TRIAL OF LABOR OR ELECTIVE REPEAT CESAREAN DELIVERY: ARE PATIENTS MAKING AN INFORMED DECISION AT KENYATTA NATIONAL HOSPITAL?

A dissertation submitted in partial fulfillment for the award of the degree of Master of Medicine (MMed) in Obstetrics and Gynecology, University of Nairobi (UON).

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This is to declare that this is my original work and has not been presented for the award of a degree in any other university. I also declare that the intellectual content of this dissertation is the product of my own work, although I have received invaluable assistance from my supervisors.

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DEDICATION

This book is dedicated to Almighty God, to my loving wife Dr. Anne Marie Mukamana, to our lovely children Kenny, Kevin and Kentin, wise beyond their years and to my MMed friends as well, without them life during this program would probably have been miserable.

ACKNOWLEDGEMENT

Writing this thesis has been fascinating and extremely rewarding. This work would have never been possible without the help of numerous friends and colleagues who have contributed to the final result in different ways. I want to express my gratitude to all of you who made this thesis possible. Thank you so much. I am heartily thankful to Associate Professor Omondi Ogutu and Dr. Samson Wanjala for their encouragement, guidance and support and their crucial way of thinking taught me not to always accept things as they seem to be. They have really motivated me and made major highlights of my study. I sincere give thanks and appreciation to Dr. John Kinuthia who ploughed through several preliminary versions of my text, making critical suggestions and posing challenging questions.

My special thanks and gratitude go to Leonard Cheserem for patiently guiding me through the analysis, the Research program Kenyatta National Hospital for providing financial support, Miss Agatha Wambui and Mrs. Martin Mwaura for their good work as investigator assistants, Dr. Lubano Kizito, Dr. Humphrey and Dr. Ruth Wamae for their time to read my work and their encouragement, my lecturers and all consultants who taught me in MMed program. I would also like to acknowledge KNH for having allowed us conduct this research in the Antenatal clinic. Last but not least, lots of thanks to all women who attended KNH ANC during the period of our data collection, this work would not have been feasible if they did not consent.

Finally and most importantly I would like to thank my wife and partner in life Dr Anne Marie for giving me the right pressure at the right time, for supporting, inspiring and motivating me. She is my rock and my career would not have been possible without her patience and devotion. I lastly offer my regards and blessings to all those not mentioned by name who supported me in any respect during the completion of this thesis.

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ABBREVIATIONS

AAFP	American Academy of Family Physicians
ACOG	American College of Obstetricians and Gynecologists
AHRQ	Agency for Healthcare Research and Quality
ANC	Antenatal Clinic
C/S	Cesarean Section
ERCD	Elective Repeat Cesarean Delivery
KNH	Kenyatta National Hospital
NIH	National Institutes of Health
NUR	National University of Rwanda
MD	Medical Doctor
MMed	Masters in Medicine
RCD	Repeat Cesarean Delivery
RCOG	Royal College of Obstetricians and Gynecologists
SPSS	Statistical Package for Social Science
TOL	Trial of Labor
TOLAC	Trial of Labor after Cesarean Delivery
US	United States
VBAC	Vaginal Birth after Cesarean Delivery

OPERATIONAL DEFINITIONS

"A trial of labor after cesarean" (TOLAC) is a planned attempt to labor by a woman who has previously undergone a cesarean delivery and desires a subsequent vaginal delivery. A trial of labor aims at avoiding an unnecessary cesarean section and at delivering a healthy baby**.**

"A VBAC" is a "successful" trial of labor resulting in a vaginal birth. A TOLAC may result in either a "successful" VBAC or a "failed" trial of labor resulting in a repeat cesarean delivery.

"A repeat cesarean delivery" (RCD) may be planned and scheduled beforehand and thus is an elective repeat cesarean delivery (ERCD).

"Maternal request for a cesarean delivery": The concept of requesting a cesarean delivery is relatively recent. In the United States and most Western countries, pregnant women have the right to make choices regarding treatment, including how they will deliver their child. A woman who wants to request a cesarean delivery should discuss this decision with her healthcare provider. The woman should also discuss the risks and benefits of maternal request for a cesarean delivery.

"Informed decision" is defined as a process of communication whereby a patient is enabled to make an informed and voluntary decision about accepting or declining medical care and has become a mainstay of contemporary medical practice. It is viewed by many as a collaborative process between the physician and patient intended to facilitate the patient's autonomy in the process of ongoing choices. 'Informed decision-making' reflects that the aim is for the patient to make the right decision about healthcare, considering all circumstances of their life. Informed decision-making and informed consent terminology can be used interchangeably.

"**Consent**" denotes the final decision of the informed decision-making or informed consent process. Consent is a basic legal principle that reflects a person's agreement to something. Informed consent, in a legal sense, reflects that a patient has received the information relevant to them to make an informed decision and they have given permission for the healthcare to be provided.

ABSTRACT

Background

With a low risk uterine rupture of 0.07% and high success rate of about 80%, trial of labor is a reasonable and safe option for most women after one previous cesarean delivery. As such physicians have both legal and ethical responsibility to provide adequate information to the patients in order to make appropriate informed decisions regarding the mode of delivery.

However, current studies suggest that the proportion of women attempting trial of labor after previous caesarean delivery has been declining in many countries. In addition, other recent studies have shown that women with prior cesarean delivery appear to know little regarding their mode of delivery and that healthcare providers' recommendations as well as their preferences exert a strong influence on patient's decision whether or not to pursue TOLAC.

In Kenya, it is unclear whether women who would be offered trial of labor after cesarean delivery (TOLAC) or elective repeat cesarean delivery (ERCD) do that based on clear understanding of risks and benefits of both mode of delivery.

Objective

This study aimed at determining whether patients with one previous cesarean delivery are making an informed decision on preferred mode of delivery.

Methods

A five-month cross sectional study targeting women with one previous cesarean delivery attending ANC at KNH was performed from September 2013 to January 2014. Data was collected from both the patients' records and interview using a structured questionnaire. Univariate and multivariate analysis was done using STATA 11.0.

Results

Two hundred and two women with mean (SD) age of 30.2 ± 4.7 years were sampled; (136) 67.2% of them chose ERCD while (66) 32.8% chose TOLAC. It was found that only (61) 30.6% (C.I: 24.4 to 37.6%) of the patients were making an informed decision. Few patients (65) 32.2% knew that the chance of successful TOLAC were high (60-80%) and most of them 97 (48%) were not aware of the chances for a successful TOLAC; More than half of the patients 109 (53.9%) were unaware of the risk of uterine rupture after one previous caesarean delivery and only few patients 64 (31.7%) knew that the risk of uterine rupture in TOLAC were low (< 1%). The majority of the patients 112 (55.4 %) did not know that the indications for previous cesarean delivery are an important factor in determining the chance of a successful VBAC. Few patients 23 (11.4%) for ERCD signed the consent form while none of the patients for TOLAC signed any consent form.

The patient preferred mode of delivery before attending ANC at KNH was significantly associated with the chosen mode of delivery after (p=0.001). The knowledge of the patients regarding the risk of uterine rupture and overall chances of success of TOLAC was found to be associated with the chosen mode of delivery (p=0.001).The patients' mode of delivery was significantly associated with the preference of the counseling doctor (p=0.001) and their qualification (p=0.020).

Conclusion

The majority of the patients 141 (69.4%) demonstrated an overall lack of information on both modes of delivery while doctor's preference affected the patient's decision.

Recommendation

There is need to develop clear standard protocols and checklists for information to be disseminated to all patients with previous cesarean delivery in subsequent pregnancies in Kenya.

INTRODUCTION

There are three possible outcomes for the woman who has had a prior cesarean delivery: a successful trial of labor culminating in vaginal birth, a failed trial of labor after cesarean delivery resulting in a repeat cesarean delivery during labor, or an elective repeat cesarean delivery.

Planning the route of delivery for the woman who has had a previous cesarean delivery should be addressed early in her prenatal care, and can begin preconceptionally. With either approach, women who have undergone a prior cesarean delivery are at risk for serious maternal and perinatal complications and should be counseled about the risk and significance of these complications. (1)

In the USA for instance, Federal Acts and regulations, as well as professional guidelines, clearly demonstrate that every pregnant woman has the right to base her maternity care decisions on accurate, up-to-date, comprehensible information. (2)

Often, informed consent is confused with the consent form. In fact, informed consent is "the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention with its risks and benefits and of the alternatives with their risks and benefits". (3,4)

The decision for elective repeat cesarean delivery or trial of labor after cesarean delivery with the goal of achieving a vaginal birth should be made by the woman in consultation with her provider. In order to make this decision, both clinicians and patients typically desire individualized information about the chance of successful TOLAC and the balance between the risk of maternal or fetal morbidity if TOLAC is unsuccessful and the risk of maternal and fetal morbidity with ERCD. (5)

This information is also important on a population level, especially in the setting of a rising cesarean delivery rate, as selection of candidates who are most likely to deliver vaginally after a previous cesarean can minimize the costs of ERCD and failed TOLAC. (5)

All health care interventions require some kind of consent by the patient, following a discussion of the procedure with a health care provider. Most health care institutions also have policies that state which health interventions require a signed consent form. These signed forms are the culmination of a dialogue required to foster the patient's informed participation in the clinical decision.

Basic or simple consent entails letting the patients know what you would like to do; giving basic information about the procedure; and ensuring that the patient assents or consents to the intervention. (3) However, women report that their healthcare providers' recommendations and preferences exert a strong influence on their decision whether or not to pursue TOLAC. (6)

In fact, improving patient education may not (7) affect the increasing cesarean section rate; it would, however, empower patients to make a well informed, educated decision and allow physicians to return to the basic principles they once pledged to follow.

The physician-patient relationship

Studies have described four models of the relationship between the physician and patient: paternalistic, informative, interpretive, and deliberative. (8) Depending on which model is used, different ethical principles emerge as relevant to ethical decision making.

In the paternalistic physician–patient model, the physician might present only information on risks and benefits of a procedure that he or she thinks will lead the patient to make the "right" decision regarding health care. At the opposite end of the spectrum, the informative model describes a physician–patient relationship in which the physician is a provider of objective and technical information regarding the patient's medical problem and its potential therapeutic solutions.

In the interpretive model, the physician helps the patient clarify and integrate her values into the decision–making process while acting as an information source regarding the technical aspects of any given medical procedure. In this model, the physician aids the patient in "self–understanding; the patient comes to know more clearly who he or she is and how various medical options bear on his or her identity". (8)

In the deliberative model, the physician's role is to guide the patient in taking the most admirable or moral (based on her values, needs, and fears) course of treatment or health–related action. It is similar to the interpretive model in that it includes a discussion of not only the medical benefits and risks but also the patient's individual priorities, values, and fears.

The process of decision making

From literature, physicians are asked to exercise judgment when determining whether information presented to the patient is adequate. The practice of evidence–based medicine involves understanding the scientific basis of treatment and the strength of the evidence and applying the results of the strongest evidence available to medical decision making. (9)

There is no ethical imperative to initiate discussion of treatment options that are either unproven or not part of accepted medical practice. The physician may, however, want to discuss investigational options so that the patient understands the unproven nature of these options and can make an informed decision about them.

Surgical and medical advice or guidance for many obstetric and gynecologic problems is based in part on science, in part on the experience and values of the physician, and in part on the physician's understanding of the patient's preferences, values, and desired outcome.

Decision-making about delivery should be shared between the provider and patient, after thorough counseling about the risks and benefits in language the patient can easily comprehend. Ideally, decision making regarding labor and birth will begin during prenatal care. Informed consent may and should initiate a discussion of risks and benefits of procedures and routines. (9)

LITERATURE REVIEW

Physicians have a legal and ethical responsibility to provide adequate information to the patient in order to make appropriate decisions regarding the planned intervention and to reduce acrimony in case of complications. (10) The benefits of obtaining informed consent extend beyond the simple transmission of information from the physician to the patient and the benefits of truly informed consent include protecting the patient's right of self-determination, engaging the patient in his or her health care, enhancing the physician-patient relationship, encouraging physicians to thoroughly review the patient's therapeutic options, reducing discontent and litigation when there are complications. (10)

Physicians must focus on the patient's understanding and consent .No intervention can be undertaken without the patient's consent, which must be voluntary and competent. (11) The legal principles of informed consent promote patient autonomy, the notion that patients should decide who touches them and how that contact is made. Thus, the physician should be wary of too much pressure, too little information, or too little attention to the patient's need for information, understanding, and comfort. (10)

Patients may not accurately remember all the facts disclosed in a discussion. (12,13) Thus, a physician must document the content of informed consent sessions. All elements of the discussion should be reduced to writing: diagnosis, proposed treatment with its risks and benefits, and alternative treatments with their risks and benefits. In order to meet the requirements for effective, informed decision making, a physician must disclose material facts relevant to decision making, including the patient's diagnosis, proposed treatment, risks and benefits of the treatment, alternative treatments along with their risks and benefits, and the risks of refusal. (3)

There are three general approaches in which jurisdictions may judge the physician's performance of his or her duty to provide enough and adequate information: the professional standard, the objective patient standard, and the subjective standard. (3)

The professional standard of care or reasonable physician standard allows the physician to determine what information is appropriate to disclose. This standard is also generally considered inconsistent with the goals of informed consent, as the focus is on the physician rather than on what the patient needs to know. The objective standard of care or reasonable patient standard focuses on considering what a typical patient would need to know in order to understand the decision at hand.

The subjective standard requires the physician to relay facts that a particular patient deems important in the decision making process. This standard is the most challenging to incorporate into practice, since it requires tailoring information to each patient. (3)

Failure to provide the necessary, relevant information in a way which truly communicates with the patient may constitute ineffective, and therefore nonexistent, consent. Recent data suggest that the national rate of TOLAC is currently less than 10%, down from 28.3% in 1985 (14) and this may be due, in part, to a lack of knowledge among patients of the risks and benefits of either mode of delivery.

First attributed to Craigin, the dictum "once a cesarean, always a cesarean" dominated American obstetrical practice for much of the twentieth century**.** (15) Cesarean section became more widely accepted as improvements in anesthesia, blood banking, and the technique of the surgery itself occurred. (16) However, large observational studies have consistently shown that women who undergo multiple repeat cesarean deliveries are at increased risk of maternal morbidity, and the risk increases with the number of cesarean deliveries. (17,18)

In 1995, the American Academy of Family Physicians (AAFP) developed an evidence based, patient-centered clinical policy on trial of labor (TOL) versus ERCD (Elective Repeat Cesarean Delivery) for the woman with a previous cesarean delivery**.** (19)

In 2001, because of new evidence, the AAFP Commission on Clinical Policies and Research decided there was a need for an updated policy or clinical practice guideline and successfully nominated this topic to the Agency for Healthcare Research and Quality (AHRQ) for an evidence review.

At the 2010 NIH consensus conference, the safety and outcomes of TOLAC were explored and the panel found it to be a reasonable option for most women (20). However, recent data suggest that the national rate of TOLAC is currently less than 10%, down from 28.3% in 1985 (14)**.** This may be due, in part, to a lack of knowledge among patients of the risks and benefits of either mode of delivery.

One study published in 2010 entitled "Vaginal Birth after Cesarean Delivery: Views from the Private Practitioner" surveyed physicians in Texas to assess their opinions regarding VBAC. The survey showed that only 52% of respondents offer VBAC to their patients. The most common reasons for not offering VBAC were maternal-fetal safety concerns and medico-legal liability concerns (21). The physicians that did not offer VBAC were also more likely to be practicing <10 years, have been involved in a law suit related to a cesarean delivery or have experienced a uterine rupture with maternal or fetal complications**.** (22)

A recent study published in journal of obstetrics and gynecology in 2012 Sarah N. Bernstein, MD and collaborators stated that candidates for trial of labor after cesarean section (TOLAC) appear to know little about the risks and benefits associated with their mode of delivery, and provider preference affects this choice. (6)

The criteria for informed decision

Physicians are required by law and medical ethics to obtain the informed consent of their patients before initiating the treatment. For the patient's informed consent to healthcare to be valid, certain principles need to be fulfilled: (3,4)**.** The patient has the capacity (ability) to make a decision about the specific issue at the specific time, and is not affected by therapeutic or other drugs, or alcohol. The consent is voluntarily given, and free from manipulation by or undue influence from family, medical staff or other social coercive influences. The discussion between the patient and the health practitioner is transparent, well balanced, and involves two-way communication which is sensitive to the situation. The patient is able to clearly understand the information because it is provided in a language or by other means the patient can understand.

As far as possible, the patient is advised in simple terms of the diagnosis if known; the nature and purpose of a proposed treatment or procedure, including the expected benefits, common side effects and alternative healthcare options; the risks and benefits of the alternative treatment or procedure; and the risks and benefits of not receiving or undergoing a treatment or procedure; a decision not to receive the healthcare offered; any significant long term physical, emotional, mental, social, sexual or other expected outcomes; the anticipated recovery implications.

The patient has sufficient time to consider and clarify any information in order to make an informed decision, taking into account the context of the clinical situation.

In turn, your patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention. The information provided and the consent given relate to the specific healthcare actually provided.

Characteristics that increase the probability of successful TOLAC

From available studies, there is good and consistent evidence that a woman who has undergone only one previous cesarean delivery performed using a transverse lower segment hysterotomy incision has a very low risk of uterine scar separation during a subsequent trial of labor; thus, TOLAC is a reasonable option for delivery (20,23). For these patients, the bulk of evidence supports a success rate of TOLAC approaching 60 to 70 percent, with a predicted uterine rupture rate of about 0.7 percent (23). Success rates are higher in patients with additional characteristics, such as a prior vaginal delivery.

Demographic factors such as Hispanic, African American, and Asian women are more likely to pursue a TOLAC, but are less likely to have a successful TOLAC when compared with non-Hispanic white women (OR for successful TOLAC for non-Hispanic Caucasians, African Americans, and Hispanics: 1, 0.69, 0.65, respectively) (23,24). Increasing maternal age, single marital status, and less than 12 years of education are also associated with a reduced likelihood of successful TOLAC (23,24). Women over age 35 years are less likely to pursue a TOLAC; those who attempt TOLAC are less likely to have a successful TOLAC and more likely to experience TOLAC-associated complications than younger women (25).

An interpregnancy interval of more than six months is desirable, as an interval of less than six months is an independent risk factor for both uterine rupture and maternal morbidity during TOLAC. Data on the effect of preexisting maternal medical disease on the outcome of a TOLAC are inconclusive. Several cohort studies of women with preexisting maternal disease, such as hypertension, diabetes, asthma, renal disease, and heart disease, reported a reduced likelihood of successful TOLAC (24). When admitted to the labor unit, women in spontaneous labor or with a high Bishop score are more likely to have successful TOLAC than women who are being induced or who have low Bishop score

(23,24). A fetus weighing more than 4000 g halves the likelihood of successful TOLAC (successful TOLAC for birth weight >4000 g (23,24)

University hospitals or those affiliated with obstetrics and gynecology residency program have higher rates of TOLAC and successful TOLAC (26,23). While most studies report that women with a twin gestation are significantly less likely to pursue a TOLAC, the overall success rate and risk of uterine rupture in this population is similar to that in singleton gestations undergoing TOLAC (27). ACOG has opined that women with twin pregnancies and one previous low transverse cesarean delivery are candidates for TOLAC if they have no contraindications to vaginal birth (28).

For women who are appropriate candidates for TOLAC, the highest success rates (over 80 percent) occur in women who have had a vaginal delivery before or after their previous cesarean delivery. (24,29) A nonrecurrent indication for the prior cesarean delivery increases the probability that TOLAC will be successful. (23,24) Patients who present in active spontaneous labor at ≤40 weeks of gestation with an appropriately-sized fetus have a highest success rate of TOLAC.

Updated evidence-based clinical practice guideline for TOLAC and ERCD

Both the American College of Obstetricians and Gynecologists (ACOG) and the National Institutes of Health (NIH) suggest that a trial of labor after cesarean (TOLAC) to attempt a vaginal birth after cesarean (VBAC) is an acceptable option for a woman who has undergone one prior cesarean delivery with a low transverse uterine incision, assuming there are no other conditions that would normally require a cesarean delivery (as an example, placenta praevia). (30)

The American Academy of Family Physicians Commission on Clinical Policies and Research convened a panel to systematically review the available evidence on trial of labor after cesarean delivery (TOLAC) using the Agency for Healthcare Research and Quality Evidence Report on

Vaginal Birth After Cesarean (VBAC). (31) The panel's objective was to provide an evidence-based clinical practice guideline for pregnant women and their families, maternity care professionals, facilities, and policy-makers who care about trial of labor and maternity care for a woman with one previous cesarean. The recommendations are as follows: Women with one previous cesarean delivery with a low transverse incision are candidates for and should be offered a trial of labor (Level A). Patients desiring trial of labor after previous cesarean should be counseled that their chance for a successful vaginal birth after cesarean is influenced by the following positives factors: maternal age <40 years, prior vaginal delivery (particularly prior successful VBAC), favorable cervical factors, presence of spontaneous labor and non recurrent indication that was present for prior cesarean delivery. The negative factors (decreased likelihood of successful VBAC) include: increased number of prior cesarean deliveries, gestational age >40 weeks, birth weight >4,000 g, induction or augmentation of labor.

Prostaglandins should not be used for cervical ripening or induction as their use is associated with higher rates of uterine rupture and decreased rates of successful vaginal delivery (Level B). TOLAC should not be restricted only to facilities with available surgical teams present throughout labor since there is no evidence that these additional resources result in improved outcomes (Level C). Maternity care professionals need to explore all the issues that may affect a woman's decision including issues such as recovery time and safety (Level C). No evidence based recommendation can be made regarding the best way to present the risks and benefits of trial of labor after previous cesarean delivery (TOLAC) to patients. The impact of counseling on patient decisions and outcomes of trial of labor after previous cesarean delivery is unfortunately unclear at present.

PROBLEM STATEMENT

There is an increasing rate of repeat cesarean delivery and decreasing number of women trying labor after one previous cesarean delivery. This is predicated to lack of adequate information for patients to make an informed decision and lack of implementation of appropriate informed consent process. In the United States for example, federal acts and regulations, as well as professional guidelines, state that every pregnant woman has the right to base her maternity care decisions on accurate, up-to-date, comprehensible information. (2)

Contrary to legal mandates, mounting evidence reveals that the application of informed consent within current health-care practice is restricted and inconsistently implemented. (32) Patients report receiving less information about treatment options and alternatives than desired and being afforded the opportunity to participate in health-care decisions less than they would prefer. (33) In addition, practitioners report underestimating patient preferences to participate in health-care decisions (32) and not integrating informed decision-making principles into practice thus highlighting a gap in care.

Clarification regarding physicians' legal responsibilities to disclose all information on the risks, benefits, and alternatives to patients prior to treatment was not specified and put into practice until the 1980s. (32)

There is increasing discussion that the rising cesarean rates are the result of a dramatic increase in maternal demand for primary cesareans. The rise of national cesarean rates coupled with the drastic decline in vaginal birth after cesarean suggest practice and policy protocols favor the propagation of cesarean sections with no medical reason (32) rather than maternal choice.

Rates of caesarean section are rising around the world, particularly in high- and middle-income countries while research data have shown that women who attempt a VBAC, the chance of achieving

vaginal birth has been variably reported between 56% (34) and 80% (35) and also while the overall risk of uterine rupture in women with a prior cesarean delivery is 0.3 percent. (20,36) However, the proportion of women attempting a VBAC has been declining in many countries (37), fuelled by negative reports of an increase in the risk of maternal and infant complications related to VBAC (36), including uterine rupture and perinatal death . The need for evidence to inform women, clinicians, and policy makers about health outcomes of intended planned mode of birth rather than actual has been highlighted as critical (38).

Acknowledgment of the importance of patient autonomy and increased patient access to information has prompted more patient–generated requests for surgical interventions not necessarily recommended by their physicians. Decision making in obstetrics and gynecology should be guided by the ethical principles of respect for patient autonomy, beneficence, nonmaleficence, justice, and veracity. (39) The influence of TOLAC counseling on the woman's decision is unclear from current studies. (40)

STUDY RATIONALE AND JUSTIFICATION

Access and availability to evidence-based information is central to informed consent for patients and it is imperative for the physicians to follow legal and ethical considerations – this improves the health outcomes. (32) Research indicates that congruency between patients' and physicians' decision-making style is associated with higher patient evaluation of physicians, as well as an increased likelihood of patient recommendations to others. (32)

In addition, patient participation in health-care decisions is positively correlated with improvement to patient–physician relationships and trust in the physician. (32) Informed consent not only ensures the protection of the patient against unwanted medical treatment, but it also makes possible the patient's active involvement in her medical planning and care. However, worldwide the practice of obstetrics and gynecology has always faced special ethical questions in the implementation of informed consent. (2)

Currently in most developing countries, patient education during antenatal clinic for a patient with one prior cesarean delivery is not adequately done and the provider does not know how much information is considered "adequate" or minimum criteria for an informed decision on mode of delivery.

At KNH, there is a rise rate of cesarean delivery as proved by the study of Akula in 2003 showing that up to 93% of the patients with one previous cesarean delivery had a RCD, with only 8% having had VBAC. (41)

From recent data in KNH, (42) rates of caesarean section have risen up from 3654 patients (35 % of all deliveries) in 2009 to a number of 3873 patients (37%) in 2011. The patients undergoing repeat cesarean section are also on the rise from a number of 1409 (38.5 % of all cesarean deliveries) in

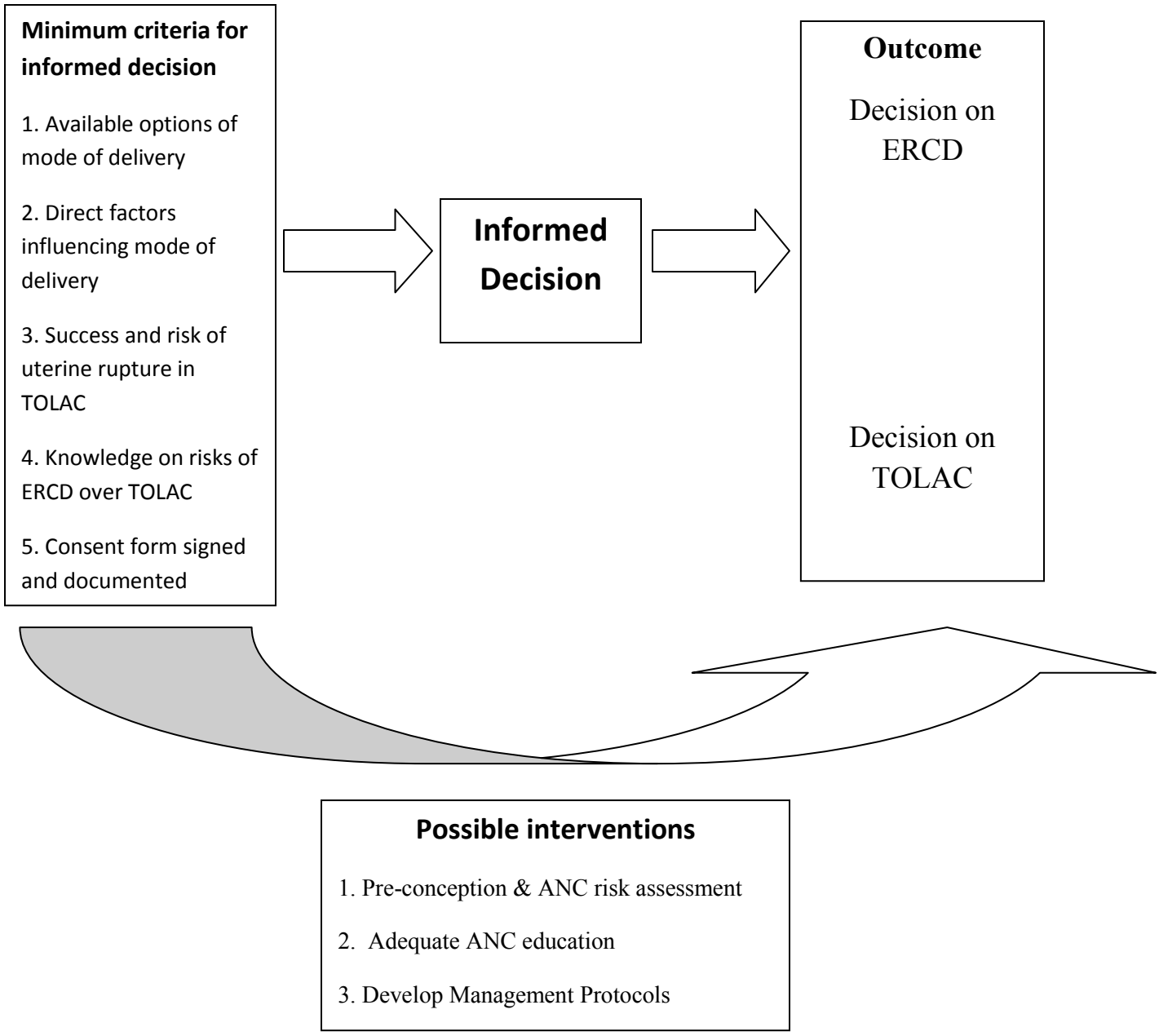
2009 to a number of patients of 1576 (41%) in 2011. This rise is probably because of lack of adequate informed decision process in a patient with previous cesarean delivery attending KNH. In addition, the proportion of women attempting a vaginal delivery after a previous caesarean section is not documented.

There is no local study done showing whether women with prior cesarean delivery presenting for either trial of labor or repeat cesarean section are making informed decision and there is no protocol nor known guidelines for criteria of informed consent.

In the antenatal clinic at KNH many women with prior cesarean delivery are not aware about the risks and benefits of either mode of delivery, and this made me carry out this study to emphasize the value of informed consent whereby a patient is enabled to make an informed and voluntary decision about accepting or declining medical care, evaluate the accuracy of informed consent form, ensure an implication of patient in his management, study the medical influence on patients' decision and to enable rational protocol or guidelines to better education of our patients since ante natal clinic.

CONCEPT FRAMEWORK

Figure 1: Diagrammatic representation of the conceptual framework



Conceptual narrative

All patients who have had a prior cesarean delivery should be informed on the following outcomes: a successful trial of labor culminating in vaginal birth, a failed TOLAC resulting in a repeat cesarean delivery during labor, or an ERCD. This information is very important to the client for an informed decision.

Prenatal care is the entry point for pregnant women into the health care system. Once the patient with one prior cesarean delivery presents in ANC, the provider should emphasize on some factors influencing the mode of delivery including assessment of pelvis, weight of the baby, medical or obstetric complications in current pregnancy, adequacy of facility for delivery (a 24 hours-theater, skilled providers,…) and types of prior uterine incisions like classical, T or J incisions, as well as transfundal incisions or myoma resections that extend into the myometrium. (43)

Patient knowledge on success chances and risk of uterine rupture of TOLAC as well as knowledge on reasons of prior cesarean delivery is also important criteria in the process of informed decision. Also, the patient needs to know the risks and benefits of both mode of delivery to make a decision and the provider should emphasize about blood loss, risk of infection, complication of anesthesia, injury to organ and time of recovery.

All health care interventions require some kind of consent by the patient, following a discussion of the procedure with a health care provider. The signed consent forms are the culmination of a dialogue required to foster the patient's informed participation in the clinical decision and have to be documented in patient's file.

For a success patient informed decision, the provider has to be trained on an adequate ANC education, preconception and ANC risk assessment and developed management protocols.

STUDY QUESTION

Are patients with one previous cesarean delivery presenting at KNH making an informed decision on the mode of delivery?

OBJECTIVES

Broad objective

To find whether patients with one previous cesarean delivery presenting at KNH are making an informed decision on the mode of delivery.

Specific Objectives

- To determine the proportion of patients who choose trial of labor over ERCD;
- To determine if the patients with one previous cesarean delivery are provided adequate information about their mode of delivery;
- To determine correlates of preferred mode of delivery among women presenting with one previous cesarean delivery;

STUDY METHODOLOGY

Study Design

This was a cross-sectional study targeting women with one previous cesarean delivery presenting at KNH for delivery.

Study site

The study was conducted in the Antenatal Clinic (Clinic 18) at Kenyatta National Hospital, which is a national referral hospital located in Nairobi, about 4 kilometers to the west of the city centre. It is

also the main teaching hospital for college of Health Sciences, University of Nairobi. The hospital caters for patients from Nairobi and its environs as well as referrals from other hospitals in the country and the greater Eastern Africa region. The hospital records more than 10,000 deliveries per year with a cesarean section rate of about 40%. KNH has several clinics, and among them clinic 18 which offers antenatal clinic services besides other reproductive health services. Consultants and registrars are divided into three firms and each firm has only one day per a week to cover antenatal clinic. There is no protocol or guidelines regarding management of pregnant women attending ANC with one previous cesarean delivery.

Study period

This study was carried out over a period of 5 months beginning September 2013 to January 2014

Study population

The study population consisted of women with one prior cesarean delivery presenting at the antenatal clinic and whose decision on the mode of delivery either by trial of labor or elective repeat cesarean delivery had already been made.

Inclusion criteria

Women with history of one prior cesarean delivery seen at KNH after decision on mode of delivery were included in the study after obtaining informed consent.

Exclusion criteria

Women with history of more than one prior caesarean delivery and those who declined to give consent were excluded from the study.

Sample size calculation

The sample size was determined to achieve an adequate rate of informed decision regarding patients with one previous caesarean delivery. However, the proportion of patients getting an informed decision on modes of delivery was not calculated from the previous studies. In this case we used the prevalence rate of 50%. The estimated sample size was calculated as;

$$n = \frac{Z^2_{\alpha/2} * P\,(1-P)}{D^2}$$

Where n = required sample size

P = prevalence of patients with one previous cesarean delivery making an informed decision

D = Precision with which to measure prevalence, set at plus or minus 5%.

The $Z_{\alpha/2}$ was the cut off points along the x-axis of the standard normal probability distribution that represents probability matching the 95% confidence interval (1.96).

Substituting the above in the formulae we got; $n \approx 384$

Based on KNH Health Information data for five years (42) showing patients done yearly elective caesarean delivery:

Year	**Patients with at least one previous Caesarean delivery**
2008	416
2009	504
2010	417
2011	463
2012	426
Average	**445**

On average, approximately a population of 445 patients with one previous caesarean delivery attend ANC yearly (about 40 patients per month). Since the total population for one year is less than 10,000, we apply the finite population correction factor (FPF)

$$n_f = \frac{Nn}{N+n-1}$$

Substituting n=384 and N=445 in the above formulae, we got the adjusted sample size of approximately 206.

Recruitment (Sampling) procedure

Before recruitment, one day training was organized to update a research assistant and data assistant/statistician on procedure and ethical guidelines of the study. At the end of the training, the research and data assistants were expected to understand well the purpose of the study, the steps of patient informed consent, the ethical guidelines of the study, how the questionnaire was supposed to be filled and how to collect data from ANC cards or patients' file.

The participant selection and recruitment were done in ANC where an investigator or research assistant reviewed all ANC cards to identify patients with one previous caesarean delivery. After having been seen by the provider the participants were invited in the study room where they were informed briefly about the study and study population. The participants interested in the study started the process of informed consent and explanation on how to fill in a structured questionnaire was given to those who had voluntarily consent.

Data collection

Consecutive consenting women completed a structured questionnaire to assess the demographic characteristics, awareness about risks and benefits of both mode of deliveries, knowledge about

complications following the prior cesarean delivery as well as indications of previous cesarean delivery, and knowledge about the mode of delivery on the current pregnancy.

Data abstraction was also collected from patients' records through a structured questionnaire by an investigator or research assistant to assess parity, level of provider, family planning goals, and relevant clinical examination, including estimated fetal weight, obstetrical ultrasound data, timing on decision of mode of deliveries and any other medical or obstetric complication and to assess the value of documentation.

Data management

The data collected from patients 'interview and records was recorded into a worksheet (see appendix) and then entered into a computer for analysis using STATA version 11. Microsoft word was used for the text while Microsoft excel helped for tables and graphs of data. After data collection, the data assistant or statistician checked the questionnaire and started coding process.

Data entry and analysis

The data recorded into a questionnaire was then entered into computer through Epidata designed database and exported to the Statistical Package for Social Science (SPSS-20) for analysis. Comparative analysis focused on patient knowledge, baseline characteristics, obstetric characteristics and antenatal care provided, and chosen mode of delivery.

Quality control

The questionnaire was piloted for 3 weeks prior to recruitment at ANC KNH to adjust the questionnaire and improve data coding. The piloting was done by the principal investigator and a trained research assistant for standardization. The questionnaires were analyzed and any flaws in the design of the questionnaire or unclear questions were withdrawn.

In order to avoid double recruitment, the participants' file numbers were entered in a register upon recruitment for serialization. This register was counter checked on a regular basis for any double entries and if any were discovered, one of the questionnaires was withdrawn and discarded and the serialization rectified before recruitment continued.

ETHICAL CONSIDERATION

Approval was sought from the KNH/UoN Ethics and Research committee before carrying out this study. Informed consent of patients was obtained before participating in the study. Standard care was given to all women regardless of whether they consented or declined to participate in the study .The records were coded and the patients' names were not used. The information collected remained confidential and was only used for the purpose of the study. No incentives were given to the study subjects. My study proposal was also presented to the department of Obstetrics and Gynecology of the University of Nairobi and clearance to carry out the study was granted.

STUDY LIMITATION

The quality of recording clinical findings and history taking had a direct impact on the study, as some clinicians did not record the clinical assessment and previous uterine incision before the decision on mode of delivery.

Sincerity of the patients and their recall on past surgical obstetrical history may have had impact on the study. Due to cost implication and academic calendar, the sample size has been recalculated using Finite Population correction factor to shorten the period of data collection.

STUDY RESULTS

The study was conducted to determine whether patients with one previous cesarean delivery were making an informed decision at Kenyatta National Hospital towards the options of delivery of either the trial of labor or elective repeat cesarean delivery. A total of 202 women participated in the study. Structured questionnaires were used in the study and STATA version 11 was used for analysis.

Table 1: Socio-demographic characteristics of the study participants

Parameters	Number	Percentage
Patient's age (years)		
20-24	25	12.4
25-29	64	31.7
30-34	77	38.1
>35	36	17.8
Educational level		
Primary	38	18.8
Secondary	92	45.6
University	72	35.6
Marital Status		
Married	190	94.0
Single	10	5.0
Separated	2	1.0
Occupation		
Employed	49	24.3
Business /self employed	92	45.5
Student	2	1
Housewife	59	29.2

From table 1 above, Most women 77 (38.1%) were aged between 30 and 34 years with their age ranging between 21- 43 years with mean± SD of 30.2 ± 4.7 years (Median=30, **IQR =18**). Most of the women were married 190 (94%). Many of the women 92 (45.6%) had secondary level of education. About 46% of the participants were mostly involved in businesses or self-employed.

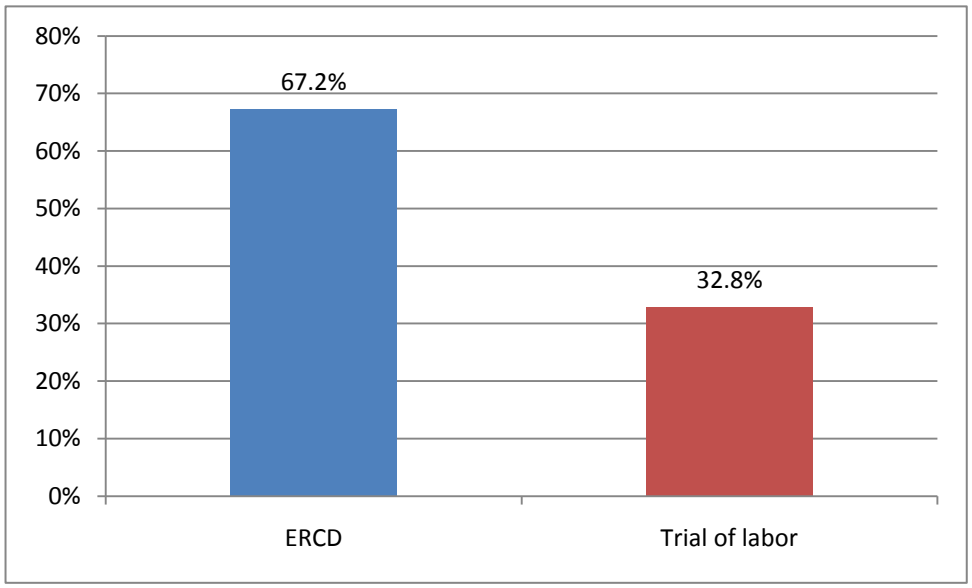
Table 2: Obstetric characteristics of the study participants

Parameters	Number	Percentage
Patient's parity		
1	153	75.7
2-3	45	22.3
>3	4	2
Outcome of previous cesarean delivery		
Well live infant	166	82.1
Live infant in distress	4	2
Premature baby	1	0.5
Still birth	11	5.4
Neonatal death	10	5
Infant death	6	3
Not documented	4	2
Medical or obstetrical complications after the previous c/s according to the patient's interview (n=32)		
Bleeding (PPH)	3	7.9
Convulsions	8	21.1
Maternal infections	8	21.1
Death of the baby(neonatal death)	15	39.5
Burst abdomen	3	7.9
Post partum psychosis	1	2.6
Patient's family planning method choice following the current delivery		
BTL	12	5.9
Natural	1	0.5
Pills	6	3
Injections	2	1
Not yet decided	181	89.6
Patient's preferred mode of delivery before attending KNH		
Trial of labor	86	42.6
Elective repeat c/s	95	47.0
Not sure	17	8.4
Any	4	2.0

As shown in table 2, the majority of patients with one previous cesarean delivery were Para one 75.7%. The outcome of the previous cesarean delivery was live birth for 82.1% of the participants. About 15.8 % (n=32) reported medical or obstetric complications following the previous cesarean

delivery, with 39.5% among them reporting early neonatal death. The majority of the women 89.6% had no contraceptive choice following the current delivery, with only 5.9% of the women preferring BTL. Before attending ANC –KNH, 47% of the patients preferred ERCD as mode of delivery while 42.6% of the patients preferred TOLAC.

Figure 2: Patient choice on mode of delivery



As shown on the figure 2 above (decided mode of delivery during ANC), the decision made on mode of delivery during ANC was ERCD for the majority of the patients with 136 (67.2%) while the decision for trial of labor was found only in 66 (32.8%) of the patients.

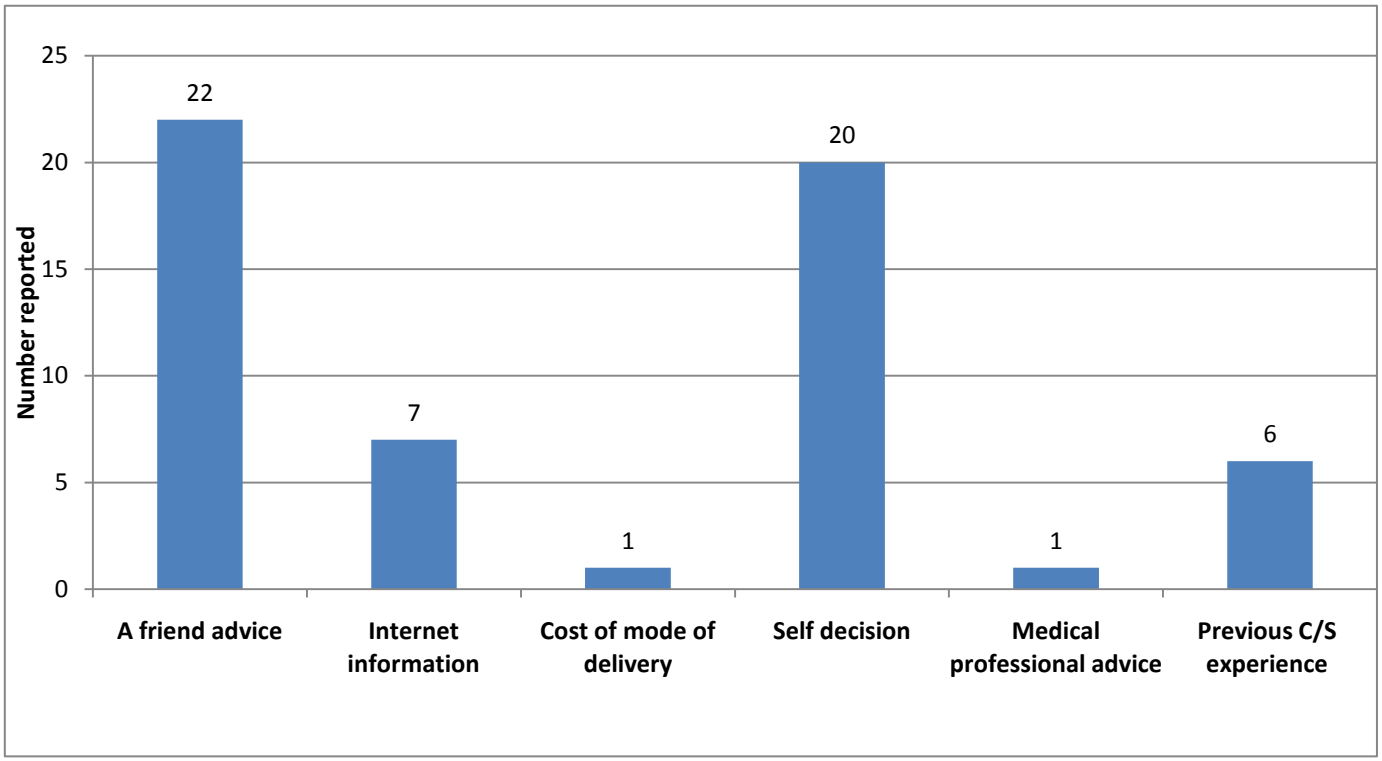
Table 3: Number of antenatal visits and information provided to patients with one previous cesarean delivery attending KNH ANC.

Parameters	Number	Percentage
Number of ANC visits at the time of recruitment		
<3	60	29.7
≥3	142	70.3
Patients informed on available options of mode of delivery		
Elective repeat c/s	126	62.4
Trial of labor	61	30.2
None	15	7.4
Patients counseled on reasons ERCD is recommended than TOLAC (n=116)		
Big baby (>3.5kg)	21	18.1
Classical scar	7	6
Small pelvis	15	12.9
Availability of 24 hours theatre/blood transfusion/skilled doctors and anesthetists	1	0.9
Mal-presentation/breech presentation	11	9.5
Bad obstetric history	3	2.6
Choice of BTL	2	1.7
Placenta preavia	21	18.1
Don't know	35	30.2
Patients counseled at discharge after previous C/S on reasons ERCD is recommended in subsequent pregnant (n=19)		
Small pelvis	13	68.5
Classical uterine incision	2	10.5
High risk of uterine rupture if any VBAC	2	10.5
BTL would also be offered	2	10.5
Counseling doctor preferred mode of delivery (perception of the patient)		
None	44	21.8
Elective repeat cesarean section	107	53
Trial of labor	51	25.2
Level of provider at ANC KNH		
Senior house officer	174	86.1
Consultant	28	13.9

From Table 3 above, the majority of the patients 70.3% had presented at ANC KNH more than three times up to the time of the study. Most of the patients 62.4% were informed on ERCD as only mode

of delivery. Few patients counseled knew that the classical scar (7 out of 116) and availability of 24 hours theater and skilled providers (1/116) are reasons to consider for recommending ERCD or TOLAC. The majority of doctors at ANC KNH were senior house officers 174 (86.1%) while consultants were represented at 28 (13.9%).

Figure 3: Factors associated with the choice of mode of delivery among patients not counseled on risks and benefits of both mode of delivery



In this figure, among factors influencing mode of delivery in patients not counseled (n=57), a friend advice was reported at 22 (38.5%) of the patients while internet information was reported at 7 (12.3%).

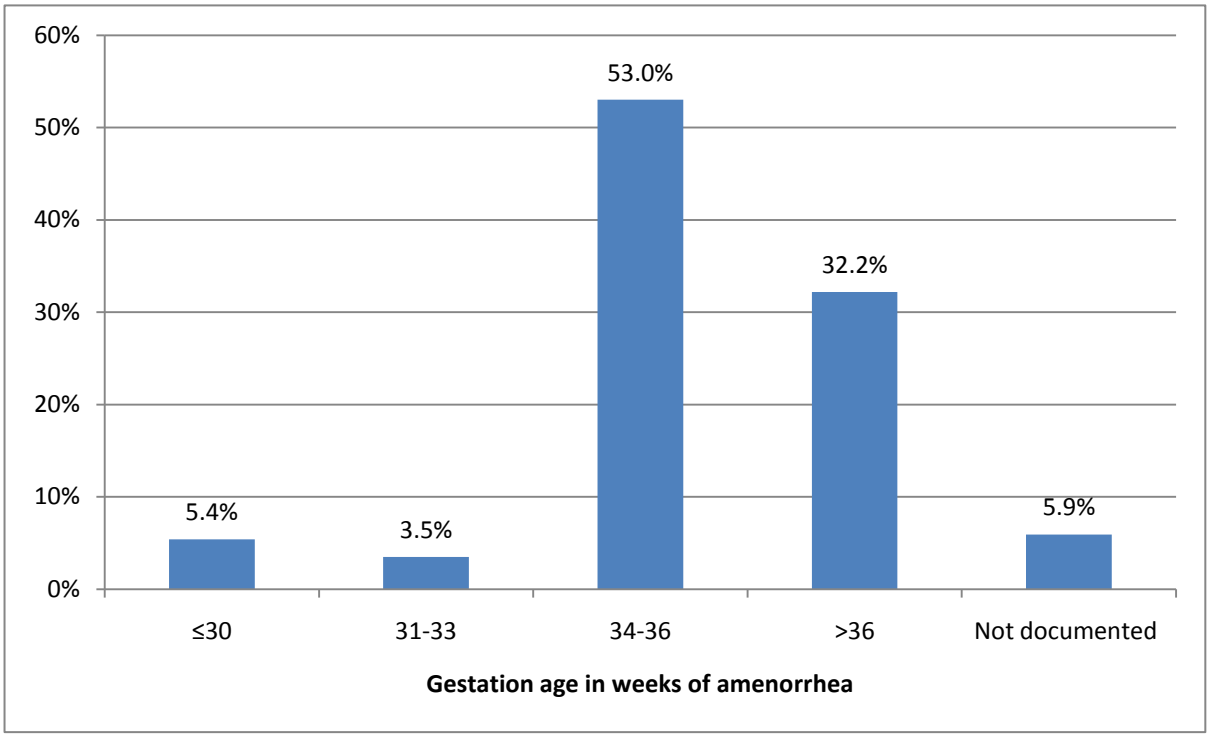
Table 4: Information provided on risks and benefits of both mode of delivery amongst one previous cesarean delivery patients attending KNH ANC.

Parameters	Number	Percentage
Patient's knowledge on risks associated with repeat C/S than TOLAC (n=163)		
Increased blood loss	124	28.4
High risk of infection	106	24.3
Complication of anesthesia	36	8.3
Rupture in case of big baby	10	2.3
Injury to organs	5	1.1
Recovery is longer	140	32.2
Limb numbness	15	3.4
Patient's knowledge on risks associated with TOLAC than ERCD (n=155)		
Uterine rupture resulting in emergency C/S	54	20.8
Failed trial of labor	114	44
Uterine rupture is > with VBAC than repeat C/S	81	31.3
Increased blood loss	5	1.9
Increased risk of infection	2	0.8
Fetal death	3	1.2
Patient's knowledge regarding overall chances of success of TOLAC		
Very high (>50%)	65	32.2
Very low (<25%)	40	19.8
Don't know	97	48
Patient's knowledge regarding the risks of uterine rupture (opening of scar)		
Very low (<1%) but increased with number of c/s	64	31.7
Very high (>50%)	29	14.4
Don't know	109	53.9
Patient's knowledge on recovery from vaginal delivery against repeat C/S		
Same	1	0.5
Longer for repeat C/S	166	82.2
Longer for a vaginal delivery	2	1
I don't know	33	16.3
Reasons for previous c/s as important factor in determining the chance of successful TOLAC according to the patients		
Yes	60	29.7
No	30	14.9
Don't know	112	55.4

From this table above, most of the patients knew a little about complications of anesthesia (8.3%), rupture in case of big baby (2.3%) and injury to organs (1.1%) as associated risks of repeat cesarean delivery. Only 32.2% of the patients know that the overall chances of success of TOLAC is very high >50%, while 48% of the patients don't know.

Regarding the risks of uterine rupture (opening of scar), more than half of the patients (53.9%) don't know there is a risk while only 31.7% know that the risk is very low < 1 % and increasing with the number of cesarean delivery. More than half of the patients (55.4%) don't know that the reasons for previous cesarean are important factor in determining the chance of successful VBAC.

Figure 4: Gestation age at the time of decision on mode of delivery for patients with one previous cesarean delivery attending KNH ANC



In this figure, for more than a half of the patients 107(53%), the decision on mode of delivery in ANC was done between 34-36 weeks, however the timing was not indicated in 5.9% of the patients.

Table 5: Antenatal clinical assessment of patients with one previous cesarean delivery attending KNH ANC.

Parameters	Number	Percentage
Medical or obstetrical complication documented during ANC		
Preeclampsia	8	4
Diabetes	2	1
Anemia	1	0.5
Sero-reactive for HIV	7	3.4
Placenta praevia	2	1
Malpresentation	5	2.5
Fibroids	5	2.5
No complication documented/indicated	172	85.1
Documented reasons for the previous cesarean delivery		
CPD/big baby	31	15.3
Malpresentation	15	7.4
APH	4	2
Failed induction	18	8.9
Prolonged labor	32	15.8
NRFS	55	27.2
Not documented	47	23.3
Medical or obstetrical complication postpartum documented after the previous cesarean delivery		
Infections	2	1
Preeclampsia	2	1
Not documented	198	98
Estimated fetal birth weight (Kg) clinically or by U/S documented at the time of the decision of mode of delivery		
<3.5	15	7.4
≥ 3.5	4	2
Not documented	183	90.6
Consent signed and documented in the file at the time of decision for mode of delivery		
Yes (Patients admitted for ERCD from ANC)	23	11.4
Booked in elective diary	92	45.8
Not documented	86	42.8

As shown in this table above, for the majority of the patients 85.1% the medical or obstetric complications were not documented/indicated for the current pregnant in patient's file. NRFS was the most common indication for the previous cesarean delivery documented at 27.2%. However for

23.3% of the patients there was no documented indication for their previous cesarean delivery. The medical or obstetric complications postpartum were not documented for the majority of the patients 98%. During the time of decision of mode of delivery, the estimated fetal birth weight was not documented in 90.6% of the patients. At the time of decision of mode of delivery, only 11.4% of the patients for ERCD consent form was signed and documented in the file while patients for TOLAC did not sign any consent and none documented in the file.

Table 6: Proposed minimum criteria for a patient with one previous cesarean delivery to make an informed decision on mode of delivery at KNH

Criteria	Frequency	Percent
Patients informed on mode of delivery (available options) (n=202)		
TOLAC	61	30.2
ERCD	126	62.4
Both	0	0
Patient knowledge on factors influencing mode of delivery (n=116)		
Classical scar as a reason for ERCD	7	6
Small pelvis as a reason for ERCD	15	12.9
Big baby as a reason for ERCD	21	18.1
Current medical or obstetric complications as a reason for ERCD	30	25.9
Adequacy of facility for delivery (A 24 hours-theater…)	1	0.9
Patient knowledge on success and risk of uterine rapture in TOLAC (n=202)		
Patient knowledge on overall chance of TOLAC success	65	32.2
Patient knowledge on risk of uterine rapture in TOLAC	64	31.7
Reasons of previous cesarean as factor of success for TOLAC	60	29.7
Patient knowledge on risks of ERCD over TOLAC (n=163)		
Increased blood loss	124	76.1
High risk of infection	106	65.0
Complication of anesthesia	36	22.1
Injury to organ	5	3.1
Recovery is longer	140	85.9
Consent form signed and documented in the patient file (n=202)	23	11.4

The table above shows the minimum proposed criteria of informed decision on mode of delivery in a patient with one previous cesarean delivery at KNH. On average, it was reported that 61(30.2%) C.I: 24 to 37% of the patients were making informed decision.

Table 7: Correlation of decision or choice before attending KNH ANC and after counseling in TOLAC and ERCD women of the study participants

Before visit (TOLAC)	**After visit (TOLAC)**		**RR(95% CI)**	**P-value**
	Yes	No		
Yes	58(67.4%)	28(32.6%)		0.0001
No	8(6.9%)	108(93.1%)	4.3(3.0-6.0)	
Before visit (ERCD)	**After visit (ERCD)**		**RR(95% CI)**	**P-value**
	Yes	No		
Yes	91(95.8%)	4(4.2%)		0.0001
No	45(42.1%)	62(57.9%)	11(4.2-28.7)	

This table above shows a significant correlation of decision or choice before attending KNH ANC and after ANC counseling in TOLAC patients and ERCD patients (P=0.0001). TOLAC Patient choice or decision before attending KNH ANC is 4 times more likely to be the same after ANC counseling (RR=4.3; P=0.0001). Also, ERCD patient choice or decision before attending KNH ANC is 11 times more likely to be the same despite KNH ANC counseling (RR=11; P=0.0001).

Table 8: **Socio-demographic correlates associated with preferred mode of delivery amongst one previous cesarean delivery patients attending KNH ANC**

Parameters	ERCD n=136	TOLAC n=66	P-value
Patient's age (years)			
20-24	16(11.8%)	9(13.6%)	
25-29	44(68.8%)	20(30.4%)	0.654
30-34	49(32.4%)	28(42.4%)	
>35	27(19.9%)	9(13.6%)	
Patient level of education			
Primary	24(17.6%)	14(21.2%)	
High school (secondary)	58(42.6%)	34(51.5%)	0.224
University	54(39.8%)	18(27.3%)	
Patient marital status			
Single	5(3.7%)	5(7.6%)	
Married	130(95.6%)	60(90.9%)	0.419
Separated	1(0.7%)	1(1.5%)	
Patient occupation			
Student	2(1.5%)	0	
Employed	32(23.5%)	17(25.7%)	0.795
Business /self employed	62(45.6%)	30(45.5%)	
Housewife	40(29.4%)	19(28.8%)	

The table above shows that there was no association with preferred mode of delivery in terms of patient's age (p=0.654), level of education (p=0.224), marital status (p=0.419) and patient occupation (p=0.795).

Table 9: Antenatal and obstetric correlates associated with the preferred mode of delivery amongst one previous cesarean delivery patients attending KNH ANC.

Parameters	ERCD n=136	TOLAC n=66	P-value
Patient's parity			
1	104(76.5%)	49(74.2%)	
2-3	28(20.6%)	17(25.8%)	0.286
>3	4(2.9%)	0	
Number of ANC visits at the time of recruitment			
<3	35(26.3%)	19(30.2%)	0.574
≥3	98(73.7%)	44(69.8%)	
Counseling doctor preferred mode of delivery			
None	29(21.3%)	15(22.7%)	
Repeat cesarean section	107(78.7%)	0	0.001
Vaginal delivery	0	51(77.3%)	
Patient's preferred mode of delivery before attending KNH			
Trial of labor	28(20.6%)	58(87.9%)	
Elective repeat c/s	91(66.9%)	4(6.1%)	0.001
Not sure	14(10.3%)	3(4.5%)	
Any	3(2.2%)	1(1.5%)	
Level of provider at ANC KNH			
Senior house officer	123(90.4%)	51(78.5%)	0.020
Consultant	13(9.6%)	14(21.5%)	

The table above shows that there was no association with preferred mode of delivery in terms of number of ANC visits (p=0.574) and patient's parity (p=0.286). However the following correlates are significantly associated with the preferred mode of delivery: counseling doctor preferred mode of delivery (p=0.001), patient preferred mode of delivery before attending KNH (p=0.001) and level of provider (p=0.020).

Table 10: Patient knowledge correlates associated with the preferred mode of delivery amongst one previous cesarean delivery patients attending KNH ANC.

Parameters	ERCD n=136	TOLAC n=66	P-value
Patient's knowledge of patients regarding the risks of uterine rupture (opening of scar)			
Very low (<1%) but increased with number of c/s	17(26.6%)	47(73.4%)	
Very high (>50%)	27(93.1%)	2(6.9%)	0.001
Don't know	92(84.4%)	17(15.6%)	
Patient's knowledge regarding overall chances of success of TOLAC			
Very high (>50%)	12(8.8%)	53(80.3%)	
Very low (<25%)	40(29.4%)	0	0.001
Don't know	84(61.8%)	13(19.7%)	
Patient's knowledge on recovery from vaginal delivery against repeat C/S			
Same	-	1(1.5%)	
Longer for repeat C/S	103(75.7%)	63(95.5%)	0.001
Longer for a vaginal delivery	2(1.5%)	0	
I don't know	31(22.8%)	2(3%)	
Estimated fetal birth weight in Kg clinically or by U/S at the time of the decision of mode of delivery			
<3.5	10(7.4%)	5(7.6%)	
≥ 3.5	4(2.9%)	-	0.372
Not documented	122(89.7%)	61(92.4%)	
Patient's awareness on risks associated with repeat C/S than TOLAC			
Increased blood loss	76(26.6%)	48(32%)	
High risk of infection	65(22.7%)	41(27.3%)	
Complication of anesthesia	26(9.1%)	10(6.8%)	
Rupture in case of big baby	8(2.8%)	2(1.3%)	0.482
Injury to organs	3(1%)	2(1.3%)	
Recovery is longer	96(33.6%)	44(29.3%)	
Limb numbness	12(4.2%)	3(2%)	

The table above shows that there was no association with preferred mode of delivery in terms of estimated fetal birth weight at the time of decision (p=0.372) and knowledge on risks associated with repeat C/S than TOLAC (p=0.482). However there was significant association with the preferred mode of delivery in terms of knowledge of patients regarding overall chances of success of TOLAC

(p=0.001), regarding risk of uterine rupture in TOLAC (p=0.001) and patient's knowledge on recovery from vaginal delivery against repeat cesarean delivery (0.001).

DISCUSSION

This study was carried out to determine whether patients with one previous cesarean delivery presenting for delivery are making an informed decision at KNH. The study was to emphasize the value of informed consent, ensure an implication of patient in her management, study the medical influence on patients' decision and enable rational protocol or guidelines to better education of our patients during ante natal care.

The following are the main findings of this study: few patients chose TOLAC and fewer patients on average were making an informed decision. Most of the patients preferred repeat cesarean delivery before attending ANC KNH and this choice was significantly associated with the patient choice after ANC counseling. Equally, patients' mode of delivery was significantly linked with the preference of the counseling doctor and their qualification. The patients appear to know little about their mode of delivery. This study also found that there was limited documentation of patient with previous cesarean delivery; few ERCD patients signed consent forms and none of TOLAC patients signed consent forms. However, this study did not establish association between preferred mode of delivery and patient's social demography (age, educational level, marital status, occupation, parity) and number of antenatal visits.

A small number of patients 66(32.8%) chose TOLAC probably because of inadequate information and influence of the counseling doctor from ANC. A recent study published by Sarah and collaborators has demonstrated different findings. (6)

The majority of the patients 141(69.4%) were not making an informed decision at KNH and this was probably because of lack of adequate information provided in ANC or largely due to poor patient education. This study proposed minimum criteria for an informed decision in a patient with one previous cesarean delivery attending KNH. No similar studies involving clear criteria to determine whether the patients with one previous cesarean delivery are making an informed decision have been done.

However, worldwide the practice of obstetrics and gynecology has always faced special ethical questions in the implementation of informed consent. (2) More studies need to be done for a generalization of our proposed criteria.

Most of the patients about 137 (68%) did not know the overall chances of success (60-80%) and the risks of uterine rupture (<1%) while TOLAC. These findings are different from the study done by Sarah and collaborators in USA (6) and the difference is due probably to Sarah's questionnaire administered to the patients at admission and not immediately in the antenatal clinic.

There was a significant correlation with patient preferred mode of delivery before attending ANC KNH and chosen mode of delivery after ANC counseling (p=0.001). This was probably due to alternative sources of information and poor antenatal patient education regarding both modes of delivery.

The most factors influencing mode of delivery in patients with previous cesarean delivery not counseled were identified: friend advice 22(38.5%) and internet information 7(12.3%). No similar study has shown the alternative source of information besides health providers counseling on decision making.

The preferred mode of delivery by patients' was significantly associated with two factors: counseling doctor's preference (p=0.001) and their qualification (p=0.020). In this study majority of the senior house officers 123(90.4%) were offering repeat cesarean delivery due to probably less experience and lack of standard guidelines in management of a patient with one previous cesarean delivery.

According to Wells (2010) physicians that did not offer VBAC were also more likely to be practicing <10 years, have been involved in a law suit related to a cesarean delivery or have experienced a uterine rupture with maternal or fetal complications**.** (22) Most inexperienced providers tend to have bias towards informed consent process of patients with one previous cesarean delivery. In addition, some patients having limited understanding of medicine would prefer to be influenced by the most senior doctors. So, a patient is likely to choose the mode of delivery preferred by most senior provider.

However some challenges associated with informed consent process are to be remembered: information that may be considered necessary or desirable in formally educated urban populations may be of little relevance in less formally educated or rural populations, or vice versa. Also, in some cultures it might not be customary to provide certain forms of information, such as describing uncertainty about the effectiveness of the treatment being tested, or information about possible alternative treatments. Some of the providers therefore apply the dictum of Craigin: "Once a cesarean, always a cesarean." (15) Because informed consent laws and principles do not specify the amount of information that must be disclosed, physicians might find useful to know what they must typically disclose.

There was no association with preferred mode of delivery in terms of patient age, educational level, marital status, occupation, parity and number of antenatal clinic. However, in literature the increasing

maternal age over 35, single marital status and less than 12 hours education are associated with a reduced likelihood of successful TOLAC. (25)

In addition, this study found a limited documentation in patient's files of patient with previous cesarean delivery. The proper documentation may be useful tool in informed consent process because the patient is not followed by the same provider throughout antenatal clinic life at KNH. Without proper documentation a patient may not get adequate and relevant information. No similar study done on proper documentation and informed decision in a patient with one previous cesarean delivery. Researchers have also shown that the patients may not accurately remember all the facts disclosed in a discussion. (12,13)

In practice, there is no consent form for TOLAC patients available in KNH ANC. Few patients for ERCD 23 (11.4%) signed the consent form while none of the patients for TOLAC signed any consent form. This is because at KNH ANC the ERCD patients sign consent form on admission while at the time of the decision the patient is only booked in elective diary. The consent form should be available at the moment of decision to prove that the patient was given information, has understood and consented.

Some of the main limitations of this study are the small sample size and lack of standardization in both patient counseling and questionnaire itself. The sample size was recalculated based on Finite population correction factor to lower the sample size due to academic calendar and cost implications.

However, this study has two major strengths: it is original and proposes minimum criteria for an informed decision process regarding a patient with prior cesarean delivery attending KNH for delivery.

Our data was obtained from an institution offering VBAC and the population was not only educated (more than 75%) but also urbanized and middle class than the average across the country. Our results may therefore represent a better informed population suggesting wider knowledge gaps throughout the country.

Our study should be considered as preliminary investigation of current practice and patterns. It is intended therefore, to provoke further interest in the subject of informed decision process in patients with previous cesarean delivery.

This study therefore recommends that standard protocols, checklists and policies should be established to better manage patients' with one previous cesarean delivery.

CONCLUSION

The patients demonstrated an overall lack of information on both modes of delivery while doctor's preference affected the patient's decision. The study showed also an overall lack of documentation in patient's file and proposed minimum criteria for informed decision.

RECOMMENDATIONS

- Develop standard protocol, checklists and policies for management of patients with a previous cesarean delivery attending KNH;
- Initiate dialogue among doctors on patients' rights as well importance of documentation and training of doctors on new protocol guidelines for patients with a previous cesarean delivery.

Dissemination plans

The results of this study have been presented at the department of Obstetrics and Gynecology, University of Nairobi. The results will also be presented at local and international conferences and offered for publication in both local and international journals. Guidelines' protocols have been initiated based of the results of this study and will be discussed for approval and use in all health institutions in Kenya.

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APPENDIX

Questionnaire
Part I: To interview the patient by investigator or Assistant investigator

Identification

0. Patient Number:
1. Patient's age:
2. Indicate your highest education level attained:
    a. University
    b. High school(secondary)
    c. Primary
    d. None above
3. Indicate the number of antenatal clinic attendance (visits):
4. Indicate your marital status:
    a. married
    b. single
    c. separated
    d. divorced
5. Indicate your occupation:
    a. Employed
    b. business
    c. student
    d. housewife

Please answer these questions based on the counseling you have received in ANC from medical professionals and your own general knowledge:

1. Before coming to clinic 18, what was your preferred mode of delivery?
    a. Trial labor
    b. Repeat C/S
    c. Not sure
    d. Any

e. None

2. When you came to ANC, did your doctor inform you about the different options of mode of delivery?
    a. No
    b. If yes, which one?
        i. Trial of labor
        ii. Repeat cesarean delivery
        iii. Both above
3. In clinic 18, did your doctor advice you about the risks and benefits of both mode of delivery?
    a. Yes
    b. If no your decision on mode of delivery was based on what? Tick all applied.
        i. A friend advice
        ii. Internet information
        iii. Cost of mode of delivery
        iv. Others. Specify.....
4. What is the decision made on mode of delivery during ANC?
    a. Trial of labor
    b. Repeat C/S
    c. Not yet
5. Do you feel your doctor preferred one method of delivery over another?
    a. my doctor did not have a preference
    b. my doctor preferred that I have a repeat cesarean section
    c. my doctor preferred that I try for a vaginal delivery
6. Are you aware about the risks associated with cesarean delivery?
    a. No
    b. If yes, which one of the following complications is more associated with repeat C/S than a VBAC (vaginal delivery after C/S)? Tick all applied
        i. Increased blood loss
        ii. High risk of infection
        iii. Complication of anesthesia

iv. Rupture in case of big baby
v. Injury to organs(in the mother)
vi. Recovery is longer
vii. Others. Specify.....
viii. Don't know

7. Are you aware about the risks associated with trial of labor (VBAC)?
    a. No
    b. If yes, which of the following risks are greater for a woman having a VBAC compared to a repeat C/S? Tick all applied
        i. Risk of uterine rupture resulting in emergency C/S
        ii. Risk of failed trial of labor
        iii. Risk of uterine rupture is higher with VBAC than repeat C/S
        iv. More blood loss
        v. More risk of infection
        vi. Others. Specify……..
        vii. Don't know
8. If you were to try for a trial of vaginal labor, your overall chances of success are:
    a. Very high (>50%)
    b. Very low (<25%)
    c. Don't know.....
9. If you try for a vaginal delivery (VBAC), the risk that your uterus will rupture (opening of the uterine scar) is:
    a. Very low (<1%), but increases each time you have another cesarean section
    b. Very high (>50%)
    c. Don't know
10. Your recovery from a successful vaginal delivery versus a repeat cesarean section is:
    a. The same
    b. Longer for a repeat cesarean section
    c. Longer for a vaginal delivery
    d. I do not know.....
11. Choose the correct statement about Repeat cesarean section and VBAC. Tick all applied

a. VBAC presents higher risk than ERCD
b. ERCD presents higher risk than VBAC
c. VBAC does not present any benefits
d. ERCD does not present any benefit
e. Don't know

12. Did your doctor inform you about any reasons why you should better deliver by ERCD than trial of labor (VBAC)?
    a. No
    b. If yes, which one? Tick all applied
        i. Big baby (> 3.5kg)
        ii. Type of uterine incision (classical scar)
        iii. small pelvis
        iv. availability of theater, blood transfusion, experienced doctors
        v. Others. Specify.....
        vi. Don't know
13. Why did you have the previous cesarean delivery?
    a. Small pelvis
    b. Big baby
    c. Fetal distress
    d. Transverse lie
    e. Bleeding (APH)
    f. Others. Specify……..
    g. Don't know
14. Have you had any complications after the previous cesarean delivery?
    a. No
    b. If yes which one? Tick all applied
        i. Bleeding (PPH)
        ii. Convulsions or increased blood pressure
        iii. Maternal infections
        iv. Death of the baby
        v. Others. Specify……

15. Was ERCD recommended to you as mode of delivery in subsequent pregnancy at discharge?
    a. No
    b. If yes, what reasons were you given?
        i. ERCD because of small pelvis
        ii. ERCD because classical uterine incision
        iii. ERCD because of high risk of uterine rupture if any trial of labor (VBAC)
        iv. ERCD because BTL will also offered.
        v. Others. Specify.....
16. Have you ever had a successful vaginal delivery following your cesarean section?
    a. Yes
    b. No
17. The reason for your previous cesarean section is an important factor in determining your chances of a successful vaginal delivery:
    a. Yes
    b. No
    c. I do not know
18. How are you satisfied with the language communication of your doctor during ANC discussion?
    a. Satisfied
    b. Not satisfied
19. How satisfied are you with your previous cesarean section experience?
    a. Satisfied
    b. Not satisfied
20. In ANC, have you been given time to ask questions for clarification:
    a. Yes
    b. No

Part II: To be filled by investigator from Antenatal cards or patient's file

1. Patient number:
2. Level of provider:
    a. Clinical officer or Midwife
    b. General practitioner
    c. Senior house officer
    d. Consultant
3. Parity of the patient:
4. Family planning method choice following delivery:
    a. BTL
    b. DIU transcesarean section
    c. Other, and specify……
    d. Not yet decided
5. Indication of the previous CS:
    a. Contracted pelvis or cephalopelvic disproportion
    b. Transverse lie
    c. APH
    d. Other and which one? .....
    e. Not indicated in the patient file
6. Estimated fetal weight birth in Kg clinically or by ultrasound documented at the time of the decision of mode of delivery:
    a. < 3.5Kg
    b. ≥ 3.5Kg
    c. Not indicated
7. Medical or obstetrical complication noted during ANC:
    a. Preeclampsia
    b. Cardiac disease
    c. Diabetes
    d. Other and which one? …….....
    e. Not indicated / documented

8. Medical or obstetrical complication post partum noted after the previous CS delivery: Tick all applied
    a. Infections
    b. Hemorrhages
    c. Anesthetic complications
    d. Longer recovery
    e. Others. Specify…
    f. Not indicated
9. Outcome of the first delivery:
    a. Well live infant
    b. Live infant in distress
    c. Premature baby
    d. Still birth
    e. Others. Specify…
    f. Not indicated
10. Patient had a vaginal delivery after the first cesarean delivery:
    a. Yes
    b. No
    c. Not indicated
11. Patient induced in the first pregnancy:
    a. If yes with what? .....
    b. No
    c. Not indicated
12. Patient mode of delivery in the first pregnancy:
    a. Elective cesarean delivery
    b. Emergency cesarean delivery
13. Obstetrical ultrasound done on this pregnancy:
    a. No
    b. If Yes. The latest at which gestation……....
    c. Not indicated
14. Decision on the mode of delivery indicated in the file on this pregnancy:

a. No
b. Yes. If yes which one and at which gestational age (GA)?
    i. ERCD and at what GA……(in weeks of amenorrhea)
    ii. Trial of labor (TOLAC) and at what GA……..(in weeks of amenorrhea)

15. Is the estimated fetal weight birth (clinically or by ultrasound) during this ANC indicated at the decision of mode of delivery?
    a. Yes. If yes, which one (in Kg)?
    b. No
    c. Not indicated
16. Consent form signed and dated in the file:
    a. Yes
    b. Patient booked in elective diary
    c. Not indicated
17. Booked ERCD is to be done at which GA (in weeks)? .....

Study Budget

Components	Unit of Measure	Duration/Number	Cost(kshs)	Total
Personnel				
Research Assistant	1	5 months	25,000	12,5000
Data analyst				30,000
Supplies				
Questionnaires	200	10	3	6,000
Consent form	200	3	3	1,800
Final report	60	4	3	720
Binding	4		800	3,200
Services				
ERC fees	1		2,000	2,000
Total				**168,720**

This study research has been sponsored by Kenyatta National Hospital, Research Program.

Patient informed consent form

Study Title: Trial of labor or Elective Repeat Cesarean Delivery: are patients making an informed decision at KNH?

Investigator: Dr. Phocas S. Biraboneye (MBCh.B), Registrar in Obstetrics and Gynecology department, University of Nairobi.

Supervisors:

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2. Dr. Wanjala Samson (MBCh.B), MMed (Obs/Gyn), Senior lecturer, Department of Obstetrics and Gynecology, University of Nairobi.

Introduction:

For women who have had a previous caesarean section, typically, their options for mode of childbirth are either a trial of vaginal birth or an elective repeat caesarean section. Both elective repeat caesarean section and subsequent vaginal delivery after a previous caesarean section have clinical risks and benefits.

The proportion of women attempting a vaginal birth after a previous caesarean section has been declining in many countries partly due to the variable chance of achieving a successful vaginal birth (reported between 56% and 80%) and partly because of negative reports of the risk of complications, both to the mother and the baby, of a having a vaginal delivery following a caesarean section.

We hypothesized that this may be due, in part, to a lack of knowledge among patients of the risks and benefits of either mode of delivery. Improving patient education may not affect the increasing cesarean section rate; it would, however, empower patients to make a well informed, educated decision and allow physicians to return to the basic principles they once pledged to follow. This study is seeking to understand whether women presenting with prior cesarean delivery are making an informed decision for either mode of delivery at Kenyatta National Hospital.

What is the purpose of this study?

I am conducting this study as research for the degree of Masters of Medicine (MMed) in Obstetrics and Gynecology. We shall determine whether the women with one previous cesarean delivery know the risks and benefits of both mode of delivery. Please read this information or have it read to you so that you understand what we are asking you to do. Feel free to ask question so that you understand fully

Why is this study important?

Studies done in other countries indicate that many patients presenting with a prior cesarean delivery appear to know little about the risks and benefits associated with their mode of delivery, and provider preference affects this choice.

This study is important because we do not know whether information presented to the patient is adequate. This information will help the hospital to emphasize the value of informed consent whereby a patient is enabled to make an informed and voluntary decision about accepting or declining medical care.

Who is in this study?

We will enroll approximately 195 women presenting with one previous cesarean delivery for trial of labor or repeat cesarean delivery at Kenyatta National Hospital and this research will run for a period of five months.

Why to participate in the study?

We would like to include you in the study because you have been admitted at KNH, you are eligible to participate in the study and we want to give all patients having one previous cesarean delivery admitted at KNH an equal chance to participate in this study so that we know the exact information behind informed consent/decision.

Is there any risk to participate in the study?

The study carries no extra risk or cost to you.

Are there any benefits to participate in the study?

If you agree to take part in this study there is no direct benefit. The results from this study will provide useful information to emphasize not only the education of patients in antenatal clinic, but also the value of informed consent whereby a patient is enabled to make an informed and voluntary decision about accepting or declining medical care.

What happens if I refuse to participate?

Participation is voluntary. If you agree you will be given a questionnaire to answer and you can still change your mind during answering. And if you don't this will not affect your care now and in the future.

Who will have information about me in this study?

Information will be shared amongst doctors. The information will be kept confidentially and securely without your name on it.

Who has allowed this study to take place?

The department of Obstetrics and Gynecology and the ethics and research committees of University of Nairobi/Kenyatta National Hospital have studied the proposed study carefully and given permission for it to be done.

What if I have questions to ask about this study?

Feel free to ask me any questions now and at any other time. You can contact me for any further clarifications.

Dr. Phocas S. Biraboneye, Tel. **(+254) 7 18 43 56 57, E-mail; biraboneye@gmail.com**

If you have any questions on your rights as a research participant you can contact the Kenyatta National Hospital Ethics and Research Committee (KNH- ERC) by calling (254-020) 2726300 Ext. 44355. E-mail: uonknh_erc@uonbi.ac.ke

Certificate of consent

I ..... have understood the information in above on what the study entails. I have had a chance to ask questions and they have been answered satisfactorily. I understand that I can withdraw from the study at any time while answering the questionnaire and that this will not affect me in any way.

I hereby consent to my participation in this study.

Patient's signature: ……. Date: ……..

Patient's name: ……..... Time: ……..

Doctor's Signature: …….. Date: ……..

Doctor's Name: …… Time: …….

Proposed informed consent form for TOLAC or ERCD at KNH

There are risks in any medical, surgical procedure or treatment. Just being pregnant carries some risks as discussed with your doctor. The following check list is designed to help you to make an informed decision regarding your delivery, given that you had a prior cesarean delivery. The method of delivery you are considering is called a trial of labor after cesarean delivery and is abbreviated "TOLAC". Your other option is to have an elective repeat cesarean delivery and is abbreviated "ERCD". Please discuss the contents of this form with your doctor and choose your option of attempting a TOLAC or ERCD to deliver your baby. However know that the following are possible outcome after a prior cesarean delivery

- ✓ A successful TOLAC culminating in VBAC
- ✓ Failed TOLAC resulting in repeat cesarean delivery
- ✓ ERCD

1. I understand that I have had one prior cesarean delivery ----------(patient's initials)
2. I understand that I have the option of an ERCD or I may attempt a TOLAC----------
3. I understand that approximately 70% of women undergo a TOLAC will successfully deliver vaginally----------

4. I understand that the risk of uterine rupture during TOLAC in someone who has had a prior uterine incision is around 1 %----------
5. I understand that TOLAC carries a lower risk to me than ERCD. The benefits of successful TOLAC include decreased blood loss, decreased post delivery complications and shorter recuperative period----------
6. I understand that TOLAC is associated with higher risk of harm to my baby than to me----------
7. If my uterus ruptures during TOLAC , I understand there may not be sufficient time to operate and to prevent death or permanent injury to my baby----------
8. The exact frequency of death or permanent neurologic injury to the baby when the uterus ruptures is uncertain, but has been reported to be as high as 50%----------
9. The risks to me after rupture of the uterus include but are not limited to hysterectomy , blood transfusion, infection, injury to internal organs, blood coagulation problems or death----------
10. Possible contraindications to TOLAC include small pelvis, previous classical uterine incision, multiple gestation, big baby and breech presentation----------
11. Excluded from considerations to TOLAC are patients unwilling to assume the added risks associated with TOLAC for themselves and their baby----------
12. I understand that during my TOLAC, the use of oxytocin , a hormone to make my uterus contract , may be an increased risk during TOLAC----------
13. I understand that if I choose a TOLAC and end up having a cesarean during labor , I have a greater risk of problems than if had an ERCD ----------
14. I have read or have had read to me the above information and I understand it. I have had all my questions answered and I have received all the information I need to make an informed choice, after discussing my options with my doctor----------

I want to attempt a trial of labor (TOLAC)

Patient's signature ..... date ..... time .....

Patient's name .....

Witness' name .....

Witness' signature .....

I want to have a repeat cesarean delivery (ERCD)

Patient's signature ..... date ..... time .....

Patient's name .....

Witness' name .....

Witness' signature .....