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Comprehension of Information for Informed Consent Among Hemato-Oncology Study Participants in Eldoret, Kenya

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Abstract: The use of Informed consent (IC) became a prerequisite for research in response to abuses of human subjects during the last half-century, yet participant's comprehension of presented information is rarely explored. Major ethical concerns arise when information offered is not well comprehended by research participants. It is therefore a fundamental concern for all researchers to ensure that there is good comprehension of informed consent information in biomedical researches hence the current study endeavored to evaluate the comprehension of information for informed consent by Hemato- Oncology study participants. A descriptive cross sectional study design was used where systematic and convenience sampling techniques were used to sample the mothers who had assented to the study and research assistants involved in recruiting (recruiters) respectively. Two sets of semi-structured questionnaires were administered to 201 mothers and 6 recruiters, separately. Data from mothers and recruiters was collected for a period of one month and analyzed using descriptive and non- parametric correlation technique of multiple correspondence analysis (MCA). The response rate was 187 (93%) and 6 (100%) for the mothers and research assistants respectively. The mean age of the mothers was 28 ± 2.24 years with most having either secondary 89 (48%) or college education 67 (36%). Their preferred language of communication was English 165 (88%) or Kiswahili 22 (12%). The mean comprehension index of IC contents by the mothers was 73.27% (Std. Dev: 28.72%). Recruiters who had more than one year experience in research used ≥ 30 min in IC process compared to ≥ 1 hour for those who had been in research for less than one year. Low comprehension levels were found among older mothers (≥ 35 years) and those with primary education, however, comprehension was higher in participants who considered the consent form to be of appropriate length 181 (97), written in an easy to understand language 173 (96) and preferably written in English 165 (88%). The level of comprehension among the mothers on IC contents was relatively high with a few recording low comprehension. 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.

Keywords: Informed Consent, Comprehension, Information, Study Participants

1. Introduction

In the recent years there has been an increase in research involving human subjects, which has in- turn lead to development of legal and ethical regulations for researches of this nature. Nuremburg code, declaration of Helsinki, Belmont report and the council for the international organization of medical research (CIOM) gives the standard guidelines that are used by institutional research committees in approving protocols in ensuring sound ethical practices.

Informed consent is an important resource for protecting

participants in research studies [1], it's obtained before a prospective participant is enrolled in a research study. The Council for International Organizations of Medical Sciences (CIOMS) 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.

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 and those subjects can withdraw at any time and the information about maintaining participants' privacy and confidentiality of research data included in the consent form [2].

The use of IC has been widely accepted in research and clinical procedures both in high or low resource settings. However, implementing the standards of informed consent in the 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 [3]. 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 [4].

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 [5].

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 [6]. Clinical experience and empirical data indicate that participants and patients exhibit wide variation in their understanding of information. Beauchamp and Childress [3], observes that some participants are calm, attentive, and eager for dialogue while others are nervous or distracted in ways that impair or block understanding. Further, 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 [6]. Some researchers advocate the use of simplified consent form while other translate the form to the local language with the intention of increasing patients' understanding [8].

The researcher's experience in consent administration is valuable contribution to quality in consenting as deficiencies in communication process may hamper understanding. Poor communication by health workers or researchers may place health literacy demands on patients [7]. Communication break down between the researcher and the study participants may be due to the use of jargon or long complex sentences, what the 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 [7].

The structure of the consent form determines comprehension of information; the document must be easy and clear to understand. Kithinji and Kass [8] affirms 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 is unlikely that most patients will be willing to read them or be able to understand the concepts discussed [9]. 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 and therefore the potential participant signs the consent with adequate knowledge of study procedures [12].

The practice of informed consent is rooted in medicine, law, and philosophy and its usage in health research has gained prominence due to need for research using human subjects in biomedical research globally. The people awareness of their human rights has also made the practice of informed consent a key requirement in research [10]. The current approaches to informed consent often follow a regulatory framework traceable to the Nuremberg code 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".

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 [10].

Study Objectives

The broad objective was to evaluate comprehension of

information for informed consent by mothers who consented for a neonatal sickle cell disease screening study program.

The specific objectives were to:

1. Assess the level of recall of information given before consenting for the study
2. Explore recruiters experience on administering informed consent.
3. Assess factors that influence comprehension of information for informed consent.

2. Methods

This was a descriptive cross sectional study design targeting study participants who had already consented for a neonates' sickle cell screening study in a hemato-oncology clinic at a teaching hospital in Eldoret, Kenya.

Systematic sampling was used for the study population of mothers who had given an informed assent for their child's participation in the sickle cell screening study. The recruiters were conveniently selected as they continued with recruiting the primary study participants.

A total of 187 mothers and 6 recruiters were sampled and interviewed in the current study after consenting to participate in the study.

Data was collected over a period of one month, using two structured questionnaires; one for the mothers who had assented to the sickle cell screening study for their new born babies and another questionnaire for the research assistants(recruiters) who had recruited the new born babies into the study.

The questionnaire that was used for the mothers of neonate on sickle cell screening participants had three parts; part A was concerned with demographic data, part B had questions on recall on the informed consent information and other general question on the consent form and part C were questions directed to the study participant. The other questionnaire for the recruiters had questions on their experience during the consenting process.

Quantitative data was analyzed with the aid of descriptive statistics and non-parametric correlation technique of Multiple Correspondence Analysis (MCA). Descriptive statistics were used to describe, summarize, and organize the data.

When the data was measured on an interval scale (for instance, when recall index was computed), the mean (the arithmetic average of values in a set) was used. Dispersion (variability) of data was given by the range (the difference between the highest and lowest value) and the standard deviation (the average difference between observed values and the mean).

The open ended questions were analyzed by creating categories, identifying themes and quotations presented by the study participants were presented in support of the thematic findings.

The Institutional Research Ethics Committee of the Moi University approved the current study. Informed consent was obtained from the women 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.

3. Results

Of the 201 and six questionnaires administered to the mothers of neonates (participants) undergoing sickle cell disease screening study in AOI and recruiters of the mothers (recruiters) for the study, 187 (93%) and six (100%), were returned, respectively.

3.1. Demographic Profile of Respondents

Descriptive results (Table 1 below) 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 are 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 who attended the clinic 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.

Every woman in the study had access to a telephone (predominantly, mobile phones), suggesting that communication among the women might not be a problem. 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.

Most of the respondents were found to be self-employed (n=106, 57%), followed by farmers (n=44, 24%) and those in formal employment (n=22, 12%). The study also found that a small number (n=9, 5%) had no gainful employment. Most of the participants (n=169, 90%) used public vehicles ('Matatus') when coming to the clinic, followed by those who used motorbikes (n=14, 8%), and those who walked (n=4, 2%). This suggested that the respondents could be people of modest means.

Table 1. *Demographic variables of respondents.*

Panel A			
Demographic variables	**Categories**	**Frequency**	**Percent**
Respondent's marital status	Married	118	63.1
	Single	60	32.1

Panel A			
Demographic variables	**Categories**	**Frequency**	**Percent**
	Divorced/	6	3.2
	Separated		
	Widow	3	1.6
	Total	187	100.0
	Primary	10	5.3
	Secondary	89	47.6
Respondent's highest education level	College	67	35.8
	University	21	11.2
	Total	187	100.0
	Yes	187	100.0
Accessibility to telephone	No	0	0.0
	Total	187	100.0
	English	165	88.2
Preferred language of communication	Kiswahili	22	11.8
	Others	0	0.0
	Total	187	100.0
	Formal- employment	22	11.8
	Self-employed	106	56.7
Respondent's occupation	Farmer	44	23.5
	Others	6	3.2
	None	9	4.8
	Total	187	100.0
	Public-vehicle	169	90.4
Means of transport	Motor bike	14	7.5
	Foot	4	2.1
	Total	187	100.0
Panel B			
Demographic variables	Range	Mean	Std. Dev
Respondent's age (n=187)	19 – 39 years	28.55 years	4.14 years
Respondent's number of children (n=187)	1 – 4	2.24	0.88
Number of household members (n=187)	2 - 9	4.60	1.32

Table 2. *Demographic variables of recruiters.*

Panel A			
Demographic variables	**Categories**	**Frequency**	**Percent**
Recruiter's gender	Male	3	50.0
	Female	3	50.0
	Total	6	100.0
Period in research	< 1 year	1	16.7
	1 – 2 years	4	66.7
	3 – 5 years	1	16.7
	Total	6	100.0

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. Most of them had two children, with the number of children ranging from one to four. The number of household members varied from a minimum of two members to a maximum of nine, with the average being five members. This was in line with the finding that the mean number of children per mother was two.

Table 3. *Model summary for Multiple Correspondence Analysis (MCA) of demographic variables.*

Dimension	**Cronbach's Alpha**	**Variance Accounted For**		
		Total (Eigenvalue)	**Inertia**	**% of Variance**
1	.566	1.827	.365	36.541
2	.431	1.526	.305	30.514
Total		3.353	.671	
Mean	.504[a]	1.676	.335	33.527

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

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 also been involved in research for between one and two years.

3.2. Relationships Amongst the Respondents' Demographic Characteristics

A Multiple Correspondence Analysis (MCA) was conducted to determine the relationships between the respondent's age, gender, marital status, and profession. This analysis did not include the recruiters, as they were too few (six). Table 3 below shows the model summary for MCA that was obtained.

Two dimensions, with Cronbach's Alpha measures of 0.57 and 0.43, respectively, were extracted. The mean Alpha value for both dimensions was 0.50, which was equal to 0.50, 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 37% and 31% of the variability, respectively. This was fairly high, suggesting that the model was appropriate.

Further, a joint plot of category points is presented in Figure 1 below.

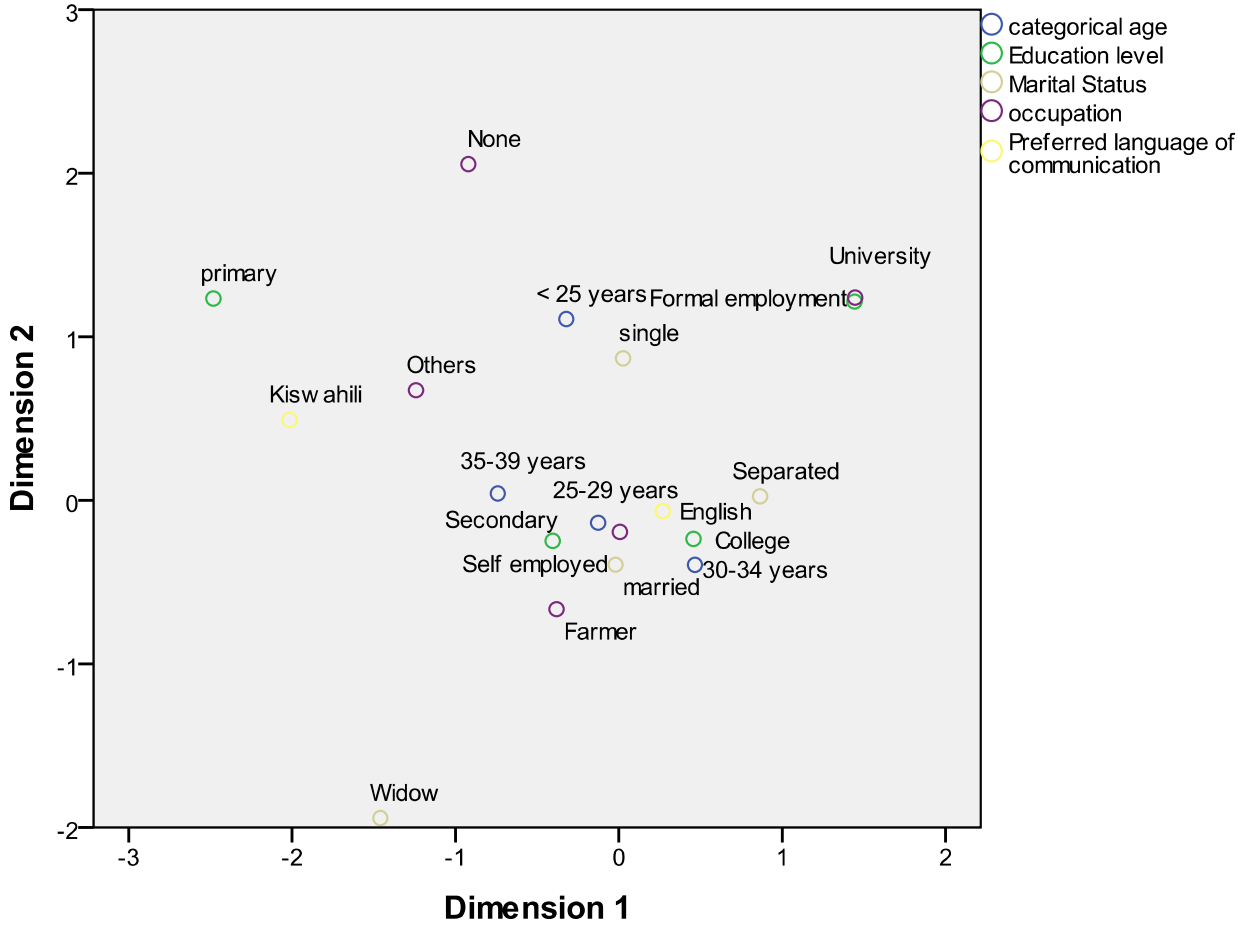

Figure 1. *Joint plot of categories for demographic variables.*

From the joint plot, the variable 'College' occurred near '30 – 34 years' and 'English', suggesting that mothers who attended college are likely to be 30 – 34 years old and are likely to prefer English as their language of communication. They are also likely to be separated. On the contrary, Mothers with primary education were likely to be unemployed and prefer to be communicated with in Kiswahili.

3.3. Level of Recall of Information

Most of the mothers in the study were able to know the purpose of signing consent forms (71%). However, sizeable proportions of mothers (one in every three mothers) had difficulties in recalling information about the purpose of the research study. Seventeen percent of the mothers thought that the study was to screen children for childhood illnesses, 16% thought that the study aimed to screen them for sickle cell disease, while 5% of the mothers could not recall any answer. Approximately one out of every four mothers could not recall 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 recalled information on who will contact them to give results (74%), what to do in case the child has sickle cell anemia (70%), and the benefits for participating in the study (77%), considerable proportions of the mothers could not recall this information. Whereas virtually every mother in the study (96%) could recall the cost of screening, 33% of them recalled, wrongly, that in case of any question, they ought to ask any doctor or recruiter instead of the investigator. This results were as summarized in table 4 below.

Table 4. *Participants recall of 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, n (%)	132 (70.6)	24 (12.8)	21 (11.2)	10 (5.3)
Purpose of study	Find children with sickle cell	Screen children illnesses	Screen for sickle cell	Don't recall
Sample responses, n (%)	116 (62.0)	32 (17.1)	30 (16.0)	9 (4.8)
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, n (%)	134 (71.7)	36 (19.3)	17 (9.1)	
Role in study	Answer questions about me	Give blood samples	Have no role	Don't recall
Sample responses, n (%)	137 (73.3)	8 (4.3)	40 (21.4)	2 (1.1)
Common risks/discomfort	Broken skin	Psychological	I don't recall	
Sample responses, n (%)	137 (73.3)	46 (24.6)	4 (2.1)	
When to receive results	As soon as possible	Immediately	I don't recall	
Sample responses, n (%)	133 (71.5)	47 (25.3)	6 (3.2)	
Who will contact you for results?	Screening nurse	Laboratory personnel	I don't recall	
Sample responses, n (%)	138 (74.2)	47 (25.3)	1 (0.5)	
If a child has sickle cell	Enrolled in care clinic	Given treatments	Will be referred by specialized care	
Sample responses, n (%)	130 (69.9)	30 (16.1)	26 (14.0)	
Benefits for participating	Counselling and education	No direct benefits	Transport and lunch	
Sample responses, n (%)	143 (76.9)	26 (14.0)	17 (9.1)	
Cost of screening	No cost	Ksh 50	Ksh 100	I don't recall
Sample responses, n (%)	179 (96.2)	0 (0.0)	0 (0.0)	7 (3.8)
Who to contact in case of question	Number on form	Recruiter	Any doctor	I don't recall
Sample responses, n (%)	125 (67.2)	12 (6.5)	49 (26.3)	0 (0.0)

The mothers' level of recall of information index was then calculated in order to easily determine each mother's ability to recall information previously presented on the informed consent form. The index was computed by summing up each mother's correct answers to the asked questions, and expressing the value as a percentage. The possible maximum score was 100% while the minimum was 0%. Table 5 below presents the descriptive statistics for the mothers' recall index.

Table 5. *Descriptive statistics for Recall Index.*

	N	Min.	Max.	Mean	Std. Dev.	Skew SE		Kurtosis SE	
Recall index	185	.00	100.00	73.2678	28.71942	-.954	.179	-.362	.355

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

The recall 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 recall any information previously passed on to them, suggesting that their comprehension of information for informed consent could be poor. The mean score for the recall index was 73.27%. This suggested that although the recall level of the mothers to informed consent contents was relatively high, one out of every four mothers could not recall the information. This showed that significant proportions of the mothers could not comprehend information for making informed consent. The standard deviation of the recall index was large (29%), showing wide discrepancies among the recall indices of the mothers.

To judge the recall levels of the mothers from the recall indices, a scale was used on the recall index scores of: 0.00-33.33% as of poor recall level; 33.34-66.67% as an average recall level; and 66.68-100% as a High recall level.

The results indicated that majority of mothers had high recall levels (n=127, 69%). Thus, approximately two out of every three mothers could recall reasonably well the informed content on the consent form previously given. However, one mother in every three had either poor or average recall of the information (Table 6 below).

Table 6. *Frequencies of recall levels among the mothers.*

Mothers Recall level				
	Poor	Average	High	Total
Frequency (n)	26	32	127	185
Percentage (%)	14.1	17.3	68.6	100.0

3.4. Responses on Consent Form Characteristics

The features comprised of length of consent form, readability (level of difficulty of language), the language used, and the mode of delivery.

Most respondents (n=187, 97%) considered the consent form to be of appropriate length, with only 3% considering it to be short. No participant in the study considered the form to be 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 8% (n=14) considering it as appropriate. No participant 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 12% (n=22) who chose Kiswahili. No participant preferred the use of mother tongue.

Most respondents (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 stand-alone method of transmitting the consent

3.5. 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.

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 hence conducted to determine the relationships between the recruiters' duration of the consent process and their gender, length of involvement in clinical trials, and the place where they administered the informed consent as tabulated below.

Two dimensions, with Cronbach's Alpha measures of 0.85 and 0.54, respectively, were extracted. The mean Alpha value for both dimensions was 0.720, which was high, showing that the dimensions extracted were reliable. The model could explain about 64% of the variance in the original variables (inertia=0.643), with dimension one and two accounting for 76% and 52% of the variability, respectively. This was fairly high, which suggested that the model was appropriate.

Table 7. *Multiple Correspondence Analysis for recruiter experiences.*

Dimension	Cronbach's Alpha		Variance Accounted For		
			Total (Eigenvalue)	Inertia	% of Variance
	1	.847	3.102	.620	62.032
	2	.629	2.014	.403	40.289
	Total		5.116	1.023	
	Mean	.761[a]	2.558	.512	51.160

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

'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. One researcher (17%) considered it to be too short whereas the remaining recruiter judged it to be long (17%).

When 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. No respondent judged the consent form as being difficult. The results suggest that the consent form in the hemato-oncology study was not difficult to read.

The recruiters were then asked what they usually do 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 benefits in the study while 33% (n=2) allowed them to choose what they wanted to do.

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 8.

Table 8. *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

Of the most 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 put 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.

3.6. Factors Influencing Comprehension of Information for Informed Consent

Since comprehension is an intangible and latent characteristic, this study operationalized this variable by using the mothers' ability to recall information previously given to them as a proxy. Thus, high recall ability signified a high comprehension level whereas a low recall level designated a low comprehension. The endogenous variable in the study was therefore, recall ability (which measured comprehension). This study also theorized that comprehension could be influenced by a triad of factors: patient, consent form, and recruiter characteristics. These three variables were thus, exogenous. The patient 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.

Since the independent variables were categorical, the endogenous variable was transformed into a discontinuous variable to allow the application of the technique of MCA. The recall levels of the mothers were categorized according to the scale on the recall index scores of; 0.00-33.33% denoting poor recall level; 33.34-66.67% as an average recall level; and 66.68-100% as a High recall level.

The results indicated that majority of mothers had high recall levels (n=127, 69%). Thus, approximately two out of every three mothers could recall reasonably well the informed content on the consent form previously given. However, one mother in every three had either poor or average recall of the information.

3.6.1. Relationship Between Participants' Demographic Factors with Recall Ability

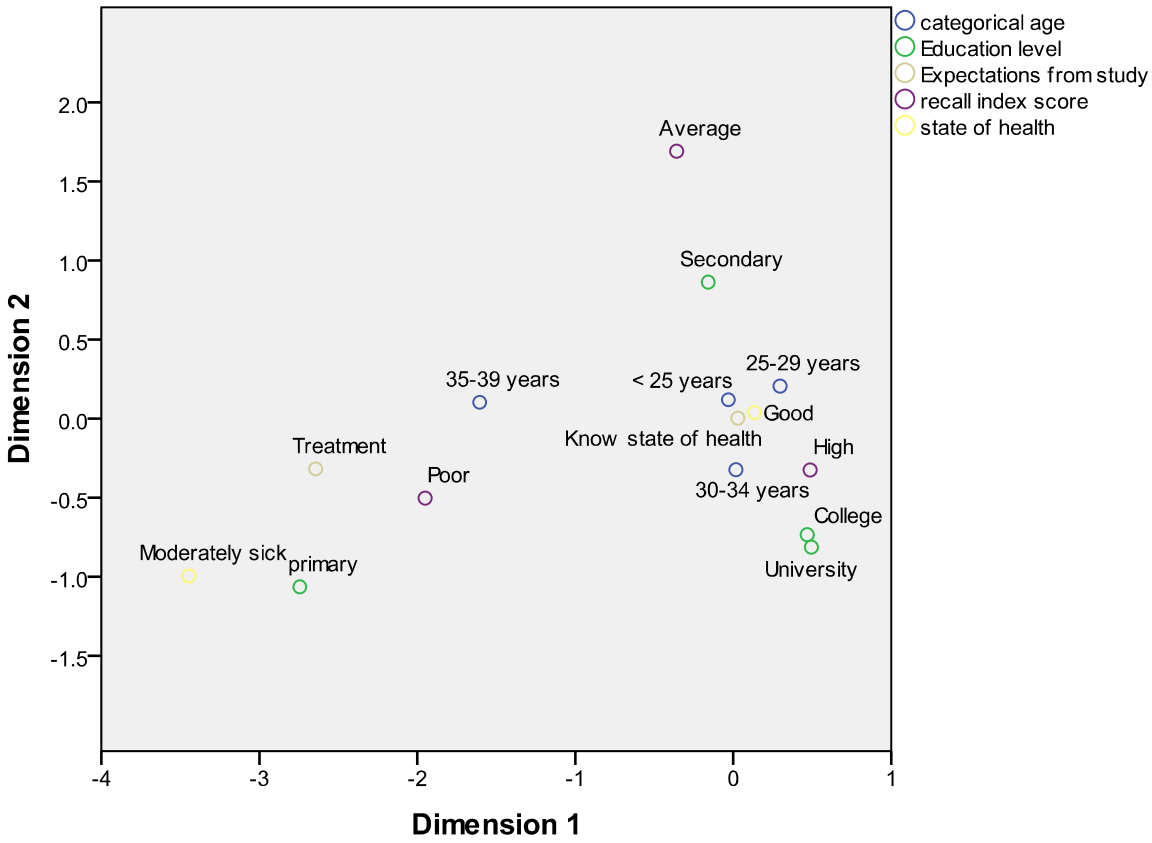

Figure 2. *Joint plot of categories for relationship between demographic factors and recall ability.*

'Primary', 'moderately sick', 'treatment', and '35 – 39 years' aggregated near 'poor' on the plot. The results show that participants with poor recall ability were primary educated, older (35 to 39 years), moderately sick, and expected treatment as a result of participating in the study. This indicated that comprehension of information for informed consent was lower in older mothers, those with primary education, those not feeling well and those with expectations of being treated.

'High' recall ability occurred near 'college', 'university', '30 – 34 years', '<25 years', '25 – 29 years', 'good', and 'know state of health'. This indicates that participants with high recall ability were well educated (college or university), relatively younger (less than 34

years), in good health, 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 an average recall ability. The results show that comprehension of information for informed consent was higher amongst mothers who were better educated, younger, in good health, and had expectations of knowing their state of health rather than getting treatment.

A similar Joint plot of categories for relationship between consent form factors and recall ability showed that: '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 recall ability. Mothers with poor recall 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.

3.6.2. Relationship Between Recruiter Characteristics with Recall Ability

Thematic analysis of the challenges faced by recruiters when administering the consent revealed that the key challenge was lack of understanding of the study by recruiters and/or potential participants. One recruiter admitted that, frequently, they take participants through the consent process, even when they do not understand the study. Recruiters who have no understanding of the study are likely to have participants having significantly lower comprehension levels of information on the consent form.

The other challenges revealed by the study were receptiveness of the process, language barriers, and difficulties in capturing participants' attention. For instance, the repetitiveness of the process makes it dreary and a recruiter may be tempted to shorten the process. Language barriers and inattentive participants reduce the effectiveness of communication, which likely lowers the comprehension of information for informed consent.

4. Discussion

The mean recall index amongst the study participants was 73.27%, which was comparable to other studies. For instance, a study by Gikonyo *et al*. [11] 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*. study [11] 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 about the contents of the consent form immediately after giving consent [12]. A study by Mark *et al*. [13], 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 [14] and Saw *et al*. [15] show that even after agreeing to or receiving care, 18% to 45% of patients are unable to recall the major risks associated with their surgeries while Wadey and Frank [16] reported that many participants cannot answer basic questions about the services or procedures they agreed to receive.

The recall levels in the studies cited mirror closely the one recorded for this study, suggesting that although the recall 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: "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" [17]. 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 potential risks and discomfort it might engender.

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 [18] 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.

The 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 had successfully administered the consent to many potential respondents in the past, they need not to prove to anyone that they are capable unlike newer recruiters who might want to coax unwilling participants to show their superiors that they can administer the consent.

Biographical variables were found to influence recall and therefore, comprehension of information for informed

consent. Comprehension of information was found to be lower in older mothers, those with primary education, those not feeling well 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, in good health, 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 recalled more than 50% of the complications, compared with 36% of those without a university education [19]. In another study of 200 patients with cancer, those who had completed high school had 35% higher scores on tests asking them to recall, within one day of undergoing informed consent, written and oral information provided to them during the consent process [20]. According to Taiwo and Kass [21], 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 recall levels of the former.

Just like this study, several other studies have found an inverse correlation between the patient's age and ability to recall information given during informed consent process. For example, among 265 patients undergoing intra-thoracic, intra-peritoneal, and vascular surgery procedures, patients over 60 years of age had less knowledge about their planned procedure immediately after the informed consent process [12]. 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 [22-23]. In addition, age-related conditions like sensory deficits and health problems reduce memory function. On the other hand, older people's substantial knowledge and experience may weaken the impact of reductions in cognitive resources [24]. 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 recall: older people might have a lower average educational accomplishment compared to younger people. In fact, 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 recall ability could be simply spurious. Indeed, in a study of 200 patients with cancer who underwent informed consent for radiation therapy, chemotherapy, or surgery, recall by age did not vary when adjusted for educational attainment [20].

The study found that a lower recall level of informed consent information was associated with moderately sick mothers compared to those who were healthy. This could be explained by the fact that sick mothers could be in pain and distracted, and hence might not receive all information given out during the informed consent process. According to Taiwo and Kass [21], patient illness hinders the capacity to comprehend, understand and to reach an autonomous decision.

This 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. A study by Sharp [25] 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 recalled. Nevertheless, Naanyu *et al*. [26] argue that, the consent form should include all elements and the length should be reasonable enough for most people to read instead of shying away. Studies [27-29] revealed 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.

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' recall ability and comprehension level. Newington and Metcalfe [18] 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 fully explain the background and rationale to potential participants, or to answer questions about particular methodologies [30-31]. 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 patients 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 [32] 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. Benatar and others [33] proposes the use of simple language, diagrams and tables to enhance recall of information by participants.

5. Conclusion

The mean recall index amongst the study participants was relatively high (73.27%) but with a wide standard deviation: 28.72%, suggesting that although the recall level of the mothers to informed consent contents was high, there were wide discrepancies among the recall indices of the mothers. A significant proportion of the mothers could not comprehend information for making informed consent.

Comprehension of information for informed consent was lower in older assenting mothers, those with low level of education, and those with expectations of being treated rather than knowing their state of health. On the contrary, 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.

Recruiter characteristics including; lack of understanding of the study, language barriers, and experience in consenting process were found to negatively influence participants' recall ability and comprehension level.

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Competing Interests

The main author- Ms. Lucy Jepekemei Chebungei will present this paper for a Master of Science in International Health Research Ethics degree at the Moi University, under the supervision of the second and third author.

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