DETERMINANTS OF INFORMED CONSENT PROCESS FOR CESAREAN SECTION IN KIAMBU COUNTY, KENYA

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DECLARATION

Student Declaration:

This thesis is my original work and has not been presented for a degree in any other University

Signature…….Date……...

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Supervisors Declaration

This thesis has been submitted for review with our approval as the University Supervisors.

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DEDICATION

This masterpiece is devoted to my dear parent, Mrs. Tanui, for supporting me throughout the period in which the project was carried out.

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ABBREVIATIONS AND ACRONYMS

CS	Caesarean Section
FANC	Focused Antenatal Care
HCP	Health Care Providers
IC	Informed Consent
KL5H	Kiambu Level 5 Hospital
MOH	Ministry of Health
NACOSTI	National Committee for Science, Technology, and Innovation.
SPSS	Statistical l Package for Social Sciences
TL5H	Thika level 5 hospital

DEFINITIONS OF OPERATIONAL TERMS

Cesarean section: Surgical operation for delivering fetus through incision in mother's abdomen

Cognitive overload: it a situation that occurs in an individual when they are given too much information to learn simultaneously, leading to the inability of the person to process the information

Clinician: Health care worker working in the obstetrics department that include doctors, midwives, nurses and clinical officers

Companion -denotes to non-medical care of the laboring woman provided during labor and birth by a loved one.

Consent: Permission or agreement to do something, for example agreeing to an operation

Emotional overwhelm- it is a state of being upset due to intense emotions such as pain that becomes difficult for the individual to manage that affects the individual capacity to act rationally and think.

Ethical dilemma: - describes the paradox in decision making between two possible moral alternatives, neither of which is unambiguously preferable or acceptable that leads to the rise of situational conflict

Intellectually demanding: - Information that requires greater critical thinking and problem-solving that may impair their ability to identify and solve challenges creatively.

Labor pain- This is the discomfort and pain concomitant with contractions of the uterus during labor.

Postnatal woman – It refers to women in the period occurring between 12 to 72 hours after birth.

Respect of Autonomy/ Self-determination: Recognizing the ability of an individual to determine their actions or choices. It espouses concepts such as truth-telling and the informed consent process.

ABSTRACT

Cesarean section (CS) is the most commonly undertaken operation in women that is associated with significant mortality and morbidity compared to normal vaginal delivery. Informed consent (IC) respects the patient's autonomy, offers collaborative care. Consenting for CS in sub-Sahara Africa is suboptimal since women receive limited, vague or no information on what the CS entails. The elements of IC process were infrequently considered at AIC Kijabe Hospital. The study sought to determine how the patient-related factors, communication related factors, information-related factors influence consenting as well strategies for ethical decision-making on consenting for CS as highlighted by patients post-delivery and clinicians. The mixed-method cross-sectional study design sought to assess IC for CS among women who delivered between periods of 12 to 72 hours in two tertiary level government facilities in Kiambu County, Kenya. The investigator applied a systematic random sampling technique to select (N= 159) post-natal women to participate in the study. Closed and open-ended questionnaires were incorporated to obtain the required information as well as findings of focused group discussion of clinicians. Data was analyzed using a computer software statistical package for social sciences (SPSS) and Microsoft Excel and presented in descriptive statistics. Primigravidas were the majority participants with percentage of 37.7%. Most of the CS conducted in Kiambu County were emergencies at 69.9%. The findings indicated that as age and parity increase, the decision to have elective CS increases, going for elective CS was influenced by parity (18.7%) and age (8.3%) respectively. Patients with higher parity are more likely to understand the information given. Birth companion helped reduce the chances of experiencing emotional overwhelm particularly those who underwent emergency CS [r(156) =-0.230 p=0.004]. . Bivariate analysis showed the following factors were significantly associated with consenting process; active participation and information given on the consenting [r(158)=-0.345, p<0.001], companion and experiencing emotional overwhelm [r(156) =-0.230 p=0.004],parity and the ability to understand the information given [r(159)=0.162, p=0.041), Labor pain and active participation [r(111)=-.210, p=0.027). Active participation of the participant in consenting process contributed to better collaboration between clinician in making the decision for CS [r(83)=0.443, p<0.001]. The results demonstrated information given to participants was not balanced. The information given largely focuses on diagnoses and indication and less on benefits, risk, alternatives or the consequences of declining treatment. Antenatal consent was considered as a helpful strategy to consent for CS by 64.9% of the participants. The study found birth companion helpful in consenting; disclosure of information was partial, brief consenting time thus existing consent process has significant gaps but can be mitigated by antenatal consent. The study recommends clinicians to provide their clients with full information that focuses on diagnosis, available alternative treatment including benefits and risk. Clinicians should be trained on proper counselling to facilitate exchange of information for the patient or surrogate to make autonomous decisions. Antenatal visits are the appropriate time to engage the client about the possibility of CS delivery through integration within FANC program education as key component of birth preparedness.

CHAPTER ONE: INTRODUCTION

1.1 Background Information

Cesarean section (CS) is the most frequently performed operation in women of reproductive age (Akhter et al., 2020). The improvement in diagnoses and early referral has led to an increase in CS deliveries at tertiary- care hospitals. Despite this painting a clear picture of improvement in the health care system, it raises alarms and the need to crosscheck the system to counter any challenges such as active involvement of the patient in decision-making regarding indication, patient–education, the choice of operative intervention, and the procedure (Verma & Rajaratnam, 2023). Betrán et al., (2018) opine that it has been proven that CS is concomitant with more significant mortality and morbidity as compared to normal vaginal delivery thus making adequate counseling fundamental before consent can be acquired.

It is imperative to note that despite CS being undertaken in good faith of the client, it does not omit the outlook of consumer protection and awareness (Verma & Rajaratnam, 2023; Kirane et al., 2015). Informed consent (IC) is a well-established principle in modern medicine that respects the patient's autonomy as well as the significance of IC (Verma & Rajaratnam, 2023). For consent to be ethically valid, it ought to attain a particular essential criterion that is the decision-making competence of the participant, disclosure and comprehension of the appropriate information, the voluntariness of the resolve, and the documentation of the arrangement (Dhumale & Goudar, 2017). Acquiring a consent that is ethically binding using criterion while a woman in labor is puzzling since there is a limited time in labor to offer the patient-specific information about the proposed therapeutic intervention for the woman to comprehend and agree to sign the consent form (Dhumale & Goudar, 2017). Similarly, women in labor might be

distressed and anxious due to labor pains that may interfere with their ability to process or benefit from the information provided to them by healthcare personnel regarding the risks and benefits of the procedure (Bhushan & Manhas, 2022; Chervenak & McCullough, 2017).

Furthermore, the stress and anxiety that often accompanies pain and the labor process may make learning and remembrance more difficult. Obtaining legal, IC insinuates that the patient has considerable comprehension of the proposed procedure, including the risks and benefits (Verma & Rajaratnam, 2023). Concern and doubt exist regarding the laboring woman's capability to offer IC for CS during the labor process. Actual participation in the IC process for laboring women is difficult, which raises issues of the quality of consent obtained that may not meet the medico-legal aspect of the IC (Chervenak & McCullough, 2017). These sentiments by Chervenak and McCullough (2017) are consistent with findings of Bester, Cole, and Kodish (2016) who postulate that the cognitive overload due to anxiety and fear of labor may interfere with an individual ability to process and attend to information hence, leading to the development of ethical dilemma in seeking for IC in the labor process.

An ethical dilemma is a circumstance that an individual requires to decide between two or more options that are morally acceptable that he or she can morally and reasonably justify or the existence of the challenge with a sensitive satisfactory resolution (Ghaderi et al., 2018). Maternal health is a dynamic and exciting area of reproductive health practice. Nonetheless, the excitement is associated with ethical challenges that contribute to higher rates of litigation in obstetrics making it challenging for practitioners because they are expected to deliver collaborative and autonomous care to persons of all ages whereas conforming to ethical principles (Ghaderi et al., 2018). Clinicians are expected to offer evidence-based practice and safe care that is receptive

to the desires of women and significant others (Hamid, 2016). Lack of consent relating to obstetric surgical procedures such as CS as well as ineffective client provider communication have been identified as issues globally thus it downplays respectful maternity care for women undergoing CS delivery (Faysal et al., 2024). Based the study of Jacques et al., (2025) in France established that 36.6% of the respondents who underwent emergency CS birth did not give their consent primarily because the professionals failed to seek consent for CS more often for fetal complication as in comparison for obstetric indications.

Based on the findings of Faysal et al., (2024) they established obstetrics as specialty that is prone to risk of litigation and blame thus HCP place significant importance on acquiring a written consent to shield themselves in the event complication occur this symbolizing the transfer of liability to the woman. This has contributed to downplaying or partial disclosure of risk to mitigate on the refusal of the proposed CS (Faysal et al., 2024). Based on the study undertaken by Tripathy et al., (2020) in India found that though patient were generally informed concerning the procedure and risk of procedure established some aspects of IC were not covered in process due to the clinical situation or inadequate time. In Zambia only half of respondents were established to adequately consented (Simiyu, Adam & Horn, 2022). Based on an inquiry conducted by Stal et al., (2015) established that midwives in Tanzania acknowledges that most women who undergone CS did not know the indication for their CS

Ethics consists of defining what is right, good, and fair and they arise in every healthcare practice, which makes it fundamental for health care providers to ensure ethical delivery of care (Ali, Coonrod & McCormick, 2016). The current medical ethics and legal interpretation of IC demand that providers need to engage the patient concerning their medical condition including the proposed treatment (Verma &

Rajaratnam, 2023). It is fundamental to note that IC does not imply the signature on the document. Nonetheless, the dialogue occurs with the patient before they sign the consent form. It is no doubt that IC is a useful way that clinician's endeavor to fulfill their mandate to respect patient autonomy while promoting nonmaleficence and beneficence (Bhushan & Manhas, 2022).

Ethical principles act as a guide to ethical action that consists of four primary moral principles such as non-maleficence, respect for beneficence, autonomy, and justice that help uphold the rights of individuals and their families (Bhushan & Manhas, 2022).The dissertation proposed the need for rethinking the doctrine of IC among women that may need CS delivery. The study proposes strategies to acquire ethically valid consent from women seeking delivery services that may require CS operation.

1.2 Problem Statement

The impact of ethical issues in reproductive health practice particularly maternal health has attracted very limited attention resulting in moral distress for clinicians, unproductivity, poor professional care, and conflict (Değer, 2023). IC has public health significance since it helps in upholding of patient autonomy through promoting shared decision between the clients and clinicians, enhance trust of the healthcare system as well as protecting the dignity and right of individuals as they receive care (Bolado et al., 2024). IC promotes principle of autonomy by enhancing patient patient-centered care (Bolado et al., 2024). On the other hand, non-consent CS leads to erosion of trust in the healthcare system that may minimize the utilization of skilled birth services including promoting short-term and long-term risk for women and children (Bolado et al., 2024). Nithiyananthan et al., (2025) who undertook their study in UK at NHS Teaching Hospital in Central London found out that the consent process for Planned

CS lack the necessary and full disclosure of risk because it was either deficient or ill-timed to facilitate the women understanding of CS delivery risk. Faysal et al., (2024) and Zethof et al., (2020) established that counselling related to consenting for CS in sub-Sahara Africa was suboptimal since women were receiving, limited, vague or no information on what the CS procedure entails. Additionally, they found some non-consented CS (Faysal et al., 2024). Similarly, non-consent care is perceived as deterrent to the utilization of skilled birth care. The quality of IC particularly for obstetric interventions are seldom in developing nations (Ababulgu, Ethiopia & Bekele, 2022). Kenya has been undergoing exponential growth in the number of litigations concerning the practice of health care providers, which has contributed to the reduced motivation of providers, which is not different from other jurisdictions as found by Hamid, (2016). Simiyu, Adam & Horn, (2022) reiterate that gaps in IC process contribute to patient dissatisfaction, poor decision making as well as reduced adherence to care and treatment, which then influence on the rise of litigations.

According to the World -Health Organization (WHO) approximates, 10-15 percent of births require CS, however, Kiambu County has a higher rate of 25% making it the county with the highest CS rate in the country as compared to the national average of 13% (Otieno, 2019). Most of the CS occurs during work days, particularly on Friday, signifying that it maybe they are done at the expediency of providers (MOH, 2016). This raises an ethical dilemma if the CS is done does not respect women's rights to choose the circumstance of birth as well their right to self-determination. IC helps to improve positive birth experiences, safeguards against conceivable harms as well as reduce the occurrence of medico-legal issues (Faysal et al., 2024). Moreover, based on WHO their no evidence that child and maternal mortality improve when the rate goes above 10%. Anything that is above 15% infers the CS procedure is perhaps being

abused (WHO, 2023). Simiyu, Adam & Horn (2022) found that some elements of IC were infrequently considered at AIC Kijabe Hospital as patients underwent elective CS. They established that in all cases, the documentation of IC discussion was not done. The other elements of IC that were not addressed included implications of CS on future pregnancies, benefits of CS including post-operative briefing.

1.3 Justification

The findings of Aderemi (2016) posit that ethical issues across childbearing are manifold and complex that usually confront maternal health providers. To paint a clearer picture of the issues, statistics show Kenya had a crude birth rate of 30.9 births per thousand populations in 2017, which makes childbirth the leading cause of hospitalization (Kenya Demographics Profile, 2018). The Statistics from the Mid-term Targets of the Kenya Health Sector Strategic Plan 2014-2018 show that one in four hospital deliveries in Nairobi and Kiambu counties are by CS. The provision of care without IC could be considered unconstitutional and unlawful due to the violation of the patient reproductive health rights. The goal of the survey was to explore the consenting process for CS among women seeking delivery services. Other than building on the body of literature, the study benefits will help inform on quality care and approaches of providing IC to mothers pending CS that will enhance respectful maternity care. The benefits will also be crucial to relatives, communities, and health care providers by ensuring due diligence is observed in the consenting process for CS.

1.4 Research Questions

1. What patient-related factors influence the IC for CS as highlighted by patients post-delivery?
2. What communication-related factors affect the IC for CS as highlighted by patients post-delivery in Kiambu County?
3. What information-related factors affect the IC for CS highlighted by patients post-delivery in Kiambu County?
4. What are the strategies in decision-making used by reproductive health providers to protect patients from harm that experience difficult to consent for CS?

1.5 Objectives

The principal objective of the study was to examine IC process for CS in Kiambu County in Kenya.

1.5.1 Specific Objectives

1. To determine how the patient-related factors affect IC process for CS as highlighted by patients post-delivery
2. To establish how communication-related factors affect IC process for CS in Kiambu County.
3. To establish how information-related factors affect the IC process for CS in Kiambu County.
4. To identify the strategies in decision-making used by reproductive health providers to protect patients from harm that experience difficult to consent for CS?

1.6 Significance

The significance of the survey was to identify the priority ethical issues related to seeking IC facing women seeking delivery services as well as reproductive health

providers as they care for the patients, families, and community as they deliver health care. The study sought to come up with approaches for obtaining ethically defensible consent for women seeking delivery services.

1.7 Limitation and Delimitation

1.7.1 Limitation

The investigation took place during Covid 19 pandemic and due to the restriction instituted the researchers limited the time of interaction with participants. The researcher was limited in accessing funds to support the study activities as well data processing. The topic under exploration was sensitive, and some respondents were not be free to answers some questions.

1.7.2 Delimitation

The use of self-reported data was susceptible to several sources of bias because the responses were prone to attribution, selective memory, exaggeration, and telescoping. The researcher overcomes this weakness by use of systematic random mad purposive sampling design that helped in minimizing the biases and errors while representing the true population.

1.8 Theoretical and Conceptual Framework

The inquiry was based on the right-based theory that is concerned with placing the individual at the center, the independence of individual action by protecting the value of their personal choice. The principles of self-determination, accountability, participation, non-discrimination, and autonomy that are inherently based on the theory. John Locke advanced the theory, and it focuses on individual welfare (Nweke & Enemuo, 2021). This theory advocates for people to be given greater opportunities to

partake in influencing decisions that affect their human right as well upscaling the capacity of those with the obligation for gratifying the right to identify and discern how to respect those rights and take into consideration they are held responsible (Nweke & Enemuo, 2021). The theory is about safeguarding both the principles and standards of human rights as incorporated into policy-making including every running of organizations.

The Conceptual framework describes the interplay between the dependent as well as confounding variables to influence the application of the doctrine of IC (*see Figure I.1*). The patient-related factors such as emotional overwhelm, intellectual ability, cultural and religious factors including the presence of a companion in labor are considered to affect the quality of discussion in seeking IC. Similarly, provider's related and institutional-related factors such as professional judgment, emotional state, available time, language complexity, and workload may largely influence the process of seeking consent.

Information-related factors: These depend on how complex and scientifically advanced is the information including how it is intellectually demanding that requires a greater threshold for the capacity of individuals to offer consent.

Communication-related factors: These factors are influenced by clinician skill in communicating complicated medical information such as by the use of decisional aids, communicating complicated concepts in easy language for aiding patient comprehension as well as increasing decisional time-frame. The clinician's skill in communication is fundamental in promoting understanding and decreasing the effect of emotional overload. In conclusions, an ethically defensible consent is anticipated to

respect the standards and principles of human right such as protecting patient autonomy, non-discrimination, self-determination, and respect of patient dignity.

On evaluating the validity of the consent, the researcher developed a score criteria based on participants responds. The researcher sought to check whether the five parameters of IC was attained which include documentation, disclosure, voluntariness, comprehension and competency by scoring against each of these parameters.

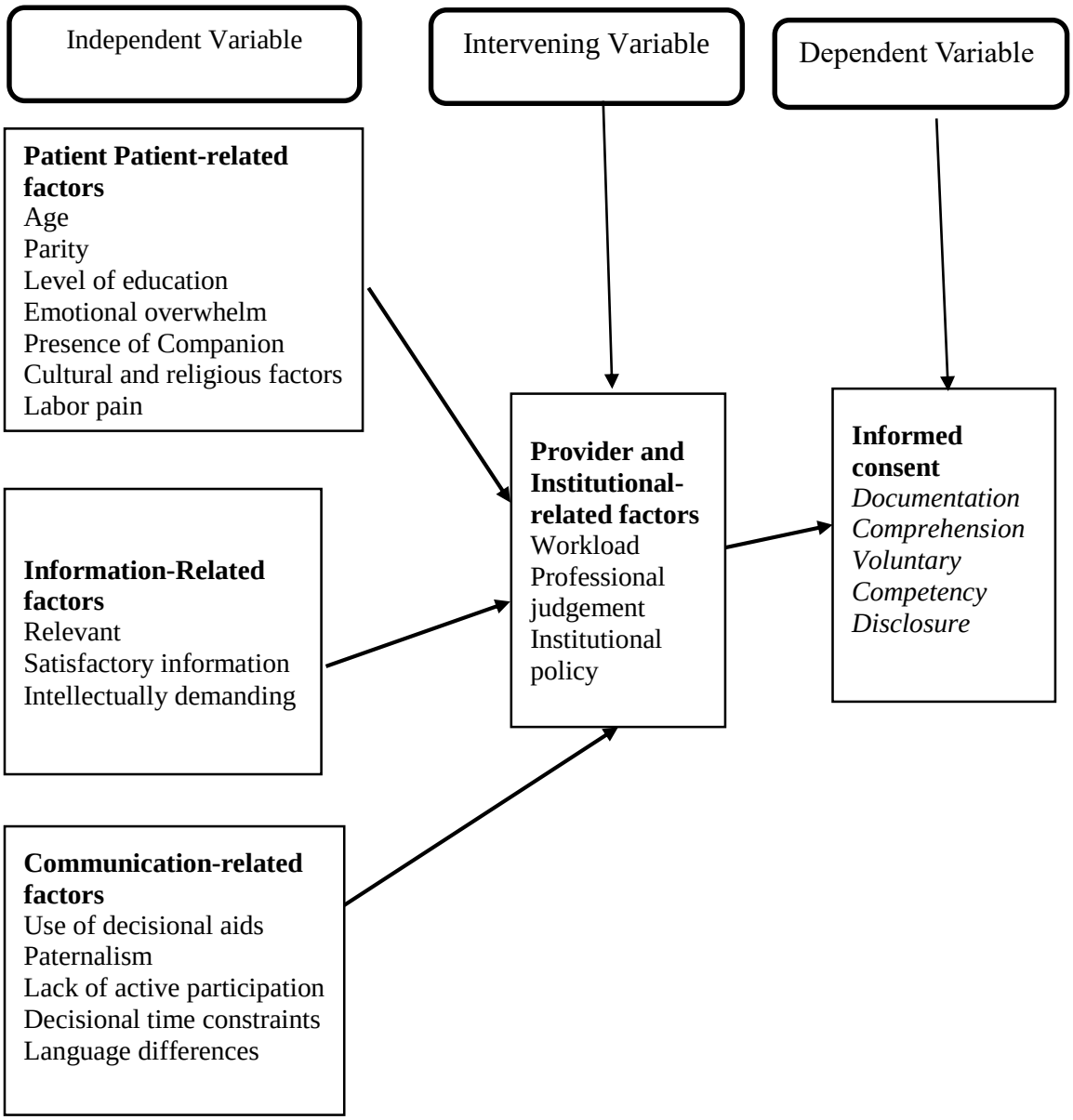

Figure 1.1: Conceptual Framework

Source Author (2025)

CHAPTER TWO: LITERATURE REVIEW

The empirical literature search was accomplished by the use of databases such as Google Scholar, MEDLINE, Embase, CINAHL, and PubMed by use of key terms like 'informed consent", "cesarean section" "ethical and valid consent'. The literature search was organized into major themes identified in the literature search.

2.1 Principles of Informed Consent

2.1.1 Scope of Informed Consent

IC is an important and reflective practice that ensures respect for human subjects in which patients are given a chance to voluntarily agree to medical intervention after sufficient disclosure of the description of the therapy (Birkeland, 2017). The IC procedure recommends for an occasion to move beyond doctor disclosure of information to an approach of shared decision making amid the physician and patient (Bakker et al., 2021; Kirane et al., 2015). Similarly, IC should be obtained in a voluntary manner that allows to them have the appropriate documentation of the IC process, which ought to be dated and signed by the subject or rightfully sanctioned representative and a witness who attest with their signature to the correctness of the consent practice (Glaser et al., 2020; Menendez, 2013). The individual must have adequate information concerning the procedure to able to answers all questions posed by the subject. The existing requirement is that the subject is informed of the benefit, risk, and alternative to the proposed treatments grounded on the increased value of patient autonomy (Bakker et al., 2021). Whenever a patient approves of the treatment modality a simple consent is the predominant ethical commitment for healthcare providers to act with beneficence towards the patient (Birkeland, 2017). Based on study undertaken by Tripathy et al., (2020) found some patient received explanation about the indication, whereas the risk, procedure and benefits of the operation were not

communicated properly. Ababulgu, Ethiopia & Bekele (2022) undertook a study to assess the quality of IC for CS in Ethiopia established that women who had undergone CS received inadequate IC for both planned and emergency CS. Kenya has guidelines on best practices for counselling on IC that reflect its preconditions before any CS is conducted (Faysal et al., 2024). Similarly, Simiyu, Adam & Horn, (2022) were able to determine that benefits of CS and post-operative briefing were not done in virtually half of planned CS that were performed at AIC Kijabe hospital.

2.2 Informed Consent Delivery Methods

Some of the approaches of delivering IC for invasive `procedures tend to differ among diverse surgeons and even among patients. The traditional processes included the use of oral dialogue between the patient and health provider ensued by the individual ratifying a document to confirming their consent (Birkeland, 2017; Menendez, 2013). Truong et al., (2020) and Kirane et al., (2015) opines that written documents and oral communication remain the commonly used methods. Likewise, videos and computer software may be utilized to unveil essential information required to acquire valid IC (Hall et al., 2017). Indeed, any delivery technique might be utilized as long as it facilitates offering the patients with risks, indications, benefits, and alternatives concerning the intended procedure (Birkeland, 2017). Based on empirical literature search their various approaches of obtaining valid consent from mothers for consent for perinatal care which includes

2.2.1 Antenatal Consent

Researchers postulate that some patients would have a preference for antenatal consent as opposed to consent during labor and they would like the information concerning the procedure given earlier in pregnancy even if they would not require it (Levett et al.,

2020). Nonetheless, Bam et al., (2021) contradict Levett et al., (2020) by stating that some patients were not entirely cozy with antenatal consent since they questioned the significance of the information and were not completely comfortable with antenatal consent since some of them were of the strong conviction it will never happen to them. Likewise, they also stated that it tends to increase the burden or anxiety if they are told earlier in pregnancy about CS. According to Wilson et al., (2018) reiterates some patients were comfortable with consent in labor but on the other hand, it offers a burden to the staff on limited time. Moreover, Smith, Levy & Yudin (2018) reiterates that provisions of antenatal consent counseling during the prenatal period showed that women had better retention and recall of intrapartum procedures. Indeed, 96 percent of their respondent's supported acquisition of IC before the onset of labor when there was adequate time for processing of information, which concurs with sentiment of Loeff & Shakhsheer (2021) that antenatal consent for interventions that can be applied during labor can help to foster patient empowerment and knowledge retention.

2.2.2 Surrogate Decision-making

Laws and statutes exist that offer guidance on how health institutions offer IC for a patient that lacks capacity (Truong et al., 2020). The designation of the health surrogate does not elapse and stays effective till the patient revokes it. In Kenya, when the patient is unable to give consent, an exception may be given when their risk to life, sight, or limb that is looming and next of kin is not sited. Then, in this scenario, at least two doctors should approve for the need for the life-saving treatment and they ought to declare in writing that they have accepted the obligation of consenting on behalf of the client by acting in their best interest. However, if the patient's situation is not an emergency, then the court ought to choose a guardian to decide on behalf of the patient (Bosire, 2017).

2.3 Factors that Impede Seeking of Informed Consent

2.3.1 Information-Related Factors

Bakker et al., (2021) reiterate that to give viable consent the recipient of care must receive the relevant information that should be satisfactory and may involve giving them information sheets that help them in making decisions. A consent form may serve as the meaningful education tool that health care workers may use as a springboard to an essential discussion concerning what to expect before and after surgery (Chervenak & McCullough, 2017).

The health care providers may use the IC process beyond notifying the patient of risks but essentially to educate the patient that might assist to reduce liability by helping to develop an alliance between the surgeon and the patient (Levett et al., 2020). Truong et al., (2020) echo the adoption of an educational approach to seek consent evolved from a waiver of responsibility to an educational tool. The consent form should essentially serve as proof that proper discussion between the clinician and the patient transpired but it should not act as a replacement for the vital dialogue and patient education (D'Souza et al., 2019; Joolaee, Faghanipour & Hajibabaee, 2017).

IC process can be limited by factors such as informational overload that may undermine the decision-making capacity of an individual since they might have experienced informational overwhelm and thus may require alternative models of making medical decision (Kassam et al., 2023). Eeckhout, Aelbrecht & Van Der Straeten, (2023) reiterates that in some clinical context the nature of information is scientifically advanced such that the patient capacity and understanding for making decision is overwhelmed, therefore making IC impossible. Based on Kassam et al., (2023) patients whose decision-making-capacity is compromised or who are overwhelmed they are at

risk of making harmful decision for themselves even without noticing it. They may also be prone to risk of having their values compromised since a patient with compromised decisional capacity could make a choice that is essentially not consistent with their values as advanced by Eeckhout, Aelbrecht & Van Der Straeten (2023). Providing patients with information that is intellectually and scientifically demanding may predispose them to cognitive overwhelm because the information is complex that demands for higher threshold of capacity for patient to offer consent (Kassam et al., 2023). Gesualdo et al. (2021) is in agreement with Kassam et al., (2023) by postulating that some medical information such risk can consist of probability estimates that need training to comprehend fully and tax the capacity of the patient to deliberate and understand.

2.3.2 Patient-Related Factors

The understanding of the information offered is a prerequisite for acquiring IC and the patient should exhibit full comprehension, nonetheless, the practical applicability of the ideal might be challenging in execution (Joolaee, Faghanipour & Hajibabaee, 2017). Several factors such as pain, anxiety, and various therapeutic interventions may interfere with the patient's capability to partake in shared decision-making. Faysal et al., (2024) found that labor pain acted as barrier to counseling process for CS by inhibiting communication, which is consistent with sentiments Bakker et al,.(2021) that labor pain negatively impacts on women decision making capacity. Bakker et al., (2021) reiterates that labor pains tend to complicate consent process by acting as communication barrier particularly in high and low-income settings. According to Ali, Coonrod and McCormick, (2016) women in labor tend to anxious and stressed due to labor pain that makes some of them resort to desperation. Health care workers tend to sometimes elude acceptable consent negotiations since they do not desire to frighten

the patient or upsurge their anxiety. Hence, to circumvent detrimental patient anxiety, health care workers might fail to entirely to reveal satisfactory information required for shared decision-making (Loeff & Shakhsheer, 2021; Aderemi, 2016).

In Somalia women with no formal education were found to have higher likelihood for them to rely on their families to engage in IC process in comparison to educated women who are more likely to make the decision independently (Faysal et al., 2024). This finding seems to concur with study undertaken in Tanzania and Malawi which ascertained that women with low level of education tend to be uninformed concerning their rights and thus they anticipated the clinicians to make clinical decision on their behalf with limited consenting counselling (Faysal et at., 2024; Bakker et al., 2021; Litorp et al., 2015).

Cultural and religious factors were found to have a bearing on Somali women ability to consent for CS since the community did not trust the indication for CS because the procedure is concomitant with limiting the number children the women can bear including occurrence of stillbirth, hysterectomy and death (Faysal et al., 2024; Abdillahi et al., 2017). Based on a study undertaken by Bakker et al., (2021) found that the competency or the capacity of an individual to convey valid consent is perhaps altered by factors such as their emotional state as well the degree of understanding achieved. Based on study undertaken by Smith, Levy & Yudin (2018) they established that women in labor in United Kingdom did not meet all elements of capacity as stipulated by Mental capacity act despite the women feeling they received satisfactory information to make their choice, they did not essentially gratify the whole criteria of capacity. It is imperative to note that the ethical importance of IC is founded on the outlook that the process offers a patient a chance to exercise their autonomy since the moral right to follow and choose their own actions and life (Glaser et al., 2020). It is

fundamental to appreciate that IC epitomizes a puzzling dilemma for health providers because to create an operational IC process they need to seek to balance their commitment to guard the individual's health through beneficence including their mandate to value patient's autonomy (Loeff & Shakhsheer, 2021; Kirane et al., 2015). The ethical principle of self-determination is a subclass of autonomy often concomitant with IC. Through self-determination, a choice to consent for the surgical procedure ought to begin at will from an autonomous individual that understands the realities and can partake in practical thinking to render that decision (Askren & Leslie, 2019).

Smith, Levy & Yudin (2018) postulate that labor is very unique for gravid women because it may be cumbersome to separate woman's decision from those of their companion or their family members that make it difficult to obtain IC in such a setting. Likewise, Ferede et al., (2024) found out that women who receive continuous emotional support from a birth companion, family, husband or community tend to improve on consented care and childbirth outcomes in Ethiopia. Eeckhout, Aelbrecht & Van Der Straeten, (2023) opines that a trusted and confidant or companion may minimize anxiety or fear from interfering with patient capacity to process and attend to information given for IC that build patient ability to make competent judgements. Patient factors such as multiparity can impact their perception of IC, thus clinicians should tailor their communication while being cognizant of their literacy and foster understanding of the management options (Smith, Levy & Yudin, 2018). Young children lack the capacity to decide on medical decisions (Eeckhout, Aelbrecht & Van Der Straeten, 2023)

2.3.3 Communication-Related Factors

Health care workers might attempt to safeguard patient rights and autonomy through suitable involvement in the IC process. Nonetheless, conformity with regulatory and legal necessities including ethical, patient, and family anxieties can make the process of IC perplexing and thought-provoking (Loeff & Shakhsheer, 2021). Shared-decision making encourages the involvement of women as it gives them a feeling of being in control as well as foster their relationship with the clinicians. Shared decision is facilitator of positive birth experience thereby promoting respectful maternity care (Zethof et al., 2020). Similarly, Bakker et al., (2021) reinforces the concept of active involvement of the patient by postulating that care should not compromise individuals' choice, and thus women should be given the freedom to decide whether the recommendations are consistent with their values and beliefs. Smith, Levy & Yudin (2018) considers shared-decision making as the gold standard as it offers clinicians a structural framework to explain the benefits, alternative treatment, and risk before the patient makes their choice. Besides, misunderstanding occurs about the crucial discrepancy between a signature on the authorization form and the individual IC. The delusion that IC is equal to the signature on the consent form can be cumbersome for health care workers that are commonly tasked with the responsibility of enabling the legal documentation of the form (Birkeland, 2017).

The participant's voluntary choice to participate is concerned with the safeguarding of the patient's right to generate health care choices that are free from undue influence or coercion (D'Souza et al., 2019). Undue influence happens when there is an offer of an improper or excessive reward to attain compliance while on the other hand, coercion occurs when there is a threat of harm to the patient when they do not comply (Lepping, Palmstierna & Raveesh, 2016).

Indeed, the Helsinki declaration of 1964 provides that the process of acquiring IC is a voluntary procedure for those with capacity and proxy consent for those that lack the capacity for example minors (Schulte, 2020). Free choice mandates that there is no distortion of information, manipulation, or omission. Persons should be entitled to the freedom to make choices and those that are unable to self-determination would be protected. The voluntary nature of the patient's decision is determined by the strength of the will of the patient that is largely influenced by fatigue or, pain and the relationship of the persuaders (Askren & Leslie, 2019).

Moreover, an ethical tension may arise between the practice of paternalism in health system and respect for patient autonomy. Whenever health care providers espouse paternalism throughout the IC process, they ignore or override individual preferences to enhance or benefit their welfare (Zethof et al., 2020; Lepping, Palmstierna & Raveesh, 2016). Ethically paternalism denotes that the clinician considers that beneficence is more critical as compared to autonomy (Dworkin,2015). Paternalism may be manifested by health care workers' influence underestimating the patient's independent decision-making. Nonetheless, the provider's proposals have a vital part in the IC process, yet health workers could interfere with the individual's objective frame of reference by perversely highlighting the risks or benefits of the procedure (Bakker et al., 2021). On the other hand, health workers may display paternalism by overstating the seriousness of patient state or switching descriptive vocabularies for quantifiable vocabularies through the IC process (Chervenak & McCullough, 2017)

Therefore, the patient's decision to undergo a procedure needs to be a true reflection of their autonomy that only happens when health care providers disclose objectively and fully all the information (D'Souza et al. 2019). This will encourage individuals to make their decision indecently when they are free from any amount of manipulation,

coercion, or undue influence (Zethof et al., 2020; Hallinan et al., 2016). Based on criminal law consent that is acquired through intimidation and threats for a medical procedure is not valid and instead, the patient should be given the decision to accept or reject a treatment freely without undue influence or coercion (Loeff & Shakhsheer, 2021). Time constraint was found to be justification for clinicians in Malawi to forego counselling for CS thus rescinding the women right to autonomy and self-determination (Bakker et al., 2021). Nonetheless, for these cases they sought the help of guardians to offer written consent on behalf of the women who were to undergo the CS whom they consider to lack capacity or even performed the emergency CS without their written Consent (Bakker et al., 2021). This findings of Bakker et al., (2021) are in agreement of the results of Lange et al., (2016) who postulated that in Benin time constraints made clinicians to prioritize emergency over the counselling of women. The findings of Bakker et al., (2021) concurs with D'Souza et al., (2019) and Hallinan et al., (2016) that time factor might limit the competence and capacity in a certain situation due to its bearing on their ability, in the circumstance to the decisions.

Bakker et al., (2021) deduced that language difference between the clinicians and women made counseling for consenting difficult because the majority of the health care worker in the rural hospital in Malawi spoke Chichewa as opposed to the women who spoke Chiyao because most them belonged to Yao ethnic group.

Smith, Levy & Yudin (2018) found that delivery discussion for IC can be more informative and consistent by use of decisional aids. The aids can be generated in the form of decisional boards, information cards or in the form of pamphlet that are intended to complement rather than replace counselling by clinicians. The use decision aid was established to improve knowledge retention as well reduce decisional uncertainty among women in labor (Smith, Levy & Yudin, 2018). Mesri, Nzenwa, &

Lunevicius (2021) is in agreement with findings of Smith, Levy & Yudin (2018) that the use of decisional aids in clinical practice help in process standardization of discussion for obtaining IC by not relying on the memory of doctors that may contribute in heterogeneity of information given to clients. These decisional aids acted as standardized documents for discussion before CS thus minimizing heterogeneity. Similarly, Bakker et al., (2021) found decisional aids to be helpful during emergency situation since it helped clinicians to use the resources such as the pre-prepare consent document to guarantee that clients receive adequate information.

2.4 Summary of Literature and Gaps Identified

Based on the literature search it is distinct that there exist gaps in the process of obtaining IC for women that undergo CS. This is primarily because the patient's capacity is threatened by patient factors, information factors and communication factors that may impair that use and attainment of IC despite the existence of international guidelines and codes. The ideal state of IC is that the information provided is accurate, comprehensible, and given in a free manner. Research studies in IC are limited in Kenya and this inquiry strives to fill this gap. It is essential to determine the strategies for seeking IC for women seeking delivery services considering that it is an understudied area of ethics. The thesis sought to look into how these issues play out for women in Kiambu County.

CHAPTER THREE: METHODS AND MATERIALS

This section delves into the research design, study variables, location of the study, sampling techniques, sample size determination, data collection instrument, and ethical considerations. The methodology describes how the researcher explored the process of consent by capturing the experiences and views of the respondents.

3.1 Research Design

The investigator embraced an explanatory mixed-method design since it used both descriptive, analytical and explorative approach that offers the respondents ability to describe, identify, and explore their experiences and views that helped in advancing practical and theoretical knowledge by suggesting viable interventions for dealing with ethical dilemmas in seeking IC. Descriptive, analytical and explorative approach aided to provide insights through description and definition of the problem. It also helped to detail the causes and consequence of the identified problem. Hence, these assists women seeking delivery services provide ethical and valid consent regarding CS and other invasive procedures.

3.2 Location of the Study

The investigation was undertaken in Kiambu County, Kenya. It traverses an area of 17,944 sq km and an estimated population of 1,002, 968. It consists of 12 sub-counties namely: Thika east, Thika west, Gatundu North, Gatundu South, Juja, Ruiru, Kiambu, Lari, Kabete, Limuru, Githunguri, and Kikuyu. The study was carried out in two teaching hospitals Thika Level 5 Hospital (TL5H), Kiambu Level 5 Hospital (KL5H) located in Thika west, and Kiambu sub-counties respectively. The study took place in the two tertiary hospitals that provide specialized obstetric care selected using cluster sampling.

3.3 Study Variables

3.3.1 The dependent variables

IC measured against parameters such as documentation, disclosure, voluntariness, comprehension and competency.

3.3.2 The independent variables

Patient-related factors, information-related factors and communication-related factors.

3.4 Study Population

The study population was conducted on postnatal women who underwent CS due to a myriad of reasons to ascertain the function of the policy of IC. The study population was postnatal women in selected hospitals in Kiambu county hospitals that have had underwent CS delivery between 12 hours and 72 hours.

3.5 Inclusion and Exclusion Criteria

3.5.1 Inclusion Criteria

The postnatal women who were between 12 to 72 hours post-delivery, who underwent CS in selected hospitals of research.

3.5.2 Exclusion Criteria

Postnatal women who were between 12 to 72 hours after delivery who underwent CS in selected hospital of study who are mentally or critically sick

Postnatal women who were between 12 to 72 hours after delivery who underwent CS but the consent of operation was given by companion or any other party.

Postnatal women who were between 12 to 72 hours after delivery who underwent CS but did not consent to participate in the study.

3.6 Sampling Technique and Sample Size

3.6.1 Sampling Technique

The two tertiary hospitals were selected using cluster sampling. The researcher adopted proportionate sampling to get the anticipated number of respondents from each hospital. Purposive sampling was utilized to choose a specific number of study participants from each postnatal ward based on their physical and emotional state. This involved selecting a respondent that meets the inclusion criteria from the postnatal women who were present in the postnatal ward till the sample size was realized.

3.6. 2 Sample size determination

The following formula was used for determining the sample size (Fischer, 1998)

$$\mathbf{n = \frac{z^2\ p\ q}{d2}}$$

Where: **n** is the desired sample size

p is the proportion of the population estimated to have the characteristic of interest, which is 10 Percent.

q = 1-p

z is the standard deviation set 1.96 and corresponds to a 95% confidence interval

d is the level of statistical significance set i.e. the measure of accuracy desired set as 0.05

$$= \frac{1.96 \times 1.96 \times 0.1 \times 0.9}{0.05 \times 0.05}$$

$$= 138.29$$

A sample of 160 participants was used to gather for non-respondents calculated by use of 15% non-response rate.

The distribution of the sample relied on the number of spontaneous vaginal deliveries as well as the number of CS deliveries in the two hospitals

Table 3.1 Distribution of Sample Size

The number of CS deliveries among the two selected hospital distributed in the period of July-September of 2019	Number of CS deliveries	Distribution of the sample
TL5H	618	86
KL5H	516	74

3.7 Construction of Research Instruments

A structured questionnaire with pre-coded probable answers on Kobo collect was utilized to collect data from postnatal women. Qualitative data was collected from two focused group discussions of reproductive clinicians that was composed of doctors, midwives, nurses and clinical officers in which their responses was then recorded on focused group discussion guide (n=6) one team from each participating hospital.

3.8 Pre-testing

Pre-testing of the survey instruments was done in Murang' a hospital, Murang' a County by use of sample of 15 individuals with 13 of them being women who had undergone CS and 2 reproductive health clinicians to correct any inconstancies in the research tools in, which anomalies and errors were modified appropriately that in consistent with recommendation of Creswell & Creswell (2023) that pretesting of research instrument, procedures and questions ensure they yield meaningful results as well as guarantee they are well- designed.

3.9 Validity

The data collection instruments were pretested using a small sample that helped to identify biases and other issues before the main study. The use of SPSS was an appropriate statistical test for analysis of the results. The sample distribution was based on established workloads of the two participating facilities thus ensuring representative sample that is essential for generalizability of results.

3.10 Reliability

The research adopted a robust sampling technique that ensured the sample was representative of the study population. The study tools were standardized after pretesting that ensured they were consistent to assess each parameter of the IC. The research assistants recruited in the study were trained about the research instrument and procedures. They were also given adequate time to familiarize themselves with user interface of Kobo collect.

3.11 Data Collection Techniques

The investigator worked with three research assistants that helped to identify the appropriate patient files, patients, and reproductive health clinicians from the maternity department. Once the decision that a particular patient meets the inclusion criteria in the study, the research participant was selected using purposive sampling. The researcher undertook a secondary data collection by extracting information from the files with the data collection tool acting as a guide, the relevant information was recovered from the file and recorded on the appropriate study tool.

3.11.1 Quantitative Data Collection Procedures

Three research assistants, who are primarily professional midwives, interviewed respondents and recorded the responses on the questionnaire as provided by the respondents as well as gather the quantitative data. The gathering of quantitative data took place between 12 to 72 hours following CS delivery. The research assistants also obtained information on patient files, which include consent for the general maternity care and CS delivery, determine if the CS operation was planned or unplanned (emergency), and when it is was unplanned, they ascertained the dilatation of the cervix when the decision for CS was arrived.

3.11.2 Qualitative Data Collection Procedures

The collection of qualitative data was through a focused group discussion guide, the questions helped get in-depth information on the subject matter from the clinicians of reproductive health services in the two participating hospitals who composed of medical doctors, midwives, nurses and clinical officers. The sessions were recorded to facilitate data storage that were later transcribed and placed in themes for analysis. The collection of data took place in a quiet room within the wards that enabled privacy. The researcher ensured no one is allowed into the room during the interviews.

3.12 Data Analysis

Data analysis was accomplished using SPSS version 22 software to carry out descriptive statistics, chi-square, and bivariate logistic regression. The variables for deliberation in logistic models to ascertain elements by indicative bivariate relationships ($p<0.05$). The report of data was prepared using tables, graphs, and charts that summarized quantitative data

3.13 Logistical and Ethical Considerations

Approval of the inquiry was attained from the Kenyatta University (KU) graduate School, KU ethical review committee, and National Committee for Science, Technology, and Innovation (NACOSTI). Clearance was acquired from the county director of research and the medical superintendents of the participating hospitals.

Electronic consent was provided for each respondent. Confidentiality of the collected information was guaranteed by enforcing the anonymity of the respondents. The interview with participants was conducted in a private setting within the ward. Similarly, participants' names were not recorded in the survey tool but instead, they were pre-coded with unique codes. The filled questionnaires were only accessed by the principal researcher since the Kobo collect had password. The data collected was only used for research purposes. Therefore, to promote disclosure, the researcher informed participants the information they gave would not be used against them or the health care provider for any legal action, but it would help in future improvement in the process of seeking consent among women who undergo CS delivery.

The participants were not coerced, intimidated, or blackmailed to partake in the inquiry. Similarly, their autonomy to participate was further heightened by allowing them the freedom to pull out at any point during the study if they so desire. Moreover, the participants were informed of their right to decline to answer any question they feel is undesirable in the process of interviewing.

CHAPTER FOUR: RESULTS

4.1 Introduction

The chapter offers the results that are organized in line with the objectives. A total of 159 of the targeted N = 160 respondents completed the survey with 54.1% (86) from TL5H and 45.9% (73) from KL5H giving a response rate of 99.38%.

4.2 Social-Demographic and Obstetric Characteristics of the Participants

The mean age of the respondents was 26.83 with an SD of 5.40. The bulk of the participants were aged between 18-24 years 39.6% (63) trailed by those aged 25-29 years at 27.7% (44). The majority of the participants were married 76.73% (122), trailed by 21.38% (n=34) who were single. The data demonstrated most of the respondents had attained secondary education 42.77% (68) followed by 36.48% with tertiary education. Based on the place of residence, the majority of the participants 69.8% stated to reside within an urban area.

Table 4.1 Summary of Demographic Characteristic of the Respondents

Variables		Frequency	Percent (%)
Age	18-24	63	39.6
	25-29	44	27.7
	30-34	36	22.6
	35-39	12	7.5
	40-44	4	2.5
Marital status	Married	122	76.7
	Single	34	21.4
	Separated	2	1.3
	Divorced	1	0.6
Highest Level of Education	Secondary	67	42.1
	College/University	58	36.5
	Primary	33	20.8
	None	1	.6
Religion	Christian	157	98.7
	Muslim	1	.6
	Traditionalist	1	.6
Place of residence	Urban	111	69.8
	Rural	48	30.2

4.2.1 Obstetric Characteristics of respondents

The distribution of participants by parity displayed in Table 4.2 shows that primigravidas were the majority with a percentage of 37.7% followed by para 2 with a frequency of 28.9%. The findings have demonstrated that most of the CS conducted in Kiambu County were emergencies at 69.9% with only 30.2% elective CS delivery. Most of the emergencies 34.6% were conducted in the latent phase of labour when the dilatation of the cervix was between 0-3 cm

Table 4.2 Summary of Obstetric Characteristics of participants

Variable	Sample Size	Frequency (%)
Parity		
Primi-gravida	60	37.7%
Para 2	46	28.9%
Para 3	36	22.6%
Para 4	11	6.9%
Multipara	6	3.8%
Caesarian Section		
Emergency CS	111	69.8%
Elective CS	48	30.2%
Dilation at Emergency CS		
≤ 3 cm	55	34.6%
4 – 6 cm	39	24.5%
≥ 7 cm	17	10.7%

4.3 Documentation of the Care

Based on the review of participants' records 57.9% had documentation of consent for general maternity care while 100% of the participants had documented of consent for CS operation on both study sites.

4.4 Patient-Related Factors on Consenting Process

Based on the results 67% (n=106) of the respondents stated that they were in a good emotional state they could understand the information while on other hand, while 30% (n=47) stated they experienced an emotional overwhelm thus they could not grasp the information given. Seventy-five percent (n=119) of participants stated emotional

overwhelm did not affect their ability to consent for CS whereas, 78% (n=124) claimed that they did not find the information given for consent to be intellectually demanding thus they could easily understand it.

The majority of the participants 54.1% (n=86) confided that they did not have a birth companion. A significant majority 67.6% (n=48) of those with a birth companion stated that having a companion helped guide them in the consenting process. Among the respondents who did not have a companion most of them 51.2% (n=44) considered that if they had a birth companion would have been helpful in the consenting process for CS. Most of the participants 63.3% (n=99) in the inquiry stated that they did not seek assistance in reaching the decision whether to accept or reject CS while 36.5% (n=58) sought assistance whether to accept or reject CS with a majority of them 72.4% (n=42) seeking assistance from birth companion followed by relative 13.8% (n=8)

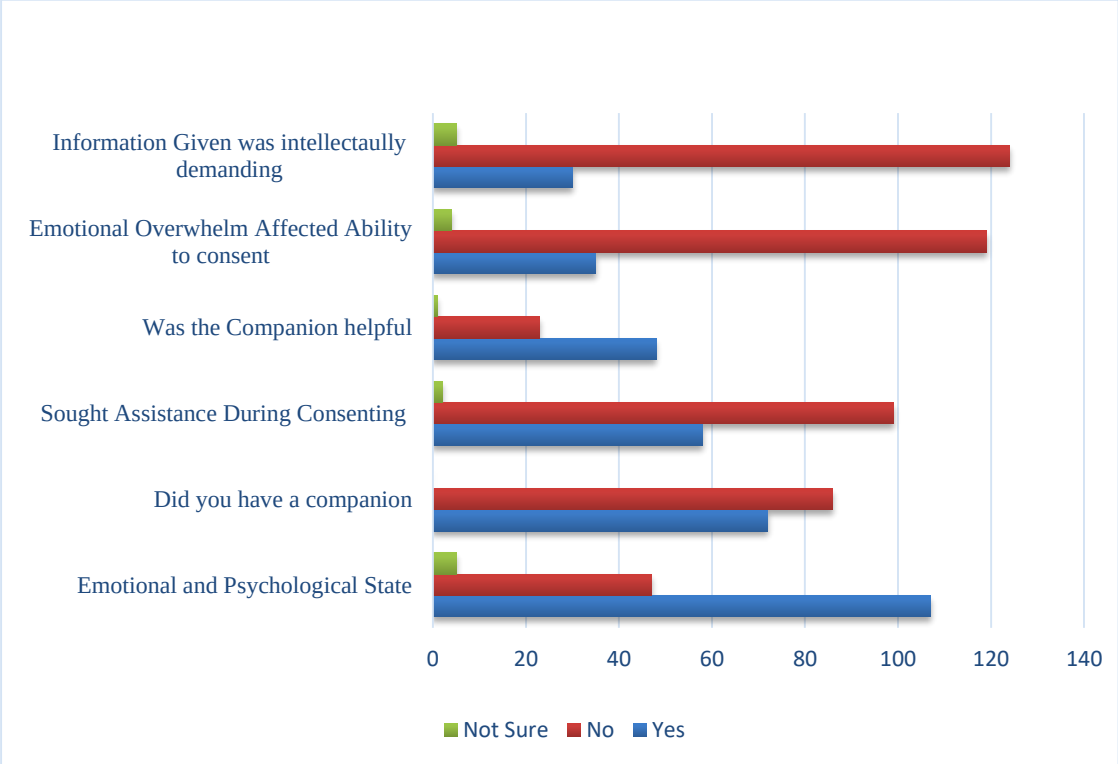

Figure 4.1 Summary of Patient-Related Factors

A Pearson correlation was computed to determine the relationship between having companion and experiencing emotional overwhelm. The analysis established there a small significant negative relationship [r(156) =-0.230 p=0.004]. Thus, having a birth companion helped reduce the chances of experiencing emotional overwhelm particularly those who underwent emergency CS though the relationship was weak.

Table 4.3 Bivariate Correlation Analysis Between Emotional overwhelm and Birth Companion in Elective and Emergency Cesarean Section

Correlations

			Emotional overwhelm	Birth companion
Emergency CS	Emotional Overwhelm on consenting for CS	Pearson Correlation	1	-.256**
		Sig. (2-tailed)		.007
		N	111	110
	companion	Pearson Correlation	-.256**	1
		Sig. (2-tailed)	.007	
		N	110	110
Elective CS	Emotional Overwhelm on consenting for CS	Pearson Correlation	1	-.129
		Sig. (2-tailed)		.386
		N	47	47
	Birth Companion	Pearson Correlation	-.129	1
		Sig. (2-tailed)	.386	
		N	47	48

**. Correlation is significant at the 0.01 level (2-tailed).

A Chi-square test for assessing the association between the level of education and ability to understand showed there was no statistical significance (p = 0.367) and no correlation (r = 0.072).

Table 4.4 Bivariate Correlation Analysis Between Level of Education and Ability to Understand consent information

Correlations			
		Level of Education	**Ability to understand**
Level of Education	Pearson Correlation	1	.072
	Sig. (2-tailed)		.367
	N	159	159
Ability to understand	Pearson Correlation	.072	1
	Sig. (2-tailed)	.367	
	N	159	159

A bivariate correlation test indicated no significant association between the participant's age and their ability to comprehend the information given [r(159) = 0.105, p = 0.188]. The bivariate correlation test exhibited a significant association between parity and the ability to understand the information given [r(159)=0.162, p=0.041]. Patients with higher parity are more likely to understand the information given.

Table 4.5 Bivariate Correlation Between Patient Social-Demographic Characteristics and Ease of Understanding of consent information

Correlations								
		Ease of understanding the consent	**Parity**	**Age in years**	**Marital Status**	**Level of Education**	**Religion**	**Place of residence**
Ease of understanding the consent	Pearson Correlation	1	.162*	.105	-.044	.072	-.123	.017
	Sig. (2-tailed)		.041	.188	.583	.367	.121	.832
	N	159	159	159	159	159	159	159

*. Correlation is significant at the 0.05 level (2-tailed).
**. Correlation is significant at the 0.01 level (2-tailed).

In assessing the association between the demographic factors and whether the CS was emergency or elective using Chi-Square analysis, there was statistically significant association for age (95% CI, r = 0.298, df = 1, 4, p = 0.002) and parity (95% CI, r =

0.438, df = 1, 4, p = 0.000). The findings indicate that as age and parity increase, the decision to have elective CS increases. A linear regression analysis was also run to assess the degree of effect the two have on planned CS. Based on the regression results, going for elective CS was influenced by parity (18.7%) and age (8.3%) respectively

Table 4.6 Regression Results on Influencers of Elective Cesarean Section

Regression Analysis Output					
Predictors	R	R Square	Adjusted R Square	Std. Error of the Estimate	Sig.
Age	.298[a]	.089	.083	.441	0.000
Parity	.438[a]	.192	.187	.415	0.000

4.5 Communication-Related Factors on Consenting Process

Most of the participants 83.6% (n=133) reiterated that information was delivered verbally. On the other hand, 11.9 (n=19) were given an information sheet with the majority of these considering the information sheet helpful.

The language that was mastered comfortably by respondents was Kiswahili 97% (n=155). Similarly, the language used predominantly by clinicians to offer counseling to clients was Kiswahili 96% (n=153), which demonstrates the clinicians' effort to minimize information disproportionateness that exists between the clinicians and their clients by primarily speaking in Kiswahili. Based on the findings it took the majority of clinicians 50.3% (n=79) around 5-10 minutes to counsel clients on the need for CS delivery. Participants acknowledged having given written consent 59% (n=94) followed by those given verbally 52% (n=82).

The majority of the respondents 94% (n=150) agreed to have made their choice freely for the CS to be conducted. The findings point out the presence of a power discrepancy

between the patient and the clinicians that may sometimes create an intimidating environment as depicted by one participant that stated that "*Staff should be friendly and offer more time to patients to ask questions*". The majority of participants 74% (n=117) acknowledged their shared decision making that indicated the collaboration with a clinician on the need for CS of delivery.

Table 4.7 Summary of Communication-related Factors

Variable	Sample Size	Frequency (%)
Delivery of Information		
Verbally	133	83.6
Written	19	11.9
Both Verbal and Written	4	2.5
Not Given	3	1.9
Relevance of Information Sheet		
Very Helpful	10	43.5
Somewhat	4	17.4
Not at All	3	13.0
Not Sure	6	26.1
Client's fluent languages		
English Only	02	1.3
Kiswahili Only	96	60.4
Vernacular Only	02	1.3
All Three	11	6.9
English & Swahili	31	19.5
Kiswahili & Vernacular	17	10.7
Languages used by Provider		
English Only	03	01.9
Kiswahili Only	130	81.8
Vernacular Only	02	01.3
English & Swahili	19	11.9
Kiswahili & Vernacular	05	03.1
How Consent was Given		
Written	76	47.8
Verbally	64	40.3
Not at all	01	06
Voluntariness of Consenting		
Yes	150	94.3
No	2	01.3
Not sure	7	04.4
Shared-decision making		
Both clinician and self	117	73.6
Clinician	37	23.3
Self	5	3.1

As illustrated in figure 4.2 below, 45% of emergency C-section cases received less than 10 minutes of counseling time compared to 16% of elective CS cases.

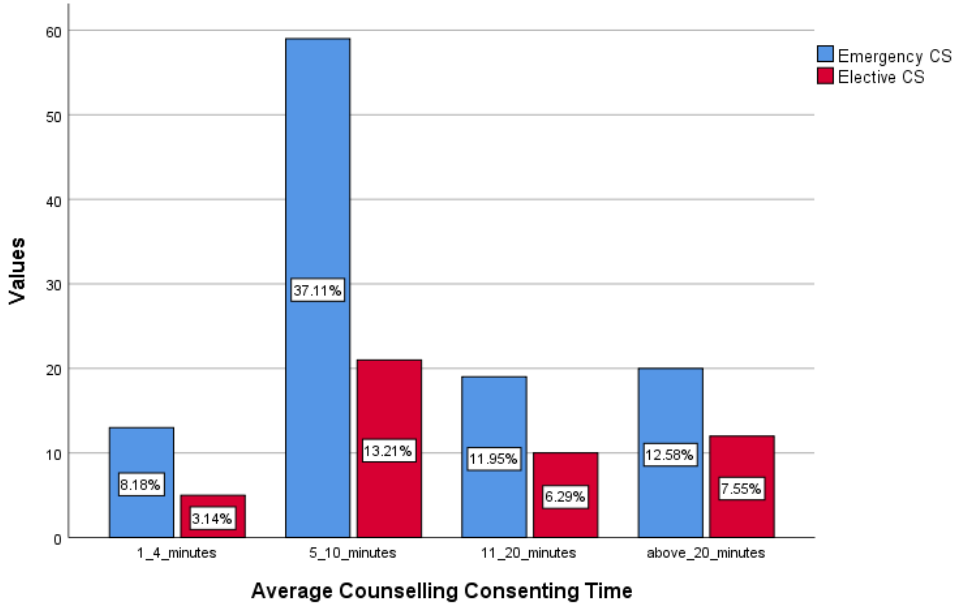

Figure 4.2 Average Counseling Time for Emergency and Elective Cesarean Section

On the other hand, on exploration of the relationship between emotional overwhelm and information given on the consenting discussion being intellectually demanding to understand showed positive correlation though the it was weak relationship, [r(158)=0.253, p=0.001] with the experience of emotional overwhelm is associated with difficult to understand the information given for counselling consenting.

The relationship between active participation and information given on the consenting discussion being intellectually demanding to understand demonstrated a moderate, negative correlation between the two variables, [r(158)=-0.345, p=0.000], difficult to understand consenting information is associated with minimal levels of active participation of the participant.

Table 4.8 Bivariate Correlation Between Difficult of Understanding and emotional overwhelm, active participation of participants

		difficult of understanding the consent	Emotional overwhelm	Active participation
Difficult of understanding the consent	Pearson Correlation	1	.253*	-.345
	Sig. (2-tailed)		.001	.000
	N	158	158	158

*. Correlation is significant at the 0.05 level (2-tailed).
**. Correlation is significant at the 0.01 level (2-tailed).

Active participation and the average counselling time showed there was moderate, negative correlation between the two variables, [r(159)=-0.312, p=0.000], a robust active involvement of the participant is associated with adequate counselling time

Table 4.9 Bivariate Correlation Between Active involvement and Average counselling of participants

		Active participation	Average counselling time
Active participation	Pearson Correlation	1	-.312**
	Sig. (2-tailed)		.000
	N	159	159

*. Correlation is significant at the 0.05 level (2-tailed).
**. Correlation is significant at the 0.01 level (2-tailed).

Similarly, Bivariate correlation between the level of education and the average time it takes to get consent shows a small significant negative association [r(159)=-.222, p=0.005], as the level of education increases the less time it takes to acquire consent.

Table 4.10 Bivariate Correlation Between Level of Education and Average counselling of participants

		Level of education	Average counselling time
Level of education	Pearson Correlation	1	-.222**
	Sig. (2-tailed)		.005
	N	159	159

*. Correlation is significant at the 0.05 level (2-tailed).
**. Correlation is significant at the 0.01 level (2-tailed).

Bivariate correlation between the relationship labor pain and active participation on better collaboration with clinician demonstrated a significant association that had weak negative correlation [r(111)=-.210, p=0.027], as labor pain intensifies the less active participation of the client affecting the collaboration with clinician on decision making for CS.

Table 4.11 Bivariate Correlation Between labor Pain and Active Involvement of the Client

		Labor pain	Active participation
Labor pain	Pearson Correlation	1	-.210*
	Sig. (2-tailed)		.027
	N	111	111

*. Correlation is significant at the 0.05 level (2-tailed).
**. Correlation is significant at the 0.01 level (2-tailed).

4.6 Information-Related Factors on Consenting Process for Cesarean Section

Based on the findings 99% of the respondents gave consent for the CS Operation to affirm their involvement in the process with only 52.2% of these receiving relevant information concerning the benefits, risks, or alternatives of the proposed treatment from the clinician. Out of these 60.9% (n=14), respondents felt the information was

fully relevant implying their full participation. The findings show that 61% of the respondents elucidate they had an opportunity to ask a question about the proposed CS before signing the consent form, which demonstrates their level of involvement. Ninety-three (58%) of the participants were given a choice of whether to accept or decline the CS in which majority of them (n=92) accepted the CS.

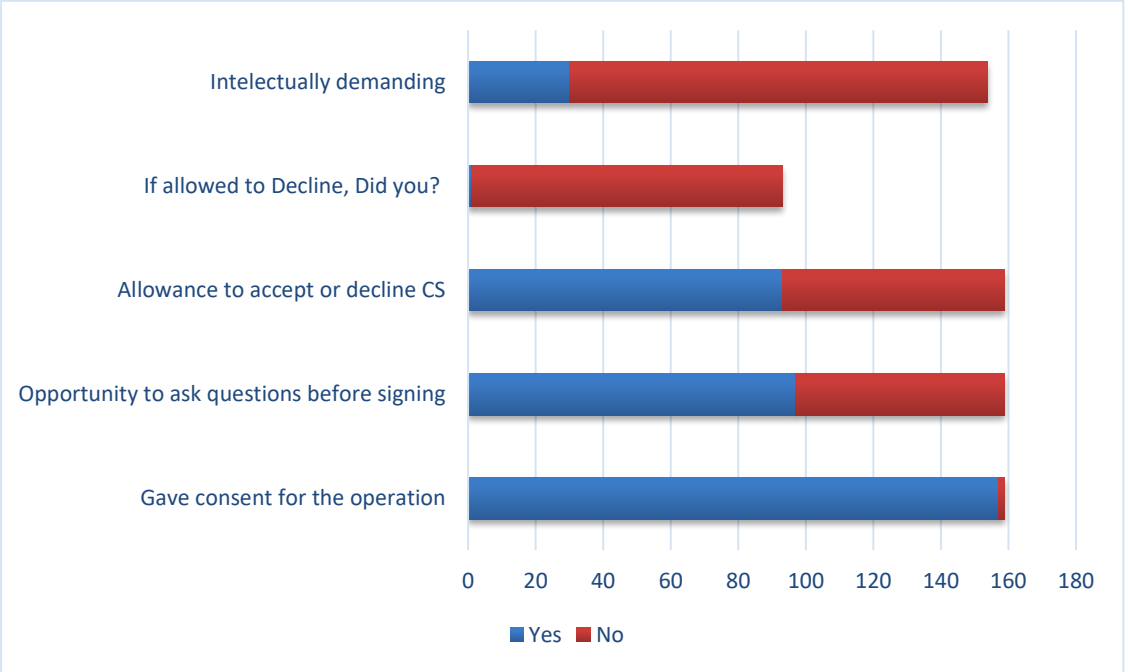

Figure 4.3 Summary of Information-related Factors on Consenting Process

The information given to participants was on diagnosis 96% (n=153), information on risk 41% (n=65), information on benefits 49% (n=78), information on indications 79% (n=126), proposed operations 53% (n=84), information on alternative treatment 47% (n=74), information on consequence of delayed or declining treatment 60% (n=95). The results demonstrate that information given to participants was not balanced and thus it is inadequate to procure consent the information given largely focuses on diagnoses and indications and less on benefits, risks, alternatives, or the consequences of declining treatment.

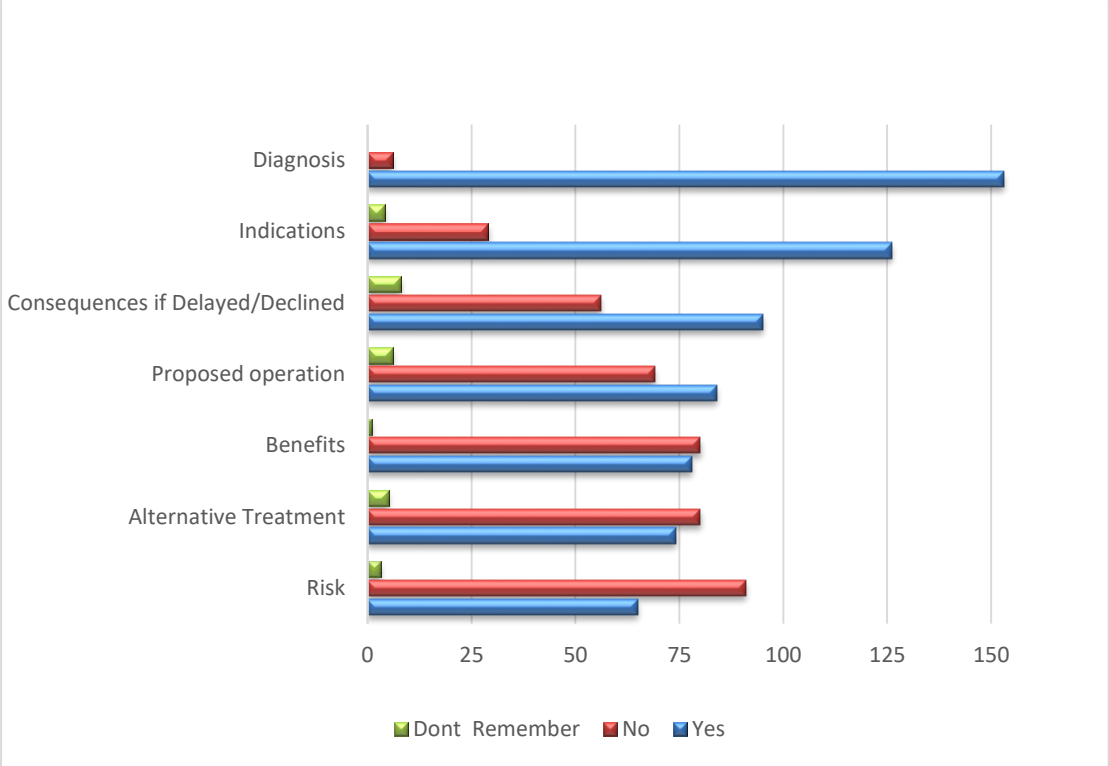

Figure 4.4 The Focus of The Information Given by Healthcare Workers in Consenting for Cesarean Section

Bivariate correlation among variables showed a significant positive correlation between active participation through asking question by the client with receiving the relevant information though the relationship was weak [r(159)=0.285, p=0.000]. The clients that received the relevant information are associated with active participation of the client since they significantly had better opportunity for asking questions before signing the consent.

Table 4.12 Bivariate Correlation Between Relevant information and active involvement of the client

		Relevant information	Asking questions
Relevant information	Pearson Correlation	1	.285**
	Sig. (2-tailed)		.000
	N	159	159

*. Correlation is significant at the 0.05 level (2-tailed).
**. Correlation is significant at the 0.01 level (2-tailed).

Bivariate correlation between labor pain and client receiving relevant information displayed a significant small negative association [r(111)=-.194, p=0.042], as labor pain increases the ability to receive relevant information associated with CS consenting diminishes.

Table 4.13 Bivariate Correlation Between Relevant information and labor pain

		Relevant information	**Labor pain**
Relevant information	Pearson Correlation	1	.194*
	Sig. (2-tailed)		.042
	N	111	111

*. Correlation is significant at the 0.05 level (2-tailed).
**. Correlation is significant at the 0.01 level (2-tailed).

The relationship between emotional overwhelm and satisfactory nature of the counselling information on information sheet displayed a moderate, positive correlation between the two variables [r(83)=-0.364, p=0.001]. Participants that experience emotional overwhelm are associated with lower satisfaction of the information given for counselling on information sheet.

Bivariate correlation between level of active participation on better collaboration with clinician and satisfaction with counselling information showed a moderate, positive correlation between the two variables, [r(83)=0.443, p=0.000]., active participation of the participant in consenting process contributed to better collaboration between clinician in making the decision for CS that was associated with higher level of satisfaction with counselling information on information sheet.

Bivariate correlation between the level of client satisfaction with counselling information and parity demonstrated a weak, negative correlation between the two variables, [r(83)=-0.218, p=0.048], as parity increases is associated with less satisfaction with the counselling information.

Table 4.14 Bivariate Correlation Between Satisfactory information counselling, and active involvement and emotional overwhelm

		Satisfactory information	Emotional overwhelm	Active participation	Parity
Satisfactory counselling	Pearson Correlation	1	-.364**	.443**	-.218*
	Sig. (2-tailed)		.001	.000	.048
	N	83	83	83	83

*. Correlation is significant at the 0.05 level (2-tailed).
**. Correlation is significant at the 0.01 level (2-tailed).

4.7 Strategies that Help Solve the Challenge of Consenting

Among participants, 64.9% (n=103) felt that antenatal consent was a helpful strategy to consent for CS. The participants did not support the idea of surrogate decision making since it took their right to determine what happens to their bodies as well their right for self-determination.

4.8 Process indicators of the Consenting Process

In evaluating and monitoring the IC Process, the researcher developed score criteria based on participants' responses. The researcher sought to check whether the five parameters of IC were attained which include documentation, disclosure, voluntariness, comprehension, and competency. This helped the researcher to monitor the effectiveness and efficiency of IC process in offering IC for CS delivery that adheres to ethical standards. Table 3 below offers a summary of scoring criteria which showed the average score of documentation was 1, disclosure 0.6, voluntary 0.7, compression 0.78, and competency 0.75

Table 4.15 Summary of Process Indicators of Informed Consent Scoring Criteria

Variables	**Elective CS**		**Emergency CS**		**Totals**	
Assigned Variable Score	**1**	**0**	**1**	**0**	**1**	**0**
Documentation	1	0	1	0	1	
Comprehension	0.86	0.14	0.74	0.26	0.78	0.22
Competency						
Emotional state to understand the consent	0.67	0.33	0.68	0.32	0.67	0.33
Did emotional overwhelm affect your consenting process	0.85	0.15	0.75	0.25	0.75	0.25
					0.75	**0.25**
Disclosure						
Diagnosis	1.0	0.0	0.95	0.05	0.96	0.04
Information on risk	0.46	0.54	0.39	0.71	0.41	0.59
Information on benefits	0.50	0.50	0.49	0.51	0.49	0.51
Information indications	0.77	0.23	0.80	0.20	0.79	0.21
Proposed operation	0.56	0.44	0.51	0.49	0.52	0.47
Alternative treatment	0.58	0.42	0.41	0.59	0.47	0.53
Information on delayed/declining treatment	0.56	0.44	0.61	0.39	0.60	0.40
					0.6	**0.4**
Voluntary						
Opportunity to ask questions before signing	0.73	0.27	0.56	0.44	0.61	0.39
Who made the decision	0.85	0.25	0.68	0.32	0.74	0.26
Was there information to decline/accept CS	0.59	0.41	0.58	0.42	0.59	0.41
Did you make the choice freely	0.94	0.07	0.94	0.06	0.94	0.06
					0.7	**0.3**

4.9 Communication and Decision-Making on CS Consenting

The qualitative data was acquired derived two distinct focus group discussions of ten participants each from the selected study sites. The content of the discussion was guided by objectives of the inquiry to assess R.H clinicians' ability to communicate and decision-making during CS consenting. The participants hinted on predominant

use of Kiswahili as captured below “We *normally use Kiswahili but sometimes we change to English or Kikuyu to reinforce their understanding*”

The consenting process focuses on the patient preparation by counselling of the underlying condition, advantages of the CS operation, the procedure including use of anesthesia, option for Bilateral ligation for clients with multiparity, consequences of CS. They are also given opportunity to decline or accept the operation “we *give mothers the opportunity to choose to accept or decline CS but depends on the level of energy*”

The clinicians acknowledged they were not adequately trained to provide ethically defensible consent for women undergoing CS as captured by their response "I *am not adequately trained but I endeavor to do my best*”.

The level of patient involvement is dependent on several factors such the urgency of the operation and level of client responsiveness “we *mostly engage patients that largely responsive that will absorb most of the information. Full involvement will sometimes depend on level of emergency and workload*.

Some of the challenges they face when seeking consent for CS including facing uncooperative patients who are unwilling to undergo the procedure as well those who in emotional and physical state that they can cannot engage in the CS consenting dialogue. Sometimes they are in dilemma on the strength of indication and may they may sometimes want to consult the seniors. The counselling time is inadequate “patients *who complicate on birthing stage a times do not comply and we occasionally want to consult*”

The discussion revealed those clinicians felt the counselling time inadequate and they acknowledged they spent on average between 3-5 minutes for patient counselling "*Ut most 2 minutes, unless the patient has questions*". There is no time enough time to reassure and listen to client. They also postulated on the influence of patient related factors influence on counselling time. This was revealed by the statement "*the patient is determinant since they want the labour pain to end*". Despite the limited time the clinicians' explanations primarily focuses on the benefits, risk of the Procedure, Alternative treatment "Yes, *we explain the reason for CS to save the baby and mother*". When it comes to matter on the risk of CS operation full exposure was based on the level of risk expected

Most of the times we appreciate that our patient appreciates the discussions that is held before CS consenting since we use languages that they easily understand "*Yes, they understand Kiswahili*". The clinicians strongly believe most their patients understand the explanations provided since they concentrate well as the discussion is ongoing. Consent is provided verbally but the agreement is sealed through signing the consent form. We appreciate that a birth companion help complement our counselling before CS since they offer support to the patient as well helping them to process the information offered "*Birth companion help to provide social support especially to the underage*".

The clinicians considered that antenatal consent provided to patient will help improve their consenting especially when it necessary during delivery and it needs to adopted as strategy for dealing with ethical dilemma when consenting for CS "*antenata*l *consent there would be more concentration especially those planned even there is temptation that it may increase the uptake of CS*". The strategies we use for decision making when consenting for CS encompasses the involvement of relatives to give consent, seeking

for advice from seniors as well keen monitoring of labour. Clinicians also use listening and giving information as strategy to get voluntary consent for CS operation *"we listen, we give information, explain the procedure, benefits and risk*" "They *are free to revoke the decision for* CS'

CHAPTER FIVE: DISCUSSION, CONCLUSIONS, AND RECOMMENDATIONS

5.1 Discussion

The inquiry demonstrated that the IC process is a worthwhile manner in which clinicians' endeavor to honor their mandate to abide by patient autonomy. However, other clinical obligations such as nonmaleficence and beneficence may impede the appropriate way to offer all the ethical obligations in certain clinical situations. The principal goal of the study was to ascertain an IC process for women who are undergoing CS delivery. The study sought to determine whether disclosure of information, comprehension, the voluntariness of the decision, documentation, and competence was attained before the provision of consent.

5.1.1 Validity of the Consent

The findings demonstrated that 100% of respondents had the agreement of CS signed, which demonstrate clinicians' respect for self-determination and patient autonomy in decision-making by agreeing to the operation, but there was no consistency in either competence, voluntariness, grasp of relevant information (comprehension) and disclosure of information. These findings concur with the results of Nanda, Duhan & Malik (2015) that undertook a cross-section study in Northern India found that case files showed good documentation. This disparity was even profound when participants were providing consent for emergency CS. The results revealed the voluntary or coerced character of the consent process by evaluating the tenets to which participants were informed, their capability to absorb information, and competency to make the decision that concurs with the findings of Megone et al., (2016). On the contrary, the consent of general maternity care that is obtained upon admission had a higher likelihood of not being documented. This raise concerns if the signed consent is

contemplated a waiver of liability for surgeons or is a preoperative discharge for CS as suggested by Menendez, (2013).

5.1.2 Patient-Related factors on Consenting Process

From the primary data, the age of the respondents did not prove to be significant in comprehending the consent form details. Therefore, it cannot be a factor in determining how to package the information in a discriminative way. A Chi-square test for assessing the association between the level of education and ability to understand indicated there was no statistical significance ($p = 0.367$) and no correlation ($r = 0.072$). These findings demonstrate that when clinicians are dealing with educated persons, they must aspire to give the full disclosure in a way they can comfortably understand. However, the primary data could be misconstrued since the mean age was around 25 years, a case which could be different for older age. Some participants also aspired for the input of others before rendering the decision to accept CS, which may include support from a birth companion, relative, or another health worker which is in harmony with the findings of Megone et al., (2016). However, 36.5% of the participants did not seek support from any other support person either since they felt to have necessary skills and understanding to decide on their own or perhaps they have complete faith in the clinicians to propose the right decision for them.

The findings of bivariate correlation between level of active participation and satisfaction with counselling information showed a strong, positive correlation between the two variables, [$r(83)=0.443$, $p=0.000$]., active participation of the participant in consenting process contributed to better collaboration between clinician in making the decision for CS that was associated with higher level of satisfaction with counselling information. A similar trend was observed on the on bivariate correlation between

active participation through asking question by the client with receiving the relevant information on consenting [r(159)=0.285, p<0.001]. The clients that received the relevant information were active participants since they significantly had better opportunity for asking questions before signing the consent. This illustrated adequate disclosure helps build the capacity of the patient, which helps to improve the level of engagement through shared decision making concurs with the findings of Megone et al., (2016) who found that shared decision-making between the clinician and patient on available health choices elicits patient values that help them arrive at a decision that respects what matters most to them. Even though the two facilities are in the same county, their consenting processes may be influenced at the organizational level that may also limit the capacity to consent which is consistent with the results of Mesri, Nzenwa & Lunevicius, (2021) .They found that setting-specific dynamics affect the completion of certain consent components leading to suboptimal quality consent thus there is need for more consistent and transparent disclosure of information to remove multiple inconstancies.

5.1.2.1 Competence or Capacity and Understanding

Individual competencies to offer valid consent can be potentially influenced by parameters such as time available to decide, emotional state, and degree of understanding achieved. In reference to emotional state, some of the respondents felt they were in a state it could affect their ability to consent competently but the majority of respondents reported making active and considered decisions despite the pain, anxiety, desperation, or time pressure. Although the views were not uniform it reaffirms that there are some difficulties for some participants thus affecting their ability to give valid consent. The clinicians stated that labor pain is a great determinant of patients' acceptance of CS since a majority of them want the pain to end.

Most of the respondents expressed a clear understanding that is in concurrence with the outcomes of Megone et al., (2016). Time was discovered to be an essential factor to influence capacity or competence for Consenting for CS due to its bearing on the processing of information. Clinicians also stated to lack adequate time to reassure, listen and counsel the clients. Some of the clients that underwent planned CS felt that they had sufficient time for decision making as they had time for gradual understanding and acceptance of the information over time which concurs with the sentiments of Megone et al., (2016) who found that non-urgent trials offered parents opportunity for gradual understanding and acceptance of information.

5.1.3 Communication-Related Factors on Consenting Process

5.1.3.1 Voluntariness and Coercion

Some participants felt that they were under pressure to accept the CS and some had to agree after the spouse advised them to accept the CS but the majority participated voluntarily thus demonstrating voluntary consent. Nonetheless, some participants stated to have experienced paternalism "*The doctors were intimidating*", which shows the disparity in the doctor-patient rapport. This makes the client vulnerable and they are prone to take doctors' instructions without question.

The findings of the study demonstrated that the time for consent is brief. Although time is not primarily a proxy for quality, a brief consent time is a likelihood to lower the quality of conversation as well as limit the client's opportunity to comprehend the information. The results affirm a robust active involvement of the participant is associated with adequate counselling time [$r(159)=-0.312$, $p=0.000$]. The study established that the practice of obtaining IC at the time of CS delivery reached is

unlikely to offer optimal time for conclusive discussion considering obstetric decisions are time-sensitive.

5.1.4 Information-Related Factors on Consenting Process

The findings displayed that the disclosure of information was not balanced. It focused on diagnosis, indications as well information on the consequence of delaying or declining treatment. Disclosure of benefits, risk, proposed operation, and alternative treatment demonstrated disparities.

The duty of disclosure of information obligates physicians to exhaustively elaborate on the diagnosis that led to the decision for the operation, the short and long-term risks, existing alternatives, benefits, as well the consequences of delaying or declining treatment rather than depending on the patient's request for disclosure. The only exception is in cases of the patient's circumstance in which disclosure may trigger mental or physical harm. Securing consent without the provision of adequate information establishes redressable negligence. The motivation of the participants to consent or decline for CS primarily depended on the benefit to mother and baby by bringing in hope in a hopeless situation which is in accord with the results of Megone et al., (2016).

Information sheet plays vital role since it offered information that client felt it was satisfactory, which illustrates that clients value supplementary written information that concurs with the findings of Truong et al., (2020). Nevertheless, bivariate correlation demonstrated that as parity increases is associated with less satisfaction with the counselling information [$r(83)=-0.218$, $p=0.048$], which may be attributed to the understanding of obstetric situations since it be easier for women with higher parity have previous experience of the labor process. Bivariate correlation established a

significant association that had weak and negative correlation on collaborative active involvement of the client in the decision-making process which showed that as labor pain intensifies the less active participation of the client thus affecting the consenting process [r (111)=-.210, p=0.027] . This finding concurs with sentiment of Bakker et al,.(2021) that labor pain negatively impacts on women decision making capacity. Participants reported having had an opportunity to ask question

5.1.5 Strategies for Decision Making on Consenting Process

The lack of clear comprehension of the inherent perceptions and ethical obligations that direct the process of IC could predispose clinicians to cultural biases, being ritualistic and unevenly forceful thus falling short of the aspired goals (Askren & Leslie, 2019). The low support for surrogate decisions was refuted by participants because they wanted to have some control over what happened to them. The focused group discussion with clinicians examined their practices in the consenting process, which covered a range of topics that overlapped with those of mothers but also delved into matters beyond those discussed by participants. Clinicians mooted fears about balancing their clinical obligation versus ensuring the acquisition of consent that is ethically defensible majorly because of medical emergencies, uncooperative and unwilling participants, and poor concentration of patients due to emotional and physical stress triggered by labour pains.

5.1.6 Antenatal Consent

Participants were found to favor antenatal consent instead of consenting during labour since they would be given information prior in pregnancy even if they were not to undergo CS then. Nonetheless, others were not wholly cozy with idea that is coherent with the findings of Megone et al., (2016).

5.2 Conclusions

The study found that the existing consent process has significant gaps since they do not lead reliably to the acquisition of valid consent for CS and thus there is an urgent need to find an all-inclusive and effective way. The findings shows that some of the clients failed to give valid consent measured against one or other five criteria of validity-comprehension, competence, voluntariness, disclosure of information, capacity to make the decision, and documentation of the process, which suggest that there exist concerns regarding the current practices in place to acquire a valid consent for CS. The results affirm that IC is not a signature but a process of interaction and communication. IC is essential for reproductive and human rights since it encourages the involvement of patients in reproductive health decisions that champions non-discrimination, bodily integrity, and the topmost possible standard of health. The majority of the CS was performed due to emergency indications.

5.3 Recommendations

5.3.1 Recommendations for the Study

Clinicians should provide their clients with full information that focuses on the diagnosis, available alternative treatments including benefits and risks. The involvement of women, equal access to information as well as obtaining their consent and input or dissent should be a continuing process to allow for a more authentic consent process.

Ethics education among R.H clinicians need to strengthened in midwifery, nursing, and medical curriculum in pre-service, in-service and postgraduate training towards inclining and recognizing that the IC process is the interchange of information. This consenting process allows patient or surrogate to render an authoritative decision that

is a true reflection of their autonomous medical decisions. Proper counseling and communication would enhance the process to improve it from simple documentation to a roadmap to allow for profound collective decision-making as postulated by Menendez (2013).

Antenatal visits are the appropriate time to engage the client about the possibility of CS delivery in certain situations in labour. The client needs counseling and communication on what is anticipated following CS delivery. The government of Kenya should integrate within FANC program education on CS delivery as part of its key component of birth preparedness.

5.3.2 Recommendations for Further Research

Additional study can focus on the influence of organizational related factors that may limit on the utilization of the policy of IC. Moreover, researchers can also explore the use of novel interactive digital techniques to improve patient understanding that can benefit clients that have limited health literacy.

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APPENDICES

Appendix I: Map of Kiambu County

Appendix II: Informed Consent Form

KENYATTA UNIVERSITY
OFFICE OF THE CHAIRMAN ETHICS REVIEW COMMITTEE

Informed Consent

My name is Raymond Tanui Sakuny. I am a Master student from Kenyatta University. I am conducting a study titled "**Informed consent process among women undergoing caesarean section in Kiambu County**". The information will be used to inform on quality care and approaches of providing informed consent to mothers pending CS delivery.

Procedures to be followed

Participation in this study will require that I ask you some questions and I will record the information you provide in a questionnaire.

Voluntarism

You have the right to refuse participation in this study. You will get the same services and care whether you agree to join the study or not and your decision will not change the care you will receive. Please remember the participation in this study is voluntarily. You may ask questions related to the study at any time.

You may refuse to respond to any questions and you may stop an interview at any time. You may also stop being in the study at any time without any consequences to the services you receive here or any other organization now or in the future.

Discomforts and Risks

Some of the questions you will be asked are on intimate subject and may be embarrassing or make you uncomfortable. If this happens, you may refuse to answer these questions if you so choose. You may also stop the interview at any time. The interview may add approximately half an hour to the time you wait before you receive your routine services.

Benefits

If you participate in this study, you will help us to learn how to provide ethical and valid consent before undergoing CS delivery that can improve delivery services for women who may undergo CS delivery.

Reward

If you agree to participate in this study, packet of milk to aid in breastmilk production will be provided.

Confidentiality

The interviews and examinations will be conducted in a private setting within the clinic. Your name will not be recorded on the questionnaire. The questionnaires will be kept in a locked cabinet for safe keeping at Kenyatta University. Everything will be kept private and only shared with the study team.

Contact Information

If you have questions about the study call Mr.Raymond Sakuny 0714745360 or Supervisor Dr. Eliphas Gitonga 0721406609 or Dr. Lister Onsongo 0700004288.

However, if you have questions about your rights as a study participant: You may contact Kenyatta University Ethical Review Committee Secretariat on chairman.kuerc@ku.ac.ke,

Participant's Statement

The above information regarding my participation in the study is clear to me. The study has been explained to me and I have been given a chance to ask questions and my questions have been answered to my satisfaction. My participation in this study is entirely voluntary. I understand that my records will be kept private and that I can leave the study at any time. I understand that I will still get the same care and medical treatment whether I decide to leave the study or not and my decision will not change the care that I will receive from the clinic today or that I will get from any other clinic at any other time.

_____ _____

Signature of participant or Thumbprint Date

_____ _____

Name of Representative/Witness (where necessary) Relationship to Subject

Investigators statement

I, the undersigned, have explained to the volunteer in a language s/he understands, the procedures to be followed in the study and the risks and benefits involved

_____

Name of Interviewer

_____ _____

Signature Date

Appendix III: Study Tool- Questionnaire

Instructions:

1.The purpose of this questionnaire is to obtain information for study objectives only.

2.Do not write your name or any other identification anywhere on the questionnaire

3.The questionnaire has four sections. Please answer the questions as accurately and completely as you can.

4. Put the filled-in questionnaire in the given envelope and seal it. Hand it over to the researcher or the research assistants.

THANK YOU FOR YOUR PARTICIPATION IN THIS STUDY

A. Demographic Data

1. Age in years (*indicate on space provided*)

   ( ) years

2. Marital status

   Single ( ) Married ( ) Separated ( ) Divorced ( ) Widow ( ) +\

3. Highest Level of education

   None ( ) Primary ( ) Secondary ( ) College/University ( )

4. Parity

   Primi-gravida ( ) Para 2 ( ) Para 3 ( ) Para 4 ( ) Para 5 and above ( )

5. Religion

   Christian ( ) Muslim ( ) Hindu ( ) tradionist ( ) Others (state)

   …….

6. Place of residence

   Rural ( ) Urban ( )

7. a) Was the CS

   Planned ( ) Unplanned ( )

   b) If unplanned at what dilatation of the cervix was the decision for CS was arrived (*from patient file*)

   0-3 cm ( ) 4-6 cm ( ) 7-8 cm ( ) 9-10 cm ( )

8. Was consent form for general care signed by the patient (*from Patient file*)

   Yes ( ) No ( )

9. Was the consent for CS signed by the patient *(from the Patient file and verification done with the patient)*

   Yes ( ) No ( )

B. Information-related factors

10. Did you give consent for the operation?

    Yes ( ) No ( )

11. a) Did you receive relevant information concerning the benefits, risks of CS, or alternatives to the proposed treatment from a clinician?

    Yes ( ) No ( ) I do not remember ( )

    b) If yes, was the information satisfactory?

    Not at all ( ) somewhat satisfactory ( ) fully relevant ( )

12. Did you have an opportunity to ask questions concerning the operations before signing the consent?

    Yes ( ) No ( )

13. Who made decision for CS to be conducted

Clinician ( ) Self ( ) both (clinician and Self) ( )

14. a) Did the health worker allow you to decline or accept CS?

Yes ( ) No ( )

b) If yes to the above question, did you decline

Yes ( ) No ( )

c) If yes to the above what happened to those who declined the operation

Coerced ( ) referred ( ) left unattended ( ) others (……)

15. Identify in the table below the information given by the health workers when seeking consent primarily focused on.

Information component	**Yes**	**No**	**I do not remember**
Diagnosis			
Information on risk			
Information on benefits			
Information on indications			
Proposed operation			
Information on alternative treatments			
Consequences of delaying or declining treatment			

C. Communication-related factors

16. a) How was the information delivered

Verbally ( ) Information sheet ( ) Not given at all ( )

b) If you were given an information sheet, was it helpful?

Not at all ( ) somewhat ( ) Very Helpful ( ) Not sure ( )

17. Which languages have you mastered comfortably? Tick appropriately

Kiswahili ( ) English ( ) Vernacular ( )

18. What is the language used by health workers when seeking consent for the operation

Kiswahili ( ) English ( ) Vernacular ( )

19. How long did it take the health worker to seek consent

1-4 minutes ( ) 5-10 minutes ( ) 11-20 minutes ( ) above 20 minutes ( )

20. How did you give consent?

Verbally ( ) Written ( ) Not at all ( )

21. a) Did you make your choice freely?

Yes ( ) No ( ) I do not remember ( )

b) If no, please

explain……

……

D. Patient-related factors

22. Were you in an emotional and psychological state that, you could understand the information?

Yes ( ) No ( ) Not sure ( )

23. Did emotional overwhelm affect your ability to consent for CS

Yes ( ) No ( ) Not sure ( )

24. Did you find the information given for consent was intellectually demanding to make it difficult to understand?

Yes ( ) No ( ) Not sure ( )

25. a) Did you have a companion in labour

Yes ( ) No ( )

b) If yes to above did he /she help you in consenting for CS

Yes ( ) No ( ) Not sure ( )

c) If No, do you think having a birth companion would have been helpful in the consenting process?

Yes ( ) No ( ) Not sure ( )

26. a) Did you seek assistance in reaching the decision of whether to accept or reject the CS?

Yes ( ) No ( ) I do not remember ( )

b) If yes, who did you seek assistance from? (*Tick all that apply*)

Birth companion ( ) another patient ( ) the health provider ( ) A relative

27. What strategies do you would think would help solve the challenge for consenting for CS

Antenatal consent ( ) Surrogate decision making ( ) Not sure ( )

28. What are your recommendations for giving consent for CS?

……

……

……

……

Appendix IV: Focus Group Discussion Tool

Describe the languages you use primarily when seeking consent from patients for CS

Describe the process of seeking consent from the patient before CS operation

Are you trained adequately provided to provide ethically defensible consent for women undergoing CS?

Describe the level of patient involvement when seeking consent for CS

Some of the challenges you face when seeking consent for CS

How much time on average do you spend giving information about the CS to the patient?

Do you think the time is adequate and please support your answer?

Do you think the information you provide is adequate to acquire informed consent?

During your explanations do you include the

Benefits…….

Risk of the Procedure……

Alternative treatment……

Do you think your patient understand the explanation that is provided to them?

How is the consent provided?

Do you think the existence of social support (companion) to the patient will help improve the process of seeking consent?

Do you think the antenatal consent to the patient will help improve the process of seeking consent?

What are the strategies for decision making on the ethical issues related to consent for CS?

Appendix V: NACOSTI PERMIT

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **197190**

Date of Issue: **21/July/2021**

RESEARCH LICENSE

This is to Certify that Mr.. Raymond Tanui Sakuny of Kenyatta University, has been licensed to conduct research in Kiambu on the topic: Informed consent process among women undergoing caesarean section in Kiambu County for the period ending : 21/July/2022.

License No: **NACOSTI/P/21/11741**

197190

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: Kenyatta University Ethical Approval

KENYATTA UNIVERSITY
DIRECTORATE OF ETHICS REVIEW COMMITTEE

Fax: 8711242/8711575
Email: chairman.kuerc@ku.ac.ke
Nairobi, 00100

P. O. Box 43844,

Tel: 8710901/12

Website: www.ku.ac.ke
Our Ref: **KU/ERC/APPROVAL/VOL.1**

Date: 7th July, 2021

Raymond Sakuny
P.O Box 43844, 00100
Nairobi.

Dear Mr. Sakuny,

APPLICATION NUMBER: PKU/2251/I1395 INFORMED CONSENT PROCESS AMONG WOMEN UNDERGOING CAESAREAN SECTION IN KIAMBU COUNTY HOSPITAL

This is to inform you that ***KENYATTA UNIVERSITY DIRECTORATE OF ETHICS REVIEW COMMITTEE*** has approved version 4 of the study protocol together with the attached consent forms dated 12.09.2020. Your application approval number is **PKU/2251/I1395.** The approval period is ***7th July, 2021 TO 7th July, 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 ***KENYATTA UNIVERSITY DIRECTORATE OF ETHICS REVIEW COMMITTEE***.
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 ***KENYATTA UNIVERSITY DIRECTORATE OF ETHICS REVIEW COMMITTEE*** 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

iv. reported to ***KENYATTA UNIVERSITY DIRECTORATE OF ETHICS REVIEW COMMITTEE*** 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 ***KENYATTA UNIVERSITY DIRECTORATE OF ETHICS REVIEW COMMITTEE***.

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.ke and also obtain other clearances needed.

To serve you better, researchers are kindly requested to access and complete a customer feedback form and sent it back online as you continue with research and upon completion of data collection found on the following websitelink;(https://docs.google.com/forms/d/1ytWefDwvyz5h1oz_VIn0xbxg3uGdlDzMXFWNDsMrRPQ/edit?usp=sharing

Yours sincerely

Prof. Judith Kimiywe

DIRECTOR- KENYATTA UNIVERSITY ETHICS REVIEW COMMITTEE.

Appendix V: Graduate School Research Authorization

KENYATTA UNIVERSITY
GRADUATE SCHOOL

E-mail: dean-graduate@ku.ac.ke
Website: www.ku.ac.ke

P.O. Box 43844, 00100
NAIROBI, KENYA
Tel. 020-8704150

Our Ref: Q139/CTY/PT/31628/2015 DATE: 5th March, 2021

Director General,
National Commission for Science, Technology
and Innovation
P.O. Box 30623-00100
NAIROBI

Dear Sir/Madam,

RE: RESEARCH AUTHORIZATION FOR MR. RAYMOND TANUI SAKUNY – REG. NO. Q139/CTY/PT/31628/15

I write to introduce Mr. Raymond Tanui Sakuny who is a Postgraduate Student of this University. He is registered for M.P.H. degree programme in the **Department of Population, Reproductive Health & Community Resource Management.**

Mr. Sakuny intends to conduct research for a M.P.H. thesis Proposal entitled, **"Informed Consent Process Among Women Undergoing Caesarean Section in Kiambu County, Kenya."**

Any assistance given will be highly appreciated.

Yours faithfully,

PROF. ELISHIBA KIMANI
DEAN, GRADUATE SCHOOL

KENYATTA UNIVERSITY OFFICE OF DEAN 10 MAR 2021 GRADUATE SCHOOL P.O. Box 43844-00100 NAIROBI

Appendix IV: Study site Approval

COUNTY GOVERNMENT OF KIAMBU
DEPARTMENT OF HEALTH SERVICES

All correspondence should be addressed to HEAD
HRDU – HEALTH DEPARTMENT
Email address: mndiritu@gmail.com
mkwasa@live.com
Tel. Nos: 0721641516
0721974633

HEALTH RESEARCH AND DEVELOPMENT
UNIT
P. O. BOX 2344 – 00900
KIAMBU

Ref. No.: KIAMBU/HRDU/21/08/13/RA_SAKUNY Date: 13th August 2021

TO WHOM IT MAY CONCERN

RE: CLEARANCE TO CONDUCT RESEARCH IN KIAMBU COUNTY

Kindly note that we have received a request by Mr. Raymond Tanui Sakuny of Kenyatta University to carry out research in Kiambu County, the research topic being on "**Informed Consent Process Among Women Undergoing Caesarean Section In Kiambu County**"

We have duly inspected his documents and found that he has been cleared by NACOSTI to carry out the research for a period ending **21st July 2022**. He thus does not need any further clearance with another regulatory body in order to conduct research within the county of Kiambu.

However, it is incumbent upon the institution where he is carrying out research to ensure that he receives adequate supervision during the process of conducting the research. This note also accords him the duty to provide a feedback on his research to the county at the conclusion of his research.

DR. MWANCHA KWASA
COUNTY CLINICAL RESEARCH OFFICER
KIAMBU COUNTY