COMPREHENSION OF INFORMATION FOR INFORMED CONSENT AMONG HEMATO-ONCOLOGY STUDY PARTICIPANTS AT AMPATH, ELDORET, KENYA

BY

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DECLARATION

By Candidate

This is my original work and has not been presented in any other University for examination.

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DEDICATION

I dedicate this study to my beloved husband, William and my children Karen, Kevin, and Kyle for their support and understanding throughout my study period.

I also dedicate this work to all who have passion in research ethics.

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ABSTRACT

Background: The use of informed consent(IC) became a prerequisite for research in response to abuses of human subjects during the last half of the 20th Century, yet participant's comprehension of presented information is rarely explored. Major ethical concerns arise when participants do not comprehend information offered them. It is therefore a fundamental concern for all researchers to ensure that there is good comprehension of informed consent information among participants.

Objectives: The study aimed to assess the level of comprehension of information given before consenting for the study, explore the recruiters' experiences on administering informed consent, and determine the factors that influence comprehension of information for informed consent by AMPATH-Hemato-oncology study participants.

Methods: The study employed a descriptive cross sectional design to collect data. The target populations were all the 833 participants (mothers) enrolled for one month in the AMPATH Hemato-Oncology study and six recruiters involved in the drafting of the participants in the study. Systematic random sampling was used to select 201 participants into the study whereas the entire population (census) of the six recruiters was used in the study. Two sets of semi-structured questionnaires were administered to the sample, and data was analyzed using descriptive and non- parametric correlation technique of multiple correspondence analysis (MCA).

Results: A total of 201 and 6 questionnaires were administered and the response rate was (93%) and (100%) for the study participants and recruiters, respectively. The mean age of the mothers was 28 years (Std. Dev., 2.24) with majority having secondary (48%) and college (36%) education. The mean comprehension index of IC contents by the mothers was 73.27% (Std. Dev. 28.72%), suggesting a reasonably high ability to understand IC information. There was a low comprehension levels among older mothers (35years or older) and those with primary education. High comprehension was observed in participants who considered the consent form to be of appropriate length (97%) ,written in an easy to understand language (96%) and preferably written in English *(*88%). Recruiters who had more than one year experience in research used less than 30 minutes in IC process compared to more than an hour for those who had been in research for less than one year. Half of the recruiters were found to have no understanding of the study hence could not properly administer the informed consent, affecting negatively the mothers' comprehension of consent information.

Conclusion: The level of comprehension among the mothers on IC contents was relatively high. Age, education level, language of transmission, length and readability of the consent form as well as recruiter experiences were all found to influence comprehension of IC information.

Recommendations: Researchers should ensure that recruiters and respondents adequately comprehend information. Since age, education level, language of transmission, length and readability influence comprehension, knowledge uptake of study participants should be tested before consenting.

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ABBREVIATIONS

AIDS- Acquired immune deficiency syndrome

AMPATH- Academic Model Providing Access to Healthcare

AOI -AMPATH Oncology Institute

CIOMS-Council for the International Organization of Medical Sciences

FDA -United States Food and Drug Administration

FKGL-Flesch- kincaid grade level index

GoK – Government of Kenya

HIV- Human immune deficiency virus

IC- Informed consent

MCA – Multiple correspondence analysis

MTRH- Moi Teaching and Referral hospital

MVT - Malaria vaccine trials

NACOSTI- -National Council for Science, Technology and Innovation

PI – Principal investigator

PICF -Patient information and consent form

QuIC- Quality of informed consent

SE – Standard error

SS – Sample size

US – United States

WHO – World Health Organization

DEFINITION OF TERMS

Appreciate- To realize the content of the study and voluntarily give an informed consent.

Autonomy-independence or freedom, as of the will or one's action

Communicate- Making ones thoughts or feelings known through asking questions, signing, or declining to sign the consent form

Comprehension- Understanding or ability to think on how to act on something

Consent - Acceptance or agreement to an opinion or course of action

Informed consent- Is the permission granted by research participant in the knowledge of possible risks and benefits of an intervention

Reason - Use of one's intellect/mind in making an informed decision that is either to accept or reject

Recruiter- A person who enrolls people to a particular study

Understand - This is to know about the details of the study, participants' role, potential risks and benefits.

CHAPTER ONE

1.0: 1ntroduction

The purpose of the research is to evaluate the level of comprehension of information for informed consent by mothers who consented for neonatal sickle cell disease screening program at AMPATH-Hemato-oncology clinic and postnatal wards (Riley mother and baby hospital) at Moi teaching and referral hospital (MTRH). The chapter provides background information of the study, research problem, significance, objectives, and the scope of the study**.**

1.1: Background of the study

In recent years, there has been an increase in research involving human subjects, which has led to development of legal and ethical regulations for researches of this nature. A research environment that was largely devoid of any ethical guidelines antedated this development. For instance, Celsius, a first century physician justified the vivisection of criminals by asserting that it was not cruel for a few criminals to suffer if many innocent people would benefit (Brady & Jonsen, 1982). Physicians carrying out vaccination trials in the 18th C used themselves or their family members as subjects for the tests. For example, Edward Jenner, considered the father of modern immunology, tested the smallpox vaccine that he had invented on his own son (Zabriskie, 2009).

Medical research witnessed some of the most egregious abuse of human subjects in the 20th C. In Nazi Germany (1933 – 1945), doctors conducted about 30 different types of experiments on prisoners and children in concentration camps without their consent. These experiments included injecting dye into the eyes of subjects to see if they would change color; removal of

bones, muscle and tissue without anesthesia; induction of head injuries; exposure to temperatures well below freezing; and the infecting of individuals with malaria. Many subjects suffered indescribable pain, mutilation, permanent disability or in many cases death (Berger, 1990). Equally obnoxious was the Tuskegee Syphilis Study (1932 -1972), a project conducted by the US Public Health Service on the natural history of syphilis without the study participants' knowledge. Six hundred poor and illiterate, African-American males, 400 of whom were infected with syphilis were followed for 40 years. The subjects were not informed about their disease, the value of the study, risk to their partners and no treatment for the disease was offered. Even when penicillin, a proven cure for the disease was discovered in the 1950s, the study continued until 1972, with participants being denied treatment. The US government was forced to close the study in 1973 because of wide-scale public outrage when the study became publicly known (Mandal, Acharya, & Parija, 2011).

Numerous other research studies were conducted in the 20th C in which subjects were not informed about the purpose of the study. For instance, in 1963, live cancer cells were injected into 22 elderly patients at Jewish Chronic Disease Hospital in New York, without their knowledge in a study of immunity to cancer. Some participants had dementia while others spoke only Yiddish. Since the investigators did not want to frighten the patients, they did not seek their consent, as they believed that the cells would be rejected (Lerner, 2004). In 1970, in San Antonio, Texas, Mexican-American women seeking contraceptives from a clinic unwittingly participated in a study seeking to determine side effects of oral contraceptives. Unknown to them, a half of the women received oral contraceptives while the other half got placebos in the first phase of study, before the roles were reversed in the second phase. Ten of the 76 subjects became pregnant while using placebo (Patch, 2016).

In 1946 (upon the end of World War II), International Military Tribunal sitting in Nuremburg tried 23 leading German physicians and administrators for, among others, conducting experiments on thousands of concentration camp prisoners without their consent. The Tribunal in its judgment in 1948 set out ten points, now known as the Nuremberg Code, which should guide the conduct of medical research. Although lacking the force of law, the Code was the first international document advocating for informed consent and voluntary participation (Mandal *et al.,* 2011). The Code also applied only to non-therapeutic human participants' research and was enacted post hoc. Consequently, the World Medical Association in 1964 developed a set of ethical standards, Declaration of Helsinki, to address therapeutic medical research. The Declaration of Helsinki, revised in 1975, 1983, 1989, and 1996, is the basis of Good Clinical Practices used today and requires, among others: informed consent from subjects, benefits outweigh risks, and research protocols to be reviewed by independent committees before commencement of research (Salman & Shaista, 2014). This declaration heralded the formation of the ubiquitous research ethics committees in various institutions.

Following the exposure of Tuskegee Syphilis Study, the US established a National Commission to identify basic ethical principles. Its product, the Belmont Report of 1979 identified three basic principles underlying all human subject research. This principles were respect for persons, beneficence, and justice (Salman & Shaista., 2014).Together with the Council for the International Organization of Medical Sciences/World Health Organization (CIOMS/WHO) guidelines (CIOMS, 2002), the various aforementioned reports give the standard guidelines used by institutional research committees in approving protocols in ensuring sound ethical practices.

One of the cornerstones of good ethical practices in medical research is the notion of informed consent (IC). CIOMS(2002) defines informed consent as receiving information necessary to make an informed choice about study participation, understanding that information, and making a voluntary decision on whether to participate in the study or not. Informed consent is an important resource for protecting participants in research studies (Rivera, Borasky, Rice, Carayon, & Wong, 2007).IC is usually obtained before a prospective participant is enrolled in a research study.

Research ethics committees require written informed consent and the use of a consent form, which inform the study participants on the purpose and procedures of the study and its potential risks and benefits of participation. An explanation that participation is voluntary, that subjects could withdraw at any time and information about maintaining participants' privacy and confidentiality of research data is included in the consent form (Tindana *et al*., 2011).

The use of IC has been widely accepted in research and clinical procedures both in high and low resource settings. However, implementing the standards of informed consent in developing countries presents several challenges due to the increase in collaborative research between low and high resource countries. Quality of informed consent process in this setting faces challenges such as less experience with the understanding of biomedical research, language, low social economic status, unavailability, and inaccessibility of health care (Beauchamp & Childress, 2009). The other challenge in implementation of IC is balancing individual autonomy, social and political choices and the need for additional protection of the vulnerable poor populations (Vreeman *et al*., 2012).

IC is a larger system of protection for people who want to help researchers evaluate new medical treatments, procedures, and prevention techniques. Such a protection mechanism is necessary, because unlike in the clinical setting in which the interests of patients and doctors converge, researchers' interests in obtaining valid scientific data can conflict with their obligation to protect the rights and welfare of the research participants (Silverman, 2011).

The bottom line is that, participants in research should understand sufficient information (the participant must have clear information about their role in the study, any risks and benefits) in order to provide informed consent. This minimum set has been defined by some authors as understanding the diagnosis, prognosis, nature, and the purpose of the intervention, alternatives, risks, and benefits by potential study participants (Beardsley, Jefford & Mileshkin, 2007). Clinical experience and empirical data indicate that participants and patients exhibit wide variation in their understanding of information. Beauchamp and Childress (2009), states that some participants are calm, attentive, and eager for dialogue while others are nervous or distracted in ways that impair or block understanding. Variation in understanding may be due to cultural beliefs and individual values.

The presentation of IC largely affects comprehension of information; consent can be presented using written, oral and video-based methods or combination of any of these methods. Each of these methods has their strengths and weaknesses. In the commonly used written IC, the writer should take consideration of the length, language and readability of the consent form. Some, for example, advocate the use of simplified consent form while other translate the form to the local language with the intention of increasing patients understanding. (Tindana *et al*., 2011).

The researcher's experience in consent administration is a valuable contribution to quality in consenting as deficiencies in communication process may hamper understanding. Poor communication by health workers or researcher may place health literacy demands on patients (Koay, Schofield & Jefford, 2012). Communication break down between the researcher and the study participants may be due to the use of jargon or long complex sentences and what medical personnel refer to as plain English may pose a challenge to patients understanding. Generally, the investigator should be aware that most patients are ignorant of medicine; therefore, necessary measures need to be employed to ensure maximum understanding of information.

The structure of the consent form determines comprehension of information; the document must be easy and clear to understand. Kithinji and Kass (2010) states that readability of a text is determined by the overall length, legibility of print, illustration, color, vocabulary, conceptual difficulty, syntax and organization. Consent documents for clinical trials in oncology have been observed to be lengthy and complex to the point that it is unlikely that most patients will be willing to read them or be able to understand the concepts discussed (Grossman, Piantadosi, & Covahey, 1994). It is therefore important to improve the length and readability of the consent forms for proper understanding of study details. Where the majority of potential participants cannot read or write alternative methods of documenting the individual informed consent process such as using audio or video tape need consideration.

Comprehension of the information received before an independent decision is made is fundamental as it ensures sufficient level of understanding of the study procedures. This causes the potential participant to sign the consent with adequate knowledge of study procedures.

1.2: Problem statement

The practice of informed consent is rooted in medicine, law, and philosophy and its usage in health research has gained prominence due to the need for research using human subjects in biomedical research globally. The people's awareness of their human rights has also made the practice of informed consent a key requirement in research. The current approaches to informed consent often follow a regulatory framework traceable to the Nuremberg code of 1948, which emphasizes that, a research subject should be so situated as to be able to exercise free power of choice, without the intervention of any element force, fraud, deceit, duress, overreaching or other form of constraint or coercion (Mandal *et al*., 2011).

Although there are regulatory frameworks on conducting ethical research, studies have shown that majority of study participants in developing nations have incomplete understanding of the key issues in the research in which they consent for (Mariner, 2003). In addition, few investigators have measured participant comprehension of IC (Chaisson, Kass, Chengeta, Mathebula, Samandari, 2011). The barriers to the informed consent process include lack of access to alternative means of treatment other than what is offered through clinical trials, illiteracy, culture, poverty, and modes of consent administration (Beauchamp & Childress, 2009).

Major ethical concerns arise when inadequate information is given to the study participants or when information offered to them is not well understood because of lack of information clarity or use of a language that is beyond the understanding of the undersigned. It is therefore a fundamental concern for all researchers to ensure the comprehension of information is guaranteed in all their biomedical researches and it is for this reason that the study endeavored

to evaluate the comprehension of information for informed consent by AMPATH-Hemato-Oncology study participants.

1.3: Significance of the study

The study will be useful because;

- It will provide information that will strengthen the administration of informed consent for improved comprehension.
- It will also provide information to policy makers and researchers in dealing with the issues that arise due to lack of comprehension of informed consent.
- The findings will inform future studies in the Hemato-oncology clinic on the possible factors that hinder full comprehension of research projects.

1. 4: Justification of the Study

Comprehension of information by study participants is pertinent in enabling them make informed consent, a key plank in good ethical practice in research studies. Informed consent is characterized by autonomous choice, implying, a research participant has to make a choice according to his or her own values. This clearly requires information to make rational decision-making, implying that high level of comprehension of study requirements is a prerequisite to IC.

There is a paucity of documented studies in Kenya on comprehension of informed consent by mothers of neonates taking part in l sickle cell disease screening. This study was therefore essential in determining the level of comprehension of information for informed consent

among mothers of neonates undergoing sickle cell disease screening AMPATH-hemato-oncology clinic and MTRH postnatal ward.

1.5: Research questions

The research questions were formulated as follows:

1.5.1: Primary research question

What is the level of comprehension of information for informed consent among Hemato-Oncology study participants at AMPATH, Eldoret, Kenya.

1.5.2: Secondary research questions

1. What is the level of comprehension of information given before consenting for the study by mothers of neonates undergoing sickle cell disease screening at in MRTH postnatal ward Eldoret, Kenya?
2. Which factors influence comprehension of information for informed consent by mothers of neonates undergoing sickle cell disease screening at MTRH Postnatal ward in Eldoret, Kenya?
3. What are the recruiter's experiences on administering informed consent to mothers of neonates undergoing sickle cell disease screening at AMPATH Hemato-Oncology clinic in Eldoret, Kenya?

1.6: Broad objective

To evaluate the level of comprehension of information for informed consent among Hemato-Oncology study participants at AMPATH, Eldoret, Kenya

1.6.1: Specific objectives

- To assess the level of comprehension of information given before consenting for the study by mothers of neonates undergoing sickle cell disease screening at in MRTH postnatal ward Eldoret, Kenya.

- To assess the factors that influence comprehension of information for informed consent by mothers of neonates undergoing sickle cell disease screening at MTRH Postnatal ward in Eldoret, Kenya.
- To explore the recruiter's experiences on administering informed consent to mothers of neonates undergoing sickle cell disease screening at AMPATH Hemato-Oncology clinic in Eldoret, Kenya.

1.7: Scope of the study

The geographical scope of this study was confined to Eldoret, specifically within the AMPATH-Hemato-Oncology Clinic and postnatal ward at Mother Riley-MTRH. The researcher evaluated the level of comprehension of information for informed consent only amongst mothers who had consented for a neonatal sickle cell screening study. Recruiters were limited to only those who consented and interviewed mothers in this study. The temporal scope for the study was a period of one month.

CHAPTER TWO

LITERATURE REVIEW

2.0: Introduction

The chapter reviews literature on the topic of comprehension of information for informed consent. The relevant conceptual framework for the research topic is also formulated and presented.

Comprehension is composed of four fundamental abilities: ability to *understand* relevant information, ability to *appreciate* the nature of situation and its likely consequences, ability to *reason* through the information and weigh options logically and ability to *communicate* the choice (Taiwo & Kass, 2009). These abilities are enabled when the barriers to effective communication are limited (minimized) by ensuring the message is clear using a language that is easily understandable, written material is readable and there is a significant indication of understanding from the consented/study participant.

It is imperative to note that decision-making is determined by information processing, too much information may cause as much of a problem as too little information. Information overloading may prevent adequate understanding and physicians exacerbate these problems if they use unfamiliar terms or if patient cannot meaningfully organize information (Beauchamp & Childress, 2009).

2.1: Comprehension of information

Comprehension is the ability to remember information or experiences and is tested by an individual being asked to comprehend information presented. Informed consent is crucial in

protecting human subjects in research by providing information on risks, benefits, and procedures of the study, allowing them to choose to participate or not in the study. However, research participants in multiple settings and in multiple studies have been shown to have incomplete or inaccurate understanding of many facets of information provided through the informed consent process (Chaisson et al., 2011).

In studies on patients undergoing surgery, Graham (2003) and Saw *et al*. (1994) showed that even after agreeing to surgery or receiving care, 18% to 45% of patients were unable to comprehend the major risks associated with their surgeries. On the other hand, Wadey and Frank (1997) reported that many participants could not answer basic questions about the services or procedures they agreed to receive. A study by Byrne *et al*. (1988) showed that 44% of the patients did not know the exact nature of their operation.

In an attempt to measure the level of understanding among participants in cancer therapy clinical trials, Joffe, Cook, Cleary, Clark, and Weeks (2001b), found that although 90% were satisfied with the IC process, 63%, 70% and 25% did not know the risk of participation, the unproven nature of the treatment, and that trials were done to benefit future patients, respectively. Hill, Tawiah-Agyemang, Odei-Danso, and Kirkwood (2008) in a placebo-controlled Retinol supplementation study among Ghanaian women found that most of them thought they were receiving an active and beneficial medication.

Misunderstanding of the consent process by participants could especially be elevated in clinical trials undertaken by industrialized nations in developing countries. Krosin, Klitzman, Levin, Cheng and Ranney (2006) in a study in Mali, West Africa, found that 93% did not

know the study side effects, 90% did not understand withdrawal criterion while 74% did not know the reason they were enrolled in the study.

Many researchers have used the participants' ability to comprehend information after undergoing the consent process to validly test for their comprehension of IC knowledge. For instance, Chaisson et al. (2011), assessed comprehension of IC using a 20-question true/false quiz administered in 6-month intervals in a placebo-controlled, randomized trial for the prevention of tuberculosis among HIV-infected adults in Botswana, after the participants had initially gone through the consent process. Sugarman and Paasche-Orlow (2006) measured comprehension by first reading to participants a simplified IC document. They then administered a test to the respondents and the extent of the score on the test was a measure of comprehension. Joffe et al. (2001b) gave a test to 287 adult patients had consented to participate in cancer clinical trial to measure their comprehension on various aspects of IC. Similarly, Krosin et al. (2006) tested for comprehension of IC information by administering a test to participants in a study. These studies thus indicate that the ability to understand (comprehension) previously given information in the IC process indicates the participants' comprehension of it.

According to Beauchamp and Childress (2009), comprehension of information is influenced by factors within the receiver of the information (study participant), the information itself (consent form characteristics) and the presenter (recruiters). Literature on these factors is now presented in the following sections.

2. 2: Study Participants

Various participant characteristics have been proposed to influence their comprehension of IC information. For example, a study done to explore the reasons for failure to comprehend major points of informed consent form found three factors related to inadequate comprehension: education, marital status and how careful participants read consent forms before signing (Cassileth, Zupkis, Sutton-Smith, & March, 1980). Participants who read the consent forms carefully were found to have higher comprehension levels.

2.2.1: Participants' educational level

In developing countries, lack of education and access to scientific concepts in biomedical research by potential participants is well known as a challenge to informed consent process. Communicating with educated patients is easier, especially if they understand scientific concepts. Studies indicated that, increased knowledge was associated with college education, speaking only English at home, use of the US National Cancer Institute consent form template, not signing the consent form at initial discussion, presence of a nurse, and careful reading of the consent form (Joffe et al., 2001b). A study done in Kenya on understanding and perception of malaria vaccine trials (MVT) revealed that a portion of participants who offered correct responses were between 29-84% and those who did not know ranged from 14-15%. This suggested that there was varying levels of knowledge for different and even highly related set of information and some major gaps in understanding (Gikonyo, Bejon, Marsh, & Molyneux, 2008).

For instance, among 54 patients who underwent head and neck surgery, 72% of those having university education comprehended more than 50% of the complications, compared with 36%

of those without a university education (Hekkenberg *et al*., 1997). In another study of 200 patients with cancer, those who had completed high school had 35% higher scores on tests, asking them on comprehension within one day of undergoing informed consent.

To demystify the hypothesis that the level of education improves comprehension, 82 healthy volunteers, of which 49 (60%) had university level education while 33 (40%) were clinical medical students, were questioned. However, only 10 participants (12%) could name the three trial drugs. The maximum number of risks remembered was six out of 23. Only 14 (17%) could name three or more potential risks of the medication they might be exposed to, whilst 17 (20%) could identify none. Most subjects (77/82, 90%) identified capsule endoscopy as the trial procedure and impaction/obstruction as its main risk (52/82, 64%). All 98.8% but one subject could comprehend the exact value of the inconvenience payment (Fortun, West, Chalkley, Shonde, & Hawkey, 2008). From the findings, one is likely to conclude that comprehension of information is not only dependent on the level of education. This coincided with Malik (2011) argument that lack of education itself is not a hindrance to understanding because illiterate people can be intelligent.

2.2.2: Participants' Knowledge and Satisfaction

Knowledge and satisfaction in clinical trials is key in the informed consent process. This is because the level of voluntariness is questionable with inadequate knowledge and lesser satisfaction. In the developing countries, most patients' do not differentiate clinical trials from routine care. Some could know the difference but the existence of alternative care may not be available (Sreenivasan, 2003). In a study done in Uganda on quality of informed consent on

malaria clinical trials parents understood many of the study details, but they were not well aware of the risks involved or of randomization. Many parents felt that they could not have refused to participate because their child was sick and they either did not know or did not believe that their child would receive treatment outside of the study (Pace et al., 2005). In the same study, the parents to the children were not worried about the risks involved in the study but the number of clinic and commitment time therefore their decision may have been based on information they found most salient.

2.2.3: Participants' age

The effect of age on comprehension of IC information has been equivocal. For example, among 265 patients undergoing intrathoracic, intraperitoneal, and vascular surgery procedures, patients over 60 years of age had less knowledge about their planned procedure immediately after the informed consent process (Lavelle-Jones *et al*. (1993). Among 54 patients who underwent head and neck surgery, patients who comprehended more than 50% of the complications they had been told were, on average 7.6 years younger than those who comprehended less than 50% (Hekkenberg*et al*., 1997). This could result from decreases in speed of information processing and working memory performance (Salthouse, 1996; Grady and Craik, 2000). On the other hand, older people's substantial knowledge and experience may weaken the impact of reductions in cognitive resources (Brown & Park, 2003).

2.2.4: Participants' Marital Status

Most studies suggest that participants' marital status might not be important in influencing comprehension of information during informed concept. For instance, Adewale, Rossouw, and Schoeman (2016), found no significant association between respondents' marital status and ability to comprehend IC information. Similarly, Kaewpoonsri *et al.* (2006) found no

significant difference between comprehension of IC information and all socio-demographic characteristics (including marital status) of participants. MacQueen, Chen, Ramirez, Nnko, and Earp (2014) found no marital status bias in comprehension of IC information in a comparison of open-ended, closed-ended, and self-perceived measures of comprehension.

2. 3: Consent Form Characteristics

Studies indicate that various characteristics of the consent form could be pertinent in influencing how study participants comprehend information in it. The elements include readability, language, and length of the consent form. Literature on these elements is reviewed in the following sections:

2.3.1: Readability

A key element of a valid informed consent is that the information should be communicated to the study participant at a language level she/he understands (Kithinji &Kass 2010). Consent forms must therefore be written at a language level that most patients can understand. A useful way of measuring the ease of reading a passage is to use readability tests. The most important are the Flesch Reading Ease and the Flesch-Kincaid Grade Level tests, which both count the number of words in a sentence, syllables and complexity of sentences to adjudge the ease of readability (Woo, Wendt, & Liu, 2009). The Flesch Reading Ease, developed by Rudolf Flesch (Flesch, as cited in, McClure, 1987) ranges on a scale from 0 (very difficult to read) to 100 (very easy to read). The school grade level that could understand the readability of a text as given by Flesch Reading Ease scores is given in Table 2.1.

Table 2.1: Flesch Reading Ease scores and the school grade level that can understand the text

Score on Flesch Reading Ease	**School grade level that can understand the writing**

100 – 90	5th grade
90 – 80	6th grade
80 – 70	7th grade
70 – 60	8th and 9th grade
60 – 50	10th to 12th grade
50 – 30	College
30 – 0	College graduate

Adapted from Flesch (1979)

Since a scale (Table 2.1) was always required to convert scores obtained from the Flesch Reading Ease into school grade levels understanding, John Kincaid modified the test to produce a ready-to-interpret US grade-level score (Woo et al., 2009). The modified test is called the Flesch-Kincaid Grade Level test and is known by other names, such as, Flesch-Kincaid Index, Flesch-Kincaid Grade Level Score, Flesch-Kincaid Scale, Flesch-Kincaid Readability Score, Flesch-Kincaid Readability Statistics and Flesch-Kincaid Grade Level Index (McClure, 1987). For example, if the Flesch-Kincaid score of a text is 5.4, then, it implies that the reading level of the text is of an average student in the US fifth grade.

The recommended readability level for health literature materials meant for general public consumption is Flesch-Kinkaid grade level 4 to 6 (Ezeome, Chuke, &Ezeome, 2011). Unreadable informed consent documents may result in patients rejecting trial participation altogether or conversely may result in their participating in a trial with inadequate consent (Buccini, Iverson, Caputi, & Jones, 2010).

The ability to read an article depends mainly on the language use and level of education. Language use in the presentation of IC can be categorized in terms of hard or simple, use of plain English or medical or legal terminologies. Simple language is easily comprehensible by primary school level participant, legal and medical languages may not be comprehensible even with individuals with high level of education. Kithinji and Kass (2010) states that

readability of a text is determined by the overall length, legibility of print, illustration, color, vocabulary, conceptual difficulty, syntax and organization. Ezeome *et al.* (2011) in a study of 33 consent forms from 33 health centres in Nigeria on content and readability of IC for surgical procedures found that risk disclosure was not mentioned in specific terms and less than 10% of the forms made provisions for interpretation. Flesch Reading Ease was used to gauge readability, with the forms found to have a range of 34.1(difficult) to 67.5(standard) with a mean of 55.2 (fairly difficult level). The study went further to show that young patients and literate adults partly understood the consent form.

Problems with readability of informed consent arise when the writer views the consent form from a legal perspective. This perspective is a stand point for many researchers as they may always want to protect themselves against litigation (Jefford & Moore, 2008). Legal connotations lead to cursory reading and inadequate comprehension.

Informed consent form written in the second language of the consented may compromise comprehension; this has led to translation of IC form from one language to another. On compressibility of translated IC document in India Jhanwar and Bishnoi,(2010) analyzed 30 informed consent translated from English to Hindu and realized the mean score determined by Flesch- Kincaid Grade Level Index was grade level 13.66 and Flesch Reading Ease score was 46.08 suggesting the significant complexity of the text.

A study done by Beardsley *et a*l. (2007) found out that higher objective knowledge on quality of informed consent (QuIC) was associated with participants having English as a first language and a higher level of education. QuIC scores also were significantly higher for trials in which the patient information and consent form (PICF) page count was seven or less. In

addition, QuIC-A scores were significantly lower for trials in which the PICF had a reading level of grade 11 or higher.

The ultimate measure of readability is the reader's ability to read and understand written material and the only way to know if a document is understandable and useful is to test it with a sample of appropriate users.

2.3.2:Language

Mostly informed consent has two components, the written and verbal component. In verbal communication, the investigator and the potential participant discusses the proposed study while the written component is also given to the participant with the aim of facilitating the discussion. Language use especially on the part of study participants in informed consent has become more legalistic making it difficult for the study participant to understand the content of the study (Naanyu, Some, & Siika., 2014).

Studies have also revealed that the extent of everyday language, the degree to which expectations of potential participants are addressed and technique of presentation of the information had an impact on comprehension of information provided about the research (Tekola *et a*l., 2009).

Plain language is straight forward and easy to understand; almost all professionals have their own languages for example, legal and medical languages. Informed consent in medical research frequently utilize both medical and legal language. For example, Krieger, Neil, Strekalova, and Sarge (2017), found that it was difficult in explaining the concept of randomization among patients with diverse levels of health literacy. The study further advised

that if English is the first language for a particular nation then the use of plain English is emphasized; however, it becomes complicated in places where English is not the first language. Therefore, to ensure good comprehension of information, translation is essential. Jefford and Moore (2008) stated that information written in plain language assist in decision making in medical treatments.

A study done to compare standard and simplified consent forms revealed that standard consent forms are written at too difficult a level for many patients to read and comprehend, especially those with low literacy skills. Simplified consent form would be less intimidating and more easily understood by individuals with low-to-marginal reading skill (Davis, Berkel, Holcombe, Pramanik, & Divers, 1998). In the study, the standard form was grade16 and simplified grade 7 and when the respondents were told to grade their attitudes towards and comprehension of the form, 97% thought the simplified were easier to read than the standard forms. To improve comprehension, consent forms should be brief and direct. They should avoid legal jargon and written at appropriate reading levels using plain English.

2:3:3: The length of the consent form

The goal of the informed consent process is to provide the potential subject with enough information so s/he can make an informed choice about whether to participate in the research. The consent form therefore should include all elements and the length should be reasonable enough, for most people shy away from reading lengthy articles (Naanyu et al, 2014).

A study done by Sharp (2009) on consent documents for oncology trials revealed that consent documents for clinical trials in oncology are lengthy and complex to the point that is unlikely that most patients will be willing to read them or be able to understand the concepts they

discuss. Another study by Beardsley et al. (2007) revealed that despite lengthier forms, important information for patients might still be missing. The informed consent document must therefore be clear and easy to understand for the potential subject so that s/he may understand the study and what is expected of her/him.

2. 4: Recruiter Characteristics

Recruiters, the people who actually enroll participants into research studies, are very crucial in ensuring understanding of IC information. Recruiters are important in delivery of information to participants and their knowledge and participation is essential in a successful informed consent process.

2.4.1: Information delivery

Recruiter should be aware that presentation of a study to participants is more than just getting a signature on the consent form. Most recruiters view consent as an action, concluded by signing a form. However, the general practice should be to promote participants understanding of research project and the voluntary nature of their decision to participate.

In an effort to minimize therapeutic misconceptions, investigators should describe for prospective subjects how enrollment in a trial differs from receiving ordinary clinical care; how the procedures, risks, and benefits in the particular trial differ incrementally from the standard treatment. For instance, Chen, Miller, and Rosenstein, (2003) say that even without knowing the details about a clinical trial, recruiter can help their patients understand some of the salient differences between clinical research and clinical practice. Importantly, participants should understand that although individuals may receive treatment in the context of both clinical practice and clinical research, the orientation of these activities is markedly different.

2.4:2: Recruiter participation and knowledge about the IC

The role of recruiter during consenting process are in two parts: a duty to obtain the voluntary agreement of patients or trial participants before treatment or enrolment; and a duty to disclose adequate information to the patient or participant before seeking this agreement (Sreenivasan, 2003). Therefore, a recruiter should take reasonable steps to ensure that the information they disclose has been adequately understood. This calls for the use of effective communication techniques, establishment of good relationship between the consented and the consenter. The fiduciary nature of the recruiter /study participant relationship as well as time constraint and the need to concentrate on relieving the patient's problem imply that clinical research informed consent forms should be as simple as possible. A good informed consent form, nevertheless, should contain enough information as to convey to an evaluator, the notion that the basic key elements of an informed consent were fulfilled during the consent process.

Recruiters who experience the process of providing written information often have the impression that participants do not grasp the appropriate information from the IC document. For example, Jeyaseelan, Ward, Papanna, and Sundararajan (2010) comment that, for major procedures, it is good practice to obtain consent some time before the procedure. This would allow time for the patient to weigh-up and evaluate the information given to him/her, thus ensuring a fully informed decision to consent. Recruiters also should know some pitfalls, including participants right to decline information especially in terminal situation (Kubota, 2000).

Empirical studies demonstrate that recruiter characteristics, especially their experience, are a predictor of good comprehension of information. Minnies *et a*l. (2008) showed that majority of the participants who were given consent information by nurses who had worked in research

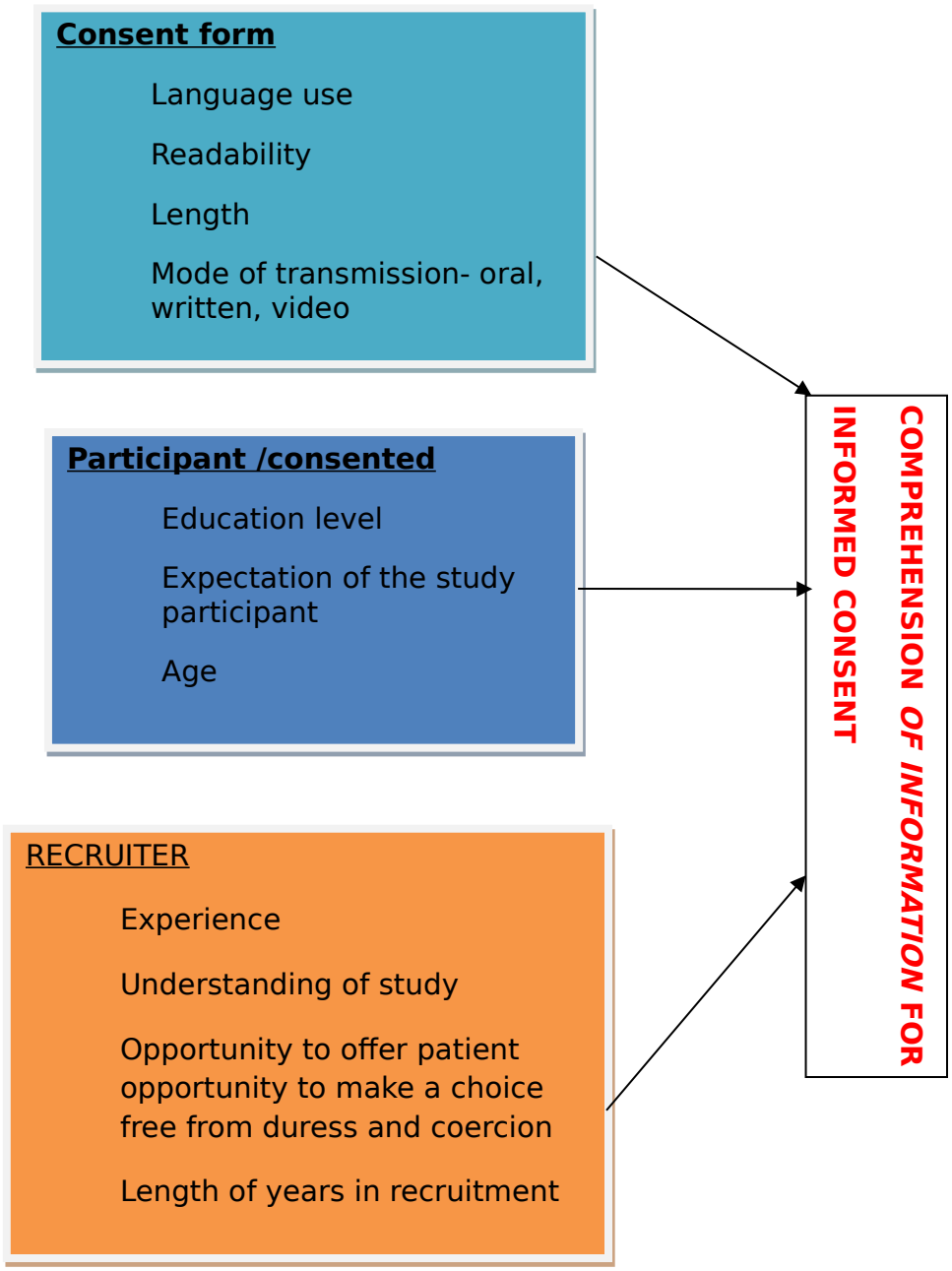
for more than two years had high comprehension compared to those handled by inexperienced nurses. Minnies went further to state that study participants' attitude toward consenting influences comprehension and consequently comprehension.

In semi structured interviews conducted with eleven individuals from three clinical research teams in London, Newington and Metcalfe (2014) reported that more experienced recruiters were more confident and felt that specific training was unnecessary, which could explain why they used less time to carry out the informed consent process. On the other hand, less experienced researchers tended to be less confident. Donovan *et al*. (2003) found no significant difference in recruitment rates between urology consultants and nurses for a prostate cancer randomized controlled trials and concluded that nurses were more cost-effective recruiters, despite spending longer hours on average with each patient.

2.5: Conceptual Framework

From literature review, this study tested the following conceptual framework (Figure 2.1) in evaluating comprehension of information for informed consent amongst mothers of neonates undergoing sickle cell disease screening at AMPATH Hemato-oncology study.

Figure 2: I Conceptual Framework



Source: Own conceptualisation

This study conceptualized that various factors promote or hinder a study participant's ability to comprehension and paraphrase information offered to them during consenting. The influencing factors emanates from the consent form, the participant and the recruiter. All the above variables could influence the comprehension of information for informed consent and they formed part of the independent variables in the study.

Within the consent form, the factors that could influence comprehension included the language used in the consent form, this arise when medical jargon or legal language is heavily used. The other element was the readability of the consent form; it was expected that a consent form that could be read with a lot of ease by a primary school leaver would enhance comprehension. The length of the consent form was also a factor, with long consent forms expected to result in poor comprehension. In addition, the mode of transmitting consent information was also included in the framework, with a combination of oral and written modes expected to result in better comprehension.

The influencing factors within the study participants included the level of education, state of health, expectation from the study, their age, and marital status. It was hypothesized that an increase in educational level and knowledge and satisfaction of participants, together with their better health status, would be expected to improve their comprehension of IC. However, the participants' age and marital status were expected either to increase or decrease the participants' ability to comprehend IC information. Participant and consent form characteristics variables are presented in the data collection tool (Appendix 2).

The recruiters were expected to have major effect in comprehension on information for informed consent, especially their experience, ability to establish rapport, confidentiality, and privacy influence comprehension. Studies have shown that participants consented by experienced recruiters score high in comprehension questions. The variables on recruiter characteristics are presented in the data collection tool of Appendix 3.

2.6: Summary

The foregoing section has presented the literature on studies that have investigated comprehension of information for informed consent and the possible determining factors. The study surveyed how studies have empirically measured comprehension and presented literature to indicate that comprehension of IC information could be dependent on study participant, consent form, and recruiter characteristics. This review shows that only a few investigators have measured comprehension of IC in Kenya. This dearth in empirical studies has been replicated in other parts of the world (Chaisson *et al*., 2011). This study was therefore essential in determining the level of comprehension of information for informed consent among mothers of neonates undergoing sickle cell disease screening in a national referral hospital in Kenya and AMPATH Hemato-Oncology clinic.

CHAPTER THREE

STUDY METHODS

3.0: Introduction

The chapter provides a detailed research methods used in the study, information on the chosen design, and basis of selecting the study participants. The identified collection, analysis and presentation of data is also highlighted.

3.1: Study design

Research design is a blueprint for research, dealing with at least four problems: which questions to study, which data are relevant, what data to collect, and how to analyze the data. The best design depends on the research question as well as the orientation of the researcher (Kothari, 2004). The research design used was descriptive cross sectional study**,** to study participants who had just consented for sickle cell screening study. Data was collected within a period of one month where a semi-structured tool was used to interview two categories of participants: mothers who consented for their babies to participate in the sickle cell screening study, and recruiters who were involved.

The descriptive cross sectional design enabled the study to evaluate the nature of relationships between comprehension of IC information and the conceptualized factors. This also helped to understand phenomena by discovering and measuring causal relations among variables and rapid collection of data from many individuals in a population. As this design did not allow the researcher to manipulate either the independent variables or the research setting, it was

apt, because of its higher external validity and less cost. Thus, the design was appropriate because it allowed the study to be completed within the constraints imposed by limited time and financial resources.

3.2: The Study Setting

The study was carried out in Academic Model Providing Access to Health care (AMPATH) Hemato- Oncology Clinic and postnatal ward (Riley mother and baby hospital) at Moi Teaching and Referral Hospital (MTRH). The AMPATH Oncology Institute (AOI) is housed under AMPATH, which is based in Eldoret, Kenya. AMPATH arises from the collaboration between Moi University (Kenya), MTRH (Kenya) and several North American institutions, with Indiana University being the anchor institution. The collaborating partners initially concentrated their efforts in HIV/AIDS prevention and treatment; however, over the past 10 years more focus has been given to the inclusion of non-communicable diseases, including cancer.

The AOI is dedicated to promoting oncology education, services, and research and facilitating the professional expertise among its members towards excellence in cancer prevention, treatment and palliative care. The centre has extended to provide comprehensive clinical oncology services in various clinical sites such as Chulaimbo, Kitale, Webuye, Iten, Turbo and Busia among others (Strother, 2013). The services offered at the centre include medical, pediatric, gynecology, pharmacy and palliative oncology. Medical and pediatric oncology offers case management and chemotherapy for adults and children respectively. The services in gynecology include case management, chemotherapy, and surgery. Palliative care in the centre includes palliative chemotherapeutics, palliative care counseling, and care of acutely ill cancer patients.

Moi Teaching and Referral Hospital (MTRH) is the second National Referral Hospital in Kenya. It is located in Eldoret, Uasin Gishu County in the Rift Valley region of Kenya. The hospital has 800-bed capacity and receive patients from western Kenya, parts of Eastern Uganda, and the southern Sudan (GoK, 2013). Riley mother and baby hospital is part of the Moi Teaching and Referral Hospital that provides maternal and neonatal services to clients from western Kenya. Up to 10,000 babies are delivered in the hospital each year (30 babies daily). The neonatal Intensive Care Unit can care for 100 babies at any given time.

3.2.1 Target population

The target population for the study was all the 833 mothers who consented for their neonates to participate sickle cell screening every month. The recruiters targeted were six and were directly concerned with recruiting participants for the sickle cell study. The sickle cell screening was a study conducted in the year 2015 with the aim of identifying neonates who had sickle traits. Those neonates found to have the traits were then enrolled to a hydroxyl-urea clinical trial study. All mothers of the neonates who participated in the screening study were consented before collection of blood samples.

3.2: Selection criteria

3.2.1:Participants' inclusion and exclusion criteria

Inclusion criteria: Mothers who consented for their neonates to participate in sickle cell screening study program met the inclusion criteria.

Exclusion criteria: Mothers who were very sick or too weak because of delivery related complications were excluded

3.2.2: Recruiters' inclusion and exclusion criteria

Inclusion criteria*:* All recruiters willing to participate in the consent process for the comprehension of IC study and had participated in the sickle cell screening study.

Exclusion criteria*:* Recruiters who were not available to participate in the consent process for the study.

3.3: Sample size determination

3.3.1: Sample size

A representative sample was identified from the target population and used in the study.

Sample size for mothers

In order to get a 95% confidence level and sampling error of 5% during the sampling of mothers in the study, the sample size was determined using the following formula (Kothari, 2004; Mugenda and Mugenda, 2003):

$$SS = \frac{Z^2(p) * (1 - p)}{c^2}$$

Where,

SS= the sample size

Z^2= 1.96 for a 95 % confidence interval (area under a standard normal curve or a student distribution with infinity degrees of freedom, which contains 95 % of the observations)

c = the desired level of precision/sampling error, which in this study was +5%.

p = the estimated proportion of the attribute of interest present in the population, such as percentage of mothers consenting to the study. Since, this proportion could not be obtained from previous studies; the study used a proportion of 0.5, which assumed maximum variability in the population. Thus, the estimated sample size was likely to be more conservative, that is, the sample size was likely to be more than what was required.

Thus,

$$SS = \frac{(1.96^2)(0.5)(0.5)}{(0.05^2)} = 385\ mothers$$

However, since the target population was about 833, the following correction for small population was used (this is because a given sample size provides proportionately more information for a small population than for a large one; Gigerenzer, 1993):

$$n = \frac{SS}{1 + \frac{(SS-1)}{N}}$$

Where, *n* is the corrected sample size while *N* is the population size.

$$n = \frac{385}{1 + \frac{(385-1)}{833}} = 263\ mothers$$

However, because some mothers were not willing to take part in the consent process, this study collected data from 201 mothers.

Sample size for study recruiters

The recruiters were drawn from the primary study (sickle cell screening), they were six of them and all were involved in the study. The entire population (census) of recruiters was used in the study and hence, no sampling was carried out. This was because as the total population was small (Six individuals), it could be studied at minimal cost and it eliminated sampling error.

3.4: Sampling techniques

Systematic sampling technique was chosen, which involves the selection of k^{th} of the sample population (Kothari, 2004). Systematic sampling as a type of random sampling, is a process that allows all subjects in the study population to have an equal chance of being selected. This sampling was adopted because the results were likely to be unbiased and hence, increasing the external validity of the study.

A sampling frame consisting of all mothers participating in the screening study was prepared and every second name on the list was selected for the study. A sampling frame is a complete list of all the members of the population that we wish to study (Kothari, 2004). The population for the consent study was drawn from mothers who gave informed consent for the child's

participation in sickle cell screening study. As stated above, all the recruiters were selected for the study in a census.

3.5: Recruitment

The researcher/principal investigator (PI) and the research assistants prepared for recruitment, by taking the participants and the recruiters through the consent form and asked them for participation in the study. The participants were tested one hour after they had been enrolled and consented for sickle cell screening study in order to minimize effects of recall of information from the consent earlier administered.

3.6: Data Collection Tools and Procedures

There were two sets of questionnaires administered; one to the mothers of neonates on sickle cell screening participants and the other, to recruiters. The two types of questionnaires were developed by the researcher following literature review of the possible antecedents of comprehension of informed consent. The questionnaire that was used for the mothers of neonate on sickle cell screening participants had three parts, A was concerned with demographic data, B had questions on comprehension of informed consent and C had questions on consent form characteristics (Appendix 2). The demographic characteristics conceptualized to influence IC comprehension were; age, marital status, level of education, language of communication and occupation. Part B consisted of 11 items that tested the mothers' ability to comprehend information previously given to them. The consent form characteristics questions consisted of the length, readability and language.

Appendix 3 was a tool for the recruiters on their experience during consenting. It consisted of questions on recruiter demographic characteristics, duration of consenting process, their

opinions on the length and readability of the consent form and challenges they face during the consenting process.

Data collection occurred in both AMPATH Hemato-Oncology Clinic and postnatal ward (Riley mother and baby hospital) of the MTRH for the recruiters and the mothers, respectively. They were provided with informed consent prior to the completion of the questionnaire. The researcher and the assistants explained and used appropriate language where the participant had a problem with either English or Kiswahili. Semi structured tools were administered by the PI and research assistants. Since the questionnaires did not contain questions about personally sensitive information or behavior (see questionnaire in the appendix 2 and 3), all participants comfortably answered all questions/items. With guidance of the researcher or the research assistants, socio-demographic data of the patients and the recruiters were established. The other variables of interest include knowledge of being in a research study, understanding of the purpose of the study, risks, benefits, confidentiality, voluntariness, and whom to contact in case of any questions. The survey developed from the expected components of an informed consent form as specified in IC and was administered by an interviewer. (Appendix 4)

Participants were expected to select the correct answer from a choice of three possible answers for each of the questions (Appendix 2). One of the answers was an exact reflection of the information in the consent document, which, if selected, was taken as an indicator of correct comprehension (***Correct answers are listed first)***. The rest of the questions in the research instruments involved asking the participant either to pick one correct answer out of a multiple of choices or writing their opinions about IC.

3.7: Pilot study

Validity refers to the extent to which an instrument can measure what it ought to measure. It therefore refers to the extent to which an instrument asks the right questions in terms of accuracy. Vanderstoep and Johnston (2009) looked at validity as the accuracy and meaningfulness of inferences, based on research results.

Content validity of the data collection tool was determined through a pilot study conducted in October 2015 in postnatal ward at MTRH. The research instrument was administered to 10 mothers of neonates. Analyzing the answers given against the drafted instrument, no changes were required.

3.8: Data analysis

Quantitative data was analyzed with the aid of descriptive statistics and relationships in the study described by the non-parametric correlation technique of Multiple Correspondence Analysis (MCA). MCA was used because the data was either nominal or ordinal and the method does not require stringent assumptions about the data, such as, randomness of the data, as in classical statistical techniques (Yazici*et al*., 2010). It also presents the correlations in an aesthetically appealing graphical form. The method transforms observed data in a nonlinear way in order to obtain transformed objects, which are as much homogeneous as possible (Gifi, 1990). MCA analyze variables that are in a single set. The fit of the model was measured by the amount of variance (also, referred to as inertia) the model could explain in the original values (lowest: 0% and highest: 100%). Variance (in absolute value) which is ≤ 0.30 is generally considered low, 0.31 to 0.67 moderate while 0.68 to 1.0 is strong (Field, 2005).

The eigen value indicates the level of relationship shown by each dimension. In addition, MCA also computes a Cronbach's Alpha for measuring the reliability of the model (Minimum: 0 and Maximum: 1), with an Alpha value of 0.5 or above deemed to be reliable (Field, 2005). The degree of correlation in the technique is measured by the closeness of the variables on the graph; the closer the variables the higher the correlation (Yazici*et al*., 2010).

Descriptive statistics were used to describe, summarize, and organize the data. Five sets of these methods were used; frequency distributions, measures of central tendency, and measures of dispersion, skewness and Kurtosis. Frequency distributions, ordered arrangement of all variables, showing the number of occurrences in each category (Norusis, 2010),these were used to summarize data. The data was then displayed using tables and pie charts. Average or typical values of the data were given by the measures of central tendency (mean). When the data was measured on an interval scale (for instance, when comprehension index was computed), the mean (the arithmetic average of values in a set) was used. The range (the difference between the highest and lowest value) and the standard deviation (the average difference between observed values and the mean) indicated dispersion (variability) of data.

Skew and Kurtosis, were calculated to determine how far the data departed from normality. Skew indicates the degree of asymmetry in the data (how concentrated data points are at the high or low end of the scale of measurement; Norusis, 2010). A negative value indicated skew to the left; a positive, skew to the right. Kurtosis describes how concentrated data are around the mean (that is, it assesses how peaked or flat is the data distribution; Mann, 1995). A negative value indicated platykurtosis (fewer items at the mean and at tails but more in intermediate regions) while a positive value indicated leptokurtosis (more items near the mean and at the tails but fewer in the intermediate regions; Norusis, 2010). Significant

departures from normality were indicated if the skew or kurtosis value were outside the benchmark ± 2.0 (Field, 2005).

The mothers' level of comprehension of information index was calculated in order to indicate each mother's ability to comprehend information previously presented on the informed consent form. The total number of questions on the consent form was eleven (part B of Appendix 2) and a mother who scored a question correctly was given one mark. The comprehension index was then computed by summing up each mother's correct answers to the asked questions, and expressing the value as a percentage. For example, if a mother answered all the questions correctly, then;

$$Comprehension\ Index = \frac{11}{11} \times 100 = 100\%$$

Consequently, the possible maximum score for comprehension index was 100% while the minimum was 0%. To judge the comprehension levels of the mothers from the comprehension indices, the scale below (adapted from Field, 2005) was used:

Comprehension index score	**Comprehension level**
0.00 – 33.33	Poor
33.34 – 66.67	Average
66.68 – 100	High

The open-ended questions were analyzed by creating categories, identifying themes and quotations presented by the study participants and were presented in support of the thematic findings. The analyzed results were then presented using tables, pie charts, and bar graphs.

Table 3.1 presents a data matrix showing a summary of techniques used to test each specific objective in the study.

Table 3.1 **Data analysis Matrix**

Objective	**Dependent Variable**	**Independent Variable**	**Nature of Variable**	**Statistical technique**
Assess level of comprehension of IC information			Categorical& continuous (comprehension index)	• Frequencies • Means • Range & standard deviation • Skew & kurtosis
Assess factors influencing comprehension of IC information	Comprehension of IC information	• Participants' characteristics e.g. education, age& marital status • Consent form e.g. readability, language & length • Recruiter characteristics	Categorical	MCA
Explore recruiters' experience on administering IC			Categorical Text	MCA Thematic analyses

3.10: Ethical considerations

The Research Ethics Committee of the Moi University approved the study. Informed consent was obtained from the mothers (participants) and recruiters, where they were informed of the intention of the research, its potential benefits and on their right to participate or withdraw from the study at any time as they wish. They were informed that there were no direct benefits from the study; however, transport to and from their place of residence was to be provided. The study participants were made aware that there were no risks involved in the study and that privacy and confidentiality was observed.

Permission sought from administrators of AMPATH-Hemato- Oncology sickle cell screening study, who were told that information obtained from the study was to be used for the purposes of this research. Further, that recommendations arising from the study will be used to improve comprehension of information for informed consent.

3.11: Study limitations

- The study examined comprehension of IC information in single study in only one public hospital in Kenya. Therefore findings from this study may not be generalizable to other regions in the country.
- The closed ended questions could limit respondents to particular responses and therefore getting wider range of responses are inhibited. Efforts were made to have open ended sections to allow for unplanned answers and opinions.

CHAPTER FOUR
FINDINGS

4.1: Introduction

This chapter provides findings from the data collected on the level of comprehension of information for informed consent among mothers of neonates undergoing sickle cell disease screening in postnatal ward (Riley mother and baby hospital) MTRH and AMPATH Hemato-Oncology study in Eldoret, Kenya and the recruiters. This chapter was guided by the following specific research questions;

1. What is the level of comprehension of information given before consenting for the study by mothers of neonates undergoing sickle cell disease screening at in MRTH postnatal ward Eldoret, Kenya?
2. Which factors influence comprehension of information for informed consent by mothers of neonates undergoing sickle cell disease screening at MTRH Postnatal ward in Eldoret, Kenya?
3. What are the recruiter's experiences on administering informed consent to mothers of neonates undergoing sickle cell disease screening at AMPATH Hemato-Oncology clinic in Eldoret, Kenya?

4.2: Response Rate

Of the 201 questionnaires administered to the mothers of neonates (participants) and 6 to recruiters of the mothers (recruiters) for the study, 187 (93%) and six (100%), were answered and returned to the researcher, respectively. The high return rate of the questionnaires was attributed to the simplicity of questions, researcher's availability and commitment during data collection time. The response rate reflected the view of Mugenda and Mugenda (2003) who indicated that a response rate of 70% and over is very good as it gives a representative sample for meaningful generalization and minimizes errors.

4.3.0: Descriptive Results on Study Participants

This section presents results on the characteristics of the study respondents, which includes their demographic features, place of residence, status of health, sources of information about the study, and their expectations from the study.

4.3.1: Demographic Profile of Respondents

The data from this section gives demographic information of the participants in the study in order to understand their profile. The information sought included the respondents' age, marital status, highest educational level, and their preferred language of communication.

Table 4.1: Demographic **information of respondents**

Panel A			
Demographic information	Categories	Frequency	Percent
Respondent's marital status	Married	118	63.10
	Single	60	32.10

	Divorced	0	0.00
	Separated	6	3.20
	Widow	3	1.60
	Total	187	100.00
Respondent's highest education level	Primary	10	5.30
	Secondary	89	47.60
	College	67	35.80
	University	21	11.20
	Total	187	100.00
Preferred language of communication	English	165	88.20
	Kiswahili	22	11.80
	Others	0	0.00
	Total	187	100.00

Panel B

Demographic information	Range	Mean	Std. Dev.
Respondent's age (*n*=187)	19 – 39 years	28.55 years	4.14 years

Key: Std. Dev = standard deviation; *n* = number of respondents; **Source:** Survey Data, 2015

Descriptive results (Table 4.1) showed majority were married mothers (*n*=118, 63%), followed by those who were single (*n*=60, 32%), separated (*n*=6, 3%), and widowed (*n*=3, 2%). Since the study collected data from all categories of mothers, the results were likely to be reflective of all opinions of mothers.

The results indicated that a majority of the mothers had secondary education (*n*=89, 48%), followed by those with college (*n*=67, 36%) and university education (*n*=21, 11%). The fewest were those with primary education (*n*=10, 5%). This indicated that the sample respondents consisted of both well-educated women and those with a modest education. Thus, conclusions from this study are likely to be balanced.

The respondents preferred to be communicated with, mainly, in English (*n*=165, 88%) or Kiswahili (*n*=22, 12%). None desired to be communicated with in vernacular languages,

indicating that most respondents could comprehend the research questions, which were in English.The participants' ages ranged from a minimum 19 years to a maximum 39 years, with the mean age being 29 years. This suggested that the mothers were relatively youthful.

4.3.2: Relationships amongst the Respondents' demographical Characteristics

Table 4.2: Model summary for MCA for demo**graphical variables**

Dimension	Cronbach's Alpha	Variance Accounted For		
		Total (Eigenvalue)	Inertia	% of Variance
1	0.57	1.83	0.37	36.54
2	0.43	1.53	0.31	30.51
Total		3.35	0.67	
Mean	0.50[a]	1.68	0.34	33.53

A Multiple Correspondence Analysis (MCA) was conducted to determine the relationships between the mothers' age, gender, and marital status (Table 4.2). The model could explain about 34% of the variance in the original variables (inertia=0.34), with dimension 1 and 2 accounting for 37% and 31% of the variability, respectively while mean cronbach's alpha was 0.50. This suggested that the model fitted the data. The joint plot of category points is presented in Figure 4.1.

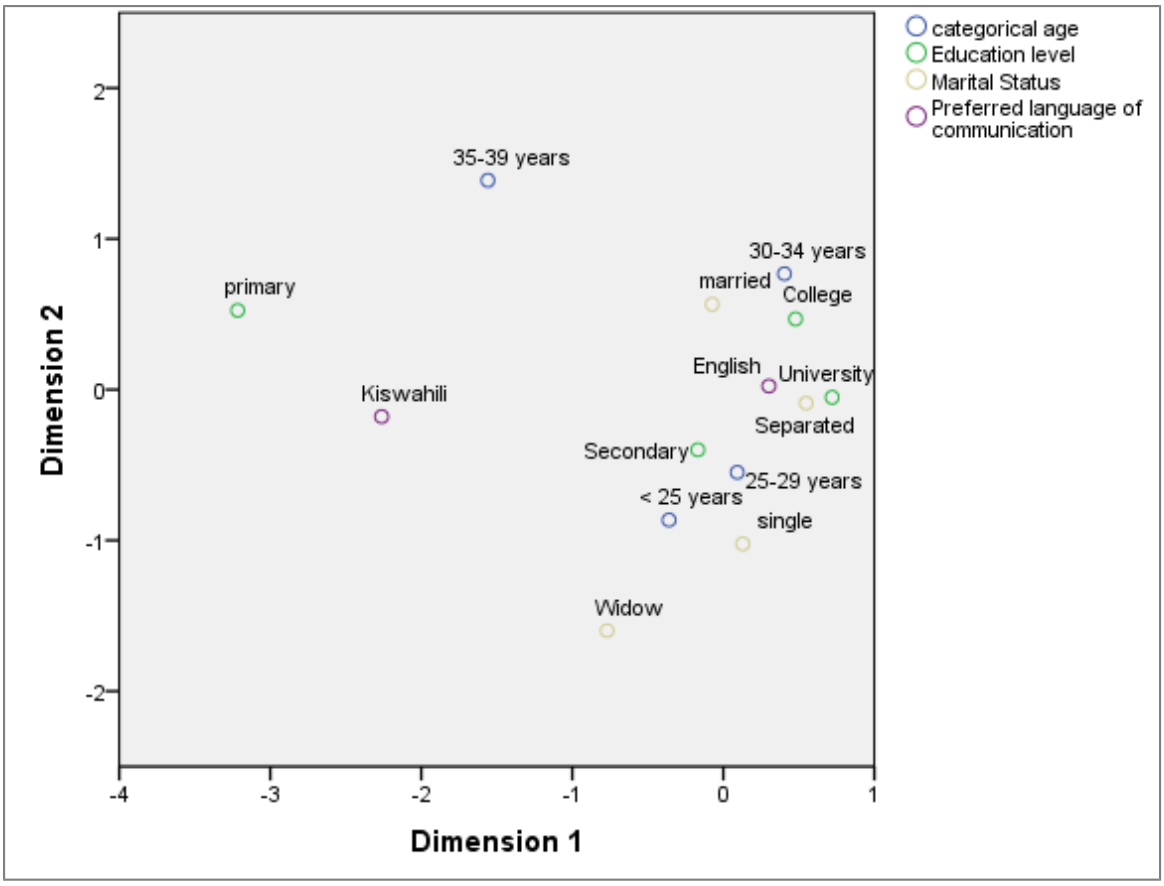


Figure 4.1: Joint plot of categories for demographical variables

'College' occurs near '30 – 34 years' and 'English', and 'married', suggesting that mothers who attended college are likely to be 30 – 34 years old, and are likely to be married. Mothers with primary education are likely to be 35 – 39 years old and prefer Kiswahili as their language of communication. University educated mothers are likely to prefer English as a medium of communication.

4.4: Recruiter's demographic information

The demographical background of the six recruiters in the study is given in Table 4.5.

Table 4.3: **Demographic information of recruiters**

Panel A			
Demographic information	Categories	Frequency	Percent
Recruiter's gender	Male	3	50.00
	Female	3	50.00
	Total	6	100.00
Period in research	Less than one year	1	16.70
	1 – 2 years	4	66.70
	3 – 5 years	1	16.70
	Total	6	100.00

Source: Survey Data, 2015

The recruiters were evenly balanced with respect to gender (each 50%), suggesting that views given in the study were balanced between male and female recruiters. Most of the recruiters (*n*=4, 67%) had been involved in research for between one and two years, suggesting that they had adequate knowledge to answer the research questions for the study.

4.5: Descriptive Results of Respondents' Responses on Consent Form Characteristics

This section presents results on the respondents' assessment of the features of the consent form used in this study. The features comprised of length of consent form, readability (level of difficulty of language), the language used, and the mode of delivery (Table 4.4).

Table 4.4: **Frequencies of respondents' responses on consent form characteristics**

Consent form Characteristic	**Respondents' Rating**	Frequency	Percent
Length of consent form	Short	6	3.20

	Appropriate	181	96.80
	Long	0	0.00
	Total	187	100.00
Language difficulty	Easy to understand	173	92.50
	Appropriate	14	7.50
	Difficult to understand	0	0.00
	Total	187	100.00
Preferred language	Kiswahili	22	11.80
	English	165	88.20
	Mother tongue	0	0.00
	Total	187	100.00
Delivery method	Oral	147	79.00
	Written	26	14.00
	All	13	7.00
	Video	0	0.00
	Total	186	100.00

Most respondents (*n*=181, 97%) considered the consent form to be of appropriate length, with only 3% considering it to be short. No mother in the study considered the form long. With respect to readability of the consent form, most of the respondents (*n*=173, 93%) found the language of the form easy, with only (*n*=14, 8%) considering it as appropriate. No mother in the study found the language to be difficult.

Most of the respondents (*n*=165, 88%) preferred English as the language in which consent forms should be written compared to (*n*=22, 12%) who chose Kiswahili. No participant preferred the use of mother tongue. Most mothers (*n*=147, 79%) considered oral mode as the most appropriate form in which the consent could be transmitted to them as opposed to those who preferred written (*n*=26, 14%) and a combination of several methods (*n*=13, 7%). No respondent chose the use of video as a standalone method of transmitting the consent.

4.6.0: Level of comprehension of Informed Consent Information

This section presents results on assessment of the level of comprehension of information by mothers given to them before consenting for the study, which was the first objective of this study.

4.6.1: Mothers' Answers to Questions Testing their Comprehension Ability

Table 4.5 presents frequencies of the mothers' answers to informed consent questions.

Table 4.5: Ability to comprehend **information on consent forms**

Purpose of signing consent form	Child can participate in study	Child can be treated	Child receive routine care	Don't recall
Sample responses	132 (70.60)	24 (12.80)	21 (11.20)	10 (5.30)
Purpose of study	Find children with sickle cell	Screen children illnesses	Screen for sickle cell	Don't recall
Sample responses	116 (62.00)	32 (17.10)	30 (16.00)	9 (4.80)
Reason for enrolment	Find if screening program can be set up	For child to be treated for sickle cell	I don't recall	
Sample responses	134 (71.70)	36 (19.30)	17 (9.10)	
Role in study	Answer questions about me	Give blood samples	Have no role	Don't recall
Sample responses	137 (73.30)	8 (4.30)	40 (21.40)	2 (1.10)
Common risks/discomfort	Broken skin	Psychological	I don't recall	
Sample responses	137 (73.30)	46 (24.60)	4 (2.10)	
When to receive results	As soon as possible	Immediately	I don't recall	
Sample responses	133 (71.50)	47 (25.30)	6 (3.20)	
Who will contact you for results?	Screening nurse	Laboratory personnel	I don't recall	
Sample responses	138 (74.20)	47 (25.30)	1 (0.50)	
If a child has sickle cell	Enrolled in care clinic	Given treatments	Will be referred by specialized care	
Sample responses	130 (69.90)	30 (16.10)	26 (14.00)	
Benefits for participating	Counseling and education	No direct benefits	Transport and lunch	
Sample responses	143 (76.90)	26 (14.00)	17 (9.10)	
Cost of screening	No cost	Ksh 50	Ksh 100	I don't recall
Sample responses	179 (96.20)	0 (0.00)	0 (0.00)	7 (3.80)
Who to contact in case of question	Number on form	Recruiter	Any doctor	I recall
Sample responses	125 (67.20)	12 (6.50)	49 (26.30)	0 (0.00)

Key: numbers in parentheses are percentages; those without are the number of mothers' who selected that answer; for every question, the first response was the correct one.

Results in Table 4.5 indicated that most of the mothers in the study were able to know the purpose of signing consent forms (*n*=132, 71%). However, sizeable proportions of mothers (one in every three mothers) had difficulties in comprehending information about the purpose of the research study. Seventeen percent of the mothers thought that the study was to screen children for childhood illnesses, at least two thirds (*n*=116, 62%) thought that the study aimed to screen them for sickle cell disease, while a very small number (*n*=9, 5%) of the mothers could not recall any answer. Approximately one out of every four mothers could not understand the reason for enrolling their children in the study, the mothers' roles in the study, common risks or discomforts involved in the study, and when to receive the results of blood samples. Although significant proportions of mothers correctly understood the information on; who will contact them to give results (*n*=138, 74%), what to do in case the child has sickle cell anemia (*n*=130, 70%), and the benefits for participating in the study (*n*=179, 77%), considerable proportions of the mothers could not understand this information. Whereas virtually every mother in the study (*n*=179, 96%) could comprehend the cost of screening, a few (n=7, 4%) of them understood, wrongly. Whom to contact in case of any question, (*n*=125, 67%) would contact the number given in the consent form while (*n*=49, 27%) would ask any doctor or recruiter.

4.6.2: Participants' Comprehension level as Measured by Comprehension Index

The mothers' level of comprehension of information index was calculated and its descriptive statistics are presented in Table 4.6.

	N	Min.	Max.	Mean	Std. Dev.	Skew	*SE*	Kurtosis	*SE*
Comprehension index	187	0.00	100.00	73.23	28.72	-0.95	0.18	-0.36	0.35

Table 4.6: Descriptive statistics for Comprehension Index

Key: N= number of respondents; Min. = minimum; Max. = maximum; Std. Dev. = standard deviation; SE = standard error

The comprehension index for mothers in the study was found to range from a minimum of zero to a maximum of 100. This showed that some mother(s) could not comprehend any information previously passed to them, suggesting that their comprehension of information for informed consent could be poor. The mean score for the comprehension index was 73.27%. This suggested that although the comprehension level of the mothers to informed consent contents was relatively high, significant proportions of the mothers could not comprehend information for making informed consent. The standard deviation of the comprehension index was large (29%), showing wide discrepancies among the comprehension indices of the mothers.

The frequencies of the comprehension index for the mothers are presented in Table 4.7.

Table 4.7: Frequencies of comprehension **levels among the mothers**

		Comprehension level			
		Poor	Average	High	Total
Mothers	Frequency	27	33	127	187
	%	14.44	17.65	67.91	100.00

The results indicated that majority of mothers had high comprehension levels (*n*=127, 68%). Thus, approximately two out of every three mothers could comprehend reasonably well the content on the consent form previously given. However, one in every three mothers had either poor or average comprehension of the information.

4.7.0: Factors influencing Comprehension of Information for Informed Consent

The second objective of this study required the assessment of factors that influence comprehension of information for informed consent. The endogenous variable in the study was comprehension of IC information, as indicated by the participants' comprehension levels. The comprehension level (index) consisted of three grades: poor, average, and high. The exogenous variables were: participants, consent form, and recruiter characteristics. The participant characteristics included biographical factors (education, gender, and age), state of health, and expectations from the study. The consent form features comprised of length of consent form, readability (level of difficulty of language), and the language used. Recruiter characteristics consisted of their experience in the consenting process.

4.7.1 Relationship between mothers' Demographical Factors with Comprehension

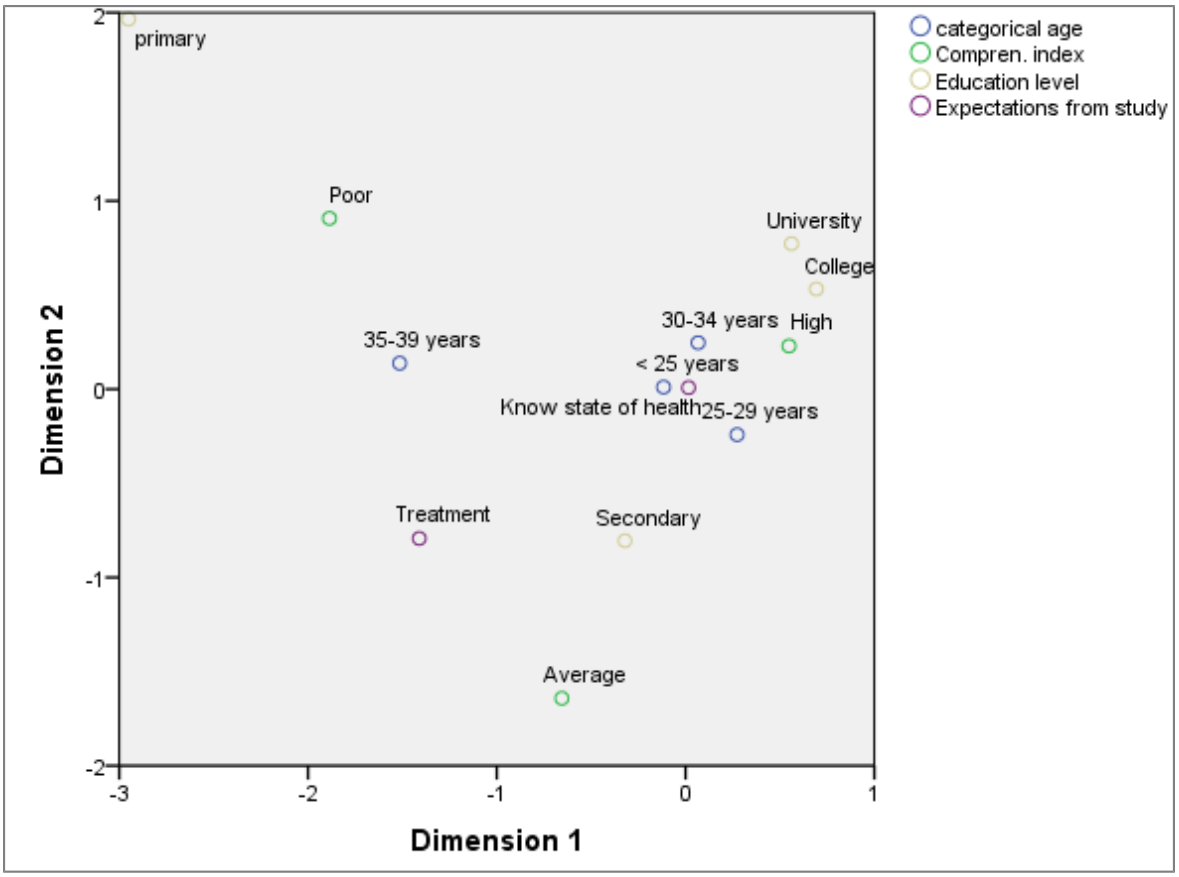
A Multiple Correspondence Analysis (MCA) was conducted to determine the relationship between the participants' demographical factors with their comprehension ability. The model summary for the MCA is presented in Table 4.8.

Table 4.8 MCA Model summary for the relationship between mothers' demographic factors and their comprehension **ability**

Dimension	Cronbach's Alpha	Variance Accounted For	
		Total (Eigen value)	Inertia
1	0.62	1.99	0.40
2	0.34	1.38	0.28
Total		3.37	0.68
Mean	0.51[a]	1.69	0.34

Key: [a] Mean Cronbach's Alpha is based on the mean Eigen value.

Two dimensions, with Cronbach's Alpha measures of 0.62 and 0.34, respectively, were extracted. The mean Alpha value for both dimensions was 0.51, which was relatively high, showing that the dimensions extracted were reliable. The model could explain about 34% of the variance in the original variables (inertia=0.34), with dimension one and two accounting for 40% and 28% of the variability, respectively. This was moderate, which suggested that the model was appropriate. The joint plot of category points is presented in Figure 4.2.



Key: Compren. = comprehension

Figure 4.2: Joint plot of categories for relationship between demographical factors and comprehension ability.

'Primary', 'treatment', and '35 – 39 years' aggregated near 'poor'. The results showed that participants with poor comprehension ability were primary educated, older (35 to 39 years), and those that expected treatment out of participating in the study. This indicated that comprehension of information for informed consent was lower in older mothers, those with primary education and those with expectations of being treated.

'High' comprehension ability occurred near 'college', 'university', '30 – 34 years', '<25 years', '25 – 29 years', 'good', and 'know state of health'. This showed that participants with

high comprehension ability were well educated (college or university), relatively younger (less than 34 years), and had expectations of knowing their state of health rather than getting treatment. 'Average' occurred next to 'secondary', indicating that mothers with secondary education were likely to have average comprehension ability.

4.7.2: Relationship between Consent form Characteristics with Comprehension

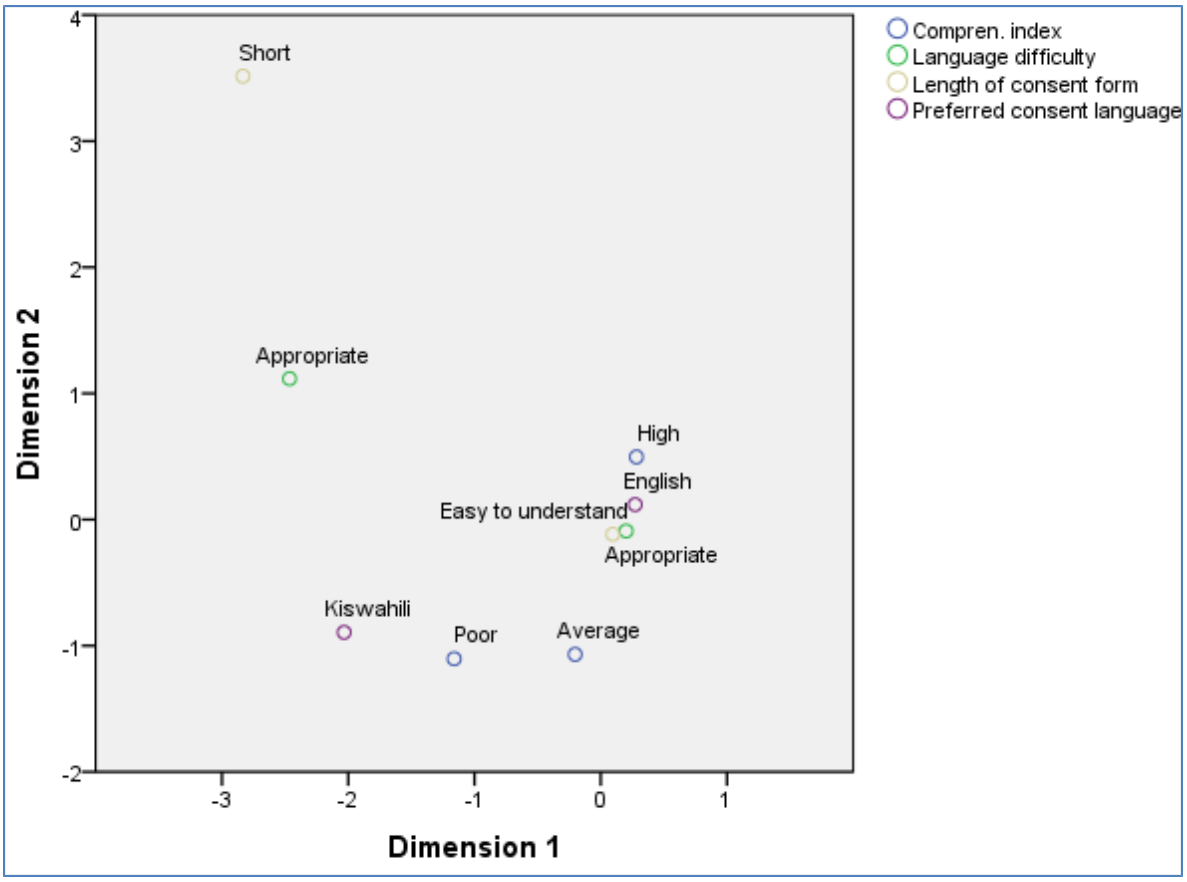
A Multiple Correspondence Analysis (MCA) was conducted to determine the relationship between the consent form features (length, readability, and the preferred language used) with the participants' comprehension ability. Table 4.9 presents the model summary for the MCA.

Table 4.9: MCA **Model summary for the relationship between consent form factors and participants' comprehension ability**

Dimension	Cronbach's Alpha	Variance Accounted For	
		Total (Eigenvalue)	Inertia
1	0.68	1.56	0.39
2	0.57	1.15	0.29
Total		2.71	0.68
Mean	0.63[a]	1.35	0.34

Key: [a] Mean Cronbach's Alpha is based on the mean Eigen value.

The MCA extracted two dimensions, with Cronbach's Alpha measures of 0.68 and 0.57, respectively. The mean Alpha value for both dimensions was 0.63, which was high, showing that the dimensions extracted were fairly reliable. The model could explain about 34% of the variance in the original variables (inertia=0.34), with dimension one and two accounting for 39% and 29% of the variability, respectively. This was fairly high, which suggested that the model was appropriate. The joint plot of category points is presented in Figure 4.3.



Key: Compren. = comprehension

Figure 4.3: Joint plot of categories for relationship between consent form factors and comprehension ability.

'High' aggregated near 'English', 'easy to understand', and 'appropriate'. This showed that mothers who considered the consent form as being of appropriate length, easy to understand, and who preferred it to be written in English had higher comprehension ability. Mothers with poor comprehension ability, on the other hand, preferred the consent forms to be written in Kiswahili. The results showed that comprehension of information for informed consent was higher in participants who considered the consent form to be of appropriate length and written in an easy to understand language, preferably English.

4.8: Recruiters' Experiences on administering Informed Consent

The third objective required an exploration of the recruiters' experiences on administering informed consent. The recruiters' were first asked about the length of time they took the potential participants through the informed consent process. Equal numbers of recruiters (n=2, 33%) were found to take less than 30 minutes, 30 minutes, and more than one hour (Figure 4.4). However, there was no recruiter found who used one hour to take the probable respondents through the consent process.

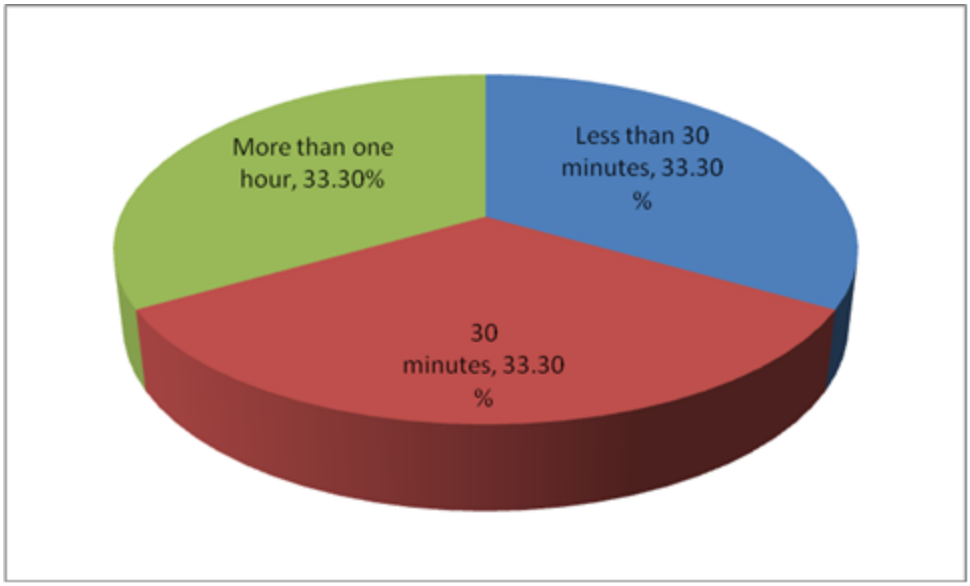


Figure 4.4: Length of time used in the consent process by recruiters

The results showed that there existed wide discrepancies in the length of time used by recruiters to take potential participants through the consent process, with some taking less than 30 minutes while others took more than one hour.

A Multiple Correspondence Analysis (MCA) was conducted to determine the relationships between the recruiters' duration of the consent process gender; length of involvement in

clinical trials, and the places informed consent is usually administered. Table 4.10: shows the model summary for MCA that was obtained.

Table 4.10: MCA Model **summary for recruiter experiences**

Dimension	Cronbach's Alpha	Variance Accounted For		
		Total (Eigenvalue)	Inertia	% of Variance
1	0.85	3.10	0.62	62.03
2	0.63	2.01	0.40	40.29
Total		5.12	1.02	
Mean	0.76[a]	2.56	0.51	51.16

Key: [a] Mean Cronbach's Alpha is based on the mean Eigen value.

Two dimensions, with Cronbach's Alpha measures of 0.85 and 0.63, respectively, were extracted. The mean Alpha value for both dimensions was 0.76, which was high, showing that the dimensions extracted were reliable. The model could explain about 51% of the variance in the original variables (inertia=0.51), with dimension one and two accounting for 62% and 40% of the variability, respectively. This was fairly high, which suggested that the model was appropriate. The joint plot of category points is presented in Figure 4.5.

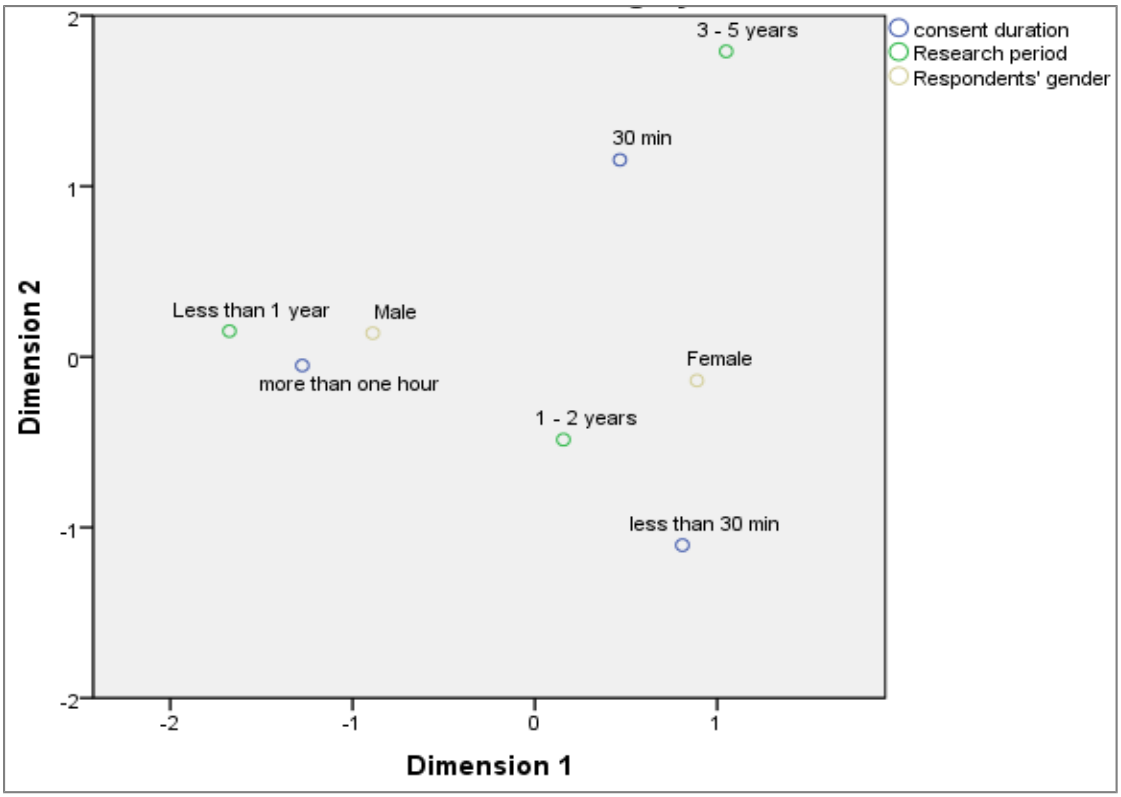


Figure 4.5: Joint plot of categories for recruiter experiences

'Three – five years' aggregate around '30 min', 'less than one year occurs near 'more than one hour' while '1 – 2 years' congregates near 'less than 30 min'. Recruiters who use a lot of time in the consent process (spend more than one hour) are likely to have less experience in consenting (less than one year). This showed that more experienced recruiters use less time in the consent process. Females are likely to be more experienced relative to males

'The recruiters' opinions on the length of the consent form for this study were also sought. The results showed that most of the recruiters (n=4, 67%) considered the forms to be of appropriate length (Figure 4.6). One recruiter (17%) considered it to be too short whereas the remaining recruiter judged it to be long (17%).

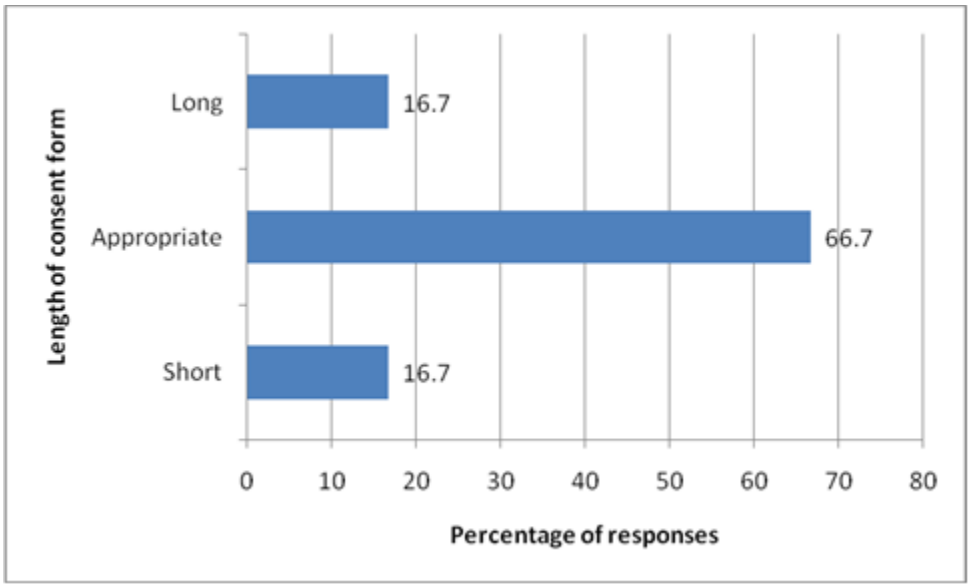


Figure 4.6: Length of the consent form in the study

The recruiters were asked to judge the readability of the consent form in the study. Four of them (67%) considered the readability of the form to be average whereas two (33%) assessed the form as being easy to read (Figure 4.7). No respondent judged the consent form as being difficult. The results showed that the consent form in this study was not difficult to read.

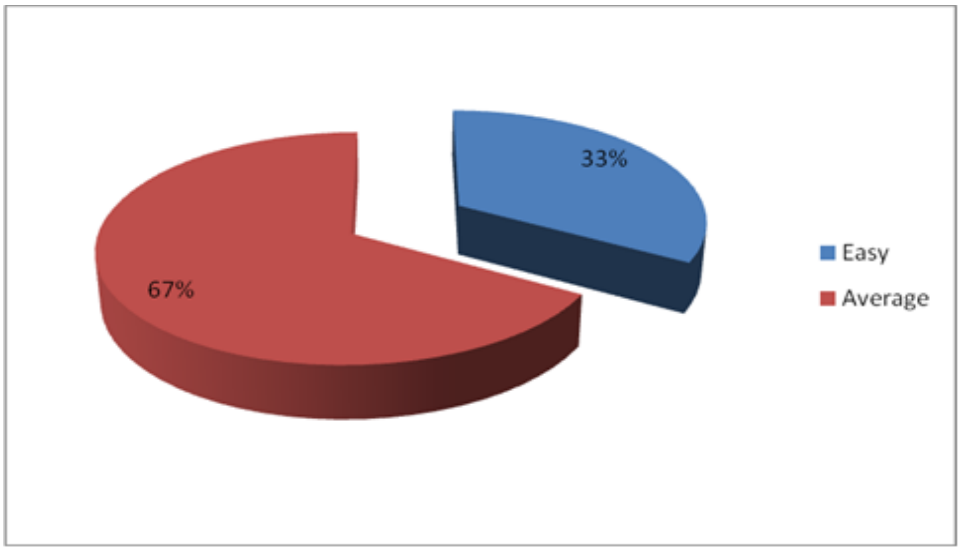


Figure 4.7: Readability of the consent form

The recruiters were asked what they usually did in case a participant refused to consent for the study. Most recruiters (n=4, 67%) usually convinced the potential respondents to participate by making them understand more on the study, its benefits and if any potential risks in the study while 33% (n=2) allowed them to choose what they wanted to do (Figure 4.8).

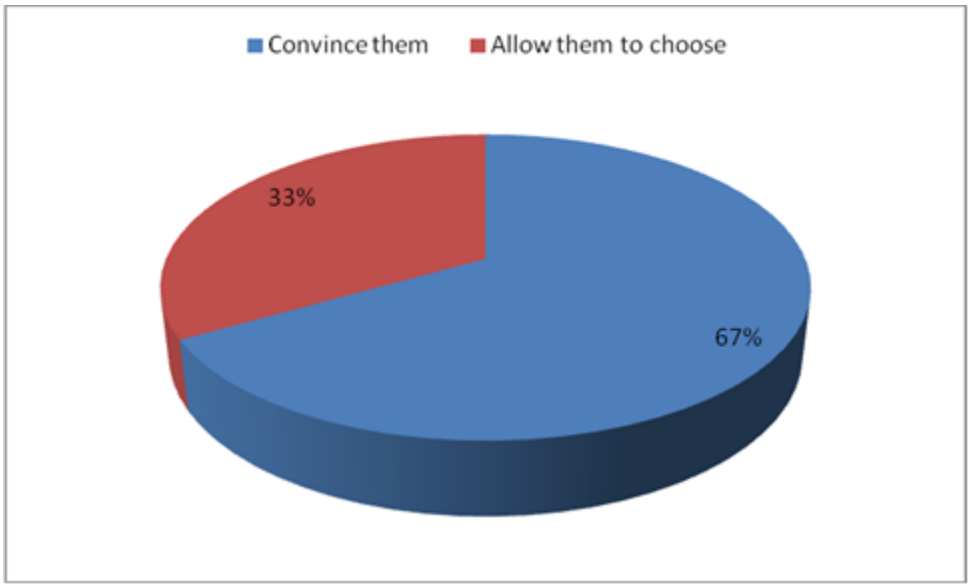


Figure 4.8: Action taken when a potential participant refuses to consent

A Multiple Correspondence Analysis (MCA) was conducted to determine the relationships between the length of the consent forms, their readability, and what recruiters do when participants refuse to consent to the study with, gender, and length of involvement in clinical trials/consenting. Table 4.10 shows the model summary for MCA that was obtained.

Table 4.11: MCA M**odel summary for the relationship between length and readability of consent forms with recruiter characteristics**

Dimension	Cronbach's Alpha	Variance Accounted For		
		Total (Eigenvalue)	Inertia	% of Variance
1	0.86	3.54	0.59	58.99
2	0.51	1.73	0.29	28.78
Total		5.27	0.88	
Mean	0.74[a]	2.63	0.44	43.89

Key: [a] Mean Cronbach's Alpha is based on the mean Eigen value.

Two dimensions, with Cronbach's Alpha measures of 0.86 and 0.51, respectively, were extracted. The mean Alpha value for both dimensions was 0.74, which was high, showing that the dimensions extracted were reliable. The model could explain about 44% of the variance in the original variables (inertia=0.44), with dimension one and two accounting for 59% and 29% of the variability, respectively. This was relatively high, which suggested that the model was appropriate. The joint plot of category points is presented in Figure 4.9.

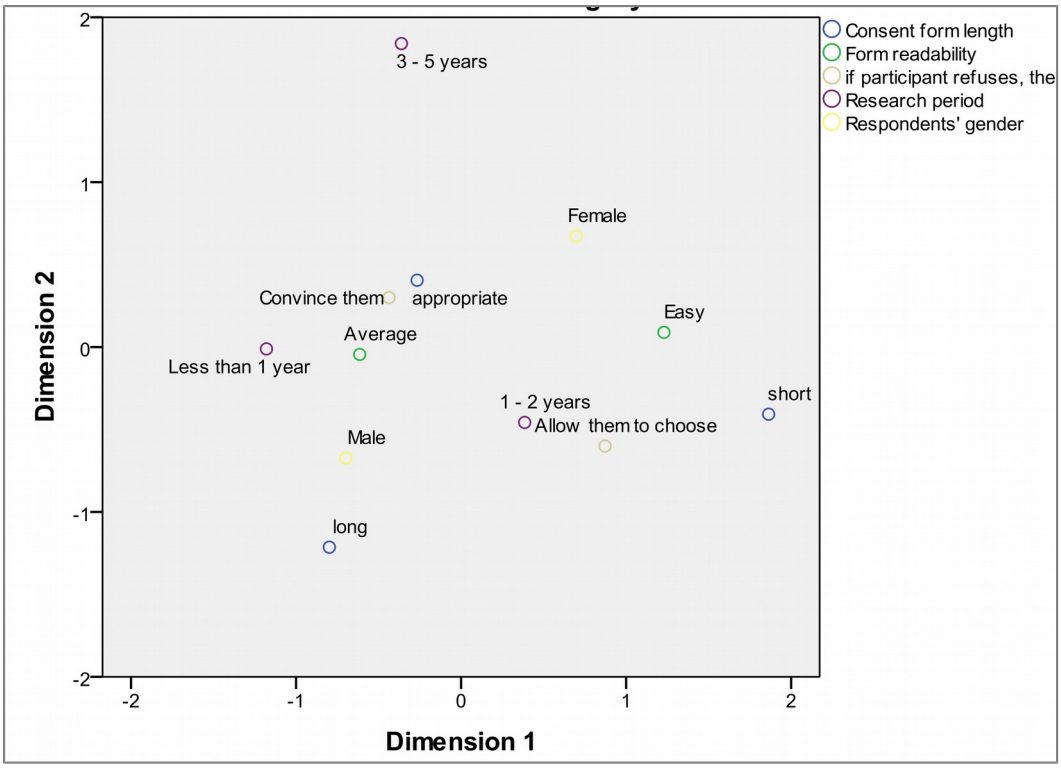


Figure 4.9: Joint plot of categories for recruiter experiences

Recruiters involved in clinical trials/consenting for less than one year are likely to consider the consent form to be of appropriate length while those with between one and two years' experience are likely to judge it as being short. Less experienced recruiters (those with less than one year in clinical trials) are likely to try to convince participants who refuse to consent for the study whereas those with 1 – 2 years' experience are likely to allow the participants to choose whatever they want.

Lastly, the recruiters were asked about the challenges they faced when administering the consent. A thematic analysis of the answers revealed four key challenges that recruiters face when attempting to get consent for a study. These themes are presented in Table 4. 12.

Table 4.12: **Key challenges when administering the informed consent process**

Key challenges	Frequency	Percent
Lack of understanding of study by recruiters and or potential participants	3	50
Repetitiveness of the process	1	16.67
Language barriers	1	16.67
Capturing participants' attention	1	16.67

One of the important challenges faced by both recruiters and potential participants was the lack of understanding of the study. Failure of recruiters to comprehend the study leads to an inability to explain fully what the study is about to participants, who consequently do not consent to the study. In the words of one recruiter:

"Explaining the consent details about the treatment part to the subject, sometimes it is very hard".

Another recruiter puts it thus:

"...mostly [the participants] *declines but sometimes they ask questions about study I cannot answer".*

When the participants do not understand what the study is about, it will be difficult for them to give consent. For instance, one recruiter talked of participants:

"Sometimes the participants do not understand what a study is about and it gives me a hard time trying to explain".

Explaining the details on the consent form to one person at a time, being asked questions and answering them and then repeating the procedure to several other people in a day makes the whole process dreary. One recruiter thus put it:

"I get tired and bored administering the same consent to over 20 clients in one day".

Inability of recruiters and potential participants to speak identical languages also creates a significant barrier to clear communication between the two parties, as they have to resort to using interpreters. One recruiter reported that:

"...language barrier some participants don't understand language used in research consent, translating is a problem".

Lastly, it is sometimes difficult capturing the attention of potential respondents because of extraneous factors. For example, a recruiter who deals mostly with alcoholics said:

"May be making the subject attentive when they don't really care about what you are saying – our subjects are mostly alcoholics".

4.9: Summary

This chapter presented the findings from the data collected on the level of comprehension of information for informed consent among mothers of neonates undergoing sickle cell disease screening in Postnatal ward (Riley mother and baby hospital) and AMPATH Hemato-Oncology clinic in Eldoret, Kenya. The study found a reasonably high mean comprehension index amongst mothers (73.27%, standard deviation: 28.72%), suggesting that although the comprehension level of the mothers to informed consent contents was relatively high, one out of every three mothers could not comprehension the information. Thus, a significant proportion of the mothers could not comprehend information for making informed consent.

Participant, consent form, and recruiter characteristics were all found to influence comprehension ability and hence, comprehension of information for informed consent.

Comprehension of information for informed consent was found to be lower in older mothers, those with primary education and those with expectations of being treated. The results showed that comprehension of information for informed consent was higher in participants who considered the consent form to be of appropriate length and written in an easy to understand language, preferably English.

The key challenge faced by recruiters during administering IC were lack of understanding of the study by themselves, repetitiveness of the informed consent process, language barriers, and difficulties in capturing participants' attention. These factors could hinder the proper administration of IC, hence, affecting negatively on participants' comprehension of IC information.

CHAPTER FIVE

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter presents the discussion of the research findings in relation to the study objectives and other related studies. The findings were used to draw conclusions, and the recommendations made were based on the conclusions drawn. Discussions of results are presented in section 5.2, conclusions are made in section 5.3, recommendations in section 5.4 while suggestions for further study are set out in section 5.5.

The general objective of this study was to evaluate the level of comprehension of information for informed consent among mothers of neonates undergoing sickle cell disease screening in postnatal ward MTRH and AMPATH Hemato- oncology clinic in Eldoret, Kenya. Specifically, the study aimed to assess the level of comprehension of information given before consenting for the study, determine the factors that influence comprehension of information for informed consent and explore the recruiters' experiences on administering informed consent.

5.2.0: Discussion

5.2.1: Level of Comprehension of IC Information by Participants

The mean comprehension index amongst the study participants was 73.27%, which was comparable to other studies. For instance, a study by Gikonyo *et al*. (2008) on the understanding and perception of malaria vaccine trials (MVT) in Kenya revealed that a portion of participants who offered correct responses ranged between 29 – 84% while those who did not know varied between 14 – 15%. The wide variation in the proportion of the study respondents offering correct answers in the Gikonyo *et al*. (2008) study reflects the large standard deviation of 28.72% obtained in this study. In a study to examine the factors influencing quality of informed consent amongst 265 patients in an academic surgical unit of a large teaching hospital, 81% and 19% of them were found to be well informed and poorly informed respectively about the contents of the consent form immediately after giving consent (Lavelle-Jones *et al*., 1993). A study by Mark *et al*. (1990), found that 82.4% of 102 participants reported that they understood everything that their physicians had described about a procedure and indicated that all of their questions had been answered. Eighteen patients had remaining unanswered questions. Other studies by Graham (2003) and Saw *et al*. (1994) show that even after agreeing to or receiving care, 18% to 45% of patients are unable to comprehend the major risks associated with their surgeries while Wadey and Frank (1997) reported that many participants cannot answer basic questions about the services or procedures they agreed to receive. A study by Byrne *et al*. (1988) showed that 44% of the patients did not know the exact nature of their operation.

The comprehension levels in the studies cited mirror closely the one recorded for this study, suggesting that although the comprehension level of participants in the studies could be relatively high, significant proportions of them might not comprehend information on the consent forms. This raises the real specter that sizeable proportions of participants could be taking part in either research or clinical trials without understanding what the studies were all about. The Declaration of Helsinki states that in medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study (World Medical Association, 2013). However, if some participants in the study do not comprehend information on consent forms, it follows that they could be blissfully participating in research without ever understanding the attendant potential risks and discomfort it might engender.

5.2.2: Factors Influencing Comprehension of IC Information

Demographic variables were found to influence comprehension and therefore, comprehension of information for informed consent. Comprehension of information was found to be lower in older mothers, those with primary education and those with expectations of being treated. On the other hand, comprehension of information for informed consent was higher amongst mothers who were better educated, younger, and had expectations of knowing their state of health rather than getting treatment. The findings from this study are in line with other studies. For instance, among 54 patients who underwent head and neck surgery, 72% of those having university education comprehended more than 50% of the complications, compared with 36% of those without a university education (Hekkenberg *et al*., 1997). In another study

of 200 patients with cancer, those who had completed high school had 35% higher scores on tests asking them on comprehension, within one day of undergoing informed consent, written and oral information provided to them during the consent process (Cassileth *et al*., 1980). According to Taiwo and Kass (2009), comprehension of information is composed of four fundamental abilities: ability to *understand* relevant information, ability to *appreciate* the nature of situation and its likely consequences, ability to *reason* through the information and weigh options logically and ability to *communicate* the choice. Educated people are likely to score more highly on all the four constructs relative to the uneducated, which could explain the higher comprehension levels of the well educated.

Just like this study, several other studies have found an inverse correlation between the patient's age and ability to comprehension information given during informed consent process. For example, among 265 patients undergoing intrathoracic, intraperitoneal, and vascular surgery procedures, patients over 60 years of age had less knowledge about their planned procedure immediately after the informed consent process (Lavelle-Jones *et al*. (1993). Among 54 patients who underwent head and neck surgery, patients who comprehended more than 50% of the complications they had been told were, on average 7.6 years younger than those who comprehended less than 50% (Hekkenberg *et al*., 1997). There could be several plausible explanations for this relationship. For instance, aging has been associated with decreases in speed of information processing and working memory performance (Salthouse, 1996; Grady and Craik, 2000). In addition, age-related conditions like sensory deficits and health problems reduce memory function (Hess 2005). On the other hand, older people's substantial knowledge and experience may weaken the impact of reductions in cognitive resources (Brown & Park, 2003). This study did not investigate any of

these factors, which could be considered by other researchers. However, there could exist a simpler explanation for the association between older age and less informed consent comprehension: older people might have a lower average educational accomplishment compared to younger people. This is because, in this study, the oldest mothers (those aged 35 – 39 years) had secondary education while university and college educated mothers were less than 25 years old and 30 to 34 years old, respectively. Thus, the negative relationship between age and comprehension ability could be simply spurious. Indeed, in a study of 200 patients with cancer who underwent informed consent for radiation therapy, chemotherapy, or surgery, comprehension by age did not vary when adjusted for educational attainment (Cassileth*et al*., 1980).

The study showed that comprehension of information for informed consent was higher in participants who considered the consent form to be of appropriate length and written in an easy to understand language, preferably English. The finding is contrary to a study by Sharp (2009) on consent documents for oncology trials showed that consent documents for clinical trials in oncology were lengthy and complex to the point that it was unlikely that most patients would be willing to read them or be able to understand the concepts they discussed. This suggested that lengthy consent documents might be off putting to read and the verbose information is likely not to be comprehended. However, as Naanyu *et al*. (2014) argued, the consent form should include all elements and the length should be reasonable enough for most people to read instead of shying away.

Studies by Davis *et al*. (1998), Jefford & Moore (2008), and Tekola et al. (2009) reveal that an increase in the complexity of language used in consent forms leads to less comprehension, which agrees with the findings of this study. The Flesch-Kincaid Grade level for the

participants consent form for this study was 7.9, which roughly meant that an eighth grader could understand the document. The level was below 8.0, which implied that the consent form was easy to read. This might explain why 93% of the respondents considered the consent form easy to understand. This finding is in line with Kithinji and Kass (2010), who stated that readability of a text is determined by the overall length, legibility of print, illustration, color, vocabulary, conceptual difficulty, syntax and organization. This was also similar to the conclusion by Beardsley *et a*l. (2007) who found out that higher objective knowledge on quality of informed consent (QuIC) was associated with participants having English as a first language and a higher level of education.

5.2.3: Recruiters' Experiences on Administering Informed Consent

The study found that more experienced recruiters used less time in the consent process. In semi structured interviews conducted with eleven individuals from three clinical research teams in London, Newington and Metcalfe (2014) reported that more experienced recruiters were more confident and felt that specific training was unnecessary, which could explain why they used less time to carry out the informed consent process. On the other hand, less experienced researchers tended to be less confident (Minnies *et al*., 2008).

This study found that more experienced recruiters, considered the consent form to be easy to read and too short, and are likely to allow the participants who refuse to consent for the study to choose whatever they want. This could be explained by the fact that having administered the consent innumerable times to participants, they are likely to have found the consent form for this study to be an easy read and short. In addition, since they have successfully administered the consent to many potential respondents in the past, they need not to prove to

anyone that they are capable unlike starting recruiters who might want to coax unwilling participants to show their superiors that they can administer the consent (Minnies *et al*., 2008).

The key challenge faced by recruiters during administering informed consent was the lack of understanding of the study by themselves and or potential participants. Other important challenges were found to be repetitiveness of the informed consent process, language barriers, and difficulties in capturing participants' attention. This indirectly showed that recruiter characteristics influence participants' comprehension ability and comprehension level. For instance, one recruiter admitted that, frequently, they take participants through the consent process, even when they do not understand the study a recruiter said *"declines but sometimes they ask questions about study I cannot answer"*. Recruiters who have no understanding of the study are likely to have participants having significantly lower comprehension levels of information on the consent form. Newington and Metcalfe (2014) reported that in addition to their professional roles, their personality and knowledge of the research project was crucial for participants to comprehend informed consent information, which was in line with the findings of this study.

Previously, scientists have raised concerns that recruiters did not have sufficient knowledge of the intricacies of the study to be able to explain fully the background and rationale to potential participants, or to answer questions about particular methodologies (Halkoaho *et al*., 2011, Ziebland *et al*., 2007). The potential benefits of allowing research scientists to recruit participants to their research include providing expert knowledge of the study processes and rationale and separating research recruitment from routine clinical care. However, this must be balanced against the potential vested interest in the research by the scientist, that may be geared more towards knowledge generation than safety of the participant. Thus, it might be

germane to include clinical research scientists as part of the recruitment team, with safeguards to guarantee that participants are not exploited.

The repetitiveness of the consent process might cause recruiters to reduce the time spent on each participant, in order to get over the dreary process quickly. However, this could force the recruiters to leave out crucial information, which could compromise the quality of the consent process. Malik (2011) argued that patients' ability to understand research is compromised by the short time frame in which information is provided, absence of background knowledge of their disease and its treatment. Language barriers between recruiters and participants will degrade the ability of the latter to comprehend information. Benetor *et al*. (2012) proposed the use of simple language, diagrams and tables to enhance comprehension of information.

5.3: Conclusion

The study evaluated the level of comprehension of information for informed consent among mothers of neonates undergoing sickle cell disease screening at AMPATH Hemato-Oncology clinic and past natal ward (MTRH) in Eldoret, Kenya. The mean comprehension index amongst the study participants was 73.27% (standard deviation: 28.72%), suggesting that although the comprehension level of the mothers to informed consent contents was relatively high, one out of every three mothers could not comprehension the information. The large standard deviation of the comprehension index also showed that there were wide discrepancies among the comprehension indices of the mothers'. This showed that significant proportions of the mothers could not comprehend information for making informed consent.

Participant, consent form, and recruiter characteristics were all found to influence comprehension ability and hence, comprehension of information for informed consent.

Comprehension of information for informed consent was found to be lower in older mothers, those with primary education, and those with expectations of being treated. On the other hand, comprehension of information for informed consent was higher amongst mothers who were better educated, younger and had expectations of knowing their state of health rather than getting treatment. The results showed that comprehension of information for informed consent was higher in participants who considered the consent form to be of appropriate length and written in an easy to understand language, preferably English.

The key challenge faced by recruiters during administering IC were lack of understanding of the study by themselves, repetitiveness of the informed consent process, language barriers, and difficulties in capturing participants' attention. These factors could hinder the proper administration of IC, hence, affecting negatively on participants' comprehension of IC information. The study found that more experienced recruiters spent the minimum time in the consent process, considered the consent form to be easy to read and too short, and are likely to allow the participants who refuse to consent for the study to choose whatever they want.

5.4: Recommendations

This study recommended the following:

Since significant proportions of participants do not comprehend information for informed consent, recruiters and researchers should take every necessary step to ensure that this is accomplished. For instance, before the study commences, there should be a review to determine knowledge uptake by participants' and for those who did not understand would

require the consent process to be repeated. This is especially important to international researchers conducting research in developing countries.

Since some recruiters admitted that they did not understand some aspects of studies, researchers should include form as part of the recruitment team, with safeguards to guarantee that patients are not exploited.

Researchers should consider some thorough training for recruiters and assist the newly accredited recruiters (for instance, by requiring them to work with experienced recruiters, as the study showed that less experienced recruiters took more time in the consent process).

Since some recruiters admitted that the process of informed consent could be boring and repetitive, the research ethics committees should require the use of varied methods during informed consent, such as a combination of oral, written, video. The committees could also consider the use self – administered consent forms on computers.

Since studies might deal with less educated participants, the consent forms/process's language must be simple and the form shortened but comprehensive enough.

5.5: Further Research

This study evaluated the level of comprehension of information for informed consent among mothers of neonates undergoing sickle cell disease screening in AMPATH Hemato-Oncology clinic in Eldoret, Kenya. Studies could be conducted in other hospitals and research settings to determine whether the factors established in this study are also important in influencing comprehension of information by the mothers. The inverse relationship between the age of mothers and comprehension of informed consent information established in this study could be explained by many factors. Studies could be conducted to delineate the exact causal

relationship between participants' age and ability to comprehension information given during the consent.

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APPENDICES

APPENDIX 1: INFORMED CONSENT FORM

My Name is Lucy Jepkemei Chebungei, I am a Student from Moi university, undertaking a course in International research ethics. I am currently conducting a study as part of the course requirement. I would like to find out the comprehension of information for informed consent by mothers of children enrolled for sickle cell screening participants at AMPATH-Hemato-Oncology Clinic and MTRH postnatal ward (Riley mother and baby hospital) from the study participants and the recruiters.

Your participation is voluntary and you are free to withdraw at any point of the interview. All your answers will be treated with anonymity, confidentiality and will used only for the purposes of research. There are no known or anticipated risks in this study. There are no financial benefits from this study apart from lunch of 500 Ksh for recruiter and transport of 200 Ksh for the study participants.

If you have any questions, before, during, or at the end of the interview, feel free to ask me.

This it will take about 20- 30 minutes for study participant and 10 minutes for recruiters.

Thank you

Signed: .....Date: .....

APPENDIX:2

DATA COLLECTION TOOL FOR STUDY PARTICIPANTS

Introduction

I am a student of Moi University, school of medicine department of behavioral science conducting a study on comprehension of information for informed consent by AMPATH Hemato-Oncology study participants. I wish to request for your consent to proceed and ask you a few questions with regard to the study. Information will be treated with utmost confidentially and will be used for the purpose of the study.

Instructions

These questions are meant for the study purpose; your co-operation will be highly appreciated.

Participation in the study is voluntary.

PART A Demographic Characteristics

Kindly respond to each of the questions below as appropriate.

1. What is your age: ---------

2. What is your marital status?

a) Married [ ]

b) Single [ ]

c) Divorced [ ]

d) Separated [ ]

e) Widow [ ]

3. What is your level of education?

a) None [ ]

b) Primary [ ]

c) Secondary [ ]

d) College [ ]

e) University [ ]

4. Which language do you prefer to be communicated with?

a) English [ ]

b) Kiswahili [ ]

c) Mother tongue [ ]

5. What is your primary occupation?

a) Formal employment [ ]

b) Self-employed [ ]

c) Farmer [ ]

d) Others [ ]

e) None [ ]

PART B- Informed consent questions

Please tick (√) the correct answer in the box provided

QUESTION	TICK THE CORECT RESPONSE
I have been asked to attend to sign a consent forms so that My child can participate in a research study My child can receive expert treatment. My child receive routine health care I don't recall	
The purpose of the research study that your child was enrolled into is To determine how any children born in the hospital have sickle cell disease To screen my child for childhood illnesses To screen me for sickle cell I don't recall	
Research staff wants to enroll my child into the research study so that The results can be used to decide if sickle cell screening program can be established in the future My child can be treated for sickle cell disease I don't recall	
What will be your role in the study To answer questions about myself To give out my blood samples I have no role its only my child who will be in the study I don't recall	
The most common risks or discomfort involved are Risks associated with broken skin such as bleeding bruising or infection Psychological disturbance I don't comprehension	
When will you receive the results of the blood samples As soon as possible Immediately I don't recall	
Who will contact you for the results The screening nurse The laboratory personnel I don't know	

If your child will be detected to have sickle cell he/she will be Enrolled in the comprehensive care clinic Will be given treatments Will be referred by specialized care	
The benefits available to me for participating in the study are Counseling and education on sickle cell No direct benefits Transport and lunch	
9.What are the cost for the screening No cost 50 Ksh 100 Ksh I don't recall	
10. In case of any question who do you contact Phone number given on the form The person recruiting you Any doctor I don't recall	

Part C: Questions on the consent form

1. How can you rate the length of the consent form that you signed?

a) Short [ ] Appropriate [ ] Long [ ]

2. The language used in the consent form was

a) Easy to understand [ ] b)Appropriate [ ] Difficult to understand [ ]

3. Which language would you have preferred the consent form to be written?

a) Mother tongue [ ] b) Kiswahili [ ] c)English [ ]

4. **In your opinion, which mode of delivery could be appropriate in transmission of the consent?**

a) Oral [ ] Written [ ] Video [ ] All [ ]

END

THANK YOU

APPENDIX 3: DATA COLLECTION TOOL FOR RECRUITERS

Introduction

I am a student of Moi University, school of medicine department of behavioral science conducting a study on comprehension of information for informed consent by AMPATH Hemato-Oncology study participants. I wish to request for your consent to proceed and ask you a few questions with regard to the study. Information will be treated with utmost confidentially and will be used for the purpose of the study.

Instructions

These questions are meant for the study purpose; your co-operation will be highly appreciated.

Participation in the study is voluntary

1.Sex

Male [ ] Female [ ]

2. How long have you been involved in administering informed consent in clinical trials?

Less than one year [ ] 1-2 years [ ] 3-5 years [ ] Over 5 years [ ]

3. How long do you consent the participants

Less than 30min [ ] 30 min [ ] One hour [ ] More than one hour [ ]

4.What can you say on the length of the consent form?

Short [ ] Appropriate [ ] Long [ ]

4. **How easy do you find reading the consent form?**

Easy [ ] Average [ ] Difficult [ ]

5. What challenges do you face when administering the consent?

-

6. If a participant refuses to consent for the study what do you usually do?

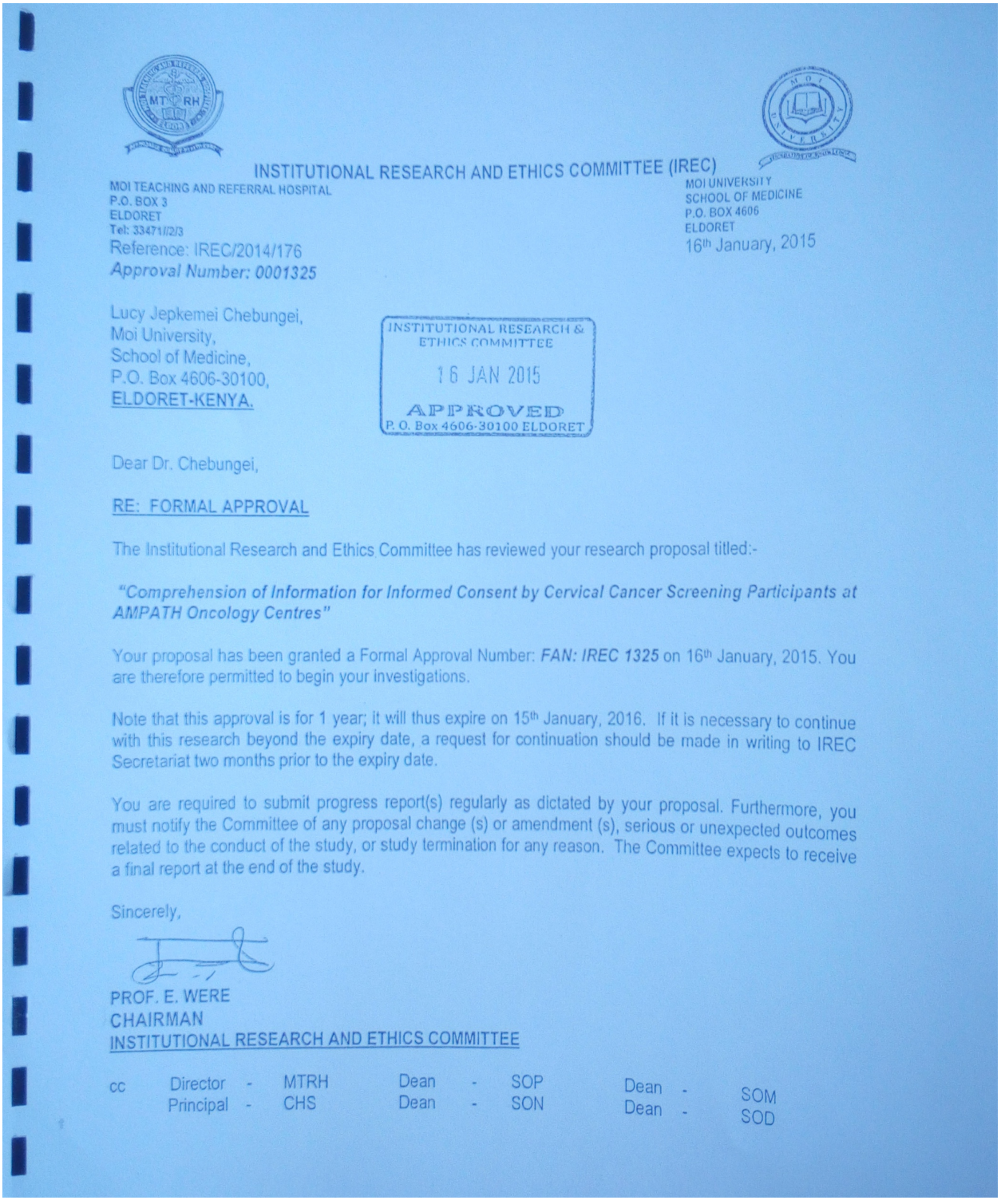
Convince them [ ] Allow them to choose what they want [ ]

END

THANK YOU

APPENDIX 4: IC FOR SINGLE CELL SCREENING STUDY

APPENDIX 5: FORMAL APPROVAL



INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2014/176
Approval Number: 0001325

16th January, 2015

Lucy Jepkemei Chebungei,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
16 JAN 2015
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Chebungei,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Comprehension of Information for Informed Consent by Cervical Cancer Screening Participants at AMPATH Oncology Centres"

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1325*** on 16th January, 2015. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 15th January, 2016. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

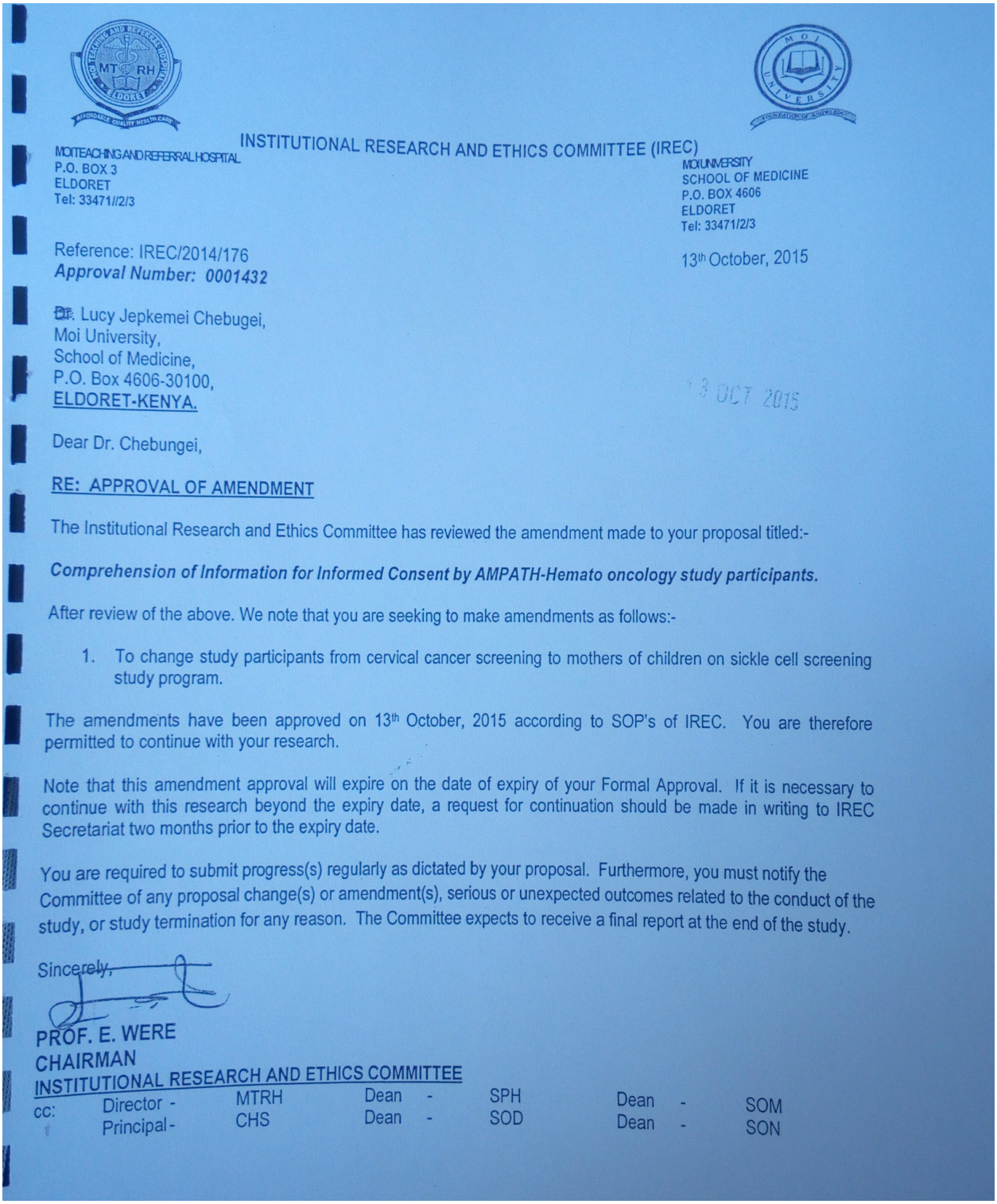
You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc Director - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

APPENDIX 6: APPROVAL OF AMENDMENT



INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2014/176
Approval Number: 0001432

13th October, 2015

Dr. Lucy Jepkemei Chebugei,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

13 OCT 2015

Dear Dr. Chebungei,

RE: APPROVAL OF AMENDMENT

The Institutional Research and Ethics Committee has reviewed the amendment made to your proposal titled:-

Comprehension of Information for Informed Consent by AMPATH-Hemato oncology study participants.

After review of the above. We note that you are seeking to make amendments as follows:-

1. To change study participants from cervical cancer screening to mothers of children on sickle cell screening study program.

The amendments have been approved on 13th October, 2015 according to SOP's of IREC. You are therefore permitted to continue with your research.

Note that this amendment approval will expire on the date of expiry of your Formal Approval. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change(s) or amendment(s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc: Director - MTRH Dean - SPH Dean - SOM
Principal - CHS Dean - SOD Dean - SON