PREDICTORS OF DECISION TO DELIVERY INTERVAL ANDOUTCOMES OF CAESAREAN SECTIONS AT KENYATTA NATIONAL HOSPITAL

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DECLARATION

I declare that this is an original write up. The relevant literature has been quoted for the part where reference has been made from other sources. This is a product of my own with guidanc from my supervisors. It has not been presented in any other University for the award of a degree

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DEDICATION

To my wife Samantha Muthoni, my lovely children Roman Mungai and Sage Uwera, thank you for being my pillar even in difficult times. Thank you for understanding my line of work and enduring my late-night calls. My beloved mother Susan Uwera for encouraging me through the good and weary moments of postgraduate training. To my late father, William Mungai Wainaina who 21 years on is constantly watching over me and ever proud of the milestones I have managed to achieve. To my aunties, uncles and the larger Wainaina family who have been my support system throughout my education.

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LIST OF ABBREVIATIONS

ACOG:	American College of Obstetrics and Gynecology
APH:	Antepartum Hemorrhage
cm:	centimeters
CPD:	Cephalopelvic Disproportion
DDI:	Decision to Delivery Interval
EmONC:	Emergency Obstetric and Neonatal Care
FSB:	Fresh Still Birth
HDU:	High Dependency Unit
KDHS:	Kenya Demographic Health Survey
ICU:	Intensive Care Unit
IUGR:	Intra Uterine Growth Restriction
KNH:	Kenyatta National Hospital
NBU:	New Born Unit
PMH:	Pumwani Maternity Hospital
PI:	Principal Investigator
RCOG:	Royal College of Obstetricians and Gynecologists
RA:	Research Assistant
SOP:	Standard Operating Procedures
TOLAC:	Trial of Labor after Caesarean Section

OPERATIONAL DEFINITIONS

Caesarean Section: The most commonly performed lifesaving obstetric operation. It refers to the delivery of a fetus which has attained a viable gestational age, placenta and membranes through an abdominal and uterine incision in cases where vaginal delivery is either not feasible or would impose undue risks to the mother or baby or both. It may be carried out under regional (spinal or epidural) or general anesthesia.

Category 1 Caesarean Section: Cases with maternal and fetal compromise and pose an immediate threat to life of woman or fetus.

Category 2 Caesarean Section: Cases with maternal and fetal compromise and no immediate threat to life of woman or fetus.

Decision to Delivery Interval (DDI): The decision-to-delivery interval (DDI) refers to the length of time between decision-making and delivery of the neonate by caesarean section. It is measured in minutes from the time a decision for emergency caesarean delivery is made to the time the baby is delivered. The recommended DDI for category 1 caesarean sections should not exceed 30 minutes and emergency obstetric care units should be capable of beginning an emergency caesarean section within 30 minutes of the decision to operate.

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ABSTRACT

Background: Maternal mortality remains high in Kenya with an estimated 510 maternal deaths reported for every 100,000 live births every year. At the Kenyatta National Hospital (KNH), maternal mortality is estimated to be around 639/100,000 live births, which is slightly higher than the national average. According to the World Health Organization (WHO), most of such deaths are preventable with prompt and adequate medical interventions, with the maximum Decision-to-Delivery Interval (DDI) for category 1cesarean sections (CS) set at 30 minutes.

Objective: To describe the predictors for DDI for category 1 and 2 cesarean sections and its effect on maternal and neonatal outcomes and the average cost of hospital stay at KNH.

Methodology: A prospective cohort study was conducted at the KNH labor ward between February 2019 and March 2019. Parturients scheduled for caesarean delivery were recruited,and a structured and pre-tested questionnaire used to capture their sociodemographic and obstetric characteristics. The indications for cesarean sections for categories (1 and 2) and the decision to delivery interval wererecorded. After birth, all mothers and neonates admitted to the New Born Unit (NBU) were followed up until discharge, and the incidence of adverse maternal and neonatal outcomes recorded. Finally, the duration of post-operative hospital stay was recorded for all mothers and cumulative cost for delivery retrieved from the NHIF office adjacent to ward 1Ain KNH. Data was exported to SPSS software for analysis and a summary of socio-demographic characteristics, obstetric characteristics, and information about the emergency cesarean presented in tables and charts. The mean duration for decision to delivery interval was compared using the independent samples T-test. DDI was then converted to a categorical variable that represents optimal DDI (≤30 minutes) and prolonged DDI (≥30 minutes) and the Chi-square test used to evaluate the relationship between DDI and maternal and fetal outcomes. The Odd ratio at 95% level of confidence was our measure of association. A $P<0.05$ was considered significant. The analysis was repeated to reflect a DDI of 60 minutes and the median cost for delivery computed.

Results: Two hundred and fifteen (215) parturients (120 category 1 CS and 95 category 2 CS) with a median age of 32 years (17-45 years) were enrolled. The sociodemographic and obstetric characteristics of women scheduled for a category 1 CS and category 2 CS were comparable, save for the number of past miscarriages which was significantly higher among parturients scheduled for a category 1 CS ($p=0.038$). The presence of a previous uterine scar (37.3%) and labour dystocia (25.4%) were the commonest indications for a CS, but their incidence did not vary significantly by the category of CS of parturients ($p=241$). The DDI was 173 minutes for category 1 CS and 185 minutes for category 2 CS. DDI was longer than the recommended (30 minutes) for 96.3% of parturients scheduled for category 1 CS and 97% for those scheduled for category 2 CS ($p=0.594$). At 60 minutes, 9.4% and 8.3% of parturients scheduled for category 1 and 2 CS respectively had delivered ($p=0.807$). The DDI at 30 minutes and 60 minutes did not influence blood loss ($p=0.222$) and the post-operative stay of mothers ($p=397$) significantly. However, at both 30 minutes and 60 minutes, the occurrence of adverse neonatal outcomes was marginal with the risk NBU admission being considerably higher at ≤30 minutes ($p<0.001$) and ≤60 minutes ($p<0.001$) DDI. The birth weight and sex of babies were comparable. The median cost for delivery was Ksh 46,577.50.

Conclusions:DDI was 173 minutes for category I CS and 185 minutes for category II CS. Failure to meet the recommended DDI of 30 minutes did not influence maternal outcomes, but increased the risk of neonates having a poor Apgar score at 5 minutes and being admitted to the NBU.

CHAPTER ONE

1 INTRODUCTION

1.1 Background

Maternal mortality remains high in Kenya at an estimated 510 maternal deaths per 100,000 live births (KDHS 2014). Direct causes such as hemorrhage, hypertensive disorders, obstructed labor, sepsis and complications of abortion result in most of these deaths(1). With the right interventions and strategies, these deaths can be prevented successfully.Even though many studies have found no correlation between DDI and adverse perinatal outcome such as stillbirth, poor Apgar score, and mortality(2,3), an association between a long DDI and an increased risk of NBU admission has been demonstrated in Kenya (4)

The main cause of high mortality rates in developing countries is delay in getting appropriate timely care. Delays in making the decision to seek care when complications develop result in patients not receiving adequate care; once the decision to seek care has been made, failure to reach the medical facility on time contributes to delays;once a medical facility has been reached, there may be a delay in receiving adequate and appropriate care(5). Maternal deaths maytherefore be attributed to a chain of delays and not necessarily a single delay.

In Kenya, the main reasons why many deliveries do not occur in medical facilities is the distance between homes and the nearest medical centres. 42% of women live too far from facilities while 21% don't have the means to get there. Another 21% don't think it's necessary. 18% noted that they couldn't get to a facility fast enough for a hospital delivery while another 17% said that hospital deliveries were expensive(6). Few women fail to deliver in health facilities because the hospitals have few female providers. Their customs don't allow male providers to attend to them. Other reasons include forbiddance by family members, poor quality of service and unavailability of health facilities(6)

Delay in reaching an appropriate medical facility is affected by the distribution of health facilities, availability of transportation, road conditions or cost of transportation(7).Delay in receiving adequate and appropriate care once the facility is reached is mainly due to operational difficulties in the healthcare delivery system(8). Such inadequacies may be characterized by shortages in supplies, equipment, lack of trained personnel, incompetence of

the available staff, or uncoordinated emergency services: health system failures have been identified as a major contributing factor to maternal deaths.

A health facility can be classified as offering either basic or comprehensive emergency obstetric and neonatal care (EmONC) based on functionality and ability to provide lifesaving emergency obstetric procedures(9). Facilities offering basic EmONC are expected to provide the following seven services: administration of parenteral antibiotics; parenteral oxytocic drugs; parenteral anticonvulsants for eclampsia; manual removal of retained placenta; removal of retained products of conception; assisted vaginal delivery (vacuum extraction or forceps delivery) and neonatal resuscitation with bag and mask. Comprehensive EmONC facilities are expected to provide caesarean section and blood transfusion in addition to those services provided by the basic EmONC facilities(9)

Emergency caesarean refers to the delivery of a fetus which has attained a viable gestational age, placenta and membranes through an abdominal and uterine incision in cases where vaginal delivery is either not feasible or would impose undue risks to the mother or baby or both. It may be carried out under regional (spinal or epidural) or general anesthesia and its indications include non-re-assuring fetal status, prolapse of the umbilical cord, severe abruption placentae, placenta previa with hemorrhage, dystocia (cephalopelvic disproportion, poor progress of labour, obstructed labour), failed vaginal birth after caesarean section, failed induction of labour, malpresentation and failed assisted vaginal delivery.

In 2010, the Royal College of Obstetrics and Gynecology (RCOG)standardized the classification of urgency of caesarean sections into 4 categories which incorporates a modified version of the classification proposed by Lucas et al (10).

Category 1: Cases with maternal and fetal compromise and pose an immediate threat to life of woman or fetus.

Category 2: Cases with maternal and fetal compromise and no immediate threat to life of woman or fetus.

Category 3: Cases with no maternal or fetal compromise but require early delivery

Category 4: Cases with no maternal or fetal compromise to be done at a time to suit the woman and maternity services.

Facilities offering comprehensive EmONC should begin a category 1 caesarean section within 30 minutes of the decision to operate(11). This depends on organizational structure,

institutional policies, staffing pattern, availability of equipment and supplies, processes involved in preparation of and moving the patient from the labour and delivery suite to the operating room, architectural specifications of the unit, availability of the operating team, preparation of operating room and the mode of anesthesia used(12,13)

Scientific studies on the factors that influence turnaround time in theatres have elucidated the need for patient prioritization while processing emergency tests, and good communication to minimize delays in initiation of emergency CS surgeries. In a single-centre prospective study by Ang et al., a 461-minute delay was reported in a trauma theatre due to delay in patient transport. The lack of appropriate testscontributed to the delay, with financial loss estimated to be £951.58/theatre/day (14). Trends between high ASA scores, old age, and absence of a senior clinician and a long TAT were also cited, but a few remedies have been proposed. According to Fletcher et al. (15), checking the paperwork of patients scheduled for an emergency CS to ensure completeness, scheduling a 15-minute telephone warning to ensure readiness, and having a dedicated cleaning team in theatre rooms can shorten processing time and thus the turnaround time of subsequent patients. Moreover, utilizing run charts to identify trends/ patterns, and improving communication within and between healthcare teams have been reported to lower turnaround time in theatres by 30-59 minutes (15,16).

CHAPTER TWO

2 LITERATURE REVIEW

2.1 Introduction

A caesarean section (CS) is the most common lifesaving obstetric operation. It is a multidisciplinary procedure comprising many tasks. The procedure requires a team of several personnel; an anesthetist and a skilled assistant, an obstetrician and an assistant, a theatre nurse or midwife to assist with the operation, a midwife, and a pediatrician to receive the baby(17) The staffs have to be assembled before the necessary complex tasks can be undertaken.

Once a decision to deliver by emergency caesarean section is made, the operating team has to be informed and the patient has to be prepared for the operation. This entails obtaining informed consent, establishing intravenous access, taking a blood sample for blood grouping and cross-matching, changing the patient into a theatre gown and attaching a label before the patient can be moved to theatre(17) Fetomaternal monitoring continues until the patient is transferred to the operating room.

2.2 Decision to Delivery Interval

The decision-to-delivery interval (DDI) refers to the length of time between decision-making and delivery of the neonate by caesarean section(10). It is measured in minutes from the time a decision for emergency caesarean delivery is made to the time the baby is delivered. The recommended DDI for category 1 caesarean sections should not exceed 30 minutes and emergency obstetric care units should be capable of beginning an emergency caesarean section within 30 minutes of the decision to operate(10).The Kenyatta National Hospital has a standardized DDI of one hour for emergency caesarean section (KNH records).

Predictors that determine the DDI for category 1 caesarean section are indications such as antepartum hemorrhage secondary to low lying placenta, ruptured uterus, abruption placenta. For category 2 caesarean sections, predictors such as cephalopelvic disproportion, failed induction of labour, malpresentation and others also determine the DDI.(18). Favorable maternal and fetal outcomes are dependent on timely intervention once a decision to deliver via caesarean section is made. Thisin turn minimize complications and adverse outcomes that accompany delays.(19)With minimization of complications, cost incurred at discharge herein

referred to as the financial implication or outcome are minimized. There are many factors that would influence cost but, in this study,only the invoiced cost at discharge was used.This enabled us to determine the cost increment of delays i.e. the cost increment if the caesarean section takes 30mins or 1 hour longer.

A 1-year prospective auditby Sunanda et al in a tertiary care hospital in India in 2016 was done. In their audit, 453 emergency CSswere evaluated and 22.1% of the delays involved shiftingthe patient to Operation Theater. The mean DDI for Category 1 CS was 36.3 ± 17.2mins, 38.1 ± 17.7 min for Category 2 CS (P> 0.05). 42.4%of emergency caesarean sections confirmed to the 30 min DDI(18). In Singapore, a retrospective study was done by Tuck et al between August 2013 and June 2014 in a tertiary general hospital. In this study, 488 CSs (Category 1: n = 28; Category 2: n = 137; Category 3: n = 184; Category 4: n = 139) were studied. The mean duration of surgery was 41.7 minutes. The mean DDI was 23.9 & 64.5mins for category 1 and category 2 caesarean sections respectively *(*P>0.05). The total duration of surgery for senior surgeons was significantly shorter than for trainee surgeons(20)

At The University of Benin Teaching Hospital in Nigeria, a retrospective study done between January and December 2012 by Onyedikachi andChukwunwendu demonstrated the major causes of delays to have been as a result of anesthetic delay and busy theatre suits.352 emergency CS cases were reviewed: 20 (5.7%) of these were performed within 30 minutes and the mean DDI was 106.3 +79.5 minutes ($P \leq 0.05$).There was no significant correlation between DDI and perinatal outcome(21). In 2014, a retrospective cross-sectional study in a referral hospital in Northern Tanzania was done by Hirani BA and Mchome et al. In this study, 598 emergency CSs were reviewed and the median DDI was 60 minutes. Out of these, 12%were operated within 30 minutes. The shortest DDI was observed in patients with a diagnosis of Cephalo Pelvic Disproportion (CPD) and uterine rupture at 40 & 45.5 minutes respectively. There was no significant association between DDI and1st and 5thminute Apgar score ($P \leq 0.05$)(22)

At the Homabay District Hospital, only 3.8% of patients were delivered by emergency caesarean section within one hour of the decision to operate while 60% were delivered within 2 hours. A majority had high parity with a mean age of 24 years(23)

In a comparative cross-sectional study done in 2012 at KNH and Pumwani Maternity Hospital by Hussein,251 women were studied: 130 and 121 in KNH and PMH

respectively.The Median DDIs were 178 minutes and 290 minutes in KNH and PMH respectively. <1% of women achieved a DDI of <30 minutes and 4% DDI 31-60 minutes(13). In his study, 37% of women had a DDI of more than 5 hours. The most common complication was wound sepsis at 6%. Prolonged DDI did not significantly increase the risk of maternal complications.

2.3 Factors that influence DDI of CS

Several factors have been shown to influence DDI and therefore service provision to patients in both the developed and the developing world. In Northern Tanzania, a retrospective cross-sectional study of 598 women by Hirani et al. (24) elucidated the relationship between the medical characteristics of patients and the DDI for caesarian section. In the study, patients with uterine ruptures and babies with Cephalopelvic Disproportion (CPD) had the shortest DDI or 40 minutes and 45.5 minutes respectively. Furthermore, according to Hirani and others, parturient with impending fetal distress, APH, and cord prolapse has a shorter DDI that women with fetus in a reassuring position and with normal fetal heart rate parameters.

At the Ladoke Akintola University of Technology Teaching Hospital in Ogbomoso, Nigeria, Owonikoko et al. (25)reported a mean DDI to CS of 145.3 ± 69.2 minutes with patient-related factors such as suspected fetal distress, fail induction, severe pre-eclampsia, and failed VBAC reported to lower DDI statistically significantly. In the study, demographic characteristics such as the age of participants did not influence DDI statistically significantly. However, hospital related factors such as shortage of theatre staff, lack of blood and blood products, delay in anesthesia administration, and power outages increased the DDI of patients scheduled for an emergency CS.

In Singapore, a retrospective review by Wong et al. (26)of the files of patients who underwent an emergency CS in from August 2013 to June 2014 shown that a majority of patients delivered within the recommended DDI of 30 minutes. However, patients who delivered at night had a significantly longer DDI, mostly due to the longer transfer times of patients from the wards to the theatre. Moreover, the individual surgical styles of health practitioners, having a history of previous CS, and the surgical experience of handler were associated with the DDI of patients.

2.4 Financial implication of caesarean section DDI

Caesarean section deliveries have increased eight-fold since the year 2000 and so as cost.The median cost of a normal delivery is approximately $45. When a CS is required the cost of delivery increases to $276(27), but is often higher when DDI is long, as was demonstrated in a one month single-centre study (prospective) in St. Mary's Hospital in the United Kingdom. In the study, financial loss to a long DDI was estimated to lead to approximately £951.58 in financial losses per theatre per year (14). Patients bear the brunt of such spillages with the length of hospital stay, increasing age, and the possession of medical insurance reported to influence the cost of CS deliveries in China (28).

2.5 Conceptual Framework

DDI for caesarean sections is dependent on a number of factors such as patient factors, the health system factors and the health care provider factors. Financial implication, maternal and neonatal outcomes are also dependent on DDI. Patient factors include socio-demographic characteristics like age, level of education, marital status and occupation as well as cultural influences.

The age of the patient may influence the DDI for caesarean section in the case of aminor who lacks the capacity to give consent for the operation, necessitating the presence of a guardian to give consent on her behalf thus prolonging the DDI. Capacity to understand the consent explanation influenced by the education and literacy levels have a bearing on DDI.Patients with low education and literacy take time to understand consent explanation hence prolonging the DDI.
Seeking consent from the spouse and other cultural practices prolongs the DDI. The patient’s general condition, level of consciousness and mental status also determine her ability to give consent for the operation thus influencing the DDI.

Obstetric characteristics e.g. parity, previous pregnancy outcome, gestational age, mode of previous deliveries and indication for caesarean delivery in the current pregnancy, all have a bearing on the DDI. Category 1 caesarean section due to placenta previa with hemorrhage, cord prolapse or ruptured uterus is likely to have shorter DDIs than a Category 2 caesarean section due to malpresentation or failed induction of labor. Delivery is expedited in Category 1 caesarean deliveries since there is an immediate threat to the life of both the mother and fetus. Similarly, poor previous pregnancy outcome(s) may influence the urgency with which

an emergency caesarean delivery is carried out. The patient's body habitus e.g. in an obese patient, may be associated with repeated attempts at spinal anesthesia or failed intubation in the case of general anesthesia, which will increase the DDI of emergency caesarean section and may lead to poor maternal and newborn outcomes.

Health system factors which influence the DDI of caesarean section include; organizational structure and institutional policies, level of staffing of nurses, obstetricians, anesthetists, pediatricians and support staff; availability of medical personnel, supplies, drugs, sterile packs and functional equipment; workload and prioritization of theatre cases as well as the availability of key support services e.g. laboratory and blood transfusion services. Poor organizational structure and unfavorable institutional policies; staff shortages, unavailability of equipment and essential supplies, all contribute to prolonged DDI and hence poor maternal and newborn health outcomes.

Healthcare provider factors such as teamwork, good communication and interpersonal relationships; level of motivation amongst members of staff; level of training and expertise as well as competence reduce the DDI. When trained competent members of staff are well motivated and work as a team with good interpersonal relationships, their productivity is enhanced and this leads to reduced caesarean section DDI with good maternal and newborn health outcomes.

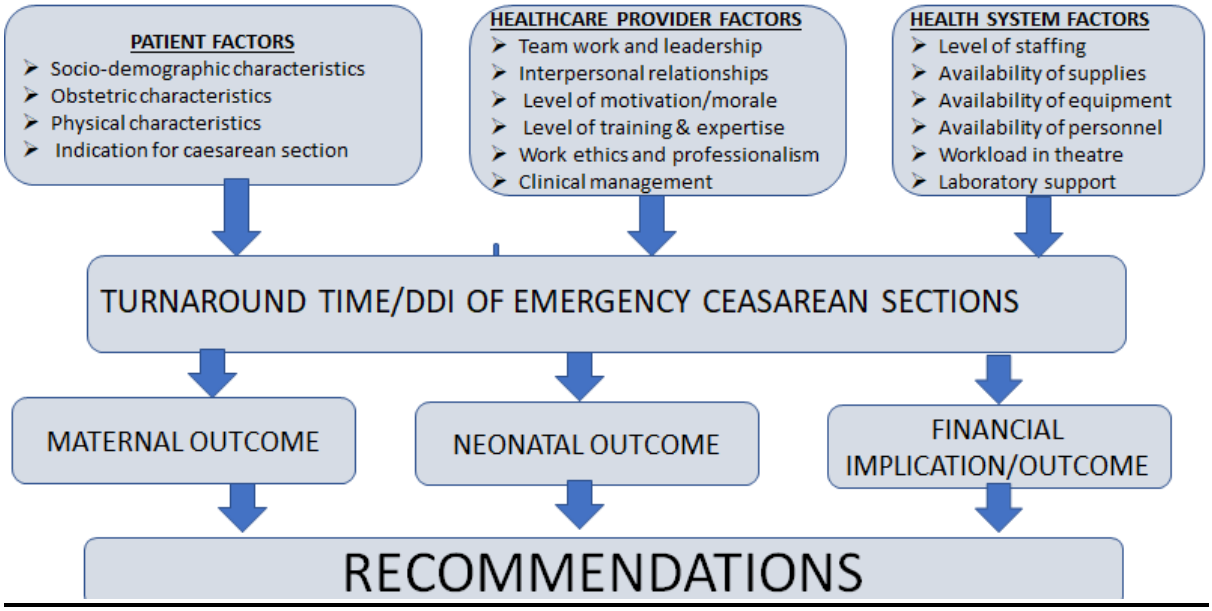

Figure 1. Conceptual Framework

2.6 Study Justification

The decision-to-delivery interval (DDI) refers to the length of time between decision-making and delivery of the neonate by caesarean section. It is measured in minutes from the time a decision for caesarean delivery is made to the time the baby is delivered. The recommended DDI should not exceed 30 minutes for category 1 caesarean sections and emergency obstetric care units should be capable of beginning a category 1 caesarean section within 30 minutes of the decision to operate. Prolonged DDI constitute a third phase delay in provision of emergency obstetric care.

A study done by Hussein in 2012 revealed that KNH has a DDI of 178 minutes. This was largely due to unavailability of theatre space and lack of additional staff to open a 2nd theatre. Recommendations included expansion of existing infrastructure, addressing staff shortage by hiring more staff and formulation of SOPs for Emergency Cesarean sections. As a result of these recommendations, KNH Maternity theatre opened a second fully equipped and functioning Maternity since 2013.

However, no evaluation has been done to compare whether the 2nd theatre had an impact on DDI and maternal and neonatal outcomes. This proposed study seeks to evaluate quality improvement in operationalizing a second 24-hour theatre in Maternity and its impact towards patient care.In addition, this proposed study analysed cost benefits and effectiveness of DDI and whether the delays result in adverse maternal and neonatal health outcomes.

2.7 Research Question

What are the predictors of decision to delivery interval and outcomes of Category 1 and 2 caesarean sections at the Kenyatta National Hospital?

2.8 Objectives

2.8.1 Broad Objective

To describe the predictors of decision to delivery interval for category 1 and 2 caesarean sections, and maternal and neonatal outcomes at Kenyatta National Hospital.

2.8.2 Specific Objectives

1. To determine the decision to delivery time interval for category 1 and 2 caesarean sections at Kenyatta National Hospital.

2. To determine the predictors ofdecision to delivery time interval for category 1 and 2 caesarean sections at Kenyatta National Hospital.
3. To determine the effect of the decision to delivery interval on maternal and neonatal health outcomes at Kenyatta National Hospital.
4. To estimate financial implication of caesarean section decision to delivery interval at Kenyatta National Hospital.

CHAPTER THREE

3 METHODOLOGY

3.1 Study Design

This was a hospital based cohort study on the predictors of decision to delivery interval and pregnancy outcomes of caesarean sections at KNH between March and February 2019. Women scheduled for delivery at the KNH operating theatre via CS were targeted.

3.2 Study Area

The study was conducted at the maternity unit of Kenyatta National Hospital. The study site is a national referral hospital, an internship centre as well as a teaching hospital for The University of Nairobi. The KNH is the oldest hospital in Kenya, founded in 1901. It serves as a national referral and teaching hospital. It has an average bed capacity of 1800. The hospital has anObstetrics and Gynecology department, with a maternity wing that conducts approximately 10,000 deliveries per year. The maternity wing of the hospital comprises of a labour ward, two operating theatres, three antenatal and postnatal wards and a newborn unit. The labour ward has a total bed capacity of 25 including 2acute rooms with five beds each, a post-delivery observation room with 4 beds and two delivery rooms, each with 2 delivery beds. Two Senior House Officers cover the labour ward daily, working 12-hour shifts each. Midwives work in 3 shifts with each shift having 6 midwives. There is also a consultant obstetrician on call 24 hours a day. The 2 operating theatres are operational 24 hours a day, handling emergency and elective cases with two in-house registrars and twoanesthetists working in 2 shifts. There are 3 nurses allocated to each theatre per shift. The department is linked to two operating theatres, a blood transfusion laboratory and is capable of providing comprehensive obstetric care. The facility has a number of specialists who offer specialized services. This facility is thus suited to carry out the study from the maternity unit. The data was collected between January and March 2019.

3.3 Study Population

This comprised women who underwent category 1 or 2 caesarean delivery at Kenyatta National Hospital. They included women who had attained a viable gestation of at least 28 weeks at the time of delivery, admitted at the KNH maternity, from home or as referrals from other health facilities for delivery or management of pregnancy related complications with indications for caesarean section.

3.3.1 Inclusion Criteria

- Patients scheduled for Category 1 or 2 Caesarean delivery
- Consented to participate in the study.
- Gestational age of 28 weeks and above.
- Patients either as referrals from other health facilities or from home.
- Patients admitted in ANC wards and scheduled for emergency CS

3.3.2 Exclusion Criteria

Patients who were not of sound mind and who were not be able to consent to the caesarean section or wish not to be included in the study.

3.4 Sample Size Calculation

The sample size was calculated using the formula below:

n= (Z^2 x P (1-P))/d^2

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = expected true proportion (estimated at **16.9%**, from a retrospective study conducted by Tuck Chin. et al (2013) from August 2013 to June 2014, at a tertiary general hospital in Singapore

d= desired precision (0.05)

Sample size of **215 patients**

3.5 Sampling Method

Consecutive sampling was used. It is a non-probability sampling technique that seeks to include all accessible subjects as part of the sample.

3.6 Recruitment Procedure

All patients undergoing emergency caesarean section at the KNH during the study period were informed of the study procedures by the researcher or his assistants after the decision to deliver them by emergency caesarean section is made. Routinely, this decision is made by the

consultants during the daily hand over ward rounds done twice in a day; the senior house officer covering the ward in between the hand over rounds usually has leeway to make the decision too, either independently or on consultation with the consultant on call.

Willing participants were consented to participate in the study and enrolled after signing an informed consent. Once consented, the principal investigator or research assistant (RA)then administered a questionnaire to collect data on the socio demographic characteristics of the patients. The RAswere nurseswith background training on basic data collection processes; they were provided with standard clocks for use during the data collection processes. The patients were then be observed through the process of preparation for the theater, the operation and immediate post-operative period until discharge.

3.7 Data Collection Procedure and Quality Assurance

3.7.1 Pretesting the Questionnaire

An interviewer guided questionnaire (annex 2), which waspre-tested among 15 patients attending delivery services at the KNH, before being used to collect data from the patients who consented to the study.

3.7.2 Administration of the Questionnaire

The pre tested questionnaire was administered to the study participants who consented to be included in the study. In addition, patients' records were reviewed to collect data on the time of decision for emergency caesarean delivery and documented in the questionnaire.The time of being received in the operating theatre, administration of anesthetic agent, skin incision and delivery of the baby was documented in the questionnaire by the researcher or his assistants using designated, standard clocks. The participants were followed up post-operatively daily in the respective postnatal wards until discharge and a documentation of the neonatal and maternal outcomes done.

Decision to delivery interval was documented using clocks of the exact same type, sourced from the one manufacturer which were placed in the labor ward and operating room at each study site and synchronized at the beginning of the study and on a daily basis thereafter.Accurate costs incurred at the time of discharge was sought from the NHIF office for each study participant.

3.8 Data Quality Assurance

The PI supervised data collection on a daily basis to ensure quality data was collected and that ethical considerations were maintained by RAs. The collected data was coded and safely kept in a lockable cabinet before entry into the excel software; this was password protected and with limited access. Data completeness was checked on daily basis and whenever possible, updates done.

3.9 Data management and analysis

Data was checked for completeness prior to entry into the Statistical Package for Social Sciences (SPSS version 24.0) for cleaning and analysis. The collected data was counter checked for completeness by the PI on a daily basis. In addition, every twentieth questionnaire was picked for quality check. The filled questionnaires were then kept under lock and key before subscription onto the excel sheet where the entered data was password protected by the PI.

The data in an excel sheet was cleaned and uploaded to the SPSS software for analysis. Descriptive data on socio-demographic, obstetric, emergency caesarean deliverywas analyzed and presented as frequencies and proportions, means and standard deviations on tables. The decision to delivery time was computed and the mean compared using paired Student's T test, using mean period from a study by Chin et al as the standard. To demonstrate association between dependent and independent variables such as age, parity, socioeconomic status, referral status and comorbidities with the decision to delivery time, bivariate analysis using Chi square tests wasdone.

Maternal and Neonatal outcome data was analyzed and presented as Frequencies and Proportions. Associations between decision to delivery interval, maternal and neonatal outcomes were presented as odds ratio. A multivariate analysis to further demonstrate the association was done. A p value of 0.05 was taken as statistically significant.

3.10 Ethical Considerations

Approval for the study was obtained from the Ethics and Research Committees of Kenyatta National Hospital/University of Nairobi. Authorization to conduct the study at the KNH was sought from the KNH administration and the Obstetrics and Gynecology Department. Participation in the study was voluntary and informed consent sought before enrolment.

Names and other participant identifier information were omitted from the questionnaires and instead a study number unique to each questionnaire was allocated for purposes of identification during data collection, analysis and presentation to ensure confidentiality of information. There were no benefits offered to participants. Patients who declined to participate in the study received the standard care without any discrimination. The normal operations of the hospital were not affected by the study.

3.11 Study limitations and mitigation

The research assistants were trained in accurate data abstraction using the structured questionnaire. All clinicians involved in the management of recruited study participants were sensitized to document the data of interest from study participant's medical records.

CHAPTER FOUR

4 RESULTS

4.1 Results Flow Chart

From January to March 2019, 230 patients were accessed for eligibility, 130 patients scheduled for category I CS and 100 patients for category II CS. Of the 130 patients who were scheduled for a category I CS, 10 patients were excluded for, 1) declining to provide consent (n=4) and 2) withdrawal (n=6). Of the 100 patients scheduled for a category II CS, 5 were exclude for, 1) declining participation (n=2) and 2) being scheduled for an elective CS (n=3). In the end, 120 participants scheduled for a category I CS and 95 scheduled for a category II CS were recruited, data collected and analysed (Figure 2).

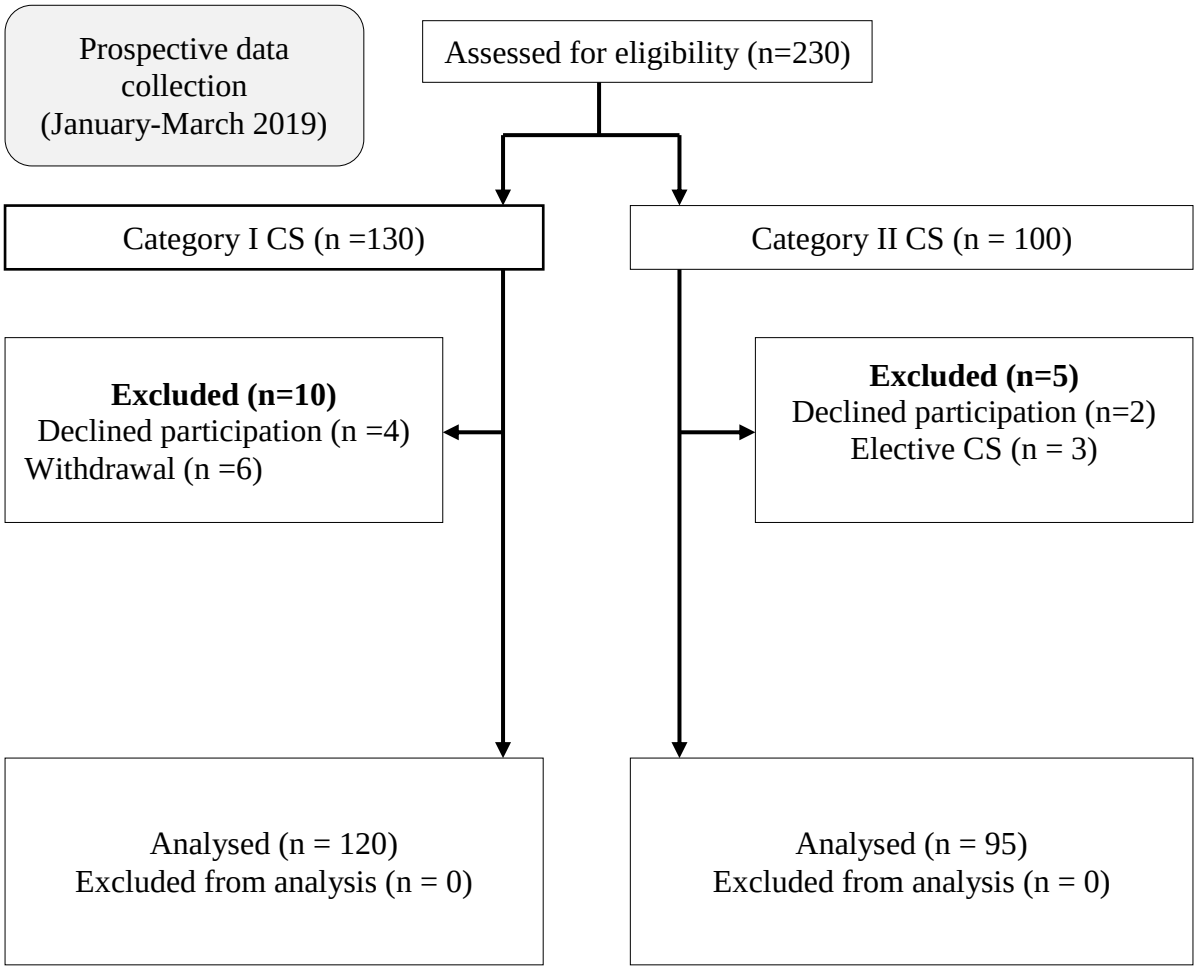

Figure 2. Study flow chart

4.2 Socio-Demographic, Reproductive, and Medical Characteristics of Patients who Underwent Category I and II CS

Two-hundred and fifteen (215) women who underwent category I [n=120)] or 2 [n=95] caesarean delivery at KNH were recruited. The mean age was 27.89±5.74 years, range of 17-45 years, 75% of whom were aged >32 years. Most women in category I (60.8%) and II (63.0%) were age group 18-29 years. One hundred and seven (89.2%) and 79 (86.8%) respectively were married, while Kikuyu was the dominant tribe at 45.7% and 42.4% in category I and category II CS groups. The age (X^2=0.10), marital status (X^2=0.27), and ethnicity of participants (X^2=6.1) were comparable. Even though more women who underwent category I CS than category II CS were more likely to have secondary education (51.7% and 50.0% respectively) and be employed (66.4% and 56.7% respectively), the differences between groups were not of statistical significance (p>0.05).

The incidence of miscarriage was higher among women had a category I (11.2%) than category II CS (3.3%) statistically significantly (X^2=5.02, p=0.03). Deliveries at term (37 to 40 weeks) were high in category II (71.8%) than I CS (70.2%) but not statistically significantly (X^2=3.34, p=0.18). Even though 11.2% more patients who underwent category II CS than I were more likely to deliver in the active phase, the difference was not statistically significant (X^2=2.88, p=0.09).

The indications for CS deliveries, mode of anesthesia, and day of the week of category I and II CS patients were different (p<0.05). Category I patients were more likely to have a malpresentation, be under the care of a senior house officer than a consultant, and present for delivery on a Monday (p<0.05). Category II patients were more likely to have a previous uterine scar, dystocia, or NRFS; be under the care of a consultant than senior house officer, and admitted for delivery on a Friday or Saturday (p<0.05). The incidence of category I and II caesarian sections did not vary statistically significantly by the rank of operation (p=0.27) and the time of operation (p=0.23) (Table 3).

Table 1. The sociodemographic, reproductive, and health characteristics of the women who underwent category I and II CS at KNH in January to March 2019

		Number of patients (%)			
		I	II	X^2	P
Age group	18-29yrs	73 (60.8)	58 (63.0)	0.10	0.74
	30-45yrs	47 (39.2)	34 (37.0)		
Marital status	Married	107 (89.2)	79 (86.8)	0.27	0.60
	Single	13 (10.8)	12 (13.2)		
Ethnicity	Kamba	14 (12.1)	14 (15.2)	6.10	0.29
	Kikuyu	53 (45.7)	39 (42.4)		
	Kisii	4 (3.5)	10 (10.9)		
	Luhya	33 (28.5)	22 (23.9)		
	Others	12 (10.3)	7 (7.6)		
Education level	No formal education	2 (1.7)	1 (1.1)	0.17	0.91
	Primary	19 (15.8)	14 (15.2)		
	Secondary	62 (51.7)	46 (50.0)		
	Tertiary	37 (30.8)	31 (33.7)		
Occupation	Employed	79 (66.4)	51 (56.7)	2.74	0.25
	Self employed	4 (3.4)	2 (2.2)		
	Unemployed	36 (30.2)	37 (41.1)		
No prev. pregnancies	Zero	40 (34.2)	41 (45.0)	5.02	0.17
	One	39 (33.3)	31 (34.1)		
	Two	25 (21.4)	15 (16.5)		
	At least three	13 (11.1)	4 (4.4)		
No of miscarriages	Zero	101 (87.1)	86 (94.5)	6.53	0.03
	One	13 (11.2)	2 (2.2)		
	At least two	2 (1.7)	3 (3.3)		
Gestation in weeks	≤36	21 (18.4)	9 (10.6)	3.34	0.18
	37-40	80 (70.2)	61 (71.8)		
	≥41	13 (11.4)	15 (17.6)		
Phase of labor	Active	73 (61.3)	66 (72.5)	2.88	0.09
	Latent	46 (38.7)	25 (27.5)		
Rank of operation	Primary	78 (65.0)	53 (57.6)	1.20	0.27
	Repeat	42 (35.0)	39 (42.4)		
Mode of anesthesia	Spinal	101 (91.8)	89 (98.9)	5.21	0.02
	General	9 (8.2)	1 (1.1)		
Operator	Registrar	111 (99.1)	88 (98.9)	0.02	0.87
	Consultant	1 (0.9)	1 (1.1)		
Day of the week	Monday	20 (17.4)	4 (4.4)	31.0	<0.01
	Tuesday	27 (23.5)	17 (18.7)		
	Wednesday	36 (31.3)	19 (20.9)		
	Thursday	16 (13.9)	15 (16.5)		
	Friday	0 (0.0)	2 (2.2)		
	Saturday	4 (3.5)	25 (27.5)		
	Sunday	12 (10.4)	9 (9.9)		

4.3 DDI for Category I and II Caesarean Sections

The decision to theatre time interval for category II CS (143 minutes) was slightly higher than for category I (130 minutes) but not statistically significant (P=0.46). The decision from theatre to anesthesia (24 and 22 minutes), anesthesia to incision (19 and 22 minutes), and incision to delivery (50 and 53 minutes) between category I and II CS patients respectively was also comparable. Overall, the decision to delivery was higher among category II (185 minutes) than I patients (173 minutes), but the 12-minute difference between the groups was not statistically significant (p=0.23).The time interval from theatre to anesthesia was within the recommended level (30 minutes) for women who underwent category I (78.1%) and II (77.5%). However, the duration from decision to theatre, anesthesia to incision, incision to delivery, and decision to delivery were higher than recommended and comparable among women who underwent category I and II caesarean section (p>0.05). The trend was similar at 60 minutes cut-off, with a majority of patients who underwent category I CS (90.6%) and II (91.7%) found to take longer than 60 minutes (Table 7).

Table 2. Decision to Delivery Time Interval for Category I and II Caesarean Sectionsat the Kenyatta National Hospital in January to March 2019

	Number of patients (%)		
	I	II	P
Decision to theatre (median time in minutes)	(130)	(143)	0.464
≤30	13 (11.4)	11 (12.4)	0.834
> 30	101 (88.6)	78 (87.6)	
Theatre to Anesthesia(median time in minutes)	(24)	(22)	0.522
≤30	89 (78.1)	69 (77.5)	0.927
> 30	25 (21.9)	20 (22.5)	
Anesthesia to Incision (median time in minutes)	(19)	(22)	0.388
≤10	16 (14.2)	7 (7.9)	0.162
> 10	97 (85.8)	82 (92.1)	
Incision to Delivery (median time in minutes)	(50)	(53)	0.450
≤30	5 (4.4)	10 (11.8)	0.053
> 30	108 (95.6)	75 (88.2)	
Decision to Delivery (median time in minutes)	(173)	(185)	0.450
≤30	4 (3.7)	2 (2.4)	0.594
> 30	103 (96.3)	82 (97.6)	
Decision to Delivery			
≤60	10 (9.4)	7 (8.3)	0.807
> 60	97 (90.6)	77 (91.7)	

4.4 Predictors of DDI

Univariate analyses using the Mann Whitney U test and the Kruskall Wallis test identified the phase of labour ($p<0.01$), rank of caesarian section ($p<0.01$), and education level of patients ($p=0.04$) as factors that influence the time from decision to delivery (DDI) through CS (Table 2). Admission in the latent phase of labour, repeat caesarean, and having a primary level of education increased the mean DDI of CS patients statistically significant. The type of caesarean section ($p=0.12$), age ($p=0.08$), marital status ($p=0.83$), referral status (0.62), history of stillbirth ($p=0.44$), and the history of abortion ($p=0.82$) did not influence DDI statistically significant (Table 4).

To identify predictors for DDI, the phase of labour, rank of CS, and education level of patients were evaluated using multiple linear regression. The phase of labour, rank of CS, and education level were identified as predictors of DDI. Patients in an active labour (t-9.4, $p<0.01$), scheduled for primary CS ($t=-2.5$, $p=0.01$) and with a secondary education ($t=-2.2$, $p=0.03$) were likelier have a shorter DDI that patients in latent labour, undergoing a repeat CS, and have primary education.

Table 3.Predictors of DDI for patients scheduled for category I and II caesarean sectionsat the Kenyatta National Hospital in January to March 2019

		Mean DDI (Minutes)	P
Phase of labour	Latent	337	**<0.01**
	Active	234	
Rank of CS	Repeat	354	**<0.01**
	Primary	223	
Education level	None	285	**0.04**
	Primary	355	
	Secondary	221	
	Tertiary	302	
Category of CS	Cat. 1	245	0.12
	Cat. 1	300	
Age	18-29	245	0.08
	30-45	311	
Marital status	Married	269	0.83
	Single	259	
Referral status	Yes	228	0.62
	No	292	
History stillbirth	Yes	211	0.44
	No	275	
History abortions	Yes	284	0.82
	No	270	

Note:

Regression Analyses		**B**	**SE**	**Beta**	**t**	**P**
	(Constant)	457.4	48.8		9.4	**0.00**
	Phase of labour	-46.1	18.2	-0.2	-2.5	**0.01**
	Rank of CS	-49.8	17.7	-0.2	-2.8	**0.00**
Education	Primary vs None	-122.6	169.2	-0.1	-0.7	0.47
	Primary vs Secondary	-105.6	48.3	-0.2	-2.2	**0.03**
	Primary vs Tertiary	-33.6	51.3	-0.1	-0.7	0.51

4.5 Decision to Delivery Interval and Maternal and Neonatal Health Outcomes

4.6 Maternal Health Outcomes

The prevalence of postpartum injury was higher when the time from decision to delivery was less than 30 minutes (33.3%) than when it was more (1.1%), but the difference was not statistically significant (X^2=4.8, p=0.18). Post OP stay of 0-3 days was lower when time was <30 minutes (66.7%) than >30 minutes (76.5%), while estimated blood loss was higher when time was >30 minutes (66.3%) than <30 minutes (40.0%) but not statistically significant

(P>0.05). The incidence of PPH was statistically significant, higher when time from decision to delivery was ≤60 minutes (17.7%) than >60 minutes (0.6%), X^2=21.57, p<0.01. However, women who delivered in ≤60 minutes after a decision than >60 minutes were less likely to have a post OP stay of 0-3 days (61.5% and 77.7%) and a blood loss ≤500mls (43.8% and 67.7%), even though the time from decision to delivery did not influence post OP stay or blood loss significantly (P>0.05) (Table 8).

4.7 Neonatal Health Outcomes

The live birth rate was higher when time from decision to delivery was ≤30 minutes (100%) than >30 minutes (96.8%) although not statistically significant. The odds of having a poor Apgar score at 5 minutes (50.0% and 1.1% respectively) and NBU admission (83.3% and 15.9% respectively) were higher when the time from decision to delivery was short (≤30 minutes) than long (> 30mins) statistically significant (P<0.05). However, the sex of babies was comparable when time was short (≤30) than long (>30), X^2=0.527, p=0.467). The live birth rate was higher when time from decision to delivery was ≤60 minutes (93.8%) than >30 minutes (97.2%) although not statistically significant (X^2=1.681, p=0.431). The odds of NBU admission (55.8% and 17.2%) was statistically significantly higher when time from decision to delivery was short (≤30 minutes) than long (> 30mins) (X^2=16.17, p<0.01), while timing did not influence the sex of babies and birth weight statistically (p>0.05), Table 8.

Table 4. Maternal and neonatal outcomes for patients scheduled for a category I and II CS at the KNH in January to March 2019 at 30 minutes and 60 minutes cut off

	No of patients (%)				No of patients (%)			
	≤30mins	> 30mins	X^2	P	≤60mins	> 60mins	X^2	P
MATERNAL								
Complications			4.80	0.18			21.5	<0.01
Bladder injury	0	1 (0.6)			0	1 (0.6)		
Postpartum injury	2 (33.3)	2 (1.1)			3 (17.7)	1 (0.6)		
Ruptured uterus	0	2 (1.1)			0	2 (1.2)		
None	4 (66.7)	175 (97.2)			14 (82.3)	165 (97.6)		
Post OP stay			0.15	0.61			1.71	0.19
0-3 days	2 (66.7)	114 (76.5)			8 (61.5)	108 (77.7)		
>3 days	1 (33.3)	35 (23.5)			5 (38.5)	31 (22.3)		
Blood loss			1.49	0.22				
≤500mls	2 (40.0)	120 (66.3)			7 (43.8)	115 (67.7)	3.70	0.05
> 500mls	3 (60.0)	61 (33.7)			9 (56.2)	55 (32.3)		
NEONATAL								
Birth outcome			0.19	0.90			1.68	0.43
Alive	6 (100.0)	182 (96.8)			15 (93.8)	173 (97.2)		
FSB	0	4 (2.1)			1 (6.2)	3 (1.7)		
MSB	0	2 (1.1)			0	2 (1.1)		
APGAR at 5			54.5	<0.01			***	
0-3	0	2 (1.1)			1 (5.9)	1 (0.6)		
4-6	3 (50.0)	2 (1.1)			5 (29.4)	0		
7-10	3 (50.0)	181 (97.8)			11 (64.7)	173 (99.4)		
Birth weight			1.40	0.23			2.54	0.11
<2500g	2 (33.3)	29 (15.3)			5 (29.4)	26 (14.6)		
≥2500g	4 (66.7)	160 (84.7)			12 (70.6)	152 (85.4)		
NBU admission			14.5	<0.01			16.1	<0.01
No	1 (16.7)	150 (81.1)			7 (41.2)	144 (82.8)		
Yes	5 (83.3)	35 (18.9)			10 (58.8)	30 (17.2)		
Sex of the baby			0.52	0.46			3.84	0.05
Female	4 (66.7)	96 (51.6)			5 (29.4)	95 (54.3)		
Male	2 (33.3)	90 (48.4)			12 (70.6)	80 (45.7)		

4.8 Financial implication of caesarean section decision to delivery interval at KNH

The financial cost of delivery ranged from Ksh 11,290 to 122,441 with a median of Ksh 46,577.50. The median cost of delivery of women whose time from decision to delivery was ≤60 minutes and >60 minutes did not differ statistically (Z=0.122, p-value=0.903), Figure 3.

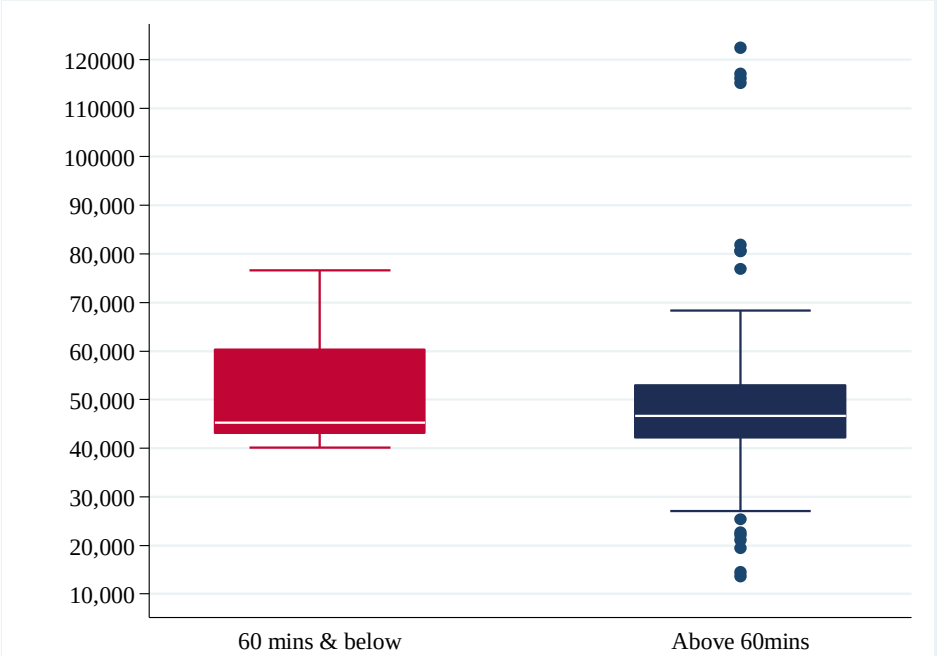

Figure 3. Financial cost of delivery incurred by decision to delivery time interval

A simple generalized linear model with Gaussian distribution and link function, log was fit to evaluate the time taken to make decision on the overall financial cost of delivery at alpha level of significance 0.05. The time taken to make decision had no significant effect of the overall financial cost of delivery (Exp (b) (95% CI) =0.97 (0.81-1.16), p=0.731).

DISCUSSION

The data showed that DDI for category I and II caesarean delivery was 173 minutes and 185 minutes respectively at KNH, which was higher than the recommended DDI of <30 minutes. A DDIof <30 minutes could be achieved in only 3.4% of patients scheduled for category I CS and 2.4% category II CS and 9.4% and 8.3% when the cut-off for DDI was extrapolated to 60 minutes. The results are in agreement with findings fromIndia where Mishra et al, while evaluating patients scheduled for emergency CS found that a DDI of <30 minutes could only be achieved in 30% of deliveries, but increased to 60% of high-risk women with cord prolapse(30). In Tanzania 12% of emergency CS patients are tended to within 30 minutes(24), while previous studies by Chege (23) and Hussein (13)in Kenya reported zero conformance to DDI of 30 minutes, with a median DDI of 178 minutes and 290 minutes reported by Hussein during category I and II CS. As such, the recommended DDI by AAP and ACOG of 30 minutes during category I and II CS patients is not feasible at KNH as it is currently constituted. The main source of delay is from decision to theatre, anesthesia to incision, and incision to delivery, which calls for a review of the existing guidelines for DDI for category I and II caesarean sections. Moreover, in a similar setting to the KNH, Hirani et al.(24) found that a time frame of 75 minutes is feasible, but needs proactive monitoring and clinical judgement of the urgency for CS births. At KNH, patients with post-partum injuries had a shorter DDI (33.3% <30 minutes and 17.7%<60 minutes), possiblyto lower the risk of adverse maternal and neonatal outcomes, and should be prioritized in decision-making.

After controlling confounding, a few factors were identified as predictors for DDI at the Kenyatta National Hospital. Even though the type of CS was not a predictor for DDI at KNH, the rank of CS was a predictor with patients undergoing a repeat CS requiring approximately 131 more to deliver after a decision has been reached. Moreover, patients in the latent stage of labor and those with a primary level of education were more likely to have a longer mean DDI with the mean difference reported being statistically significant. Factors such as age and the history or abortions could not be used to predict the amount of time a patient would take from decision to delivery.

There weresignificant associations between DDI of CS patients and maternal outcomes when the optional DDI was defined at less than 30 minutes and at less than 60 minutes. The risk of postpartum injury was significantly higher when DDI was >30 minutes and >60 minutes. Gupta et al. (18) reported similar results in India in 2017, in which failure to meet the

recommended DDI of <30 minute was significantly associated with an increased risk of adverse maternal outcomes. However, compliance to the recommended DDI was significantly higher at 42.2%, probably because of bias. In our study, health practitioners were unaware of the potential outcomes of the study. Gupta, on the other hand, had a sensitisation meeting with anaesthesiologists, obstetricians, or neonatologists and discussed the expected time intervals for decision to delivery, which might have introduced bias. Moreover, unlike Gupta who had a large cohort of emergency CS patients (453 women), we had a significantly lower sample size but still reported similar results.

Occurrence of adverse neonatal outcomes was significantly higher when DDI did not conform to the recommended time of <30 minutes. The odds of NBU admission were higher when DDI was <30 minutes. More women with a DDI <30 minutes bore children with a low birth weight (<2500 grams) and had a higher odds of having neonates with a poor five-minute Apgar score (4-6). Our results differed markedly with those reported in literature. Hirani et al. found no significant association between DDI of CS and the occurrence of neonatal complications - a finding that was corroborated by Mishra et al. in 2017. In the study, composite neonatal outcomes were comparable between patients who underwent category I and II CS up to DDI of 60 minutes. Unlike in the study by Gupta, our physicians were not sensitised on the potential outcomes of our study. Occurrence of neonatal outcomes have also been reported to vary markedly by region, peaking in Africa.

An evaluation of the financial indication of the DDI for category I and II CS revealed the patients are likely to spend between 11,290 and 122,441 Kenyan shillings. The median expenditure is about 47,000 Kenyan shillings, with the median cost of delivery estimated to be the same for patients who undergo category I and II caesarean sections. Furthermore, the cost of delivery did not vary statistically significantly by the DDI of patients when the optimal DDI was specified to be <30 minutes and 60 minutes. Even though local studies that we compared our results with are limited, there is consensus that a delay in delivery by category I and II CS represents a sizeable cost, which is a burden not only to patients but also the health system. In the United Kingdom (UK), financial loss due to delay in delivery is estimated to reach £951.58 theatre day every year(14) with the NHS Institute for Innovation and Improvement approximating that over £7 million can be saved every year by improving the efficiency of theaters (16,29)

CONCLUSIONS

- The DDI of 120 category I CS patients and 95 category II CS patients who delivered at KNH from January to March 2019 was 173 minutes and 185 minutes respectively
- The predictors for DDI at KNH were the phase of labour, rank of caesarean section, and the education level of patients
- Maternal outcomes were associated with DDI at KNH
- DDI had a minimal impact on neonatal outcomes at KNH
- The median cost for caesarean section was Kshs. 46,577.50

RECOMMENDATIONS

- There is a need to shorten DDI to avert adverse maternal and neonatal outcomes.

APPENDICES

Appendix 1: Consent Forms

(1) CONSENT EXPLANATION:

Title of the study: Predictors of decision to delivery interval for category 1 and 2 caesarean sections, its financial implication and maternal and neonatal outcomes at Kenyatta National Hospital.

Principal Investigator: Dr. Richard Wainaina Mungai.

Introduction: Dr. Richard W. Mungai is a postgraduate student in the Department of Obstetrics and Gynecology at the University of Nairobi. He is carrying out a study to find out the causes of delay in category 1 and 2 caesarean deliveries and its effects on the health of the mother and the newborn at Kenyatta National Hospital. You are being requested to participate in this study.

Purpose of the study: The study will evaluate the predictors of decision to delivery interval for category 1 and 2 caesarean sections, its financial implication and maternal and neonatal outcomes at Kenyatta National Hospital.

It also aims at making recommendations on reducing caesarean section decision to delivery interval with a view of improving maternal and newborn health.

Procedure: If you agree to participate in the study, you will be interviewed by the principal investigator or his assistant after having been attended to by your healthcare provider. The interviewer will complete a questionnaire by verbally asking you questions, the nature of which will be about your particulars, previous pregnancy outcome(s) and current delivery including details of your newborn baby. Your name will be omitted from the questionnaire to ensure your anonymity at all times.

The interviewer will also access your medical records/file to obtain any additional information required which you may not be privy to. The information gathered will be stored safely under lock and key by the principal investigator who will then code and enter it into a password-protected computer database prior to analysis. In addition, the PI/RA will follow you through the process of preparation for the Caesarean section till 24 hours after the delivery. Critical information including the timings of each of the event will be documented.

Benefits: There is no direct benefit to you by participating in this study. However, you will have a greater opportunity of interacting with your health care provider, hence a better chance to learn more about your condition and contribute to the better health of mothers who are delivered by caesarean section and their newborn babies.

Risks: There is no associated danger to your health or well-being by participating in the study. You may be asked questions which could be of a disturbing nature as they touch on personal matters. However, you are not obliged to answer such questions if you so wish.

Confidentiality: Any information you provide will be treated as confidential. Your confidentiality will be maintained at all times by omitting your names from the questionnaire and instead, each questionnaire will be randomly assigned with a study number for purposes of identification in the study. The completed questionnaires will be stored in a lockable filing cabinet only accessible to the principal investigator and his research assistant. Data from the questionnaire will be entered into a password-protected computer database for storage which will be accessible only through the principal investigator. Only the study numbers will be used during data analysis and report writing of the study and at no point will any detail that might identify an individual be provided. There shall be no mention of names or identifying information in the report or publication which may arise from the study. The information obtained will be used only for the purpose of the study.

Compensation: There will be no compensation for participation in the study.

Voluntarism: Your participation in the study is voluntary and you are free to withdraw from participating in the study at any time if you so wish. Should you decline to participate or withdraw from participating in the study, you will not be denied any service by the hospital.

Contact Information: If you have any questions regarding the study, you may contact *Dr. Richard Wainaina Mungai* through Mobile phone no**;** *0721791530.*

In case of any concern about ethics, please contact:

KNH/UON - ERC,
P.O. Box 19676 – 00202,
Nairobi.
Telephone number (254 – 020) 2726300 Ext 44355.
Email: uonknh_erc@uonbi.ac.ke

(2) CONSENT FORM

I _____, the undersigned, acknowledge that I have been provided with detailed information about the nature of the study by Dr/Mr./Mrs./Ms _____. I have read and understood the explanation above and have been given adequate opportunity to ask questions about the study. I hereby agree to participate in the study without any coercion whatsoever. I am aware that my participation in the study is voluntary and that I can withdraw from the study at any time.

Signature of Participant _____ Date _____

Signature of Researcher/Assistant _____ Date_____

Appendix 2: Questionnaire

Unique Study Number …….

Date……….

Category of caesarean section

- ❑ **1**
- ❑ **2**

Socio-demographic data:

1. Age ..... years.
2. Marital status
   - ❑ Single
   - ❑ Married
   - ❑ Divorced
   - ❑ Widowed

3. Level of education:
   - ❑ No formal education
   - ❑ Primary school level
   - ❑ Secondary school level
   - ❑ College/University level

4. Occupation:
   - ❑ Unemployed
   - ❑ Employed

5. Ethnicity
   - ❑ Kikuyu
   - ❑ Luhya
   - ❑ Luo
   - ❑ Kalenjin
   - ❑ Kamba
   - ❑ Kisii
   - ❑ Others

Was the patient referred to this hospital in labour from another health care facility?

- ❑ YES
- ❑ NO

Obstetric data:

1. What is the parity at the time of delivery: Para ……..
2. What is the number of children previously delivered alive ……...
3. What is the number of stillbirths delivered previously ……
4. What is the number of miscarriages previously……...
5. Gestational age at the time of delivery …… Weeks
6. At what phase of labor was the decision for emergency cesarean section made;
   - ❑ Latent
   - ❑ Active

Information pertaining to the emergency caesarean section:

1. Rank of emergency caesarean section:
   - ❑ Primary
   - ❑ Repeat

2. Indication for emergency caesarean section:
   - ❑ Non-reassuring fetal status
   - ❑ Placenta previa with hemorrhage
   - ❑ Abruption placenta
   - ❑ Cord prolapse
   - ❑ Ruptured uterus
   - ❑ Dystocia (Prolonged labour/poor progress of labour, CPD and Obstructed labour)
   - ❑ Previous uterine scars
   - ❑ Failed VBAC
   - ❑ Malpresentation
   - ❑ Failed induction of labour
   - ❑ Pre-eclampsia/Eclampsia
   - ❑ Multiple pregnancy
   - ❑ Failed assisted vaginal
   - ❑ Other.....

3. Mode of anesthesia administered:

- ❑ General anesthesia
- ❑ Spinal anesthesia
- ❑ Epidural anesthesia

4. Seniority of the operator:

- ❑ Registrar
- ❑ Consultant

5. Day of the week when caesarean section was performed:

- ❑ Monday
- ❑ Tuesday
- ❑ Wednesday
- ❑ Thursday
- ❑ Friday
- ❑ Saturday
- ❑ Sunday

6. What time was the caesarean section was performed:

- ❑ 0800 Hrs. – 1959 Hrs. (Daylight)
- ❑ 2000 Hrs. – 0759 Hrs. (Night time)

The decision-to-delivery interval:

1. What time was decision to operate made ……. Hrs.
2. What time was patient received in theatre ……...Hrs.
3. What time was anesthesia administered ……Hrs.
4. What time was baby delivered …….. Hrs. (in case of twin delivery, refer to first twin)
5. What was the time interval between?
   (i) Decision making and arrival in theatre …….. Minutes
   (ii) Arrival in theatre and administration of anesthesia ……. minutes
   (iii) Administration of anesthesia and delivery of the baby …….. Minutes
   (iv) Duration of the C- Section……. minutes
6. What was the Decision-to-delivery interval …….. minutes

7. If decision-to-delivery interval > 30 minutes, reason(s) for delay in carrying out the operation: (Tick where applicable)

- ❑ Lack of consent.
- ❑ Results of laboratory investigations deemed necessary before the operation were not ready.
- ❑ Blood deemed necessary prior to the operation was not available.
- ❑ Theatre was being used for another emergency operation.
- ❑ Unavailability of anaesthetist.
- ❑ Unavailability of obstetrician.
- ❑ Unavailability of pediatrician.
- ❑ Delay in moving the patient to theatre due to the huge workload and staff shortage.
- ❑ Lack of anesthetic drugs and or medical gases.
- ❑ Lack of medical supplies.
- ❑ Unavailability of sterile packs.
- ❑ Delay in anaesthetizing the patient due to multiple attempts at spinal anesthesia or difficult intubation.
- ❑ Shortage of personnel to open a second theatre.
- ❑ Long turnaround time for preparation of theatre between operations.
- ❑ Poor interpersonal relations and lack of communication between members of the various teams in labour ward and theatre.
- ❑ Lack of motivation/low morale amongst theatre staff.
- ❑ Other……

Maternal outcome (Tick where applicable/appropriate)

1. What maternal complication occurred (tick where appropriate):

- ❑ None
- ❑ Ruptured uterus
- ❑ Postpartum hemorrhage
- ❑ Acute renal failure
- ❑ Severe anemia
- ❑ Congestive Cardiac Failure
- ❑ Pulmonary edema
- ❑ Fever
- ❑ Poor reversal from general anesthesia
- ❑ Death

- ❑ Other ……

2. What was the estimated blood loss at C- section? …….mls

2. What was the duration of postoperative hospitalization ……Days

3. If postoperative hospital stay was > 3 days, what were the reason(s) for prolonged hospital stay: (tick appropriately?)

- ❑ Admission to HDU or ICU Dialysis
- ❑ Severe Pre-eclampsia/Eclampsia
- ❑ Severe anemia/CCF
- ❑ Cardiac disease
- ❑ Wound/Puerperal sepsis
- ❑ Other……

Newborn outcome:

1. What was the condition of the baby at delivery?

- ❑ Alive
- ❑ Fresh stillbirth
- ❑ Macerated stillbirth
- ❑ Congenital anomaly

2. What was the birth weight of the baby …… Grams

3. What was the Apgar score at 5 minutes.....?

4. Was the Baby admitted to NBU?

- ❑ Yes
- ❑ No

5. What was the sex of the baby?

- ❑ Male
- ❑ Female
- ❑ Ambiguous

Financial Costs

What was the invoice cost from medical records of mothers at discharge, Kshs ……..

Appendix 3: Dummy Tables

Table 1: Socio-demographic characteristics of the study participants

CHARACTERISTICS	**n (%)**
AGE (YEARS) **<18** **18-20** **21-25** **26-30** **31-35** **>35**	
MARITAL STATUS **Single** **Married** **Divorced** **Widowed**	
LEVEL OF EDUCATION **No formal education** **Primary** **Secondary** **College/University**	
OCCUPATION **Unemployed** **Employed** **ETHNICITY** **Kikuyu** **Luhya** **Luo** **Kalenjin**	

Kamba **Kisii** **Others**	
REFERRAL STATUS **Not referred** **Referred**	

Table 2: Obstetric characteristics of the study participants.

CHARACTERISTICS	n (%)
Previous live births	
0	
1	
2	
3	
4	
5	
Previous stillbirths	
0	
1	
2	
3	
4	
Previous miscarriages	
0	
1	
2	
3	
4	
Gestation (Weeks)	
32-36	
37-40	
41-42	
Phase of labor	
Latent	
Active	

Table 3; Indication for Caesarean Section

Indication	n (%)
Previous uterine scar	
Dystocia(pl,cpd,obs lab)	
NRFS	
P.previa	
Malpresentation	

Table 4; Rank, Mode of Anesthesia, Surgeon, Day and Time of cesarean section

	Cat 1	Cat 2	X^2	P
Rank of Operation Primary Repeat				
Mode of Anesthesia Spinal General Epidural				
Surgeon Medical Officer Registrar Consultant				

Day of the Week **Monday** **Tuesday** **Wednesday** **Thursday** **Friday** **Saturday** **Sunday** **Time** **0800-1959 hrs(Daytime)** **2000-0759 hrs. (Night)**				

Table 5; Decision to Delivery Interval for Emergency Caesarean Section

Time Interval(minutes)	
Decision to theatre **≤30** **> 30**	
Theatre to Anesthesia **≤30** **> 30**	
Anesthesia to Incision **≤10** **> 10**	
Incision to Delivery **≤30** **> 30**	
Decision to Delivery **≤30** **> 30**	

Reasons for delay in performing the Emergency Caesarean section

Reasons for delay	
Lack of consent. Results of laboratory were not ready. Blood deemed necessary prior to the operation was not available. Theatre was being used for another emergency operation. Unavailability of Anesthetist. Unavailability of obstetrician. Unavailability of pediatrician. Delay in moving the patient to theatre due to the huge workload and staff shortage. Lack of anesthetic drugs and or medical gases. Lack of medical supplies Unavailability of sterile packs. Delay in anaesthetizing the patient due to multiple attempts at spinal anesthesia or difficult intubation. Shortage of personnel to open a second theatre.	

Long turnaround time for preparation of theatre between operations. Poor interpersonal relations and lack of communication between members of the various teams in labour ward and theatre.	

Table 7; maternal outcomes of study participants

OUTCOME	
Maternal Outcome None Ruptured uterus Postpartum hemorrhage Acute renal failure Severe anemia Congestive Cardiac Failure Pulmonaryedema Fever Poor reversal from general anesthesia Death Other	
Post OP stay in days 0-3 days >3 days	
Reasons for Prolonged stay (>3 days) Admission to HDU/ICU Preeclampsia with severe features Severe anemia/ CCF Wound sepsis Puerperal sepsis Other	

Table 8; Neonatal Outcomes of the study population

OUTCOME	
Condition of Baby at Delivery Alive FSB MSB Congenital Anomaly	
APGAR score at 5 mins 0-3 4-6 7-10	
NBU admission Yes No	
Sex of the Baby Male Female Ambiguous	

Table 9; Invoiced Cost on Discharge

Cost in Kshs	

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