by 70%. Randomization, placebos, risks, and voluntariness were problematic with respect to

informed consent and is consistent with literature that demonstrated randomization, placebos, risks, and voluntariness are particularly likely to be misunderstood among subjects in both the developed and developing world (24). If participants do not understand the information provided during informed consent process their consent is meaningless and invalid (32).

Education level, ages and patients' comprehension of informed consent process.

Education can better equip individuals to access and use information and services to maintain and improve their own health and their family's health. Education can also impact positively the level of society health such as youth age groups and physical functioning in older people (33). Studies have shown that, Comprehension of informed consent process can be attributed by education level and age of the participants. A study done in Vietnam, approached adults who had enrolled within the past 3–90 days in a clinical or epidemiological study on the education level, language and informed consent process revealed that comprehension and satisfaction with the informed consent process were marked low among persons with lower educational levels (34).

In India, study was undertaken as part of a clinical trial on the effectiveness of nutritional supplementation on malnutrition in under-5 children in the Kaniyambadi block of Vellore district to assess whether participants subjected to group counseling recall the informed consent better than those subjected to individual counseling. This study demonstrated that in group counseling participants had poor comprehension of informed consent due to the different level of education (35). Another study on optimizing the HIV and AIDS informed consent process in India, examined pregnant women's understanding of group education and counseling (GEC) on HIV/AIDS provided within an antenatal clinic in Maharashtra, this is clinical practice, revealed that complex constructs such as informed consent was conveyed with low level of education which may not be sufficient to ensure true informed consent (36).

A trial was conducted among participants of an HPV Sero-prevalence study in Northern Ethiopia to assess the effect of rapid ethical assessment (REA) on comprehension, retention and quality of the informed consent to participants showed that maximizing comprehension of informed consent process was a challenge due to low-education and poor resources setting.

Participant with higher education level (secondary education level) were found more likely to obtain higher scores in comprehension assessment than those with no formal education. The REA was thus a potential modality to improve comprehension of informed consent process (37). A study developed in 2007 demonstrated a multivariate analysis of factors that hinder the understanding of the informed consent and found that participants who best understood the texts are those with higher educational levels, with reading habits, internet access facility and with a higher income (38).

A study done in Mwanza Tanzania on comparison of closed-ended, open-ended and perceived informed consent comprehension measures for a mock HIV prevention trial discovered that, the open ended questions for assessing comprehension of informed consent process seemed better than close ended questions. But for the patient, who had low education, were difficult to apply and to know if they understood the process. Open ended question for low education patient resulted to poor comprehension of informed consent process (28).

Memory on medical information is often seen to be poor and inaccurate, especially when patients are old or anxious. Patients tend to focus on diagnosis-related information and fail to register instructions on treatment. Simple and specific instructions are better recalled than general statements. Patients can be helped to remember medical information by use of explicit categorization techniques (39).

Patients' sources of HIV and AIDS treatment information

Equity in health does not stop at the availability drugs, but includes the provision of adequate information to patients regard to treatment in order to achieve a full health potential. Equity in health care provision not only relate to equity in access of health care, but also to the provision treatment related information, enabling patients to make decisions. So focused on the internet as a source of information and PLWH information needs in order to boost their health and well-being (30).

Study conducted in Potchefstroom, North-West Province, the respondents indicated their sources of information on HIV and AIDS. This included more than one source of information, namely health care workers (87.3%) (n = 69), magazines (67%) (n = 53), schools (31.6%) (n = 25), television and radio (87.3%) (n = 69), clinics (92.4%) (n = 73) and family members (50.6%) All these source of information were seen to help in the understanding of information (21).

Also another study in Kwazulu South Africa on the sources and types of information of self-care symptom management strategies for HIV and AIDS, documented that people living with HIV and AIDS use multiple sources such as health care providers, self, media, readings, and social network, to gather information related to their infection which also helped in the self-care management for AIDS and HIV (40).

In a study that examined the HIV knowledge in Southern U.S clinics, results confirmed, people living with HIV and AIDS especially those with low literacy skills, were most likely to have their physicians as a sole source of HIV information. There is inequality in access to health care information including HIV and AIDS so for patients with more than one source of information will be more knowledgeable and comprehend better than those patient who depends on physician as sole source of information (41).

So doubt has been created in the comprehension of treatment information on informed consent, due to some patients have ability to access information from other sources than health care providers, and others depend only to health care provider. This indicates that the informed consent process (both group and individual) when combined with enhanced education and counseling materials could lead to excellent comprehension of informed consent issues.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

A cross-sectional study design was used. Considering the facts that the aim was to assess the level of comprehension of informed consent towards treatment among people living with HIV and AIDS at Mwananyamala Hospital, and was implemented from June to August 2017. A quantitative approach seemed relevant because measuring participants' comprehension needs standardized tools, which included numerical measurements. Quantitative observation is an objective gathering of information which focuses on numbers or measurements while basing results on statistics and numeric analyses.(38,42)

3.2 Study population

The study population included people living with HIV and AIDS attending CTC at Mwananyamala hospital and on treatment. The study main questions and Objectives required involvement of these PLWHA respondents, because they are already given information from health care providers and consented on their treatment.

3.2.1 Inclusion criteria

Confirmed HIV positive aged 18 - 65 years who has ability to comprehend information and capable of giving consent. Patients were on treatment for more than one month for easy to measure their treatment adherence and stress free.

3.2.2 Exclusion Criteria

We excluded from the study, all patients who were seriously ill, mental illness and cognitively impaired person, any patients below 18years and above 65yrs, those patient not speaking Kiswahili selected language of questionnaire. Those mentioned are conditions limit ability to comprehend information.

3.3 Study area

The study was conducted at Mwananyamala Care and Treatment Clinic (CTC) which is situated in Kinondoni Municipality, Dar es Salaam. Dar es Salaam region has five districts

namely Kinondoni, Temeke, Ilala, Ubungo and Kigamboni. Kinondoni, Ilala and Temeke municipalities, each has referral hospital namely; Mwananyamala, Temeke and Amana respectively. Within these referral hospitals, there is HIV Care and Treatment Clinic (CTC).

Mwananyamala was selected randomly out of the 3district referral hospitals, by using lottery method, three pieces of papers were written a name of one referral hospital, then folded, placed in bowl and mixed thoroughly. The blind-folded researcher then picks one piece of paper tags from the bowl. The piece of paper picked by the researcher is the area for the study. (43).

3.4 Sample size determination

The following formula used to calculate sample size

$n= Z^2*P(1 – P)/ d^2$

Where,

Z=Percentage point corresponding to a given significance level. In this study significance level kept at 5%, resulting to Z=1.96

P = estimated prevalence of PLWHA in Tanzania is 4.7% =0.047 (44).

d= absolute sampling error=0.05

n = sample size.

Thus, $n= 1.96^2 *0.047(1-0.047)/ 0.05^2=68$

To compensate for non-response during data collection, the sample size increased by 10%,

Therefore; n= 68/ (1-0.1) = 75

So, according to United National for AIDS (UNAIDS) prevalence of PLWHA in Tanzania is 4.7%, as where P was obtained, and as a resulted 68 number of participants. When compensation for non-response was calculated, 75 numbers of participants were obtained.

3.5 Sampling Procedure

In this study, simple random sampling was employed to select participants. Simple random sampling is a probability sampling in which all members of the population have an equal chance of being selected (45). A lottery technique was used to select participants in which eligible patients attending to the hospital assigned with numbers. To comply with the rule of thumb for probability sampling more than 78 patients (n+1) were numbered. This increased the degree of sampling with replacement. For credibility the numbers were subjected to the online computer software namely; http://www.randomresult.comto generate numbers of participants to be enrolled in the study (46).

Recruitment of participants was done during clinic hours (9am to 2pm) from Monday to Friday on which HIV clinic is conducted, except for public holidays. Identification of eligible patients was done by the attending nurses as they arrive to the clinic. Those who were aware of their HIV status referred to either research assistants or the investigator for enrollment into the study.

3.6 Variables

3.6.1. Dependent variable

- Comprehension of treatment preliminary information's among PLWHA

3.7.2. Independent variables

- Socio economic and demographic factors- age, sex, and education level
- Environmental factors-sources of information (doctors, nurses and other sources such as magazine, Friends, internet, books)
- The dependent variable was examined against the independent variables

3.7 Pretesting of data collection tools

A study pilot conducted at Sinza district hospital in Ubungo District. The questionnaires pretested on a random sample of 10 HIV and AIDS patients. This pilot pretest provided a clear applicability of the questions and average time allocated to questionnaire to one participant.

3.8 Data collection tools and procedure

In order to achieve the set objectives, questionnaire with close-ended questions was used for data collection. Although all questions are composed in English, they were translated and asked in Kiswahili which is common medium of communication for participants and then translated back to English for analysis.

Questionnaires were divided into two groups:-

Group A, aimed at obtaining the demographic profile of participants including age, gender, education, and marital status.

Group B, aimed at obtaining comprehension of treatment preliminary information among people living with HIV and AIDS on informed consent process. A scale of 0-7 used. Higher scores range 5-7indicating adequate or good comprehension, moderate score was 4 for average comprehension and lower score was 0-3for poor comprehension of treatment preliminary information (28)**.**

Treatment Preliminary information given on informed consent process consist 7 elements. (Purpose of the treatment, Procedures on treatment, Benefits of the treatment, Risks, Side effect, Time duration of the treatment and Voluntariness).

Indicators for comprehension of purpose, Side effects or Risks were as follows;

Ability to mention at least one common,

Purpose

Suppress HIV multiplication, Restore and preserve immunologic function, and Prevent HIV transmission.

Risks,

Drugs resistance and Treatment failure.

Side effects,

Some side effects, like headaches or occasional dizziness, may not be serious. And other side effects, such as swelling of the throat and tongue or liver damage, can be life-threatening.

Then comprehension scored as shown in the table below

Table 1: Comprehension of treatment information of informed consent process was scored like this table below.

Purpose of treatment	1
Procedures during treatment	1
Benefits	1
Risks	1
Side effect	1
Voluntariness	1
Time duration of the treatment	1

The table contains 7 elements of treatment information given to HIV and AIDS patients of informed consent process. If a patient answers correctly, he/she scored 1 mark for one element and scored 0 for a wrong answer for each element. At the end, scores were summed up to obtain a total score for each participant.

3.8.1 Validity of the tool

The comprehension assessment tool used has been adapted from tools used in successfully completed trials within multiple levels of international ethics and regulatory review. The tool initially developed from VAXGEN phase III HIV Vaccine trial conducted in Bangkok (47). This was modified for used in hypothetical Pre-exposure prohylaxis trial consent form. And then tool used on comparison of close ended, open ended and perceived informed consent comprehension measures for a MOCK HIV prevention trial among women in Mwanza, Tanzania (28). The assessment was comprehensive and detailed, including seven components. Those components were reflect required elements of informed consent such as purpose,

procedure, risks, benefits, voluntariness, side effect and time duration, while the point reflects the specific content to address required element (28,47).

3.9 Data Management

The filling of questionnaires was supervised by the principal investigator. This was ensured that the data collected is correct and answers/responses are well understood by participants.

The filled questionnaires examined on daily basis to check for quality of questionnaire conducted on that particular day so as to track back missed responses from the participants.

The data collected using questionnaire, have to be verified for completeness of filling. The data was coded prior to entering and feeding the information into statistical package SPSS version 20+ to run frequencies of the data. Data cleaning was done to ensure there is no information missing.

3.10 Data analysis

Data collected from participants via questionnaire and analyzed by using computer software named Statistical Package for Social Sciences (SPSS) version 20+. The analysis involved descriptive statistics to describe the sample population in frequency, tables and cross tabulations between independent and dependent variables and Chi-square test for association of variables or Fishers' exact test for showing association between study variables for cells with less than five during statistical analysis. Continuous variables represented by means and standard deviations and Categorical data by whole numbers and percentages. P-value of < 0.05 considered statistically significant. Data analysis based on specific objectives.

Data presented as,

Comprehension of treatment preliminary information among people living with HIV and AIDS on Informed consent process- categorical variable frequency, percentages, bar chart.

Age – frequency, percentages

Gender- categorical variable; frequency, percentages

Educational level- categorical variable; frequency, percentages

The association between HIV and AIDS patients' comprehension of treatment preliminary information and source of information, age, gender, education level, achieved by using chi-square test.

3.11 Ethical consideration

The aims and benefits of the study explained to the study participants. Subsequently, written informed consent was provided to the participants. Participants were asked to indicate their own willingness to participate by consenting to the study. Participants' information kept confidential with no any identifying features. Access to the data limited to the researcher.

3.12 Ethical clearance

Ethical clearance to carry out this study sought from Muhimbili University of Health and Allied Sciences (MUHAS) Research and Publication Committee. Permission to conduct the study at Mwananyamala obtained from the Director of Clinical Services and District Medical Officers (DMO's) of Kinondoni.

CHAPTER FOUR

4.0 RESULTS

A total of 75 people living with HIV and AIDS were recruited for the study. Table 2 shows age group, Sex distribution and education level of the participants.

Table 2: Demographic details of respondents by age, sex, and education level

Variable		Number of respondents and percentages (%)
Sex	Male	32(42.7)
	Female	43(57.3)
Total		75(100)
Age	18-33	37(49.3)
	34-49	26(34.7)
	50-65	11(14.7)
Total		74(100)
Education status;	No education	04(5.3)
	Primary education	18(24)
	Secondary education	24(32)
	Tertiary education	21(28)
	No completed education	08(10.7)
Total		75(100)

4.1 Comprehension of treatment preliminary information

Half (50.7%) of the 75 participants (Table 3) have good individual comprehension of treatment preliminary information. More than half female (51.2%) have poor comprehension and 62.5% of male have a good comprehension.

Table 3: Comprehension of treatment preliminary information

Comprehension of treatment preliminary information.	Frequency (%)		
	Male	Female	Total
Good comprehension	20(62.5)	18(41.9)	38(50.7)
Average comprehension	5(15.6)	3(6.9)	08(10.7)
Poor comprehension	7(21.9)	22(51.2)	29 (38.6)

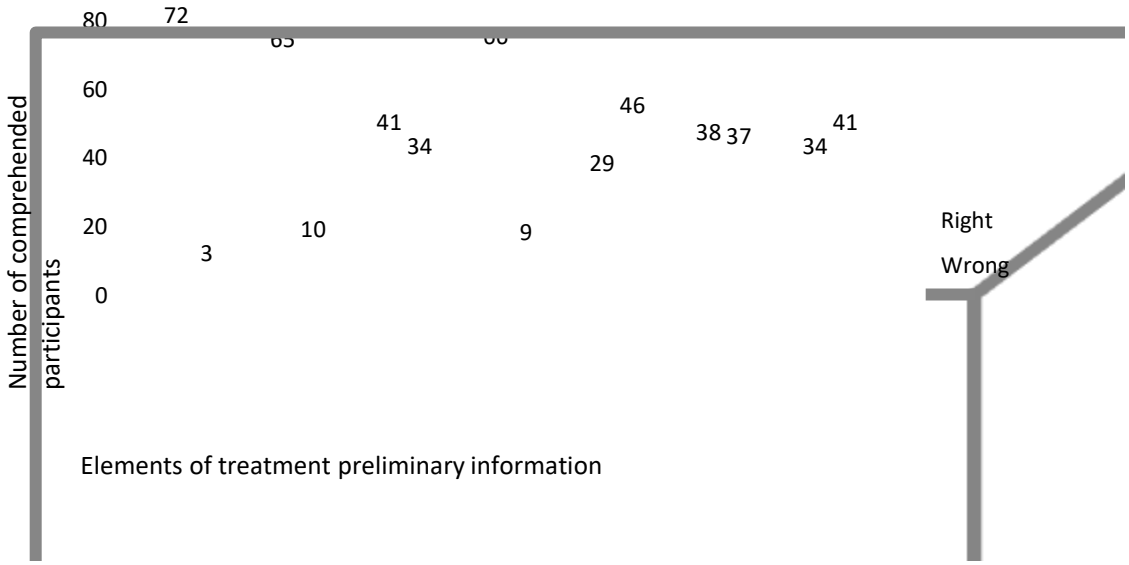


Figure 2: Bar graph contains results of 7 elements of treatment preliminary information given to HIV and AIDS patients.

Figure 2 above shown that, Majority 72(96%) of the 75 participants in the current study were comprehended the purpose, which included treatment for HIV and AIDS and opportunistic infection. More than half 46(61.3%) of the participants were not comprehended about risks.

4.2 Association of patients' comprehension of their treatment information with demographic characteristics (age, gender, and educational status).

Table 4, shows 59.5% of 18-33 years patients have good comprehension while 63.6% of 50-65 years patients have poor comprehension. There was no significant association between age with Patients' comprehension, p value observed from Fishers' Exact test was p= 0.253.

Table 4: Association between patients' comprehension with Age

Age	Comprehension level			
	Good comprehension n=38	Average comprehension n=8	Poor comprehension n=28	*P-value
	n (%)	n (%)	n (%)	
18-33 years	22(59.5)	5(13.5)	10(27.0)	0.253
34-49 years	12(46.2)	3(11.5)	11(42.3)	
50-65 years	4(36.4)	0(00)	7(63.6)	

*= fishers' exact test used.

n (%) = frequency(%)

Table 5, show secondary education and tertiary education respondents have good comprehension than primary education, no completed education and no education respondents. About 60% of male who possessed Tertiary education level have good comprehension than female. There was significant association between Patients' comprehension of treatment preliminary information of informed consent process with educational level and sex, p value observed from Fishers' Exact test was $p<0.05$

Table 5: Association between Patients' comprehension with education level and sex

Education level	Comprehension level						*P –value
	Good comprehension		Average comprehension		Poor comprehension		
	Male	Female	Male	Female	Male	Female	
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
No education	-	1(5.6)	-	-	-	3(13.6)	0.001
Primary education	1(5.0)	1(5.6)	2(40.0)	-	4(57.1)	10(45.5)	
Secondary education	5(25.0)	9(50.0)	3(60.0)	3(100)	1(14.3)	3(13.6)	
Tertiary education	12(60)	7(38.9)	-	-	1(14.3)	1(4.5)	
No completed education	2(10)	-	-	-	1(14.3)	5(22)	
Total	20(100)	18(100)	5(100)	3(100)	7(100)	22(100)	

*= Fishers' exact test used

n(%) = frequency (%).

4.3 Association of patients' comprehension of their treatment information of informed consent with sources information.

Table 6 below shows 86.4% of female had doctors and nurses only as sources of information have poor comprehension. All Male who have good comprehension obtained extra sources of information. There was significant association between sources of information and Patients' comprehension of informed consent, p value observed from Fishers' Exact test was $p<0.05$

Table 6: Association between Patients' comprehension with sources of information and each gender

Comprehension level	Sources of information						*P value
	Doctors and Nurses		Doctors, nurses & Others		Total		
	n=33(44%)		n=42(56%)		n=75(100)		
	Male	Female	Male	Female	Male	Female	
	n (%)	n(%)	n (%)	n(%)	n (%)	No (%)	
Good comprehension	0(0.0)	5(27.8)	20(100)	13(72.2)	20(62.5)	18(41.9)	0.012
Average comprehension	1(20)	3(100)	4(80)	0(0.0)	5(15.7)	3(6.9)	
Poor comprehension	5(71.4)	19(86.4)	2(28.6)	3(13.6)	7(21.9)	22(51.2)	

* =fishers' exact test used

n(%) = Frequency (%)

CHAPTER FIVE

5.0 DISCUSSION

This chapter provides a brief discussion of the major findings from the study on comprehension of treatment preliminary information that can be used to improve informed consent process towards treatment among people living with HIV and AIDS.

Regarding comprehension about treatment preliminary information, half 50.7% of participants had good comprehension of their treatment preliminary information in which included purpose, procedure, benefit, risk, side effect, voluntariness and time duration of treatment. Participants comprehended purpose, procedure, benefit and time duration well, than risks, voluntariness and side effects. Quite similar to the observation made by Chaison, Valley, Joglekar and Woodsong. They proved that Majority of participants comprehended given information of informed consent and would tend to answer questions correctly, that were related to study purpose and procedures, while some questions related to risks and voluntariness were answered incorrectly. (24,25,48,49).

However, The current study findings differ from study done by Fitzgerald et al, on HIV-1 transmission involved poorly educated volunteers, before enrolled in the study, participants were assessed if they understood the informed consent information, the results showed that first meeting research participants from developing countries were unable to understand more than 80% of an Informed Consent (19).

The current study finding correlated with studies done by Chaisson et al and Vallely et al demonstrated that participants comprehended information of informed consent because it was repeated assessment or continuous informed consent to HIV and AIDS participants. Health care provider has a duty to cover all the point about HIV and to make a patient understand them before expressing a choice. According to United Republic of Tanzania MoHSW, national comprehensive guideline for HIV Testing and Counseling , health care provider provides information about treatment in which purpose, procedure, risks, benefits, voluntariness, harms and time duration for treatment are explain to the patient and patients

need to understand information given of informed consent process so as to enable them to make a free choice (17). However Oduro et al and Staunton et al revealed that, some patients failed to understand some of the aspects such as risk and voluntariness in trials or treatment (18,50), this lead to invalid consent. A valid consent can be obtained from informed person who comprehended all aspects of formation given on informed consent (15).

The current study show 44% of people living with HIV and AIDS received their treatment preliminary information from medical doctors and nurses only, while 56% received their treatment preliminary information from doctors, nurses and other sources such as internet, magazine, and friends, this being in disagreement with a studies in Southern U.S and Lilongwe, Malawi, the results confirmed that, most of people living with HIV and AIDS especially those with low literacy skills, were most likely to have their physicians as a sole source of HIV information, where, a few remained patients obtained more treatment information from media, magazine and internet (41,51). Majority 60% of the study participants were educated, that why they have ability to access other sources of information and not only receiving information from nurses and doctors. A studies done by Hall et al and Cohn et al found that people with higher education has reading habit and access internet (38,52). In current study also shown that majority of Male participants have higher education which lead to access more information from different sources than nurses and doctors, as a result of good comprehension to male.

When patients' comprehension of their treatment preliminary information comprising of seven components such as purpose, procedure, benefits, risk, time duration, side effects and voluntariness was assessed in relation with sources of treatment preliminary information, there was significant association between sources of treatment preliminary information with patients' comprehension with P value of 0.012. The current study findings were consistent with the study done in Mwanza, Tanzania and Kwazulu, South Africa which revealed that sources of information lead to comprehension of information on informed consent process (25,40). Observed findings might be explained that, Patients with more sources of information than from doctors and nurses comprehended better than those who depend on physician as sole

sources. According to Sherlock and Brownie, demonstrated that, the use of educational materials in order to obtain the informed consent, as well as multimedia interactive process leads to increased understanding of participants the implication procedure (53).

The current study demonstrated a lack of significant association of age (p=0.253) to the patients comprehension of their treatment preliminary information these results are consistent with the study done by Assumpção et al , which showed no association between accuracy score with g (p=0.2)age (54). The two studies differ from Kessels R. who said that "Memory on medical information is often seen to be poor and inaccurate, especially when patients are old or anxious" (39). Kessels R. result contradicted the current study and study done by Assumpção et al, because an engagement and commitment of some patients with their treatment, is independent of their age.

However, a significant association between level of education, gender and patients' comprehension was observed (p-value = 0.001), and Male 60% who possessed Tertiary education level have good comprehension than female. Shafiq and Breese et al findings are consistent with current study findings that, comprehension of informed consent process were markedly higher among people with higher education levels, there was ($p<0.001$) significance association between education level with comprehension of informed consent process observed (34,55). The current study result contradicted with studies done by Assumpção et al and Ssali et al which shown that understanding study information was not closely related to an ability to read and write (54,56). Also Fitzgerald et al, with poorly educated volunteers, also showed that participants from developing countries are able to understand more than 80% of complex Informed consent if initiatives are taken to secure knowledge instead of simple meeting (19). The study expectations and what evidenced in literature, the participant with good comprehension has highest education level. Observed relation between education levels with comprehension of treatment preliminary information on informed consent process might be explained as, education level as a result to good comprehension or poor comprehension. Comprehension are compromised by lack of education which lead to difficult translating scientific terms, processing large amount of information in time limited setting (28).

5.1 Limitations

Assessing understanding was a very difficult task to accomplish. Checking understanding of the consent process without having to observe the process itself is a limitation.

The understanding of the study questionnaire by interviewers might have had some impact on the way some patients responded to the questionnaire, but researcher tried to make more elaboration to each question into Kiswahili, in which enhanced respondents to understand all ambiguous sentences.

CHAPTER SIX

6.0 CONCLUSIONS AND RECOMMENDATION

6.1 Conclusions

Informed consent is a medical legal requirement to patient. In true informed consent, comprehension is one of the important elements to be considered in order to reach informed decision, to enhance treatment process and allow patients to take their responsibility.

The study clearly indicated that, level of comprehension of informed consent towards treatment preliminary information among People living with HIV and AIDS is poor, especially for female. Their lack of adequate sources of information towards treatment on informed consent was associated with lower level of formal education. All above factors affect greatly 51.2% of female comprehension of informed consent towards treatment. Therefore, more than half of female consent is not meaningful.

6.2 Recommendations

Doctors, nurses and other members of the health care team should take more action on improving patients' comprehension and make sure patients covered all elements within informed consent towards treatment by providing more elaboration especially for female and those who are mostly low education level.

Providing supplemental written materials; using video educational tools; and having structured discussions at CTC level for their clients.

These findings suggest that the study sites should take additional efforts among illiterate people, to achieve adequate comprehension among them. A more, interactive, client-centered consent process, repeated back and serially reassessing and re-explaining until the patient demonstrates recall and comprehension might help to enhance comprehension significantly.

Lastly, more research is needed to determine the methods to increase comprehension, especially for participants with inadequate or marginal reading skills.

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APPENDICES

Appendix 1: Questionnaire for People living with HIV/AIDS

SECTION A: DEMOGRAPHICS

Q1 What is your age? _

Q 2 What is your Gender?

a) Male ( )

b) Female ( )

Q 3. What is your Level of Education?

a) No education ( )

b) Primary school education ( )

c) Secondary school education ( )

d) Tertiary education ( )

e) Incomplete education ( )

Q 4. What is your marital?

a) Married ( )

b) Widow ( )

c) Divorce ( )

d) Single ( )

SECTION B: Comprehension of treatment preliminary information given to people living with HIV and AIDS on informed consent process.

1. If you were going to tell a friend, what this treatment is about?
    a) HIV and AIDS
    b) Opportunistic infections

2. Have you been told how long the treatment will last?
    a) Yes, if yes answer question 3
    b) No, if no go to question 4

3. For how long?
    a) Life long.

4. What are the main things you will do?
    a) Attending clinic
    b) Medication adherence
    c) Weighing
    d) Assessment of opportunistic of infection

5. What are the benefits of treatment?
    a) Live a long
    b) Health life

6. What are the risks of treatment?
    a) Poor adherence – drug resistance and treatment failure.
    b) Drug interaction

7. What are the side effects of medication?

    a) Some side effects, like headaches or occasional dizziness, may not be serious.

    b) Other side effects, such as swelling of the throat and tongue or liver damage, can be life-threatening

8. .Do you think this process seen as a contract between the you and your care giver?

    a) Yes, if yes, answer question 9

    b) No, if NO, go to 10

9. What does your consent mean?

    a) Willing to start treatment

    b) Agreement

    c) Promise

10. Have you been told you can freely decide to enroll in the treatment?

    a) Yes

    b) No

11. Where did you get the treatment information?

    a. Doctor and Nurse

    b. Doctor, Nurse and others(such as internet, magazine and friends)

Appendix 2: Questionnaire – Swahili Version

DODOSO KWA WAGONJWA KUPIMA UELEWA WA RIDHAA WANAYO ITOA KATIKA MATIBABU YAO.

A. UTANGULIZI

1. Umri _____
2. **Jinsia**

a) Mwanamke ( )

b) Mwanaume ( )

3. Je umeolewa au kuoa?

a) Sijaolewa ( )

b) Sijaoa ( )

c) Nimeolewa /sijaoa ( )

d) Nimeachika ( )

e) Nimefiwa ( )

4. Kiwango cha Elimu

a) Sijasoma kabisa ( )

b) Shule ya msingi ( )

c) Shule ya sekondari ( )

d) Chuo na kuendelea ( )

e) Sijamaliza elimu ( )

SEHEMU B; UELEWA WA MAELEZO YA AWALI YA MATIBABU YANAYOTOLEWA KWA WATU WANAOISHI NA VIRUS VYA UKIMWI, KATIKA MCHAKATO MZIMA WA RIDHAA

1. Kama ungekuwa unakwenda kuwaambia rafikizako. Tiba hii ina husu nini?
    a) Kupunguza makali ya virus vya ukimwi
    b) Magonjwa nyemelezi
2. Je,umeambiwa kwa muda gani matibabu yatadumu?
    a) Kama NDIYO, jibu swali la 3
    b) HAPANA,endelea swali la 4
3. Kwa muda gani?
    a) Maisha yote
4. Ni mambo gani makuu utafanya?
    b) Kuhudhuria kliniki
    c) Kunywa dawa
    d) Kupima uzito
    e) Tathimini ya magonjwa nyemelezi
5. Nini faida ya matibabu,?
    a) Kuishi muda mrefu
    b) Afya njema
6. Ni madhara gani unaweza kuyapata katika matibabu yako?
    a) Mahudhurio hafifu–Usugu wa dawa na kushindwa kwa matibabu
    b) Mwingiliano wa dawa,- husababisha madhara
7. Ni madhara gani yanawezatokea wakati wa kutumia dawa?.
    a) Baadhi ya maudhi madogo madogo, kuumwa,kichwa, usingizi
    b) Madhara,mengine, kuvimba,koo,naulimi, kuharibika kwa ini, yanaweza kuwa hatari sana.
8. Je, unafikiri huu mchakato nimakubaliano kati yako na muuguziwako?
    a) Kama NDIYO,jibu swali la 9
    b) Hapana endelea swali la 10

9. Je, ridhaa yako ina maana gani?
    a) Kukubali kujiunga kwenye matibabu
    b) Makubaliano
    c) Kuahidi/ kutoaahadi
10. Je ,unajua kuwa upo huru kujiunga au kutokujiunga na matibabu?
    a) Ndio
    b) Hapana
11. Wapi umepata maelezo ya matibabu yako
    a) Daktari na muuguzi
    b) Daktari,muuguzi na kwingine(mitandaoni, marafiki na magazetini)

Appendix 3: Study Consent Form – English Version

You are being asked to consent for your participation into a study that aims to assess comprehension of informed consent process among people living with HIV and AIDS. We are asking you to participate in this study because you are among of the people/member who can provide enough information about what happen during informed consent process in treatment.

Study procedures

This study is expected to involve a total of 149 participants from questionnaire. If you decide to be in our study, we will request you to answer a few questions on your opinion, knowledge, and experience regarding comprehension of informed consent process among people living with HIV and AIDS. The expected time to spend to answer questionnaire is from 10minutes to 20minutes depending on an individual participation.

Confidentiality

The information we get from you will be kept confidential, you are information will be accessed only by research members of this study. In any way, information will not be linked to your individual name and will no implication to your current and future status to social services including health services in the area. Your name will not be mentioned in any paper or report about this study. Your identity to this study will base on the agreed identification item (ID).

Benefits

There is no direct benefit for you participating into the study. However, the information that you are going to provide to us will help in improving CTC services in relation to patient needs.

Participation

Participation into the study is voluntary. You have the right to decline participation or withdraw from the study at any point of answering questions. Your decision to participate or not will not in any way interfere with your ability to receive any available CTC and other health services in this area. Moreover, you’re not subjected to say why you are quitting the study.

If you agree to participate into the study, please, give your signature at first place below.

Signature of the participant…….Date……..

Signature of the researcher…….Date……..

THANK YOU

Appendix 4: Study Consent Form – Swahili Version

HATI YA RIDHAA YA USHIRIKI KATIKA UTAFITI

Unaombwa ridhaa yako kushiriki katika utafiti huu ambao unalenga kutathimini uelewa wa mchakato mzima wakutoaridhaa kwamatibabu kwa watu wanaoishi na virus vya ukimwi.Tunakuomba wewe binafsi kushiriki kwasababu wewe ni mmoja wa watu muhimu ambae unaweza kutupatia taarifa za kutosha ,nakujua nini kinaendelea wakati wa mchakato mzima waridhaa ya matibabu kwa mgonjwa.

Utaratibu wa ushiriki

Utafiti huu utashirikisha wanaopata huduma CTC, hivyo patakuwa na kujibu maswali ,mtu mmoja mmoja ila jumla kuu tunategemea iwe 75 washiriki.Ukikubali kutoa ridhaa ya kushiriki katika utafiti huu tutakuomba kukuuliza maswali machache kuhusu suala la uelewa wa maelezo y amchakato wakutoa ridhaa kwaajili ya matibabu kwa mtu anaeishi na virus vya ukimwi. Tunategemea kutumia dakika 10 au 20 dakika hivi kutegemeana na ushiriki wa mtu binafsi.

Usiri

Taarifa zote tutakazo zipata kutoka kwako tutazitunza kwa usiri mkubwa.Taarifa zako zitaweza kuonwa na wanaohusika na utafiti huu tu. Kwa vyovyote vile, taarifa zako hazitahusishwa na jina lako katika hali yoyote ile, na hivyo, taarifa zako hazitakuletea kuathirika kwa aina yoyote katika kupata huduma zako za afya katika eneo lako.Jina lako halitakuwepo katika ripoti ya utafiti huu.Utambulisho wako katika utafiti huu utafuata utaratibu na tutakakubaliana.

Faida,

Hakuna faida yoyote kwa mshiriki, isipokuwa taarifa yako itasaidia kuboresha huduma itolewayo na CTC kwa wagonjwa wake.

Ushiriki

Mshiriki yupo huru kushiriki utafiti. Kwa sababu zao, wana haki ya kukataa au kujiondoa kwenye utafiti. Kama ilivyo ni hiari, unaweza amua kutojibu swali lolote utakaloona kama huku ridhishwa nalo.Hata baada ya kuridhia, unaweza kujitoa kushiriki. Uamuzi wako wakushiriki au kutoshiriki hauingiliani na haki yako ya kupata huduma za afya na matibabu.

Kibali cha utafiti

Kibali cha ruhusa ya kufanya utafiti huu imetoka kamati ya maadili ya utafiti ya chuo kikuu muhimbili,nakukubaliwa na mganga mkuu wa manispaa ya Kinondoni.

Unakubali kushiriki?

NDIO (endelea)

HAPANA (muache)

Sahihi ya Mshiriki…….Tarehe……..

Sahihi ya Msaili…….Tarehe……..

ASANTEN KWA KUSHIRIKI

Appendix 5: Ethical Clearance

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR OF POSTGRADUATE STUDIES

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Ref. No. MU/ PGS/SAEC/Vol. X/ 3rd August, 2017

Ms. Shukran Harun
MSc Bioethics
MUHAS.

RE: APPROVAL OF ETHICAL CLEARANCE FOR A STUDY TITLED: "COMPREHENSION IN DOUBT: A INFORMED CONSENT PROCESS AMONG PEOPLE LIVING WITH HIV AND AIDS AT MWANANYAMALA HOSPITAL"

Reference is made to the above heading.

I am pleased to inform you that, the Chairman has, on behalf of the Senate, approved ethical clearance for the above-mentioned study. Hence you may proceed with the planned study.

The ethical clearance is valid for one year only, from 2nd August, 2017 to 1st August, 2018. In case you do not complete data analysis and dissertation report writing by 1st August, 2018, you will have to apply for renewal of ethical clearance prior to the expiry date.

Prof. Andrea B. Pembe
DIRECTOR OF POSTGRADUATE STUDIES

cc: Director of Research and Publications
cc: Dean, School of Public Health and Social Sciences