GAPS IN INFORMED CONSENT PROCESS AMONG WOMEN WHO HAVE UNDERGONE ELECTIVE CAESAREAN SECTION AT AIC KIJABE HOSPITAL, KIAMBU COUNTY KENYA

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A Thesis Submitted to the Institute of Postgraduate Studies of Kabarak University in Partial Fulfilment of the Requirements for the Award of the Master of Medicine in Family Medicine Degree

KABARAK UNIVERSITY

NOVEMBER 2022

DECLARATION

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DEDICATION

I dedicate this research proposal to the AIC Kijabe Hospital's Obstetrics and Gynaecology department and my supervisors, Doctors Mary B. Adam and Eli Horn in recognition of their unconditional support during the pursuit of this academic task.

ABSTRACT

Informed consent is a legal and ethical requirement that allows respectful and dignified care. Informed consent process includes decision-making capacity, provision of adequate information, and voluntary consenting without coercion. The aim of this study was to examine the informed consent process for elective C-sections at Kijabe Hospital with a focus on identifying gaps. This was a cross-sectional study. A structured questionnaire assessing 15 elements of informed consent process was administered to 137 women who were consecutively sampled. Descriptive statistics were used for socio-demographic data. The 15 elements were aggregated. T-tests were used to evaluate the associations between aggregate score and chance to address patients' questions and concerns and time taken to obtain consent. P-value of less than 0.05 was considered statistically significant. Data were analyzed using STATA. Most participants (70.8%) were between 26-35 years of age, 75% had tertiary education, 94.7% were married, and 89.1% had more than two previous deliveries. There was no statistically significant association between each socio-demographic characteristic and the aggregate score on informed consent process. Of the 15 elements of informed consent, only benefits, implications on future pregnancy and postoperative briefing were infrequently addressed at 59.1%, 57.7% and 67.9% respectively. Documentation of informed consent process was not done at all, although consent forms were signed invariably. 97.1% of the participants had a chance to ask questions and have their concerns addressed. Averagely 10 minutes were spent on obtaining consent. Allowing a chance to address patients' questions and concerns and taking more time to obtain consent was associated with a higher aggregate score, a p-value of 0.01. Overall, the consenting process was working well. Allowing chance to address patients' questions and concerns and spending more time to obtain consent were associated with an in-depth informed consent process.

Keywords: *Informed Consent, Elective Caesarean Section.*

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ABBREVIATIONS AND ACRONYMS

ACOG	American College of Obstetrics and Gynecology
AIC	African Inland Church
ANC	Antenatal Clinic
BTL	Bilateral Tubal Ligation
ERB	Ethics Review Board
ICF	Informed Consent Form
KDHS	Kenya Demographic and Health Survey
KMPDC	Kenya Medical Practitioners and Dentists Council
KNBS	Kenya National Bureau of Statistics
KNH	Kenyatta National Hospital
NACOSTI	National Commission for Science, Technology and Innovation
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
RCOG	Royal College of Obstetricians
SPSS	Statistical Package for Social Scientist
UHC	Universal Health Coverage
UK	United Kingdom
VBAC	Vaginal Birth after Caesarean Section
WHO	World Health Organization

OPERATIONAL DEFINITION OF TERMS

Informed Consent: In this study, this referred to the process by which a clinician appropriately discloses adequate information to a competent patient to enable her to make a voluntary choice to either accept or refuse treatment.

Gaps in Informed Consent: In this study, information gaps referred to the lack of a discussion or recollection of any of the following elements of informed consent for caesarean section: the name and nature, benefits and indications, serious and frequently occurring risks, alternative(s) and the associated benefits and risk of the alternative options including no caesarean section, the anaesthesia and analgesia options available and their associated risks and benefits. Process gaps referred to the estimated amount of time taken when obtaining informed consent in minutes and the lack of chance to address all of the patients' questions and concerns.

Elective Caesarean Section: In this study, this referred to a planned delivery of a baby or babies via an incision in the anterior abdominal wall and uterus that for whatever indication is scheduled ahead of time. There is no urgency or emergency.

Clinician: In this study, this referred to any healthcare worker, especially those working in the obstetrics department which includes; obstetricians, family physicians, residents (registrars), medical officers, clinical officers, nurses, medical and clinical officer interns.

CHAPTER ONE

INTRODUCTION

1.1 Introduction

This chapter includes the background, statement of the problem, the purpose of the study, the objectives, research question, justification of the study, the scope, limitations and assumptions of the study.

1.2 Background of the Study

Informed consent is an essential component of good quality medical practice worldwide. It is both a legal and ethical requirement in healthcare. It emanates from the ethical principle of autonomy which grants that every human being of age has the right to determine what happens to her body(Beauchamp, 2011). Due to this owed bodily integrity, patients have the right to accept or refuse interventions on or in their bodies. Without complete informed consent, any intervention to their body may amount to battery.

A valid informed consent essentially consists of the presence of three aspects; decision-making capacity in the patient, adequate information delivered in a comprehensible language and manner to the patient with ascertainment of comprehension, and voluntariness in the permission to intervention(s) where coercion or undue influence from family, friends, and healthcare workers is absent (RCOG, 2015).

How much information to divulge to the patient has for a while been based on the reasonable patient's standard which requires the clinician to disclose relevant information that an average patient with reasonable needs and expectations would need to make an informed healthcare decision(Shah et al., 2020). However, a landmark case of Montgomery versus Lanark shire Health Board in the United Kingdom in 2015 has

influenced this standard to slowly change towards the subjective patient's standard which requires a clinician to provide the information that the patient wants and needs to make her healthcare decision(Coulter et al., 2017). This is further shifting the medical decision-making process from a paternalistic model to a shared decision-making model where clinicians and patients work in a partnership to choose interventions that are evidence-based and are informed by the patient's preferences(Coulter & Collins, 2011).

The consenting process should not only listen to the patient's concerns but also elicit her values, beliefs, preferences, and healthcare needs, and address them. In as much as sufficient information ought to be shared, room for negotiations or shared decisions ought to be availed as well.

Essential to this complete information sharing is the ability of the clinician to obtain consent from women in the obstetrics department to properly communicate risk, comprehensively appraise patients on the available treatment options, and support the patient's choice that represents her preferences. One of the surgical procedures that can be used to gauge the quality of informed consent is a caesarean section.

A caesarean section is one of the most common major surgery performed worldwide(Sung & Mahdy, 2020). In Kenya, almost every qualified medical doctor has performed a cesarean section as part of training either as a medical officer intern, medical officer, or registrar. It is a lifesaving surgical procedure for both the mother and her baby that is performed at level three, four, five and six hospitals in Kenya.

Worldwide there is a notable rise in the caesarean section rate. Reasons for this steady rise are multifactorial and are still poorly elucidated. Some contributing factors include; growing cases of litigations change in maternal characteristics, changes in the style of

obstetrics practice, economic, social and cultural shifts (Betrán et al., 2016). Broadly, a cesarean section is performed either as an emergency case or an elective case. This is further categorized from category one to four i.e. from immediate threat to life of mother and baby to a delivery at a time of suit to mother and clinicians (Torloni et al., 2011). Emergency cesarean section is often performed as a result of a life-threatening medical or obstetric emergency in pregnancy or when a woman is in labor, often there is haste in order to save the mother's or baby's life. An elective cesarean section on the other hand is where for an absolute or relative obstetric indication, delivery via surgery is preferred as the safest or sometimes the only way but usually, there is ample time to plan and schedule the delivery of the baby. Most primary caesarean sections lead to subsequent cesarean sections since most hospitals in Kenya don't have the capacity to assess risk and support vaginal birth after caesarean section (VBAC) as recommended by the American College of Obstetricians(ACOG, 2019).Luckily, AIC Kijabe hospital has this capacity. Most hospitals in the world including AIC Kijabe hospital have some theatre days specifically preserved for elective caesarean sections.

For caesarean section, complete informed consent information includes; the name and nature of the proposed cesarean section, the indications and benefits of caesarean section, risks involved in caesarean section, alternatives to caesarean section and related risks and benefits of the option including no intervention at all, anaesthesia and analgesia options available and their associated risks, the implication of this cesarean section on future pregnancy and delivery, right to accept, defer, or refuse cesareans section, any extra procedure that might be deemed necessary intraoperatively, and voluntary acceptance of the surgical procedure(NICE, 2019). The contents of the informed consent process should be documented in the patient's file in order to be legally sufficient, and not just a signed consent form.

There has been a notable global rise in litigations, especially with obstetric care(Glaser et al., 2017). Poor communication has been cited as one of the commonest causes of these litigations(Krause et al., 2001). Communication in healthcare is directly related to the presence or lack of complete information when obtaining informed consent for tests, medication, surgery, and research, among other interventions. The information given should be relevant, up-to-date, sufficient, concise, and consistent. The patient's comprehension should also be ascertained.

Due to the lack of urgency in the nature of an elective caesarean section, clinicians have ample time and multiple opportunities to collect and share all information as well as respond to the patient's concerns regarding the scheduled caesarean section. Patients too have time and a chance to ask questions and have their concerns allayed before, during and after surgery. This is however not reflected in the practice of informed consent as shown below.

Some studies show that the practice of the informed consent process for surgery addresses diagnosis, nature of the surgery, and benefits or indications for general elective surgery fairly well (Ntonjira, 2012; Latika et al., 2015). But inadequately addresses the other elements of informed consent including; risks involved in the proposed surgery (often, only major risks are discussed) (Ogunbode et al., 2015).Alternative(s) to the proposed surgery including no treatment and the associated risk and benefits of either, anesthesia options available and the respectively associated risks, and documentation of the informed consent process. Also notable is that most of the time informed consent is not obtained by the operating surgeon and most patients don't even recall who obtained informed consent from them (Ochieng et al., 2014). Some of the factors affecting the informed consent process include; the age of the patient, cadre or specialty of the

clinician obtaining informed consent, language barrier, heavy workload and time constraints for clinicians, and emergency versus elective nature of surgery (Lubansa, 2010).A most recent study in Southern Malawi showed that women's lack of education and dependence on other people to make decision also affected the informed consent process as well (Bakker et al., 2021).

All possible elective surgeries in any specialty, elective cesarean section is a unique primary care major obstetric surgery in that it can be sanctioned by all clinicians working in the obstetrics department. In Kenya, it can be performed by all doctors. And so, knowledge about it and competence in it should be evident even when obtaining informed consent evidenced by complete information sharing.

Currently, it is not known how complete the informed consent process for elective cesarean section is in Kenya and worldwide, there is some data focusing on informed consent in general elective surgery, little on cesarean section (both emergency and elective) and none focusing on elective cesarean section. The aim of this study is to determine the gaps in the informed consent process for elective cesarean section at AIC Kijabe hospital by assessing the patients' recollection of information on the informed consent process based on their immediate experience.

1.3 Statement of the Problem

The requirement of informed consent for elective caesarean section is an internationally recognized standard of medicinal practice. In Kenya, the Kenya Medical and Dentists' Practitioner's council (KMPDC) requires all clinicians to obtain informed consent before performing any surgical procedure such as elective caesarean section both as an ethical and legal obligation. At AIC Kijabe hospital informed consent for elective caesarean section is a matter of hospital policy as well as legal and ethical obligations. This

requires the clinician obtaining the informed consent to be knowledgeable about caesarean section and also have the ability to properly communicate risk, educate patients on available treatment options, and support patients' preferences as part of the consenting process. Gaps in the informed consent process may lead to poor medical decisions by patients, poor adherence to treatment, patient dissatisfaction with care offered which in turn leads to an increase in litigations.

1.4 Study Justification

With both increases in the general population and access to better obstetric care worldwide, there is a notable increase in caesarean sections. As a result there is also a notable global rise in litigations especially in obstetric care (Glaser et al., 2017). Poor communication has been cited as one of the commonest causes of these litigations (Krause et al., 2001). Informed consent for elective caesarean section is both a legal and an ethical requirement everywhere. An adequate informed consent process increases the patient's knowledge and is associated with the patient's satisfaction with her decision regarding the elective caesarean section (Hallock et al., 2017). Gaps in the informed consent process are associated with increased dissatisfaction and poor adherence to the recommended care as well as a rise in litigations. To improve the quality of obstetric care offered to our patients at AIC Kijabe hospital and Kenya as a whole, we must identify and address any gaps in the informed consent process for elective caesarean section. Currently, there is a paucity of data regarding gaps in informed consent for elective caesarean sections in the literature. In Kenya, only one study I found addressed gaps in informed consent for general elective surgeries. This study was designed to identify the specific gaps in the informed consent process for an elective caesarean section as well as the practice of obstetrics in AIC Kijabe Hospital. The study not only contributes to the much-needed knowledge and data on this topic but also improves the quality of the

practice of obstetrics by informing targeted training of clinicians on the informed consent process and by increasing the patient's awareness of the essential questions to inquire of prior to any elective surgery.

1.5 Purpose of the Study

The purpose of this study was to determine if there wiretaps in the informed consent process among women who had undergone an elective caesarean section at AIC Kijabe Hospital. The cesarean section offered the best way to assess gaps in informed consent since it is the most common surgery in sub-Saharan Africa whose knowledge and competence are expected across healthcare cadres.

1.6 Objectives of the Study

The following constituted the objectives of this study among women who had undergone an elective caesarean section at AIC Kijabe Hospital:

i. To describe the socio-demographic characteristics of women who had undergone elective caesarean section at AIC Kijabe Hospital.

ii. To describe which elements of the informed consent process were most frequently addressed and those that were frequently missed when obtaining consent for elective caesarean section at AIC Kijabe Hospital.

iii. To describe how the process factors (time spent on obtaining consent and the chance to address patient's questions and concerns) were associated with the gaps in the informed consent process for elective caesarean section at AIC Kijabe Hospital.

1.7Research Questions

Based on the objectives above, the following constituted the research questions for this study among women who had undergone an elective cesarean section at AIC Kijabe Hospital:

i. What were the socio-demographic characteristics of the women who underwent elective caesarean section at AIC Kijabe Hospital?

ii. What were the gaps in the informed consent process for elective caesarean section at AIC Kijabe Hospital?

iii. Was there an association between (1) time spent on obtaining informed consent as well as (2) the chance to address all of the patient's questions and concerns and gaps in the informed consent process for elective cesarean section at AIC Kijabe hospital?

1.8 Hypothesis

i. There were gaps in the informed consent process for elective caesarean section at AIC Kijabe Hospital.

ii. There were fewer gaps in the informed consent process when more time is taken to obtain informed consent and all patients concerns and questions are addressed.

1.9 Significance of the Study

Caesarean section is one of the most common surgeries performed worldwide. Worldwide, cesarean section rates range from 0.6% in South Sudan to 58.1% in the Dominican Republic (Boerma et al., 2018). In Kenya, caesarean section rates range from 2.9% in Northeastern Kenya to 20.7% in Nairobi as per the last national evaluation(KDHS et al., 2015). In AIC Kijabe hospital, the caesarean section rate is

about 25% for primary cesarean section and about 40% overall based on the audits. The elective caesarean section makes approximately 50% of all the caesarean sections performed there annually. In most parts of the world caesarean section is considered a primary care surgery. In Kenya, it is performed at level III, IV, V and VI hospitals as part of both primary and tertiary care.

All clinicians including nurses, clinical officers, and medical officers have some training on this life-saving surgical procedure. But a great number of patients go through the elective caesarean section without complete information being made available to them for various known and unknown reasons as evidenced by the filled incomplete standardized consent form and poor documentation in the patient's filed record. These reasons could be patient-related, clinician-related or both (Lubansa, 2010;Chima, 2013). There is a standardized consent form for all surgeries at AIC Kijabe Hospital. This standardized consent form does give room for complete information regarding the elective caesarean section since it has a blank space to fill in more information. A copy of the standardized informed consent used at AIC Kijabe Hospital is attached in appendix I.

It is a gross violation of the human right to bodily integrity as well as the right to health to administer either medical or surgical interventions or both without adequate informed consent. This amounts to battery (Penal Code Laws of Kenya 2012, n.d.251). Also, inadequate informed consent is linked to patient dissatisfaction with care which can result in poor adherence to treatment and/or litigations. But good patient knowledge and understanding of the scheduled elective surgery immensely contribute to her satisfaction.

This study aimed at evaluating the amount of shared information recommended as elements of the informed consent process, comprehension of the information given to women undergoing elective caesarean section at AIC Kijabe hospital, and the women's participation in the informed consent process.

This study was designed to generate information that would guide improvements to the current informed consent process for women scheduled for elective caesarean section by identifying gaps in the elements of informed consent as recalled by patients and describing the association between the gaps and two informed consent process elements namely; time taken to obtain informed consent and the chance for all the patient's concerns and questions to be addressed. This study also provides a basis for more studies in this area, especially the clinician factors and other system factors associated with gaps in the informed consent process.

1.10 Scope of the Study

This study limited itself to the assessment of the fifteen information and process elements of informed consent (excluding assent or dissent) in elective caesarean sections (excluding emergency CS) in AIC Kijabe hospital based on the patient's immediate experience.

This study was confined to the AIC Kijabe hospital's postnatal ward where post-cesarean section patients were admitted. AIC Kijabe hospital is in the Lari division of Kiambu County, Kenya, approximately sixty kilometers from Nairobi by road. The County covers an area of 2543.5 square kilometers. Kiambu County borders Nairobi and Kajiado counties to the south, Machakos county to the east, Murang'a county to the north and northeast, Nyandarua County to the North-west, and Nakuru county to the west. Kiambu County lies between latitudes 00 25 'and 00 10' south of the Equator and longitudes

36031’ and 370 15’ east(Kiambu County Government, 2009). Kiambu County is a county in the former Central Province of Kenya. Kiambu County’s capital is Kiambu town and its largest town is Thika. The county is adjacent to the northern border of Nairobi county and has a population of 2,417,735(KNBS, 2019, p. 7). The county is predominantly rural, but its urban population is increasing due to the influence of Nairobi city’s rapid population growth.

1.11Assumptionsof the Study

There is an increasing trend in the caesarean section rates in the world. With every primary caesarean section performed, the likelihood of the performance of a subsequent one increases. Then in Kenya, there was a focus on Universal Health Coverage (UHC) which targeted an increase in access to healthcare by all, an important aspect of UHC is quality healthcare. The absence of gaps in the informed consent process for elective caesarean section was a marker of good quality healthcare. The lack of gaps in the informed consent process implied that women made a more informed choice to accept or refuse elective caesarean section or the safe and legitimate alternative if available and applicable.

In as much as local and international regulators of medical practice recommend informed consent for any surgery, there was no formal training in obtaining valid and complete informed consent in most learning institutions’ curricula. There was also no standard consent form for caesarean section nationwide in as much this caesarean operation is done in most parts of the country at different levels of care. In literature, there was a paucity of data regarding the absence or presence of gaps in the informed consent process for elective caesarean section in Kenya. This study, which was non-interventional intended to contribute to the body of knowledge on the gaps in the

informed consent process for elective caesarean section in Kenya and worldwide. The results of this study would hopefully not only raise the women's awareness of what to expect when consenting for a cesarean section or any other surgery but also provide a basis for evaluating gaps in the clinician's knowledge and practice of obtaining informed consent for elective caesarean section.

1.12 Limitations of the Study

This study being a cross-sectional study, it was difficult to measure a true cause and effect relationship between gaps in informed consent and time taken to consent in minutes as well as with the chance to ask questions and raise concerns. A longitudinal study to assess the true cause-effect relationship based on my findings in this study should be considered.

Recall bias was recognized as a possible limitation; however, most women were asked about their experiences within seventy-two hours of admission and surgery which shortened the recall period hence reducing recall bias.

Distress in patients; since the study was done post-surgery, some patients still had some distress due to significant postoperative pain. Some had a bad experience with the surgery. Still, some had bad outcomes with the surgery such as the loss of their baby. Patients who had maternal or fetal complications were excluded due to possible psychological harm by the study. For those in significant pain, recruitment was withheld until they were comfortable.

I ensured post-operative pain was well controlled before any consent or interview via questionnaire was administered. The study was done on postoperative days one, two or three on which most patients were generally fairly stable for discharge. But in case the

patient was still in significant pain, I liaised with the attending clinical team to give them adequate analgesia or any other service that could alleviate the patient's discomfort before consenting or interviewing.

The study questions could have caused or prolonged grief to patients with maternal or fetal complications especially if their complications were related to any of the elements of informed consent that were not addressed in advance. In obstetric care, this could be grounds for litigation(s) which would then have had far-reaching effects on the patient, her relatives, clinicians and the hospital as an institution. Also, postoperative complications often negatively affect information recollection of the informed consent processing biased recollection based on the experienced complication. In as much as excluding them from the study might have skewed the study findings; I chose to protect them from possible psychological harm from both an ethical and legal standpoint of view by excluding them.

Lack of privacy might have skewed the patients' responses: due to the design of the AIC Kijabe hospital's postnatal ward, patients' beds are next to each other i.e., less than two meters apart and not in private rooms and hence there was no assurance of privacy in the conversations held bedside. Most interviews were held in a low tone to try and ensure privacy and confidentiality.

Also, interviews were held at a time when the neighbor was asleep and when nurses, doctors or other healthcare workers were not performing their clinical duties. When this was not possible, the patient was asked to shift temporarily to a far-off empty bed for the interview in full view of her baby. We didn't need to use the private room in the unit that was usually meant for psycho spiritual counselling. Privacy and confidentiality were not a challenge for the patients admitted in the private or semi-private postnatal rooms.

Lastly, this study was conducted in one institution, a tertiary, teaching and mission hospital. However, generalization of these study findings would be stronger if it were done at multiple sites including government and private hospitals as well as lower than level 6 mission hospitals.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter includes a general overview of the literature related to the main concepts of elective cesarean section and adequate informed consent as well as a review of literature based on the three objectives of this study. The chapter ends with a conceptual framework.

2.2What is Informed Consent?

Informed consent is the process by which the treating health care provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment (Appelbaum, 2007a). Jonser further describes informed consent as the voluntary or willing acceptance of a medical intervention by a patient after adequate disclosure by the attending physician on the nature of the proposed intervention with its risks and benefits and those involving the available alternatives (Jonser AR, n.d., p. 22).

Informed consent is indeed a process that takes time and intentional effort from both parties and is not merely pending a signature on a consent form .Legally speaking, written consent may show some evidence that consent was obtained but it is not proof that consent was valid. Even so, documentation should include all the elements of the procedure as discussed(Medical Protection Society. UK, 2015).The informed consent process denotes the physician's engagement and the patient's choice both of which are important in the physician-patient relationship.

Informed consent emanates from the ethical principle of autonomy which seeks to respect every person's freedom of choice as a human being(Tom L, Beauchamp : James

F. Childress, n.d.,).For autonomy to suffice, two conditions must be met; the patient should be competent to make independent decisions and the patient should be free from coercion when making her healthcare decision(Summers, n.d.-a, p. 44).The clinician has to consider task-specific competence and not just general competence when assessing for competence since patients can have competence for one task and not another. Also, the clinician should look out for intermittent competence, where a patient might be competent hours earlier and then later incompetent and vice versa because of their medical condition(Summers, n.d.-b, p. 45).Regular evaluation of patient's competence is thus necessary to ensure continued patient involvement as much as possible. Properly administered informed consent is both a legal and an ethical right of every patient, he or she can choose to accept or refuse the recommended medical treatment or intervention. It is also the ethical duty of the physician to involve the patient in his or her health care.

Simply put, therefore, informed consent is where the patient freely authorizes a treatment plan geared towards a mutually agreed treatment goal and this authorization is considered as informed when the physician discloses the diagnosis and prognosis to the patient and the patient understands it fully including the available treatment options and their respective risks and benefits as well as the alternative treatment options including the no treatment option. And the disclosure of the information should be done in a language that is understandable to the patient regardless of her linguistic or intellectual capabilities.

2.3 Purpose and Benefits of Informed Consent

Informed consent serves to protect the patient from receiving treatment or medical interventions they do not desire or want. It allows them to actively participate in their healthcare. In this way, informed consent protects the patient's autonomy. Autonomy as

an ethical principle guarantees freedom of choice and freedom of expression which is provided for in the Bill of Rights that states;“every person has the right to freedom of conscience, religion, thought, belief and opinion.”) “a person shall not be compelled to act or engage in any act that is contrary to the person’s belief or religion.”32(1, 4)(Constitution of Kenya, 2010), and “a person should be allowed to express themselves freely.”33(1)(Constitution of Kenya, 2010).

Ensuring that informed consent is sought properly before any elective caesarean section, demonstrates the clinician’s respect for the patient’s moral right to her bodily integrity, her right to self-determination regarding her reproductive and sexual capacity, as well as offering support to her freedom in making medical decisions within her most concerning relationships(ACOG Committee, 2009, p. 1).

So informed consent serves more than one purpose; first, it protects the patient’s rights as a human being and a patient in a legal sense, second, it supports the patient’s execution of self-rule and decision-making capacity, third, it promotes efficiency in healthcare from an administrative standpoint, and fourth, it creates an environment that allows trust to flourish in the physician-patient relationship that is necessary for allowing interventions to take place on mutually agreed goals of care(Hall et al., 2012).When properly done, informed consent is likely to reduce litigations which have been linked largely to poor communication and rapport between the clinician and patient(Krause et al., 2001).

Other benefits of informed decision-making include; increased patient liking of the clinician and increased likelihood that the patient would recommend the clinician to other patients (Krupat et al., 2004),improved social and physical functioning of the patient because of active participation in decision-making(Hack et al., 2006),heightened

commitment to treatment plans and improved clinical outcomes (Loh et al., 2007), increased feeling of responsibility to self-health and to that of the baby (Harrison et al., 2003), increased satisfaction and perception of experience as well as enhanced emotional wellbeing (Christiaens & Bracke, 2007).

Physicians need to take time when consenting patients to allow full disclosure and comprehension. In practice, time is a scarce resource and yet it is a key factor for predicting patient comprehension and hence the ability to be fully informed. For comprehension to effectively happen, time must be spent, spending about fifteen to thirty minutes on the consenting process has been shown to enhance comprehension(Fink et al., 2010).

2.4 Decision-making Capacity and Undue Influence

Decision-making capacity assessment is implicit in the informed consent process and it includes the patient's ability to; understand the relevant information as given by the physician, appreciate the medical situation and its consequences with and without treatment, reason about the treatment options and consequences by way of comparison, and eventually communicate the preferred choice (Appelbaum, 2007b). This decision-making capacity assessment criteria comprises the legal standards of competence assessment in many jurisdictions in case of litigations. The four key parts of this assessment include understanding, appreciating, reasoning, and expressing one's choice. Validated and reliable tools for everyday decision-making capacity assessment in a clinical setting that evaluate these elements are available (Lai et al., 2008).

This assessment is meant to strike a balance between honoring the patient's autonomy and protecting her from the consequences of making bad medical decisions(Kim, 2006).The patient's decision-making capacity is dependent on multiple factors including;

age or maturity, level of education, intellectual acuity, level of consciousness, cultural background, native language, willingness and chance to ask questions when consenting, and the manner in which the relevant information is relayed among other factors(ACOG, 2009). As such, the physician's role is not only to deliver information but also to ensure that the patient comprehends the relevant information to enable her to make an informed choice regarding the delivery of her baby.

Apart from comprehension, it is of utmost importance that the clinician allows the patient to make her choice without coercion, pressure, or any undue influence (ACOG, 2007). Physicians need to be aware that their personal and professional opinions, beliefs and values as well as experiences among others might influence the way information is relayed to patients and as such, they may become potential sources of bias that can to some degree result in undue influence (ACOG Committee, 2009).

Avoiding undue influence does not mean abandoning patients, most if not all patients need a lot of support in making their informed choice, this can be achieved through truthful communication, collaboration, and clinical empathy where the clinician is sensitive enough to recognize and respond to the patient's emotional signals(ACOG, 2013). When faced with more complex circumstances, most patients prefer to have a caring partner and a medical expert in their clinician and not just as a conveyor of medical information (Bullock, 2003).

The clinician's professional role is to help the patient clarify, articulate and integrate her beliefs, values, preferences, and priorities into her decision-making process for the therapeutic intervention while acting as the source of the technical medical information regarding the surgical procedure(ACOG, 2013). The clinician needs to interpret the patient's values for the patient because the patient's values are not necessarily known or

fixed but may vary depending on the specific circumstance they are being applied to. This is the interpretive model of the physician-patient relationship which not only requires the clinician to inform the patient but also engage the patient in a counselling manner as opposed to the old paternalistic model where the clinician is assumed to know everything and just instructs patients(Emanuel & Emanuel, 1992). Thus, the physician should consider the patient's experiences, preferences and expectations while counselling them.

2.5 Complete Informed Consent: Information Disclosure Standards and its Exceptions

Complete disclosure refers to open communication of all relevant information by the physician to enable a patient to make a preferred decision regarding her care(ACOG, 2007).Three legally acceptable criteria that form the basis on which the complete informed consent process is adjudicated are; (i) the subjective standard which requires the clinician to disclose relevant information that a particular patient needs to know and understand to enable her to make her healthcare decision based on her unique needs, (ii) the reasonable patient standard which requires the clinician to disclose relevant information that an average or ordinary patient with reasonable needs and expectations would need to know to be an informed participant in the decision making process, and, (iii) the reasonable clinician standard which requires the clinician to disclose relevant information that a typical clinician would reveal about the procedure or what is the common practice of the profession (Shah et al., 2020). Reasonable patient standard is applied more commonly but it is up to the attending clinician to decide which standard to apply for each patient.

Exceptions to the requirement of informed consent or adequate disclosure of information should be limited. They include; (i) life-threatening medical emergencies where there is no adequate time for obtaining informed consent, (ii) incapacitated patient in which case there should be efforts to offer substituted judgement or treat from the patient's best interest basis with the help of a surrogate, (iii) when the patient voluntarily waives her right to give consent either explicitly or implicitly in which case the reason for the waiver must be sought and documented (Shah et al., 2020).And (iv) where other ethical obligations override the requirement to obtain informed consent i.e. in matters of general public health concerns (ACOG Committee, 2009).(v) Withholding of information from a patient based on the reasoning that the information will only increase both the cognitive and emotional burden to the patient leading to confusion rather than clarity in making her healthcare decision is contentious (Epstein et al., 2010).

These criteria point to what needs to be shared preoperatively during information disclosure which entails; the diagnosis and description of the patient's medical condition, a description of the name, nature, purpose, risks, and the likely complications of the proposed treatment, the available alternative treatment with associated risks and benefits including no treatment option, as well as the chances of success of the proposed treatment as compared to other options(ACOG Committee, 2009).This information should be consistent, sufficient, accurate, up-to-date, evidence-based and relayed in a comprehensible manner to allow the woman to make a decision that reflects her self-determination, autonomy and control over her health matters. Hopefully, her decision will also reflect the integration of the information given with her healthcare needs, values, beliefs, and preferences(Goldberg, 2009; Schenker & Meisel, 2011). In Kenya, the law is not exquisite on what constitutes adequate information yet, thus international standards apply.

For Caesarean section, the complete information disclosure includes; the name caesarean section and what it entails, the purpose or indication of the caesarean section, the benefits of the caesarean section, understanding and voluntarily agreeing to the necessity of caesarean section, the risks involved in the procedure, addressing the woman's concerns raised about the procedure, informing the woman of her right to accept, refuse or defer the caesarean section, alternative procedure to caesarean section such as vaginal birth after caesarean section(VBAC), or no surgery(caesarean section) at all and the associated consequences of no surgery, the available anesthetic options (regional and general), post caesarean section analgesia options, the implications of the caesarean section on future pregnancies and delivery options, and a pre and post-procedure briefing on the procedure events and outcomes, patient's express statement on what procedure should not be performed without further discussion with her for whatever reason, and any extra procedures that might become necessary intra-operatively (NICE, 2021). Of these, what must be documented include; the nature of the procedure, risks and benefits of the procedure, reasonable alternatives, and evaluation of the patient's comprehension of these elements (Shah et al., 2020).

Regarding who should obtain informed consent for elective surgery, common practice is that the most junior officer or admitting officer obtains consent from patients. Recommended good practice requires that informed consent be obtained by someone who is capable of performing the procedure by themselves or has received special training in advising patients about the procedure being consented to(Anderson & Wearne, 2007). It is the responsibility of the attending clinician to ensure that if they delegate the consenting process, the colleague given the duty is confident to do so. It is also the responsibility of the clinician assigned the duty to obtain consent to ensure that he or she performs within his or her competence and to avoid tasks that are beyond his or

her competence(Department of Health.NHS, 2009).

2.6 Special Circumstances and Obtaining a Valid Informed Consent

Informed consent is not just getting the patient to append a signature on a consent form. Some challenging circumstances require even more attention to the consenting process. Such circumstances include; a differing opinion between or among specialists regarding the proposed surgery, surgery requiring multiple consent stages or clinicians, refusal of surgery by the patient, when the patient is undecided about the proposed surgery, patients with diminished decision-making capacity needing surgery, assent for children and adolescents, and also consent for the involvement of trainees (Jones et al., 2005).

For informed consent to be considered ethically and legally valid, it should have these three components; (i) the patient must have the capacity to make an informed decision; she should be competent, able to understand the information provided and communicate her decision, (ii) she has to give the consent voluntarily, she holds the right to give or refuse consent and should in no way be influenced or coerced by healthcare providers, family members or friends, iii) adequate disclosure of information with time allowed to reflect and raise concerns. The key information here includes the benefits and risks of the proposed surgery, alternative treatments, and implications of not undergoing the proposed treatment (RCOG, 2015).

2.7 What is a Caesarean Section?

Caesarean section is a surgical procedure involving the incision of both the anterior abdominal wall and the uterus to deliver an offspring or baby(Merriam Webster, 2020). It is a common obstetric surgical procedure performed worldwide mostly by obstetricians, but also by general surgeons and general practitioners. When indicated, the caesarean section has been shown to prevent some maternal and neonatal morbidity and

mortality (NICE, 2019, p. 47). However, there are no morbidity or mortality benefits to both the mother and baby when the caesarean section is not medically indicated (WHO, 2015).

2.8 Indications for Caesarean Section

Some of the most common indications for primary caesarean section are; non-reassuring fetal status, arrest of dilatation, multiple gestations, preeclampsia, macrosomia, maternal request, arrest of descent, malpresentation (breech, face, transverse, unstable lie), cord prolapse, placenta previa, placenta accrete (Barber et al., 2011), uterine rupture, previous caesarean section (Mylonas & Friese, 2015).

Depending on the indication, a caesarean section is broadly performed either as an emergency or elective procedure, this is an urgency-based classification. Caesarean section can also be classified based on the woman's characteristics such as maternal and pregnancy characteristics. Other classifications are based on where, by whom, and how the caesarean section is performed including the surgical technique (Torloni et al., 2011).

The urgency-based classification is further classified into four categories: category I; immediate threat to the life of woman and fetus - delivery within 30 minutes, category II; maternal or fetal compromise which is not immediately life-threatening- delivery within 1 hour, category III; needing early delivery but no maternal or fetal compromise, and category IV; deliver at a time that suits the patient and the obstetric team(Lucas et al., 2000).The elective caesarean section comprises categories three and four of the urgency-based classification. It, therefore, allows room for planning and scheduling for term delivery preferably at thirty-nine weeks of gestation (Prediger et al., 2020).

2.9 Risks Involved in Caesarean Section

In as much as an elective caesarean section benefits both mother and baby, it also has risks that can be broadly classified into; (i) intraoperative such as infection, organ injury (especially to the bladder, intestines, ureters among other organs), anaesthesia associated complications, need for blood transfusion, hysterectomy. (ii) postoperative complications (such as thromboembolism, persistent postoperative pain and intraabdominal adhesions, and (iii) risk associated with subsequent pregnancy such as ectopic pregnancy, intrauterine growth retardation and preterm delivery, spontaneous abortion, stillbirth, uterine rupture, infertility and placental attachment abnormalities (Mylonas & Friese, 2015). Another approach to this classification is; immediate i.e., happening intraoperatively, short-term i.e., hours to days shortly after surgery, and long-term i.e., months to years after surgery respectively. If these complications occur, they affect the woman's current health, her baby's health, and even her future pregnancies if she desires to have more children.

2.10 Caesarean Section Versus Vaginal Birth (The Alternative)

Elective caesarean section should not necessarily be viewed as an equal alternative to vaginal delivery because it is a surgical procedure that is associated with increased risk for the mother and child and so the woman should be fully aware of what she is agreeing to (Mylonas & Friese, 2015). However, the caesarean section has some benefits over vaginal delivery such as reduced abdominal and perineal pain during birth, and reduced vaginal injuries otherwise experienced in vaginal birth. But there is no significant benefit of caesarean section over vaginal birth in terms of abdominal and perineal pain four months after birth, injuries to nearby organs, uterine rupture and pulmonary embolism. Vaginal birth has reduced risk in the duration of hospital stay, hysterectomy and cardiac arrest compared to elective caesarean section (NICE, 2019, p. 47).

2.11 Caesarean Section Rates and Trends

Lower caesarean section rates are preferred, higher rates have negative implications for health equity (WHO, 2010). The World Health Organization (WHO) recommends caesarean rates of 10% to 15% (WHO 2015). However, there is a notable increase in the caesarean section rates worldwide, as high as 40.5% in Latin America and the Caribbean and as low as 7.3% in Africa (Betrán et al., 2016),developed countries seem to have higher rates than developing countries. In Kenya, the caesarean rate is approximated at 8.7% (KDHS 2014), Kiambu County where AIC Kijabe hospital is located had a caesarean section rate of 20.1% only second to Nairobi County at 20.7 % (KDHS 2014).

2.12 The Gaps in the Informed Consent Process for Surgery in Obstetrics and Other Specialities; the Previous and Current Practice Globally

A systematic review of informed consent in Nigeria found that 70% to 95% of patients gave consent for surgery. Litigations did not affect the enforcement of good medical practice. They also noted that informed consent was affected by the level of education, close extended family system, urbanization, available healthcare financing option as well as religious practices (Ezeome & Marshall, 2009).An audit of informed consent for elective surgery in gyneacology, orthopaedics, general surgery and surgery subspecialties in Nigeria found that of the eighty patients studied, 93.75% of patients knew their diagnosis, 42.6% of these were informed of the diagnosis by attending consultants, however, no consultant was involved in completing the informed consent form. 85% understood the nature of the procedure. Only 26.25% knew alternatives to the procedure, a 36.25% knew at least one complication of the procedure, and only 15% knew the anesthesia options available and the associated complications. About 15% of consent forms were properly filled (Adisa et al., 2008). Ngim et al in Nigeria also found that all patients had signed a consent form but still, 42.6% did not understand the contents of the

consent form and 67.1% did not understand the implication of what they signed. This confirmed that informed consent is not just a signature on a consent form. They concluded that the practice of informed consent was not adequate (Ngim et al., 2008).

Ogunbode et al (2015) in a cross-sectional study that sought to audit the informed consent process for both elective and emergency caesarean section from a patient's perspective, found that in 81.5% of cases, consent was obtained in the labour ward with only profuse bleeding and blood transfusion requirement commonly discussed as risks involved. In 64% of cases, consent was signed by the woman while in 26.85%it was signed by the husband. Of note, 81% of respondents underwent emergency caesarean section in the study. They concluded that in as much as most patients were satisfied with the consent process, only major risks were discussed (Ogunbode et al., 2015).

Another cross-sectional study in Zambia that sought to assess the adequacy of informed consent of both elective and emergency caesarean section found that only in 7.3% of cases were risks involved in caesarean section procedure discussed, implications on future pregnancies were disclosed in 18%, anaesthetic options were discussed in 4.6% and documentation of the informed consent process was done only in 14% of all cases. Overall, 51.3% were adequately consented according to his criteria. He also found that factors that significantly influenced the informed consent process were; age, emergency versus elective caesarean section, the outcome, whether consented by the nurse or doctor, availability of chance to address patient's concerns or questions and knowledge of the right to decline procedure. There was notable variation in the information provided to patients on the various elements of informed consent pointing to the need for a standardized consent form and training of healthcare workers (Lubansa, 2010).

Yet another cross-sectional study in India that mirrored Lubansa's study that also assessed the adequacy of informed consent for caesarean section, in general, found that

92.8% of patients were informed of the name of the procedure, 98.2%were informed of the nature of the procedure, 85.7% were informed of the indication of the procedure and 85.7% agreed that the procedure was necessary. Only 32.4% were informed of the risks involved in the procedure, 26.78% were allowed to ask questions and 44.64% were informed of their right to accept or refuse the procedure. Only 19.64% were informed of the available anesthesia options. Also notable is that only 7.14% were debriefed after the operation. They concluded that most patients were well informed of the procedure, however, some elements of the informed consent were not well addressed (Latika et al., 2015).Another cross-sectional study in India found that only 71% of patients had proper knowledge of the indication for caesarean section and of these only 25% were properly explained to about the nature of the caesarean section and associated complications (Kirane et al., 2015).

In the United Kingdom, a retrospective review of 116 consent forms for caesarean section and instrumental delivery at a tertiary hospital found that there was adequate documentation of major risks involved in the procedures but did not address or document the risk of laceration of baby's scalp and the possibility of hysterectomy to the recommended auditable standards. They also noted that patients who consented to elective caesarean section were more likely to recall risks as compared to those who consented and underwent emergency caesarean section (Glennon et al., 2011).Another cross-sectional study that examined patients' experience of informed consent in elective and emergency surgeries found that 90.1% of patients who underwent elective surgery stated that an opportunity to ask questions was important to them (Perić et al., 2018).

In Uganda, a survey at three teaching hospitals involving patients from various surgical disciplines found that 80% of patients were informed of the indication for surgery, 56.1% had all their concerns addressed before the operation, 17% did not know what surgery

was performed, and 81% agreed and gave permission for the surgery. Only 23.7% were able to identify who consented to them, and 22.4% recalled the surgeon who operated on them. 20% of the patients were not satisfied with the information given before and after surgery (Ochieng et al., 2015).

An earlier cross-sectional study among surgeons at the same three teaching hospitals in Uganda found that the average working experience for most respondents was 4.8 years, 48.85% of the surgeons obtained informed consent before surgery all the time, 51.2% of the surgeons did not obtain informed consent all the time. Most informed consent was not obtained by the operating surgeon, some consent forms were signed at admission even before a definitive diagnosis was made, and the consent forms were not adequate (Ochieng et al., 2014).

A cross-sectional survey of the informed consent process for all elective surgeries at Kenyatta National Hospital by Ntonjira in Kenya found that 97.2% of respondents knew the nature of the surgical procedure, 76.7% knew of the anaesthesia option given, 89.4% knew of the benefits of the surgical procedure, only 53.7% knew of the benefits the preferred anaesthesia. Of note, 78.8% and 76.3% were not informed of the possible complications of the surgical procedure and the preferred anaesthesia option respectively. Only 8.8% were counselled on alternative treatment to surgery and of these, 92.2% were not informed of the benefits of the alternatives to surgery. 84.4% were not informed of the alternative anaesthesia options. She concluded that the informed consent process then well addressed the nature of the procedure and the preferred anesthesia options with related benefits but inadequately addressed associated complications, alternative treatments and associated risks and benefits (Ntonjira, 2012).

In South Africa, a descriptive cross-sectional survey among doctors, nurses, and patients that sought to evaluate whether the quality of informed consent at public hospitals met

international ethical standards as well as national regulation found that; most doctors spent five to ten minutes on consent, they disclosed information required by patients but most had inadequate knowledge of national laws regarding consent. Interns and registrars scored lowest while consultants scored highest on the informed consent aggregate scores. Among consultants, radiologists and anesthesiologists scored lowest while internists, general practitioners, obstetricians and gynecologists scored highest. Nurses scored lowest compared to doctors. Challenges to informed consent included language difficulties, lack of interpreters, increased workload and limited time (Chima, 2013).

In Ethiopia, Teshome and team while assessing the comprehensiveness of surgical informed consent for women undergoing obstetric and gynecologic surgeries found that all except one woman gave written informed consent before the operation, 54.3% were emergency surgeries, 8.3% gave their consent while on the operating table. 73.9% were informed of alternative treatment or lack of one. 88.3% were informed of the preferred anaesthesia option and of these (88.3%), 87.4%were informed of the anaesthesia complications associated with the preferred type. Only 54.2% were offered at least six of the thirteen components of surgical informed consent evaluated based on Royal College of Obstetricians (RCOG) recommendations. Also, only 18.4% were consented to by the surgeon who operated on them, 36.65% of patients could not recall who consented to them. Their conclusion was that the informed consent process was not comprehensive and emphasized the need for standardized preoperative counseling (Teshome et al., 2018).

In Malawi, a pre-and post-intervention survey of a multi-component tool sought to assess the association between the tool and women's recollection of informed consent information for caesarean section. Elements assessed were the indication, nature,

common complications, the implication for future pregnancy and verbal consent inquiry. The tool comprised a standardized checklist, a six-step guide wall poster and on job communication training for health workers. They found that information recollection significantly improved post-intervention (Zethof et al., 2020, p.).

Another most recent qualitative study in Southern Malawi that explored the healthcare workers' beliefs and experiences as they related to the principles and the practice of informed consent for caesarean section found that healthcare workers preferred written consent. The preference is based on fear of blame and litigation. Out of fear of the patient's refusal to give written consent, which in turn would pose an ethical dilemma of whether to do good or respect the patient's autonomy, they only partially disclosed the risks involved in the surgery (Bakker et al., 2021).

Qualitative evidence systematic review aimed at determining which domains determine the quality of informed consent for surgery as perceived by clinicians and patients synthesized their finding into these six; innate patient attributes greatly affect the informed consent process, and transfer of knowledge is an essential component of the consent process, the consent process is a practice of communication skills by clinicians and patients, patient's desire to be the ideal patient impairs her ability to actively participate in the consent process, trust can be forged or destroyed through the consent process, and also other people, physical condition and treatment options influenced decision-making (Convie et al., 2020).

AIC Kijabe hospital policy requires all patients scheduled to undergo any surgical procedure whether minor or major to have signed a written informed consent after adequate pre-operative counselling. Any intraoperative changes have to be notified to the patient and consent is sought for additional surgical intervention, if need be, from the patient if awake or her next of kin if the patient is under general anesthesia. If the patient

is below the legal age of consent which is eighteen years in Kenya, then consent is sought from her parent or legal guardian after her assent is obtained. If she is an emancipated minor i.e., married, her husband (if above eighteen years) with help of her parent(s) or guardian(s)are requested to give consent after her assent is obtained. In the unlikely event of an emergency or an unconscious patient with no next of kin available then consent can be given or signed by a consultant on behalf of the patient. A signed consent form is valid for twelve weeks after which if the surgical procedure is not done, fresh consent had to be obtained.

In practice at AIC Kijabe hospital, pre-anesthetic evaluation of patients in general surgery, orthopaedics, gyneacologyetc., was done, where patients were reviewed by anaesthesia trainees and qualified anaesthesia officers in the ward to assess their suitability for the recommended surgery but not so for elective caesarean section. Most patients if not all had their first encounter with the anesthesia team in the operating room. This possibly presented a challenge for obtaining adequate informed consent because there often was limited time in the theatre.

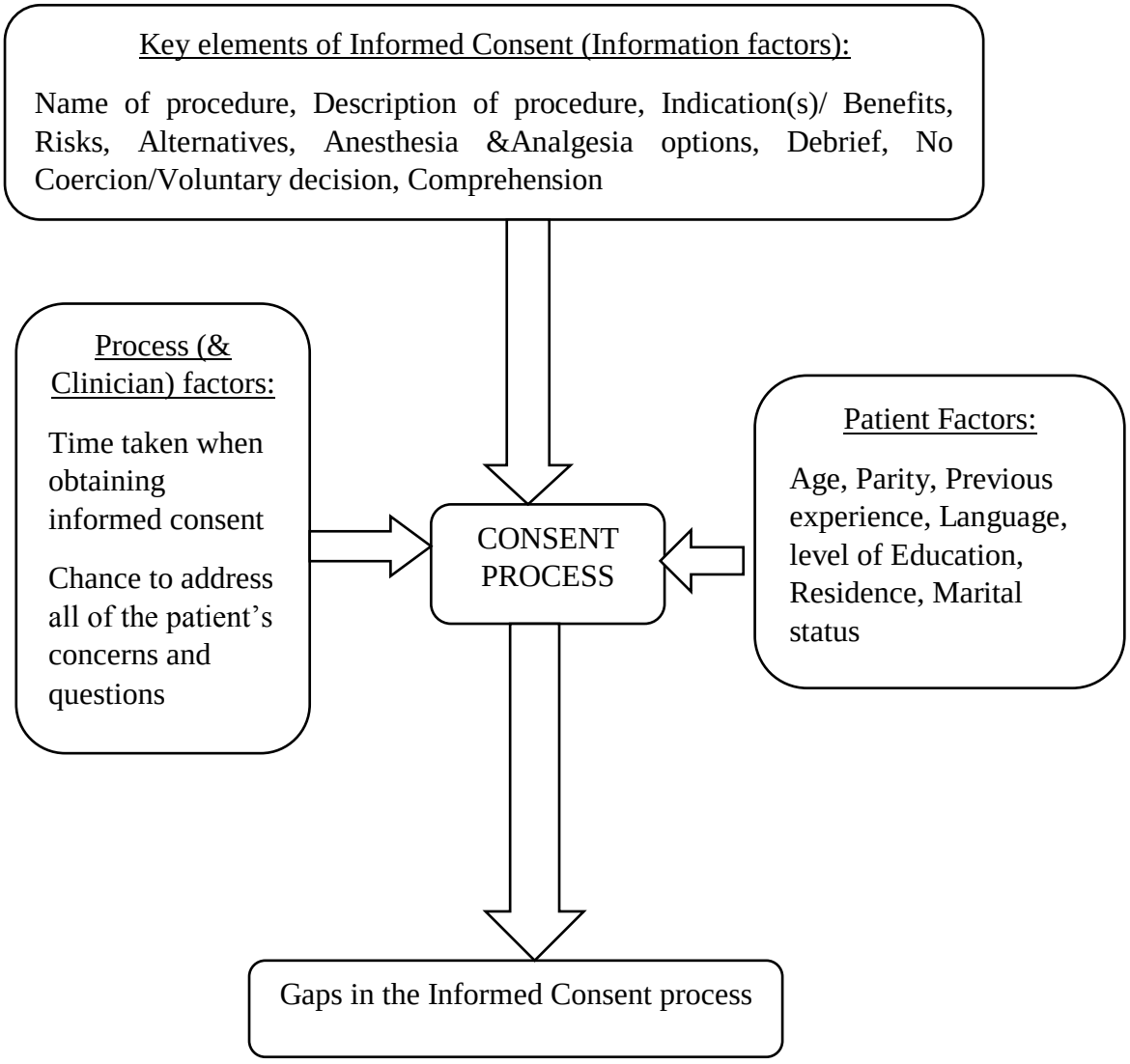
Overall, women must be satisfied or feel supported in their choice for their planned delivery. After having been involved in the decision-making for an elective caesarean section and having understood the indications, risks involved, the procedure itself, alternative treatment, risks of not choosing the surgery and all concerns having been allayed, the woman will then feel well communicated to and supported in her decision to have the caesarean section as the preferred option for delivery of her baby. Dissatisfaction with the caesarean section procedure and its outcome are less when a thorough informed consent process is adhered to and this eventually might lead to fewer litigations.

It was not well known to what extent the available informed consent process offered women the opportunity to make an informed decision about their elective caesarean section at AIC Kijabe Hospital. This study sought to determine the gaps in the informed consent process for elective caesarean section at AIC Kijabe Hospital through patients' recollections of the informed consent process. A study of this nature that explored the patient's role in the informed consent process for elective cesarean section had not been done at AIC Kijabe Hospital and Kenya at large.

2.13 Conceptual Framework

Figure 1

Conceptual Framework



CHAPTER THREE

RESEARCH DESIGN AND METHODOLOGY

3.1 Introduction

This chapter includes the research design, study location, study population, selection criteria, sampling method and sampling size, data collection procedure, ethical consideration and the data analysis procedures.

3.2 Research Design

The study was a cross-sectional study design conducted in the year 2021. This cross-sectional study sought to determine if there were gaps in the informed consent process among women who had undergone an elective caesarean section at AIC Kijabe Hospital during a specific time period. The study design enabled us to assess the information and process aspects of the informed consent process at the same period. There was no follow-up over an extended period of time that was expected for this study hence the choice of this design. This study potentially forms the basis for further research or interventions on informed consent.

3.3 Location of the Study

The study was conducted at AIC Kijabe hospital's general postnatal ward, as well as the semi-private and private wards where post-caesarean section women were admitted in the hospital. Most of the patients in this study were in the general postnatal ward. AIC Kijabe hospital is a non-profit health institution that was founded in 1915 by African Inland missionaries. It is located in the Rift Valley escarpment at a rural town called Kijabe which is in the Lari sub-county of Kiambu County, Kenya.

Kiambu County borders Nairobi and Kajiado counties to the south, Machakos county to the east, Murang'a county to the north and northeast, Nyandarua County to the North-west, and Nakuru County to the west. Kiambu County lies between latitudes 00 25 'and

00 10’ south of the Equator and longitudes 360 31’and 370 15’ east (Kiambu County Government, 2009). Kiambu County has a population of 2,417,735(KNBS, 2019, p. 7). The county is predominantly rural, but its urban population is increasing due to the influence of the neighboring Nairobi city’s rapid population growth.

The AIC Kijabe hospitals’ markedly improved health care standards and the variety of specialty services being offered at affordable prices make it attractive to the urban populations since it competes favorably with the other big private and public hospitals in Nairobi. These attractive features together with extensive marketing have seen an increase in the urban client base too. AIC Kijabe hospital not only offers care to patients but also training to healthcare professionals including interns (medical officer and clinical officers), residency for general surgery, orthopedic surgery, and family medicine, fellowships in pediatric surgery, pediatric critical care, and there were plans to start residency programs in obstetrics and gynecology and anesthesia as well as a fellowship in plastic surgery.

Practice and training in the obstetrics department involved students at various levels of learning from nursing students, medical students on electives, interns(clinical officers and medical officers), registered clinical officers and medical officers working with the obstetrics team, registrars in obstetrics and gynecology, family medicine, and general surgery.

Then, the attending consultants’ team comprised six obstetrics and gyneacology consultants and one family physician. As such, AIC Kijabe Hospital with its robust obstetric practice and by virtue of being a teaching hospital especially multiple surgery specialties, with varied clinician cadre and experience and providing care to both rural and urban dwelling patients provided good information on the gaps in the informed consent process for an elective caesarean section as a study location.

Pregnant women attending the antenatal clinic came from the urban, peri-urban and rural communities because the hospital is in a rural setup as described above and is accessible to clients from towns within Kiambu and Nairobi County as well as other neighboring counties. There were 3 antenatal clinics that the hospital ran. The general antenatal clinic located at the Family clinic in the main hospital run daily from Monday to Friday managing approximately 20 "walk-in" patients per day. The clinic is staffed by nurses, clinical officers, medical officer interns, medical officers, family medicine residents, a family physician and obstetrics and gyneacology consultants. Most of these clinicians also attended to the patients on the wards when admitted for delivery via spontaneous vaginal delivery or cesarean section.

The obstetrics high-risk clinic is a scheduled clinic that handles pregnant women with high-risk pregnancies such as multiple gestations and pregnancies complicated by medical conditions. The high-risk clinic handles approximately 10 patients a day. A Family physician and/or a consultant obstetrician were always available for consultation when called upon in any of those clinics. There was also a private clinic that is run once a week by an obstetrician &gynecologist which attends to both obstetrics and gyneacology private patients and hospital staff.

Discussions about elective caesarean section for women, who for any obstetric or medical reasons qualified, began in any of those clinics and in fact scheduling for a theatre day was often done during the antenatal clinic visits. Once the diagnosis was made and an indication for elective caesarean section was confirmed, an appropriate delivery time was selected based on the maturity of the baby, the safety of the mother and baby, available space on the proposed date and comfort of the woman with the proposed date. Once a date was agreed upon between the couple or the woman and the clinician attending to her, the date was booked via an online calendar platform called

Setmore which was accessible by all clinicians working in the obstetric department at all times. The booking included the patient's name, phone number, and a brief obstetric history.

The patient was called via the mobile phone number she had provided on the day before the booked date for surgery if she hadn't already presented to the hospital by 6:00 pm to confirm if she still intended to deliver in AIC Kijabe hospital. Once the patient arrived at the hospital, she was admitted by both the day or on-call team and send to the post-natal ward where she rested for a night as some blood works and other preparation measures for surgery were carried out. Often, the consent form for elective cesarean section was signed the night before the operation in the postnatal ward and was often obtained by the medical or clinical officer intern or any other cadres of clinicians/doctors who were available as well.

Elective cesarean sections in AIC Kijabe were scheduled for Tuesdays, Wednesdays and Fridays, but occasionally spillover cases were done on the following day except for weekends. Post-surgery women were taken back to the postnatal ward where they were joined by their babies unless the baby needed admission to the nursery for whatever reason. Patients were fully taken care of by the hospital staff while on the post-natal ward and no caretakers were allowed to stay in the ward with the patient. Visitation was however allowed at designated times of the day. Due to COVID-19 and related regulations, patients were only allowed one visitor at a time and just once a day at 12:30 pm. Most patients were later discharged home by day two or three post-operation. Only those with complications stayed longer. This study was conducted mostly in the postnatal wards well as the semi-private and private wards of the AIC Kijabe hospital where the study population was located preferably on day two, or three i.e., discharge day or a day before.

3.4 Population of the Study

The study population was about 137 women above 18 years of age who had attended AIC Kijabe antenatal clinics at least once and were admitted to the AIC Kijabe hospital's general postnatal ward, semi-private or private postnatal ward after an elective caesarean section. Women below 18 years of age were excluded because they were below the legal consenting age of 18 years in Kenya. Also, elective caesarean sections were rare in this age group in the hospital. They often underwent emergency caesarean section as indicated and they rarely had repeat (elective) caesarean section by 18 years of age. For the whole year preceding this study there was no teenage pregnancy at AIC Kijabe Hospital. Consent for any woman under 18 years of age who underwent either elective or emergency caesarean section was given by guardian or parent after her ascent was obtained. For the emancipated minors i.e., those married or leading a household, their assent was supplemented by the husband (if above 18 years of age) or guardian's consent and an attending consultant's consent.

The women who had complications post-operatively i.e., excessive bleeding, visceral injuries, bad outcomes or baby admitted to nursery for any reasons were also excluded to protect them from any psychological harm that might befall them due to the questions asked from the questionnaire especially if the complication to mother or baby related to the elements of informed consent discussed.

Inclusion Criteria:

i. 18 years and above
ii. Women Scheduled for elective caesarean section through any AIC Kijabe hospital's antenatal clinic.
iii. Understood English and/or Swahili

Exclusion Criteria

This criterion includes women above 18 years of age but presented with the following:

i) Any arising emergency caesarean section before the scheduled elective caesarean section.

ii) Post-operative foetal or maternal complications like fresh stillbirth, foetal death, moderate to severe pain, infection, etc.

3.5 Sampling and Recruitment Procedure

Study participants were sampled using the convenient sampling technique, I consecutively recruited every postnatal woman who met inclusion/exclusion criteria & consented to study until the desired sample size was achieved. All postnatal women approached were willing and participated in this study except one who respectfully declined. Before approaching the potential participants, I first checked in the department's Setmore booking list to ensure participants attended any of our antenatal clinics, then checked the previous day's theatre list to ensure that the participants underwent elective caesarean section as scheduled, after that, I then checked the nurses' handover book record to ascertain the participant's allocated bed number and which post-operative day she was at to ensure they all fall within 72 hours post-surgery in order to minimize recall bias. With the participant's name and bed number I then approached the participant, ensuring COVID-19 preventive measures, I introduced myself and allowed the participant to introduce herself. I then inquired of her comfort or pain status and once I confirmed she was pain-free or only mild pain, I went ahead to introduce the research topic and asked her if she was willing to participate to which most patients gladly accepted to participate. Once verbal consent was given, I introduced a detailed written consent for the study and once the consent was signed after thorough explanation

and giving room for questions and clarifications, I then started administering the questionnaire which had been digitized on a mobile app called Red Cap.

Whenever a participant needed to pick a phone call, use the washroom, have her meals, reach out to the clinical team, I would stop the interview to allow her to do that and then we resumed the interview whenever she was ready. I also answered lots of medical questions not related to this study as raised by the participants. It took me approximately four months to finish the recruitment process and data collection. A research assistant partly helped in about 15% of the interviews but got engaged elsewhere and could not continue. Hence, I did the rest. To avoid single interviewer bias it would have been better to recruit another research assistance but time to could not allow. Still, patient responses gotten between us were not different.

3.6 Sampling Frame and Sample Size

In the year 2020, there were 1166 caesarean sections in AIC Kijabe hospital, of these, 641(55%) were emergency cases while 525 (45%) were elective cases. The average monthly elective caesarean sections were 45 cases. Specifically, the months of March, April, May and June had 62, 49, 62 and 40 elective caesareans respectively in the year 2020. That most recent data was useful in calculating the sample size using the Cochran (1963) formula that was developed to yield a representative sample for proportions as shown below.

Cochran Formula:

$n = Z^2 p (1-p) / d^2$

Where:

n is the sample size (if the target population is infinite or more than 10,000).

Z is the standard normal deviation at the required confidence interval (the critical value

for alpha), at a statistically significant P-value of 0.05, Z = 1.96.

P is the target population estimated to have the characteristics being measured(if no estimate is available, Fisher et al recommend using 50% {0.5}.

d is the degree of precision (5%), is the maximum error we would expect to make at a 95% confidence interval (level of statistical significance set at 0.05).

Therefore:

$n=1.96^2 \times 0.5(1-0.5)/ 0.05^2= 384$

But since the target study population is less than 10,000

This sample size is further calculated (adjusted) using the following formula;

$$nf=n/ 1+n/N$$

Where:

nf is the desired sample size when the target population is less than 10,000

n is the desired sample size when the target population is more than 10,000 as calculated above which was 384

N is the estimate of the target population size i.e., number of elective cesarean section cases within a similar duration of data collection i.e., 3-4 months same time the previous year. Which were 213 cases of elective cesarean sections (62,49,62,40 in March, April, May, June 2020 respectively).

Therefore:

nf= 384/ 1+384/213 = 137

nf= 384/ 1+1.8028

nf=384/ 2.8028

nf= 137

Using this formula, the minimum required sample size was 137. A sample size of 137 women was targeted in this study.

3.7 Instrumentation

Data collection tools: a structured study questionnaire (appendix I)was used to collect the socio-demographic data, evaluate for gaps in the informed consent process by assessing participants' recollections of the different elements of informed consent discussed, and to collect any other relevant information. The elements of informed consent assessed were; the name, nature of caesarean section, indication(s), risks and benefits of the operation, alternative(s) to caesarean section, available anaesthesia and analgesia options, the impact of caesarean section on future pregnancies, right to accept, refuse or defer caesarean section, any extra procedures that might be deemed necessary during surgery, patient's comprehension and voluntary permission to surgery, any outward expression of unwanted procedure(s) during caesarean section as well as a postoperative briefing on procedure events and outcomes.

The study questionnaire was a reliable tool. It was adapted from the study by Lubansa at the School of Medicine, University of Zambia(Lubansa, 2010), which had also been used in a published study by Latika et al in India(Latika et al., 2015).It was modified with permission from Dr David Lubansa to suit the study population's language needs and also to accommodate updates to the guidelines since the two studies were done. The updates were; any extra procedures that might be deemed necessary during surgery, the patient's express statement on what procedures should not be carried out without further discussions with her, and the available postoperative analgesia options. The questionnaire was also peer reviewed by two local research experts at this hospital and finally, it was piloted among a few patients within the study population before being administered to the study participants. The questionnaire was reviewed again by the local experts after piloting.

The patient's hospital record file was used to corroborate some of the responses given to the interview questions such as the indication for elective caesarean section, fill obstetric history, and assess for the documentation of the informed consent process and signing of the consent form.

3.8 Data Collection Procedures

Both verbal and written consents (appendix I) for the study were sought and obtained in succession by the principal investigator after creating rapport with the study participant. This was done bedside in the general post-natal ward, semi-private or private wards of AIC Kijabe Hospital.

After consenting to the study and with proper adherence to COVID-19 prevention measures, data were then collected by administering the study questionnaire (appendix 1) to every participant through a face-to-face interview by the principal investigator on a postoperative day two or three or just before discharge until the desired sample size was attained. The study questionnaire was digitized on a mobile application enabled platform called RedCap to ease data collection and allow direct data entry.

The structured study questionnaire was administered in either English or Swahili depending on the participant's language preference and the need to mitigate any language barrier. Further clarification was sought for the 'Yes' responses on the questionnaire to ascertain patient's response. Frequent checks were performed to ensure completeness of the responses to the various parts of the questionnaire.

3.9 Data Management and Analysis

Data were collected and entered directly into RedCap, the application offered preliminary analysis and allowed quick assessment for incomplete or inconsistent data and immediate correction. The principal investigator had login/administrative rights to

the research project. The RedCap application's administrator only had access to unidentified (coded) data on his end and as such the participants 'confidentiality was maintained. Signed written informed consent forms were kept under lock and key only accessible to the principal investigator because they had participant's identifiers.

Raw unidentified data was automatically backed up in the Redcap's server for the project. Back up of raw data from RedCap was also stored as a backup file on an external hard drive and kept under lock and key only accessible to the principal investigator. After completion of data collection and entry, data was exported from RedCap in both Excel and STATA formats for analysis. Data cleaning and sorting were done in preparation for analysis. Data were analyzed using software for statistics and data science (STATA) and Microsoft Excel. P-value of < 0.05 was considered of statistical significance. There was no missing data at the analysis stage.

Descriptive statistics were used to determine the frequency of the socio-demographic characteristics of the participants. The association between the categorical cut aggregate score (less than 14 and more than 14 out of a possible total score of 15) on the elements informed consent process and each socio-demographic characteristic was tested using a series of bivariate linear regression analyses, a p-value of < 0.05 was considered a statistically significant association.

The information gaps of informed consent were measured as an aggregate score (0to 15) and expressed as frequencies/percentages. The time taken to obtain informed consent was estimated in minutes while the chance to address all patients' questions and concerns was expressed as a Yes or No.

T-test was used to determine any statistically significant association between the aggregate score on the elements of the informed consent process and the chance to

address all patients' questions and concerns. Similarly, a t-test was also used to examine any statistically significant association between the aggregate score on the elements of informed consent and the time taken to obtain informed consent. P-value of less than 0.05 at 95% CI indicated a statistically significant association.

A simple linear regression analysis between the aggregate score of the elements of the informed consent and the time taken to obtain consent was then performed and a linear regression equation was reported. Further, a scatter plot with fitted predictor values to determine if there was any visible linear association between the aggregate score and the time taken to consent was yielded. The results were presented in tables, graphs, and a scatter plot.

3.10 Ethical Considerations

Permission was sought from the Institute of Postgraduate Studies (IPGS) of Kabarak University after successful defense of the proposal to seek ethical approval from Kabarak University Research Ethics Committee (KUREC) for the study. Upon KUREC approval, a research permit was sought from the National Commission for Science, Technology and Innovation (NACOSTI) and a final ethics approval from the AIC Kijabe hospital ethics review board (ERB)was sought before the commencement of data collection.

The nature and purpose of the study were fully explained to the study participants and then both verbal and written informed consent for the study was obtained. There were no unforeseen harmful effects to the study participants or death. None of the participants expressed psychological distress needing psychological counselling services.

The study participants' anonymity was protected through the use of codes and not patients' names when entering data into the RedCap. The participant's initials were used instead of full name as well on the written consent form to boost anonymity.

The study participants' confidentiality was maintained at all stages of the study, none of the information shared was discussed with the attending clinical team, I used codes when entering data not identifiers, conversations were held in privacy and the written consent forms were kept in a locked cupboard with the key only be accessible by the principal investigator, myself.

The study participants' privacy was maintained by administering the questionnaire in a private room in the post-natal unit and not bedside, or an empty far-off bed from the next patient or in their private room for patients in the semi-private and private wards. If impossible I conducted the interview when the neighbor was asleep. The interviews were done outside visiting hours to further better privacy.

There were no cost implications or monetary incentives given to the study participants. Acceptance or refusal to participate in the study did not in any way alter the clinical care due for the study participant admitted to the hospital.

CHAPTER FOUR

DATA ANALYSIS, PRESENTATIONAND DISCUSSION

4.1 Introduction

This chapter presents the findings, interpretations and discussion according to the objectives, research questions and/or hypotheses. Based on the objectives of this study, the research questions were: (a) what were the socio-demographic characteristics of the women who underwent elective caesarean section at AIC Kijabe Hospital? (b) what were the gaps in the informed consent process for elective caesarean section at AIC Kijabe Hospital? (c) was there an association between (1) time spent on obtaining informed consent as well as (2) chance to address all of the patient's questions and concerns and gaps in the informed consent process for elective caesarean section at AIC Kijabe Hospital?

4.2 General Information

There was a 100% response rate, all one hundred and thirty-seven women sampled accepted and participated fully in the study. Only one woman approached declined to consent and participate in the study for personal reasons. Those who consented fully complied with all parts of the study. There were no withdrawals from the study, neither were there any adverse events that necessitated reporting or halting the study. On average it took approximately fifteen minutes to administer one questionnaire, ranging between 10 minutes to 30 minutes.

4.3 Demographic Data

One of the objectives was to describe the socio-demographic data of the women who underwent caesarean section at AIC Kijabe hospital and to hopefully evaluate how this in any way affects the aggregate score for gaps in informed consent.

4.3 Objective 1: Description of the socio-demographic characteristics of the participants

Table 1

Socio-demographic characteristics

Patient characteristic	**n, (%) total N=137**
Age (years) (mean, IQI)	32.26, (29.0 ,35.0)
Age category (years), n (%)	
18 - 25 years	8 (5.8)
26 - 35 years	97 (70.8)
Above 35 years	32 (23.4)
Level of education, n (%)	
Primary	5 (3.6)
Secondary	29 (21.2)
Tertiary	103 (75.2)
Marital status, n (%)	
Single	7 (5.1)
Married	130 (94.9)
Parity after this cesarean section, n (%)	
<2	11 (8.0)
2 to 4	122 (89.1)
>4	4 (2.9)
Residence, n (%)	
Nairobi city (High density)	42 (30.7)
Other towns (Medium-density)	79 (57.7)
Village (low density)	16 (11.8)
Do you understand and speak either Swahili or English well? n (%)	
Yes	131 (95.6)
A little	6 (4.4)

Most (70.8%) of the participants were between the age of 26 to 35 years with a mean age of 32 years. Only (5.8%) participants were under 25 years of age.75.2% of the women had a tertiary education followed by secondary education at 21.2%, least was primary education at 3.6%.94.9 % of the participants were married. These findings were almost similar to those of both Lubansa and Latika's studies (Latika et al., 2015; Lubansa,

2010).Only 5.1% were single. None was separated or widowed. Most, 89.9% had two to four previous pregnancies carried to term and delivered. 8%had fewer than two pregnancies and only 2.9% of the participants had more than four previous pregnancies.57.7% of the participants came from smaller towns, 30.7% came from Nairobi city, while only 11.8% came from a village. Despite the hospital being located in the rural Kiambu, only 11.8% came from a village. This could be due to low population in the village or high cost of care at Kijabe hospital which is unaffordable for the villagers even if such cost was affordable for urbanites. Residence described where the participants lived at the time of the study. Most of the participants (95.6%) spoke and understood both English and Swahili very well. Only 4.4% had little comprehension of the two languages. This could be attributed to the high levels of literacy in Kiambu County and its environs as well as most urban or semi-urban regions in the region where these patients came from.

4.4 Objective 1: Association between the participant's socio-demographic characteristic and the aggregate score on the informed consent process

Table 2

Association between the participants' socio-demographic characteristics and the aggregate score on informed consent process

Score Category	<14 (n=127,92.7%)	14 (n=10,7.3%)	P-value
Age (years), median (IQI)	32.0 (29.0; 35.0)	31.5 (26.8; 33.3)	0.29
Age category (years), n (%)			
18 - 25 years	7 (87.5)	1 (12.5)	
26 - 35 years	89 (91.8)	8 (8.2)	
Above 35 years	31 (96.9)	1 (3.1)	0.53
Level of education, n (%)			
Primary	4 (80.0)	1 (20.0)	
Secondary	29 (100.0)	0 (0.0)	
Tertiary	94 (91.3)	9 (8.7)	0.15
Marital status, n (%)			
Single	6 (85.7)	1 (14.3)	
Married	121 (93.1)	9 (6.9)	0.47
Parity after this caesarean section, n (%)			
<2	10 (90.9)	1 (9.1)	
2 to 4	113 (92.6)	9 (7.4)	
>4	4 (100.0)	0 (0.0)	0.83
residence, n (%)			
High density	38 (90.5)	4 (9.5)	
Medium-density	75 (94.9)	4 (5.1)	
low density	14 (87.5)	2 (12.5)	0.47
Understands and speaks either Swahili or English well? n (%)			
Yes	121 (92.4)	10 (7.6)	
A little	6 (100.0)	0 (0.0)	0.48
When did the discussions begin? n (%)			
ANC Visits	123 (92.5)	10 (7.5)	
Night to operation	4 (100.0)	0 (0.0)	0.57

A series of bivariate linear regression analyses of each of the patient socio-demographic characteristics versus the aggregate score on the informed consent process was performed which found that there was no statistically significant association between

each socio0demographic characteristic tested and the aggregate score on the gaps.

None of these socio-demographic factors had statistically significant associations with the aggregate score on gaps in informed consent as all the were greater than 0.05. This was unlike Lubansa's study that noted that the age of the participant was associated overall adequacy of informed consent (Lubansa, 2010).This was also unlike a literature review finding by Sherlock and Brownie which concluded that patients' level of education(literacy) and language competency were important determinants to fully provide informed consent (Sherlock & Brownie, 2014). Although most of the participants in this study read and understood English and Swahili well, the difference in level of education had no influence on aggregate score on gaps in informed consent. Each patient is unique with unique needs, preferences, values, and expectations hence addressing her uniqueness probably mattered more than any of these socio-demographic characteristics.

4.5 Objective 2: Description of the elements of informed consent that were either frequently or infrequently addressed i.e., the gaps

Table 3

Frequencies of the elements of informed consent as addressed at Kijabe hospital

Answer: **Elements of informed consent,**	**Agree** **n(%)**	**Disagree** **n(%)**
Was the consent process documented?	0 (0.0)	137 (100.0)
Were you told the name of your operation?	116 (84.7)	21 (15.3)
Were you told what the operation entails? i.e., it is a delivery of the baby via	115 (83.9)	22 (16.1)
Were you told why you needed to have the operation?	130 (94.9)	7 (5.1)
Were you informed of the benefits of the planned caesarean section to you and your baby?	81 (59.1)	56 (40.9)
Did you understand and feel that the operation to deliver your baby was necessary?	136 (99.3)	1 (0.7)
Were you told that the planned caesarean operation has some potential risks?	119 (86.9)	18 (13.1)
During the informed consent process, did you have all your questions and concern	133 (97.1)	4 (2.9)
Did you feel like you had the right to accept, refuse, or defer the caesarean operation	129 (94.2)	8 (5.8)
Were any extra procedures that might become necessary during your elective caesarean section discussed with you?	98 (71.5)	39 (28.5)
Were you informed of the available anaesthesia and post-operative analgesia options?	109 (79.6)	28 (20.4)
Was the implication of this planned caesarean section on your future pregnancy and delivery option?	79 (57.7)	58 (42.3)
Were you briefed on the outcome of your operation afterwards?	93 (67.9)	44 (32.1)
Was there any alternative(s) to the planned caesarean section discussed with you?	45 (32.8)	92 (67.2)

In all cases, documentation of the informed consent process discussions was not done at

all when the patient record was checked. However, the informed consent form was signed and recorded in all cases. Only words like ‘consent signed’, ‘consent form signed’, and ‘signed consent form’ were found in the patient’s file record.

Most (97.1%) of the participants had their questions and concerns addressed before going to the theatre. This was a great indicator that the women were respected and that they were also ready for surgery.

Alternative(s) to caesarean section was discussed with most participants. However, the reason it looked like it was infrequently (32.8%)addressed is that most women had more than one previous scar as an indication for the caesarean section and thus had no other option of delivery mode, hence their response of ‘disagree ‘was not necessarily because it was not discussed but meant that there was no alternative. The other elements were frequently addressed as noted from the frequencies against each as shown above.

In all cases, documentation of the informed consent process discussions was not done when the patients’ record files were checked. However, the consent forms were signed and recorded in all cases. Only words like ‘consent signed’, ‘consent form signed’, and ‘signed consent form’ were found in the patient’s file record. This was almost similar to Lubansa’s study in Ghana which reported that in 14% of cases documentation of the informed consent process was well done but consent forms were properly filled in only 56% of cases (Lubansa, 2010).

On documentation, signing of the consent form is just one aspect, documenting discussions held with the patient is the other important aspect. Signing the consent form is not adequate consenting (Ricketts et al., 2019). Alternatively, a consideration for a more comprehensive consent form specific for each surgery documenting the quality and duration of each element of informed is important. The generic consent form at AIC

Kijabe hospital only addressed the name of the procedure, indication, any extra procedures that might become necessary during surgery, anesthesia options(unspecified) but lacked alternatives to surgery, benefits of surgery that are recommended for documentation (Shah et al., 2020). Lack of documentation could have been attributed to time constraints and lack of knowledge on the ethical and legal obligation to document discussions held while obtaining informed consent. The assumption that filling and signing the consent form was adequate could also have contributed to the lack of documentation of the discussions held before signing the consent form.

The name, nature of the procedure, indication, and agreement on the necessity of the procedure by the patient were frequently addressed in 84.7%, 83.9%, 94.7% and 99.3% of cases respectively, this was relatively similar to the findings in other studies (Latika et al., 2015; Ntonjira, 2012; Lubansa, 2010). These elements were part of the current consent form and that might have contributed to their frequent address.

The benefits of the caesarean section to both mother and baby were addressed in 59.1% of cases only, this was much lower compared to a previous Kenyan study done at Kenyatta National Hospital (KNH) in which 89.4% of patients who underwent elective surgeries in multiple specialties were informed of the benefits of their surgical procedure (Ntonjira, 2012). It is possible that the benefits of the procedure were confused with the indication for the procedure. Once patients understood and agreed to the indication, some people forgot to discuss the benefits of the procedure. Also, some clinicians might have been unaware of the benefits of caesarean section to the mother and baby as opposed to vaginal delivery and that is why it was not frequently discussed. The balance between the success of the planned caesarean section and complications or risks from the surgery is better calculated by the patient when discussions about benefits versus risks of the procedure are held (Anderson & Wearne, 2007).

Risks of the planned caesarean section were discussed in 86.1% of cases. This was almost similar to findings by Ntonjira at KNH in which 78.8% of patients had discussions about potential risks or complications of the scheduled elective surgery. Our findings were much better than similar studies by Lubansa and Latika in which only 7.3% and 32% of participants respectively had discussions about risks (Latika et al., 2015; Lubansa, 2010). Most clinicians and nurses working in the obstetrics department were taught and dealt with these complications often and that might have contributed to the frequent address. Also, the current standard consent form at AIC Kijabe hospital had risks of surgical procedure included hence they were less frequently missed. The most commonly discussed risks were; death, excessive bleeding, injury to adjacent organs and infection.

Any extra procedure that might become necessary during caesarean section such as blood transfusion, hysterectomy was addressed in 71.5% while patients outwardly expressed any unwanted procedures during caesarean section in 7.3% of cases. The most unwanted procedure during surgery by all these participants was bilateral tubal ligation (BTL). This stemmed from discussions initiated by clinicians either in the ANC clinic or when signing the consent form on the wards whether the woman wanted the BTL procedure for contraception or not. These two elements were part of the update to the guidelines.

The available anaesthesia options and the recommended one was discussed in 79.6% of participants. This was almost similar to Ntonjira's findings at KNH in which anesthesia options were discussed in 76.7% of patients. This finding was however far much better than findings in similar studies by Lubansa, Teshome, and Latika in which it was only discussed in 4.7%, 11.7%, and 19.64% respectively (Latika et al., 2015; Lubansa, 2010;

Teshome et al., 2018). Intraoperative and postoperative analgesia option was an update to the guidelines too and as such had not been reported previously. AIC Kijabe hospital is a training site for anesthesia for registered nurses and consenting for anesthesia and analgesia is part of their training. This could have contributed to the higher frequency in addressing this element of informed consent. Most consenting for analgesia and anesthesia actually happened in the operating room.

The implication of the current caesarean section of the woman's future pregnancy and delivery options if she still desired pregnancy was discussed in 57.7% of the participants. In as much as this was among the less frequently addressed elements of informed consent in AIC Kijabe hospital, still, it was better than what similar studies previously by Lubansa and Latika found (18% and 32.1% respectively). Most patients were having repeat cesarean sections and so most clinicians might have assumed most women already knew their mode of delivery for the next pregnancy. Also, some clinicians might have assumed that the woman is done having babies or that since next pregnancy and delivery are far away, no need to discuss it in that sitting.

Regarding postoperative briefing on the events and outcome of the elective caesarean section, 67.9% of the participants were briefed. It was better than findings in similar studies by Latika and Lubansa in which post-operative briefing was only done in 7.1% and 7.4% of participants respectively. The post-operative briefing was done either in the operating room, post-operative recovery unit (PACU) or in the ward. Arising emergency cases in between the scheduled elective cases interfered with the immediate post-operative briefing (i.e., in PACU) for some patients as the operating surgeons were urgently needed elsewhere. Also, during that period renovations were ongoing in theatre and the obstetrics and gynecology team only had one operating room and one operating

team at ago which meant surgeries were back-to-back leaving little room for immediate postoperative briefing. However, due to the importance of post-operative briefing and despite such challenges, the operating team handed over the briefing to the ward team or would debrief the patients after they were done with surgeries for the day.

Alternative(s) to the planned cesarean section was discussed in more than 32.8% of participants as reported. However, the reason it was reported as infrequently (32.8%) addressed was because most women had more than one previous scar as an indication for the caesarean section and thus had no other option of delivery mode, hence their response of 'disagree' was not necessarily because it was not discussed but it meant that there was no alternative. Commonly discussed alternatives to caesarean section were the regular vaginal delivery and vaginal birth after caesarean section (VBAC) both of which were available at AIC Kijabe hospital.

All patients' questions and concerns were addressed in 97.1% of the participants before the operation. This was way better than the findings of the studies by Ochieng' et al, Latika, and Lubansa in which 56.1%, 26.8% and 24.7% of the patients had all their questions and concerns addressed before surgery respectively (Latika et al., 2015; Lubansa, 2010; Ochieng et al., 2015). About 90.3% of patients in a study by Perić reported that having the opportunity to ask questions was important to them (Perić et al., 2018).

4.6 Objective 3a: The association between the chance to address the patient's questions and concerns and the aggregate score on the informed consent process

Table 4

Association between the chance to address the patient's questions and concerns and the aggregate score on the informed consent process

Two-sample z test

Group	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf.	Interval]
0	4	6.5	.5	1	5.520018	7.479982
1	133	10.16541	.086711	1	9.995463	10.33536
diff		-3.665414	.5074631		-4.660023	-2.670804

diff = mean(0) - mean(1) z = -7.2230

Ho: diff = 0

Ha: diff < 0	Ha: diff != 0	Ha: diff > 0
Pr(Z < z) = 0.0000	Pr(|Z| > |z|) = 0.0000	Pr(Z > z) = 1.0000

Test of proportion (t-test) was performed to test the association between the chance to address patient's questions and concerns and the aggregate score on the informed consent process which found a statistically significant association between the two, with a p-value of 0.01.The chance to ask questions and have concerns addressed was considered a great marker of respect for the participant's autonomy in the informed consent process. It gave the patient room to express her values, preferences, beliefs and wishes. Addressing this element was considered most dignifying in the informed consent process in this study.

The 97.1 % of the participants who were given a chance to ask questions and have their concerns addressed had an aggregated mean score of 10.2 while the 2.9% who were not given a chance to ask questions or have their concerns addressed during the informed

consent process had an aggregated mean score of 6.5. This result suggested that giving patients a chance to raise questions and concerns and addressing them resulted in better-informed consent process. This chance probably allowed more time for discussions or just the freedom to freely express oneself in the other elements of informed consent both from the clinician and patient's side as they mattered. It signaled to the patient that the clinician was not in a hurry to leave.

4.7 Objective 3b: The association between the time taken to consent and the aggregate score on the informed consent process

The time taken to obtain consent entailed either reading through the consent form for the patient and discussing each section and ascertaining comprehension, ending with signing of the consent form or handing over the consent form to the patient to read for herself, allow her to ask questions if any and eventually sign the consent form after comprehension. It was a mean of 10.15 minutes, minimum time taken was one minute, with a maximum of sixty minutes and a median of ten minutes. This finding was close to what Chima found in his study in South Africa that most doctors spent five to ten minutes on obtaining consent (Chima, 2013). Only one patient in this study took sixty minutes and still had an aggregate score of ten out of possible fifteen. She was generally anxious about the caesarean section and only relaxed after the surgery. The recommended time that maximizes patients' comprehension and eventually gives proper informed consent is fifteen to thirty minutes (Fink et al., 2010). So, despite favorable aggregate scores on informed consent, perhaps the time taken to obtain informed consent can be improved. Although most (in 97.1% of participants) discussions about scheduled cesarean section were initiated during the antenatal clinic visits, it was difficult to quantify the time spent on informed consent in the antenatal clinic.

Table 5

Association between the time taken to obtain consent and the aggregate score on informed consent

Two-sample z test

Variable	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf.	Interval]
score	137	11.0292	.0854358	1	10.86175	11.19665
durati~t	137	10.15328	.0854358	1	9.985834	10.32074
diff		.8759124	.1208244		.6391009	1.112724

diff = mean(score) - mean(duration_of_co~t) z = 7.2495

Ho: diff = 0

Ha: diff < 0	Ha: diff != 0	Ha: diff > 0
Pr(Z < z) = 1.0000	Pr(|Z| > |z|) = 0.0000	Pr(Z > z) = 0.0000

An unpaired t-test comparing the mean of time taken to consent versus the mean of the aggregated score on the informed consent process found a statistically significant association between the time taken to consent and aggregated score (P-value of 0.01).

A simple linear regression analysis was further performed to determine any linear association between the aggregated score and the time taken to obtain consent. The following equation was yielded, Y = 10.74 + 0.028x (y – score, x-time taken to consent).A scatter plot with fitted predictor aggregated score showed a weak if any positive linear association. This suggested that spending more or less time did not necessarily translate to few or more gaps in the informed consent process respectively.

The more the time taken to obtain informed consent the better the aggregate score on the informed consent. This result suggests that the more time was taken to obtain informed consent the higher the aggregate score, meaning fewer gaps and hence a better

consenting process. However, there was a weak positive linear association between the two. There were times where lesser time was taken but still had an aggregate score of more than twelve out of a possible aggregate score of fifteen. The highest aggregate score of fourteen was experienced between five minutes and thirty minutes. From this study's findings, it can be suggested that at least five minutes need to be spent to obtain an adequate informed consent. It was hard to pick a maximum time but 30 minutes was the most time at which a maximum aggregate score was obtained suggesting it could be limit. So, based on these findings, I recommended five to thirty minutes as the time required to obtain adequate informed consent.

More time allowed the clinician to share more information with the patient as deemed necessary. More time also gave patients room to ask questions and raise concerns as well as allow the chance to address those questions and concerns. More time still gave the patient room to process and comprehend the information shared before signing the consent form.

CHAPTER FIVE

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter includes a summary of the discussion of the findings based on each objective, study limitations and generalization of findings statement, conclusion, and recommendations.

5.2 Summary

There are multiple ethical challenges that could arise when offering obstetric care especially regarding sharing of information in order to obtain informed consent for elective caesarean section. This study set out to determine if there were gaps in the informed consent process for elective caesarean section at AIC Kijabe Hospital.

Generally, the reason AIC Kijabe frequently addressed most of the elements of informed consent could be attributed to the elective nature of the caesarean section studied, scheduling or planning of caesarean sections early on during the antenatal clinic visits, hence early initiation of discussions about the planned surgery. Also, AIC Kijabe was conducive training and learning environment where consultants were readily available to train and be consulted in the obstetric clinic, wards and in the operating room, this equipped the whole obstetrics team for any questions or concerns from patients. Admission a day prior to surgery allowed the patient to settle in and while in a relaxed environment sign the consent form. The consent form was often signed the night of operation. Well-staffed obstetrics department in terms of human resource played a big role. The culture of compassionate care in the hospital which aligned with the hospital's mission statement must have played a big role in honoring or respecting patients as part of the services offered and this allowed patients to freely interact with their caregivers

and ask questions or raise concerns whenever necessary.

5.2.1 Description of the Socio-demographic Characteristics of the Participants

Most of the participants were between the ages of 26 to 35 years with a mean age of 32 years. Very few patients were under 25 years of age.75.2% of the women had a tertiary education followed by secondary education at 21.2%, least was primary education at 3.6%.

94.9 % of the participants were married. Only 5.1% were single. None was separated or widowed. Most, 89.9% had two to four previous pregnancies carried to term and delivered. 8% had fewer than two pregnancies and only 2.9% of the participants had more than four previous pregnancies.57.7% of the participants came from smaller towns, 30.7% came from Nairobi city, while only 11.8 came from a village. Residence described where the participants lived at the time of the study. Most of the participants (95.6%) spoke and understood both English and Swahili very well. Only 4.4% had little comprehension of the two languages.

None of these socio-demographic factors had statistically significant associations with the aggregate score on gaps in informed consent as all the p-values were greater than 0.05. This was unlike Lubansa's study that noted that the age of the participant was associated overall adequacy of informed consent (Lubansa, 2010).This was also unlike a literature review finding by Sherlock and Brownie which concluded that patients' level of education(literacy) and language competency were important determinants to fully provide informed consent (Sherlock & Brownie, 2014). Although most of the participants in this study read and understood English and Swahili well, the difference in level of education had no influence on aggregate score on gaps in informed consent. Each patient was unique with unique needs, preferences, values, and expectations hence

addressing her uniqueness probably mattered more than any of these socio-demographic characteristics.

5.2.3 Description of the Elements of Informed Consent that were either Frequently or Infrequently Addressed i.e., the Gaps.

Of the fifteen elements of informed consent assessed, three elements of informed consent were infrequently addressed namely; the benefits of the planned caesarean section on the mother and baby at 59.1%, discussion about the implication of the planned elective caesarean section on the woman's future pregnancy and delivery option(s) at 57.7%, and postoperative briefing on the outcome of surgery at 67.9%. Still, these elements were addressed in more than half of the participants. But documentation of the informed consent process discussions was not addressed at all in all cases. All other elements were adequately addressed when obtaining informed consent for elective cesarean section at AIC Kijabe hospital.

5.2.4 The Association Between the Chance to Address the Patient's Questions and Concerns and the Aggregate score on the Informed Consent Process

Most (97.1%) of the participants had their questions and concerns addressed before going to the theatre. These 97.1 % of the participants who were given a chance to ask questions and have their concerns addressed had an aggregated mean score of 10.2 while the 2.9% who were not given a chance to ask questions or have their concerns addressed during the informed consent process had an aggregated mean score of 6.5.

Test of proportion (t-test) was performed to test the association between the chance to address patient's questions and concerns and the aggregate score on the informed consent process which found a statistically significant association between the two, with a p-value of 0.01.This result suggested that giving patients a chance to raise questions

and concerns and addressing them resulted in better-informed consent process.

The chance to ask questions and have concerns addressed was considered a great marker of respect for the participant's autonomy in the informed consent process. It gave the patient room to express her values, preferences, beliefs and wishes. Addressing this element was considered most dignifying in the informed consent process in this study.

5.2.5 The Association Between the Time Taken to Consent and the Aggregate Score on the Informed Consent Process

The minimum time taken to obtain consent was one minute, with a maximum time of 60 minutes while the median time was 10 minutes. The mean was 10.15 minutes. This finding was close to what Chima found in his study in South Africa that most doctors spent five to ten minutes on obtaining consent (Chima, 2013). Although notable is that in 97.1% of the participants the discussions about the planned cesarean section began in the ANC clinic.

An unpaired t-test comparing the mean of time taken to consent versus the mean of the aggregated score on the informed consent process found a statistically significant association between the time taken to consent and aggregated score (P-value of 0.01). A simple linear regression analysis further performed showed a weak if any positive linear association. The highest aggregate score of fourteen was experienced between five minutes and thirty minutes. The recommended time that maximizes patients' comprehension and eventually gives proper informed consent is fifteen to thirty minutes (Fink et al., 2010). These findings were in keeping with this recommendation and perhaps also implied that if most discussions were initiated in ANC visits, then time spent on obtaining informed consent just before surgery could be shortened with similar aggregate score outcomes.

5.3 Conclusions

Overall, the consenting process for elective caesarean section at AIC Kijabe Hospital was working well. Almost all patients had a chance to ask question and raise concerns. Giving patients a chance to ask questions and raise concerns and addressing them resulted in a higher aggregate score signaling an in-depth informed consent process and respect for patient's autonomy.

The more time taken to obtain informed consent, the higher the aggregate score, however, this was a weak positive linear association. Of the recommended 15 elements of informed consent process, the documentation of informed consent process in patient's file, benefits of CS, post-operative briefing, and the implication of that CS on future pregnancy were infrequently addressed. The Socio-demographic characteristics had no effect on the aggregate score on informed consent process.

With adequate training and practice, obtaining informed consent as a skill can be improved on by all in clinical practice.

5.4 Recommendations

5.4.1 Policy Recommendations:

1. Train all clinicians to document the informed consent process discussions in the patient's record file.
2. Develop a comprehensive informed consent form specific for each surgical procedure such as the caesarean section and not just a generic one for all as is. Preferably in a check-list format.

5.4.2 Recommendations for Further Research

1. A qualitative study to explore why the documentation of the informed consent process in the patient's file record, the benefits of elective caesarean section, post-

surgery briefing and the implication of this CS on future pregnancy are infrequently addressed.

2. To quantitative study to assess the clinicians' knowledge of the informed consent process for elective caesarean section at AIC Kijabe Hospital.

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APPENDICES

Appendix 1: IPGS Letter of Introduction to KUREC

BOARD OF POST GRADUATE STUDIES

Private Bag - 20157
KABARAK, KENYA
http://kabarak.ac.ke/institute-postgraduate-studies/

E-mail: directorpostgraduate@kabarak.ac.ke

28th April, 2021

The Chairman
Research and Ethics Committee
Kabarak University

Dear Sir,

RE: SIMIYU BRAMWEL WEKESA - GMMF/M/1366/09/16

The above named is a candidate at Kabarak University pursuing Master's degree in Family Medicine. He is carrying out a research entitled "***Gaps in Informed Consent Process among Women Undergoing Elective Cesarean Section at AIC Kijabe Hospital, Kiambu County Kenya***". The student has defended his proposal and has been authorised to proceed with field research.

The information obtained during this research will be used for academic purposes only and will be treated with utmost confidentiality.

Please provide the student with KUREC clearance to enable him to obtain NACOSTI research permit.

Thank you.

Yours faithfully,

KABARAK UNIV DIRECTOR POST GRADUATE STUDIES 23 APR 2021 PRIVATE BAG 20157, KABARAK

Dr. Wilson O. Shitandi
DIRECTOR, INSTITUTE OF POST GRADUATE STUDIES

Appendix II: IPGS Letter of Introduction of NACOSTI

KABARAK UNIVERSITY
OFFICE OF THE DIRECTOR
INSTITUTE OF POST GRADUATE STUDIES

Private Bag - 20157
KABARAK, KENYA
http://kabarak.ac.ke/institute-postgraduate-studies/

E-mail: directorpostgraduate@kabarak.ac.ke

28th May 2021

The Director General
National Commission for Science, Technology & Innovation (NACOSTI)
P.O. Box 30623 – 00100
NAIROBI

Dear Sir/Madam,

RE: SIMIYU BRAMWEL WEKESA – GMMF/M/1366/09/16

The above named is a candidate at Kabarak University pursuing Master's degree in Family Medicine. He is carrying out a research entitled "***Gaps in Informed Consent Process among Women Undergoing Elective Caesarean Section at AIC Kijabe Hospital, Kiambu County Kenya***". He has defended his proposal and has been authorised to proceed with field research.

The information obtained in the course of this research will be used for academic purposes only and will be treated with utmost confidentiality.

Please provide the student with a research permit to enable him to undertake the research.

Thank you.

Yours faithfully,

KABARAK UNIVERSITY DIRECTOR POST GRADUATE STUDIES 29 MAY 2021 PRIVATE BAG - 20157, KABARAK

Dr. Wilson O. Shitandi
DIRECTOR, INSTITUTE OF POST GRADUATE STUDIES

Appendix III: Data Collection Tools

Informed Consent Form for this Study

Informed Consent Form for the immediately postnatal women are now admitted in the AIC Kijabe hospital postnatal ward following an elective cesarean section who we are inviting to participate in research titled:

"Gaps in Informed Consent process among women who have undergone an elective caesarean section AIC Kijabe hospital, Kiambu County. Kenya."

Principal Investigator: Simiyu Bramwel Wekesa

Organizations: Kabarak University and AIC Kijabe Hospital

Before you decide whether to participate in this study, it is important for you to understand why the research is being done and what it will involve.

You are excluded from this study if any of the following apply to you.

Exclusion Criteria	**Y(Yes) or**	**N (No)**
Did you undergo an emergency Cesarean section from whatever indication?		
Are there any complications following delivery/surgery such as alot of pain, excessive bleeding, fetal demise, infection?		

Please take time to read and discuss the following information and ask questions if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part in this research.

Thank you for reading this.

This Informed Consent Form has two parts:

i. Information Sheet (to share information about the research with you)
ii. Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I am Bramwel Wekesa, a medical doctor currently undertaking my postgraduate studies in Family Medicine and Community Health at Kabarak University and AIC Kijabe Hospital as the clinical training site. I am conducting a study on informed consent for elective caesarean section also referred to as planned caesarean section, a fairly common surgical procedure related to pregnancy and delivery worldwide. Since you have undergone an elective caesarean section, I would like to invite you to be a participant in this research.

Purpose of the research

Caesarean section is a fairly common surgical procedure offered to pregnant women who for one reason or another cannot deliver spontaneously via the vagina. it is both an ethical and legal requirement that before any surgical procedure such as caesarean section is undertaken, informed consent is sought from the patient. This study aims to evaluate your understanding and recollection of the circumstances which led to you having to undergo an elective caesarean section and the role you played in the consenting process. The study will also allude to your overall satisfaction with the consenting process and the surgical procedure.

Research Intervention(s)

There will be no medical or surgical interventions involved as part of the research except the indicated caesarean section itself and other normal care as deemed by the clinical team for the patients.

Participant selection

We are inviting all women who delivered at AIC Kijabe Hospital via elective caesarean section after antenatal clinic follow-up from anywhere to participate in this research.

Voluntary Participation

Your participation in this research is entirely voluntary. You decide whether or not to participate in this research. Regardless of your choice, all the services you are due at the AIC Kijabe Hospital postnatal ward will continue and nothing will change. If you choose to participate, know that you are at liberty to change your mind at any time.

Protocol

If you understand and agree to the purpose of this study, you will be given written consent to sign. After which a research assistant will ask you, a few questions from a questionnaire while more information will be acquired from your medical records. The process will take between half an hour to forty-five minutes at most but the entire study will span over three to four months.

Risks

There are no anticipated risks to you while participating in this study.

Benefits

If you have any questions regarding the surgical consent process and elective caesarean section procedure, the research assistant and the principal investigator will be happy to address them. However, you will not be given any money or other gifts as an incentive for participating in this study. Overall, the study will hopefully improve the quality of care in obtaining informed consent for caesarean sections and other surgical procedures at AIC Kijabe Hospital through raising awareness of a proper consenting process.

Confidentiality

The information that we collect from this research project will be kept confidential. The information about you that will be collected during the research will be put away and no one, but the researcher will be able to see it. Any information about you will have a number on it instead of your name to conceal your identity. Only the researcher will know what your number is, and we will lock that information up under a lock and key. It will not be shared with or given to anyone except Bramwel Wekesa, the principal investigator.

Sharing the Results

The knowledge gained from doing this research will be shared with you through community meetings before it is made widely available to the public. Your confidential information will not be shared. There will be small meetings in the hospital and the community, and these will be announced. After these meetings, we will publish the results so that other interested parties may learn from our study.

Right to Refuse or Withdraw from the Study

Your refusal to participate in this study is your right and doing so will not in any way affect your clinical care in AIC Kijabe hospital. You will still have all the benefits that you would otherwise have at this hospital. Also, if after accepting to participate and feel or think otherwise afterwards, you are free to stop participating in this study without losing any of your rights as a patient here. Be assured that your clinical care will not be affected in any way.

Who to Contact?

If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact Bramwel Wekesa on 0727270116 or email bwekesa@kijabehospital.org or at brsimiyu@kabarak.ac.ke.

This proposal has been reviewed and approved by the Institutional Research Ethics Committee (IREC) of both Kabarak University and AIC Kijabe Hospital. The Ethics and Research committee's task is to make sure that research participants are protected from any kind of harm. If you wish to find out more about the IRECs, contact Carol Mwangi for the AIC Kijabe Hospital IREC on 0720896182 or Dr. James Kay 0724887431 for the Kabarak University IREC.

PART II: Certificate of Consent

I confirm that I have read and understood the purpose of this study as contained in the information sheet.

I have had the opportunity to ask questions and get satisfactory answers about the study.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences on my clinical care. In addition, should I not wish to answer any particular question or questions, I am free to do so. I understand that my responses will be kept strictly confidential. I willingly give permission for members of the research team to have access to my anonymized responses. I understand that my name will not be linked with the research materials, and I will not be identified in the reports that result from the research.

I agree to take part in the above study.

Print Name initials of Participant (code)_____

Signature of Participant _____ Date _____

If illiterate

(A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.)

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date_____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that she will be asked a few questions regarding the consent process for her elective caesarean section and some more information will be collected from her medical records.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly to the best of my knowledge and ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF (informed consent form) has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____Date _____

Fomu ya Makubaliano kwa Funzo Hili

Fomu arifuya makubaliano kwa wanawake ambao wamejifungua tu kwa sasa wanalazwa katika Hospital ya A.I.C Kijabe wadi ya akina mama waliojifungua kufwatia upasuaji ulioamuliwa tunawaalika kushiriki katika utafiti uitwao: *"Pengokatika njia ya makubaliano kati ya wanawake wanaojifungua kwa upasuaji wakuamuliwa katika Hospitali ya A.I.C Kijabe eneo la Kiambu, Kenya".*

Mtafiti Mkuu: Simiyu Bramwel Wekesa

Mashirika: Chuo Kikuu cha Kabarak na Hospitali ya A.I.C Kijabe

Kabla ya kuamua ikiwa utashirik ikatika mafunzo haya, ni muhimu kwako kufahamu kwanini utafiti unfanyika na utahusisha nini.

Unazuiwa kutoshiriki katika mfunzo haya ikiwa yoyote yafuatayo yanakuhusu

Kanuni za uzuiaji	**N (Ndiyo) au**	**H (Hapana)**
Ulijifugua kupitia upasuaji wa dharura kwasababu yoyote ile.		
Kuna matatizo yoyote kufuatia kujifungua/ upasuaji kama uchungu mwingi, kuvuja damu kwa wingi, kifo cha kijusu, ambukizo.		

Tafadhali uchukue wakati wako kusoma na kujadili habari ifuatayo na uyaulize maswali ikiwa kuna chochote kisicho eleweka au ikiwa ungependa habari zaidi. Tafadhali chukua wakati kuamua ikiwa ungetaka kushiriki au la katika utafiti huu.

Asante kwa kuyasoma haya.

Hii fomu arifu ya makubaliano ina sehemu mbili:

i. Ukurasa wa habari (Kujuliana/kugawana habari kuhusu utfiti nawe)
ii. Cheti cha makubaliano (kwa sahihi ikiwa utakubali kushiriki)

Utapewa nakala yote ya fomu ya makubaliano.

SEHEMU YA KWANZA: Karatasi ya Habari

Utangulizi

Mie ni Bramwel Wekesa, daktari na kwa sasa nayasomea masomo yangu endelevu ya ki-digrii katika utabibuwa familia/jamaa na afya vijijini katika Chuo Kikuu cha Kabarak na Hospitali ya A.I.C Kijabe kama mahali ninajifunzia utabibu. Nina ongoza funzo/utafiti kuhusu makubaliano arifu kw aupasuaji wakujifungua ulio amuliwa, pia hujulikana kama upasuaji uliopangwa, upasuaji wakawaida unaohusiana na ujauzito nakujifungua duniani mwote. Kwa kuwa umewahi kufanyiwa upasuaji wakuamuliwa, ningependa kukualika kuwa mshirika katika utafiti huu.

Kusudi la utafiti

Upasuaji wa ujauzito ni upasuaji wa kawaida unaofanyiwa wanawake wajawazito ambao kwasababu hii au nyingine hawawezi kujifungua kwa haraka kupitia njia ya uzazi. Ni hitaji la kimaadili na halali kwamba kabla ya upasuaji wowote kama upasuaji wa ujauzito kufanyiwa makubaliano arifu huchukuliwa kutoka kwa mgonjwa. Funzo hili linalenga kupima kufahamu kwako na kumbukumbu za hali iliyokufanya kufanyiwa upasuaji wakuamuliwa na vipi ulihusika katika njia ya makubaliano. Funzo litakuridhisha na njia ya makubaliano ya upasuaji.

Uingiliaji wa utafiti

Hakutakuwa na uingiliaji wa kimatibabu au upasuaji utakao husika kama sehemu ya utafiti ila upasuaji uliotajwa na utunzaji wakawaida kama inavyofikiriwa na timu yakimatibabu kwa wagonjwa.

Uchaguzi wa mshirika

Tunawaalika wanawake wote waliojifungulia katika Hospitali ya A.I.C Kijabe kupitia kwa upasuaji ulioamuliwa baada ya ufuatilivu wa kabla ya kujifungua kutoka popote kushiriki katika utafiti huu.

Kushiriki kwa kujitolea

Kushiriki kwako katika utafiti huu ni kwa kujitolea kabisa. Ni chaguo lako ikiwa utashiriki au hapana. Bila kujali uamuzi wako, huduma zote unazozihitaji katika Hospitali ya A.I.C Kijabe katika wadi baadaya kujifungua zitaendelea na chochote hakita

badilika. Ukiamua kushiriki,ujue kwamba unaweza kubadilisha fikira zako wakati wowote.

Mapatano

Ukielewa na ukubaliane na kusudi la funzo, utapewa makubaliano yalioandikwa uweke sahihi. Ambapo msaidizi wa utafiti atakuuliza maswali machache kutoka kwa orodha ya maswali wakati huohuo habari Zaidi itahitajika kutoka kwa rekodi yako ya matibabu. Shughuli hii itachukua kati ya nusu saa au dakika arobaini na tano lakini funzo hili litaendelea kwa muda wa zaidi ya miezi mitatu hadi minne

Tahadhari

Hakuna tahadhari zozote zinazokusudiwa kwako unapoendelea kushiriki katika funzo.

Faida

Ikiwa una maswali yoyote kuhusiana na makubaliano ya upasuaji na upasuaji ulioamuliwa, msaidizi wautafiti na mchunguzi mkuu watafurahi kukushughulikia. Ingawa hutapewa pesa zozote au zawadi zingine kama kivutio kushiriki katika funzo hili. Kwa jumla funzo kwa matumaini litaboresha hali ya utunzaji katika kupata makubaliano arifu kwa upasuaji na njia za upasuaji katika Hospitali ya A.I.C Kijabe kupitia kufanya watu wajue njia mwafaka ya makubaliano.

Siri

Habari tunayokusanya katika mradi wa utafiti itawekwa ki-siri. Habari kukuhusu itakayokusanywa wakati wa utafiti itawekwa na hakuna yeyote ila mtafiti ataweza kuiona. Habari yoyote kukuhusu itakuwa na nambari juu yake badala ya jina lako,kukuficha. Mtafiti tu ndiye atakayejua nambari yako ni ipi na tutafungia habari hiyo kwakufuli. Haitapeanwa kwa yeyote ila Bramwel Wekesa, mchunguzi mkuu.

Kujulishwa Habari

Maarifa au elimu iliyo patikana kutokana na utafiti huu itapewa wewe kupitia mikutano ya vijijini kabla ya kupewa uma. Habari yako ya siri haitatolewa. Kutakuwa na mikutano midogo hospitalini na vijijini, na hii itatangazwa. Baada ya hii mikutano, tutachapisha matokeo ili walio na hamu waweze kujifunza kwa funzo au utafiti wetu.

Haki yakukataa au kujiondoa katika funzo

Kukataa kwako kushiriki katika funzo hili ni haki yako na kufanya hivyo hakutadhuru kwa njia zozote matibabu yako katika hospitali ya A.I.C Kijabe. Bado utakuwana faida zote ambazo ungekuwa nazo hospitalini. Pia, ikiwa baada ya kukubali kushiriki nauhisi au ufikiri vinginevyo, una uhuru kusimama kushiriki katika funzo hili bila kupoteza haki zozote zako kama mgonjwa hapa. Uhakikishiwe kwamba utunzaji wako ki-kliniki hautadhurika kwa njia yoyote.

Utakao wasiliana nao

Ikiwa una maswali yoyote, wawezakuyauliza sasa au baadaye, hata baada ya utafiti umeanza. Ikiwa ungetaka kuyauliza maswali baadaye, waweza kumjulisha: Bramwel Wekesa kwanambari 0727270116 au barua pepe bwekesa@kijabehospital.org au kwa brsimiyu@kabarak.ac.ke.

Pendekezo hili limerudiwa na kutubaliwa na kamati ya utafiti (IREC) na maadili ya Chuo Kikuu cha Kabarak na Hospitali ya AIC Kijabe, ambayo ni kamati na kazi yake nikuhakikisha kwamba washiriki wa utafiti wamekingwa na madhara. Ikiwa ungetaka kujua zaidi kuhusu IREC, mwone Carol Mwangi kutoka kamati ya utafiti na maadili ya Hospitali ya AIC Kijabe kwa nambari 0720896182 au Dkt. James Kay 0724887431 kutoka kamati ya utafiti na maadili ya Chuo Kikuu cha Kabarak.

SEHEMU YA PILI: Cheti cha makubaliano

Nadhibitisha kwamba nimesoma na kufahamu madhumuni ya utafiti huu kama ilivyo katika karatasi ya habari. Nimekuwa na nafasi ya kuuliza maswali na nikapata majibu ya kuridhisha kuhusu mafunzo.

Ninaelewa kwamba kushiriki kwangu ni kwa kujitolea na nina uhuru kujiondoa wakati wowote bila kupeana sababu yoyote au bila kuweko matokeo yakinyume. Pamoja na hayo, nikikosa kujibu swali lolote au maswali, nina uhuru kukataa.

Ninaelewa kwamba majibu yangu yatawekwa siri kabisa. Nawapa ruhusa washirika wa timu ya utafiti kuweza kufikia majibu yangu yasiyo na jina. Ninaelewa kwamba jina langu halite husishwa na dhana za utafiti, na sitatambuliwa katika ripoti zitakazotokea kuhusu utafiti.

Nakubali kushiriki katika mafunzo haya.

Jina la Mshirika.....

Sahihi ya Mshirika.....

Tarehe..... (Siku/Mwezi/Mwaka)

Ukiwa hajui kusoma au kuandika

Shahidi anayeweza kusoma au kuandika ni lazima aweke sahihi (ikiwezekana, mtu huyu anahitaji achaguliwe na mshirika na asiwe na uhusiano na timu ya utafiti). Washirika wa sioweza kusoma au kuandika wanahitaji waambatanishe alama ya kidole gumba pia.

Nimeshuhudia ussomaji sahihi wa fomu ya makubaliano kwa mshirika mhusika, na mtu amekuwa na nafasi yakuyauliza maswali. Nadhibitisha kwamba mtu amepeana makubaliano kwa uhuru.

Jina la Shahidi..... ***Na kidole gumba cha mshirika***

Sahihi ya shahidi.....

Tarehe.....

Siku/Mwezi/Mwaka

Taarifa ya mtafiti au anayetoa makubaliano

Nimesoma kwa ufasaha karatasi liyo na habari kwa mshirika na kwa kadiri ya uwezo wangu, nimehakikisha kwamba mshirika anafahamu kwamba mshirika ataulizwa maswali machache kuhusu makubaliano ya upasuaji ulio amuliwa na habari nyingine itatolewa kwa rekodi yake ya hospitali.

Na dhibitisha ya kwamba mshiriki alipewa nafasi kuyauliza maswali kuhusu mafunzo, na maswali yaliyoulizwa na mshirika yamejibiwa vilivyo na kwa uwezo wangu. Nadhibitisha kuwa mtu hajalazimishwa kutoa makubaliano, na makubalianao yametolewa kwa uhuru na kwa kujitolea.

Nakala ya hii fomu ya makubaliano imepewa mshirika.

Jina la mtafiti/mtu anayetoa makubaliano.....

Sahihi ya mtafiti/mtu anayetoa makubaliano.....

Tarehe.....

Siku/Mwezi/Mwaka

Study Questionnaire

Date: …… Sequential ID. Number. …….

DETERMINATION OF THE GAPS IN THE INFORMED CONSENT PROCESS AMONG WOMEN WHO HAVE UNDERGONE AN ELECTIVE CAESAREAN SECTION AT KIJABE HOSPITAL.

All sections of this questionnaire must be filled

Is translation to Swahili required for this interview?

Yes No

PART A: INFORMATION EXTRACTED FROM PATIENT'S MEDICAL RECORD (FILE)

1. Participant's initials ……...
2. Age (years) ……...
3. Level of education

   None Primary Secondary Tertiary
4. Parity after this caesarean section ……...
5. Marital status

   Single Married Widowed Divorced
6. Residence:

   Nairobi city (High density) Other towns (Medium-density)

   Village (low density)

7. Past obstetric history:

Pregnancy number?	Year of Delivery	Duration of pregnancy	Mode of Delivery	Birth weight

8. Duration since this caesarean section

   Hours ……. Days …….

9. Outcome of this caesarean section:

   Term Live Birth Preterm Live Birth

10. In the patient's clinical note, what is the written indication for this cesarean section.....
    .....
    .....

11. Was the consent process documented?

    Yes No

12. If yes to Q10 above, highlight what was discussed and documented

    ……
    ……
    ……
    …….....…

Part B: Information from Face-To-Face Interview with the Patient

1. Do you understand and speak either Swahili or English well?

   Yes No A little

2. Were you told the name of your operation?

   Agree Don't Remember Disagree

3. Were you told what the operation entails i.e., it is a delivery of the baby via a cut in the abdomen?

   Agree Don't Remember Disagree

4. Were you told why you needed to have the operation?

   Agree Don't Remember Disagree

5. If you agree to Q3 above, what was the reason(s) (indication{s}) for your operation? (patient's own words)

   ……

   ……

   …….....

6. Were you informed of the benefits of the planned caesarean section to you and your baby?

   Agree Don't Remember Disagree

7. Did you understand and feel that the operation to deliver your baby was necessary?

   Agree Don't Remember Disagree

8. Were you told that the planned caesarean operation has some potential risks?

   Agree Don't Remember Disagree

9. If agree to Q6 above, what risks were discussed? (patient's own words)

   ……

   ……

   ……

   ……

10. During the informed consent process, did you have all your questions and concerns answered?

    Agree Don't Remember Disagree

11. Was there any alternative(s) to the planned caesarean section discussed with you?

    Agree Don't Remember Disagree

12. If yes to Q 9 above, what was/were the alternative(s)?

    ……

    ……

    ……

13. Did you feel like you had the right to accept, refuse, or defer the caesarean operation to a time when you are ready?

    Agree Don't Remember Disagree

14. Were any extra procedures that might become necessary during your elective caesarean section i.e., blood transfusion or hysterectomy etc. discussed beforehand?

    Agree Don't Remember Disagree

15. Was there any particular procedure that you expressed that you did not want to be done on you whatsoever during the cesarean section unless discussed prior with you? Yes None

16. Were you informed of the available anesthesia and post analgesia options and was the recommended option(s) discussed?

    Agree Don't Remember Disagree

17. Was the implication of this planned caesarean section on your future pregnancy and birth (if you still desire pregnancy) discussed?

    Agree Don't Remember Disagree

18. Were you briefed on the outcome of your operation afterwards?

    Agree Don't Remember Disagree

19. If yes to Q14 above, what was discussed? (patient's own words)

    ……

    ……

    ……

20. When did the discussions about your planned caesarean section begin?

    ANC Visits Night to operation

21. In your next pregnancy (if you so desire), do you prefer or expect to deliver via:

    Vaginal delivery Caesarean section Not sure

22. Who obtained the informed consent from you?

    Nurse Clinical Officer Intern Medical Officer Intern

    Clinical Officer Medical Officer Resident

    Consultant. Don't know Don't remember

23. Approximately how long in minutes did the informed consent process take?

    ……

    ……

    ……

Appendix IV: KUREC Approval Letter

KABARAK UNIVERSITY RESEARCH ETHICS COMMITTEE

Private Bag - 20157
KABARAK, KENYA
Email: kurec@kabarak.ac.ke

Tel: 254-51-343234/5
Fax: 254-051-343529
www.kabarak.ac.ke

OUR REF: KABU01/KUREC/001/03/05/21

26th May, 2021

Simiyu Bramwel Wekesa,
Kabarak University.

Dear Wekesa,

SUBJECT: ETHICS REVIEW DECISION

Kabarak University Research Ethics Committee (KUREC) received application for a protocol titled "GAPS IN INFORMED CONSENT PROCESS AMONG WOMEN WHO HAVE UNDERGONE ELECTIVE CAESAREAN SECTION AT AIC KIJABE HOSPITAL, KIAMBU COUNTY KENYA" on 4th May, 2021. The protocol was reviewed and discussed during a virtual meeting held on 20th May, 2021 at 1000 Hours. The committee considered the application in accordance with the Kabarak University procedures on review of research protocols for ethical clearance and decided as follows:

1. **PROPOSED STUDY SITE**

   AIC Kijabe Hospital

2. **KUREC DECISION**

   Approved for data collection for a minimum period of ONE year from 26th May, 2021

This approval is subject to the following conditions:

i. The researcher shall obtain a RESEARCH PERMIT from NACOSTI before commencement of data collection & submit a copy to the Kabarak University Institute of Postgraduate Studies (IPGS);
ii. The researcher shall immediately notify KUREC in case of any adjustments to the protocol;
iii. The researcher shall within 7 days of occurrence notify KUREC of any adverse events associated with the conduct of this study;
iv. The researcher shall apply for extension of the study period should the initial 1 year expire before completion of data collection;
v. The researcher shall submit study progress reports to KUREC after every 6 months and a full report at completion of the study/project

Thank you.

Sincerely,

KABARAK UNIVERSITY
INSTITUTIONAL RESEARCH ETHICS COMMITTEE
26 MAY 2021
APPROVED
P.O. PRIVATE BAG - 20157, KABARAK

Prof. Jackson Kitetu PhD.

KUREC-Chairman

Cc Vice Chancellor
DVC-Academic & Research
Registrar-Academic & Research
Director-Research Innovation & Outreach
Institute of Post Graduate Studies

Appendix V: NACOSTI Research Permit

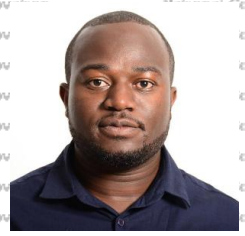
REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **705308**

Date of Issue: **09/June/2021**

RESEARCH LICENSE



This is to Certify that Dr.. Bramwel Wekesa Simiyu of Kabarak University, has been licensed to conduct research in Kiambu on the topic: Gaps in informed consent process among women who have undergone elective cesarean section at AIC Kijabe Hospital, Kiambu County, Kenya. for the period ending : 09/June/2022.

License No: **NACOSTI/P/21/11068**

705308

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

Appendix VI: AIC Kijabe Hospital Institutional Ethics and Research Review Committee Approval Letter

KIJABE HOSPITAL INSTITUTIONAL ETHICS AND RESEARCH REVIEW COMMITTEE

PO Box 20 Kijabe 00220, Kenya
Tel: 0709728200/637
Fax: 020-3246335
E-mail:researchcoord@kijabehospital.org
Website: www.kijabehospital.org

REF: KH/IERC/0009/2021 Date: 21/07/2021
PROTOCOL NO: KH/IERC/02178/0103/2021

Dear Bramwel Wekesa,

RE: STUDY TITLE: GAPS IN INFORMED CONSENT PROCESS AMONG WOMEN WHO HAVE UNDERGONE ELECTIVE CAESEREAN SECTION AT AIC KIJABE HOSPITAL.

This is to inform you that **KH IERC** has reviewed and approved your above research proposal. Your application approval number is KH/IERC/02178/0103/2021**.**The approval period is starting from 21/07/2021 to 21/07/2022.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KH IERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KH IERC within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KH IERC within 72 hours.

v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to KH IERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.keand also obtain other clearances needed.

Please do not hesitate to contact the AIC Kijabe Hospital IERC Coordinator (researchcoord@kijabehospital.org) for any clarification or query.

We wish you all the best in the study.

Thank you,

Yours sincerely,

Peter Halestrap.

BMBCh, MRCGP, DCH, DRCOG, MA (OXON)

Chair, AIC Kijabe Hospital IERC

Appendix VII: International Conference Participation Certificate

KABARAK UNIVERSITY

Certificate of Participation

Awarded to

Dr. Bramwel Simiyu

for successfully participating in the Kabarak University School of Medicine and Health Sciences & School of Pharmacy International Research Conference from 20th – 21st October 2021 and presented a paper entitled ***"Gaps in informed consent process among women who have undergone elective cesarean section at AIC Kijabe Hospital, Kiambu County. Kenya."***

Conference Theme

Transforming Healthcare In Africa

Dr. Pamela Kimeto
Dean, School of Medicine and Health Sciences

Dr. Moses Thiga
Director Research, Innovation and Outreach

Kabarak University Moral Code

As members of Kabarak University family, we purpose at all times and in all places, to set apart in one's heart, Jesus as Lord.

(1 Peter 3:15)

Kabarak University is ISO 9001:2015 Certified

Appendix VIII: List of Publication

Kabarak Journal of Research & Innovation
www.kabarak.ac.ke

RESEARCH ARTICLE

Gaps in Informed Consent Process Among Women Who Have Undergone Elective Caesarean Section at AIC Kijabe Hospital, Kiambu County Kenya

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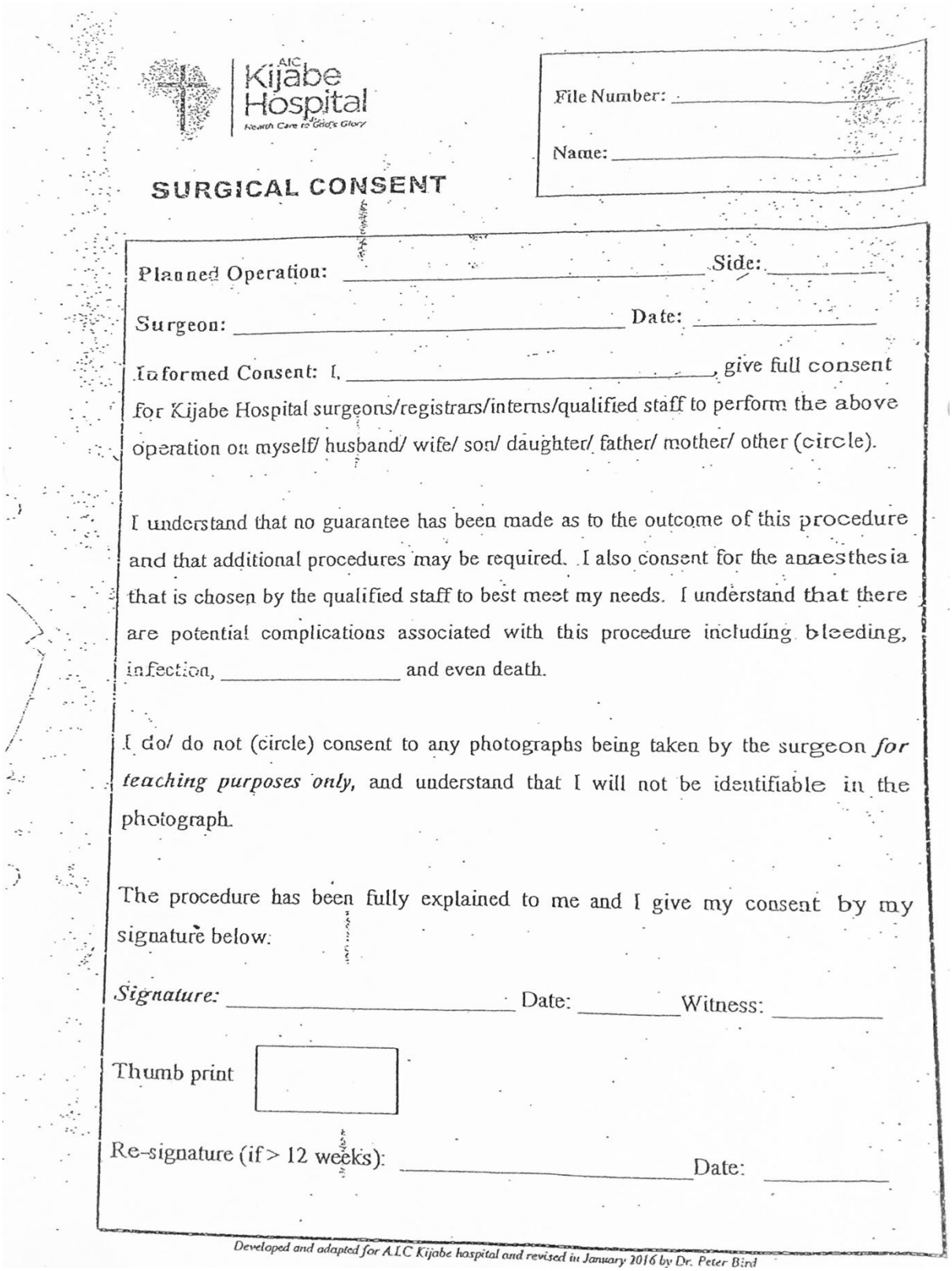
ABSTRACT

Informed consent for elective C-sections is both a legal and ethical requirement. It includes the patient's decision-making capacity, provision of adequate information, and voluntary consent. The aim of the study was to examine the informed consent process for elective C-sections at Kijabe Hospital with a focus on identifying gaps. The study design was cross-sectional and a structured questionnaire assessing 15 recommended elements of the informed consent process was administered to 137 women post-surgery. Descriptive statistics were used for sociodemographic data. The 15 elements of informed consent were aggregated and expressed in frequencies. Data were analyzed using Microsoft Excel and STATA. The results demonstrated excellent compliance with 100% of files having a signed consent form. However, documentation of the informed consent discussion(s) was not done in all cases. Infrequently addressed elements were; the benefits of surgery, post-surgery briefing and implications on future pregnancy at 59.1%, 57.7% and 67.9% of participants respectively. The average time spent obtaining consent was ten minutes. Of note is that patients' questions and concerns were addressed in 97.1% of participants. In conclusion, all other elements of the informed consent process were frequently addressed except, documentation of the process, benefits of surgery, post-operative briefing, and implications of the surgery on future pregnancy.

Key Words: elective cesarean section, gaps, informed consent

Appendix IX: The Generic AIC Kijabe Hospital Consent Form



AIC Kijabe Hospital
Health Care to God's Glory

File Number: _____

Name: _____

SURGICAL CONSENT

Planned Operation: _____ Side: _____

Surgeon: _____ Date: _____

Informed Consent: I, _____, give full consent for Kijabe Hospital surgeons/registrars/interns/qualified staff to perform the above operation on myself/ husband/ wife/ son/ daughter/ father/ mother/ other (circle).

I understand that no guarantee has been made as to the outcome of this procedure and that additional procedures may be required. I also consent for the anaesthesia that is chosen by the qualified staff to best meet my needs. I understand that there are potential complications associated with this procedure including bleeding, infection, _____ and even death.

I do/ do not (circle) consent to any photographs being taken by the surgeon *for teaching purposes only*, and understand that I will not be identifiable in the photograph.

The procedure has been fully explained to me and I give my consent by my signature below.

Signature: _____ Date: _____ Witness: _____

Thumb print

Re-signature (if > 12 weeks): _____ Date: _____

Developed and adapted for A.I.C Kijabe hospital and revised in January 2016 by Dr. Peter Bird

Appendix X: Written Permission from Dr David Lubansa to use questionnaire

From: David Lubansa dclubansa@yahoo.com
Subject: Re: Permission to use your THESIS Study Questionnaire
Date: 17 March 2020 at 07:10
To: Bramwel Simiyu brsimiyu@kabarak.ac.ke

Regards , ok I have seen it now . .The the questionnaire was not really validated . The adequacy was defined by me through my supervisor .
I have permitted you to use the work in your thesis . I will be interested in you sharing your findings with me .

Dr. Lubansa

On Friday, March 13, 2020, 11:01:05 AM GMT+2, Bramwel Simiyu <brsimiyu@kabarak.ac.ke> wrote:

Dear Dr. Lubansa,
I am Dr. Bramwel Wekesa from Kenya, currently undertaking my Master of Medicine in Family Medicine at Kabrak University, Kenya.
I have an interest in medical ethics and I am greatly interested in a study on informed consent for my master's degree.

I had previously contacted you at my topic picking level inquiring if I could use your questionnaire tool. Just a follow up to the same;

Requesting your permission to use the questionnaire tool
Requesting your permission to modify the questionnaire tool to suit our setting/ study needs.
Q: How did you validate this questionnaire, was it used elsewhere before you?
I see in your appendix 5- there is a description of "Adequacy", please share any new insights you have on this definition and the challenges you encountered when defending your thesis. how did you overcome those challenges?

+254 727270116 is my phone number and I may give you a call some time this week. Attached below is your study I am referring to;
Thank you and looking forward to your positive response.

Yours faithfully

Dr. Bramwel Wekesa
Family Medicine and Community Care Resident Kabarak University/ Kijabe Hospital, Kenya.

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