EFFECT OF A COLOUR CODE TOOL TO PRIORITIZE EMERGENCY CAESERIAN SECTION ON DECISION TO DELIVERY TIME INTERVAL AND PREGNANCY OUTCOMES AT KENYATTA NATIONAL HOSPITAL: A QUASI-EXPERIMENTAL STUDY

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DECLARATION

This is to declare that this research is my original work, carried out with the guidance of my supervisors. References made to work done have been indicated.

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CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is an original work of Dr. Samuel Gatei Ngatia, a Master of Medicine Student in the department of obstetrics and gynaecology, university of Nairobi, under the guidance and supervision of Dr. Kireki Omanwa, Dr. George Gwako and Dr. Allan Ikol. This work has not been presented in any other university for the award of a degree.

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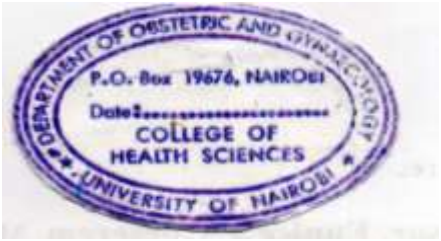

DEDICATION

I dedicate this book to the hundreds of thousands of women who die each year while giving birth, for their untold suffering and bravery.

To my parents and siblings for the prayers and moral support and to Kenyatta National Hospital for sponsoring the study.

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LIST OF ABBREVIATIONS

ACOG: American College of Obstetricians and Gynaecologists

APGAR: Appearance Pulse Grimace Activity Respiration

CPD: Cephalo-pelvic Disproportion

CS: Caesarean Section

CD: Caesarean Delivery

DDI: Decision to Delivery Interval Time

ERC: Ethics and Research Committee

EUA: Examination under Anaesthesia

FSB: Foetal Stillbirth

IUFD: Intrauterine Foetal Demise

KNH: Kenyatta National Hospital

NBU: Newborn Unit

NICU: Neonatal Intensive Care Unit

PI: Principle Investigator

PMH: Pumwani Maternity Hospital

RCOG: Royal College of Obstetricians and Gynaecologists

RA: Research Assistant

OT: Operating Theatre

OPERATIONAL DEFINITIONS

Caesarean Section: The most common obstetrical operation aimed at saving life**.** It involves making incisions in the abdomen and uterus to deliver the fetus, placenta, and membranes when vaginal delivery is not feasible or would pose undue risks to the mother and baby. Depending on the situation, a general or regional anesthesia may be used.

Category 1 Caesarean Section: Situations where there is maternal and fetal compromise at the time of delivery and whose lives are in immediate danger.

Category 2 Caesarean Section: Deliveries in which there is no immediate threat to a woman's life or the baby's life, but maternal and fetal compromise exists.

Category 3 Caesarean Section: For cases in which there is no compromise to the mother or fetus, but the delivery must be undertaken as soon as possible

Category 4 Caesarean Section: When both mother and doctor agree that no maternal or fetal compromise exists, the delivery can be performed whenever it is convenient for the mother and the doctor.

The decision-to-delivery interval (DDI): The time between deciding and delivering the newborn by caesarean section. When an emergency caesarean delivery is decided, the time from that decision to delivery is measured in minutes.

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ABSTRACT

Background

Caesarean section (CS) rates of 10% to 15% are recommended by the World Health Organization to reduce maternal and perinatal complications. Even though there is well-documented evidence of increased maternal mortality associated with caesarean deliveries, the rate of caesarean deliveries has been increasing worldwide. It is recommended that caesarean sections under category I be delivered within 30 minutes, but the goal has remained elusive. It appears that prolonged DDI is associated with poor neonatal outcomes with numerous studies linking it to the condition. The aim of this study is to introduce a colour coding tool to classify emergency caesarean section at Kenyatta National Hospital maternity unit and assess its impact on pregnancy outcome and DDI.

Objective

To evaluate the effect of a colour code tool to prioritize emergency Caesarean Section on DDI and pregnancy outcome at the Kenyatta National Hospital.

Methodology

A quasi experimental, before after study design of parturient requiring emergency Caesarean section at Kenyatta National Hospital (KNH) maternity unit conducted between August 2020 and October 2020. It was done in two phases: Phase I, the period before the introduction of colour code, and phase II, the period after the introduction of colour code. Sampling was conducted using consecutive sampling. Participants were followed up through theatre and post operatively and the DDI, maternal and neonatal outcome were captured using a structured questionnaire. Data collected was analysed using STATA version 15.

Results

Two hundred and eighty-six patients were included (one hundred and forty-four in phase I and one hundred and forty-two in phase II. Patient's demographic and obstetric characteristics were comparable between the two groups. With a p value of 0.012, the median decision to delivery time interval for phases I and II, respectively, was 256 minutes and 169 minutes. A shorter decision to delivery time interval was linked to color coding (adjusted odds ratio 1.63 (1.02 to 3.14)). Both groups' newborn and maternal outcomes were comparable.

Conclusion

Our results indicate that the three-color code tool's deployment greatly reduced the time between the decision and delivery but had no effect on the neonatal or maternal outcome.

Recommendation

Use of the three-color coding system to reduce the turnaround time for Caesarean sections. To identify obstacles to obtaining the goal DDI, more research must be conducted.

CHAPTER ONE

1.0 INTRODUCTION

Caesarean sections are performed when vaginal deliveries are not possible or are too risky for the mother or infant. The fetus, placenta, and membranes are delivered through abdominal and uterine incisions.

Because of this, it is a life-saving surgery that can prevent maternal and perinatal mortality and morbidity. Being a surgical procedure, it carries additional risk and can result in perinatal mortality and morbidity.

In both high-income and low to middle-income countries, the rate of caesarean sections has increased over the years, posing a great concern worldwide. At present, Caesarean Sections account for 18.6% of all global deliveries; 6% in low-income countries and 27.2% in high-income countries (1). Compared to the WHO recommended Caesarean Section rates of 10% to 15% (2), these rates are higher.

Kenya continues to have a high maternal mortality rate, with 362 deaths per 100,000 live births (KDHS 2014) (3). In most cases, these deaths are caused by direct causes such as hemorrhage, hypertension, obstructed labour, sepsis, and complications related to abortion. Emergency CS is an important intervention aimed at reducing such deaths.

Kenyatta National Hospital has a busy maternity unit conducting about 10,000 deliveries annually with a CS rate of 27% to 30 %(1). The comparative high rate of CS has been attributed to the hospital being a tertiary referral hospital serving the whole country. Despite this high rate there exist no standardized way of classifying emergency caesarean section. Over the years, this has been left for the doctor on duty to determine in his or her own manner the urgency of each case. Introducing this tool in such a busy maternity setup with limited resources is likely to yield a reduced DDI, better maternal and neonatal outcomes. It will also enable proper audit of obstetrics and anaesthetic outcomes.

Traditionally CS have been classified as either ‘elective’ or ‘emergency’. An outcome of obstetrics or anesthesia can't be accurately measured and evaluated due to this categorization. A single 'emergency' category does not capture the full spectrum of urgency that occurs in obstetrics. Furthermore, by not defining the urgency of individual cases, it has an impartial effect on decision to delivery interval time.

A systematic review published in 2011 ascertained 27 classification systems for CS which were grouped into 4 general types derived from the main unit being classified (5). A classification based on degree of urgency was ranked among the best classification systems for its simplicity, ease of implementation, and reproducibility. Classification based on degree of urgency mainly looks at four categories:

Category 1 Caesarean Section: Situations where there is maternal and fetal compromise at the time of delivery and whose lives are in immediate danger.

Category 2 Caesarean Section: Deliveries in which there is no immediate threat to a woman's life or the baby's life, but maternal and foetal compromise exists.

Category 3 Caesarean Section: For cases in which there is no compromise to the mother or foetus, but the delivery must be undertaken as soon as possible

Category 4 Caesarean Section: When both mother and doctor agree that no maternal or foetal compromise exists, the delivery can be performed whenever it is convenient for the mother and the doctor.

The classification system, however, does not include a communication tool that would enable the delivery team to be aware of the CS urgency in a timely manner. As an intervention, this study aimed to introduce a colour code tool for categorizing emergency CS and evaluate its effects on DDI and pregnancy outcomes.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Rate and current trends in Caesarean Section

In the last three decades the CS rate have increased to unprecedented levels, with the current global rate ranging from 6% to 27.2% in the low income and high-income regions, respectively (1). This is despite the international healthcare community and WHO recommendation of an ideal rate of 10-15% at population level following an ecological study and systematic review done in 2014(2).

CS rates are lowest in Africa, with an average of 7.3%, which varies from 3.5% in sub-Saharan Africa to 27.8% in Northern Africa (1). Yet, the absolute and yearly increases in CS rates in low and middle-income countries have been remarkably high. In addition to providing high quality obstetric care, many other factors contribute to this trend, including fear of pain, anxiety over genital alterations after vaginal delivery, mistaken belief that cesarean delivery is safer than vaginal delivery, legal concerns, and a lower tolerance for complications or results other than perfect babies (6)(7).

Gichangi P et.al in 2001 did a study looking at national and hospital based Caesarean Section rate in Kenya. The proportion of hospital-based Caesarean Sections was 6.3% of all births (range 0.3-37 %), whereas the proportion of population-based Caesarean Sections was 0.95 % (range 0.1%-4%). Despite reporting very low national population-based CS rates the hospital-based CS rates showed a rising trend with the highest rate at Kenyatta National Hospital ranging from 27% to 30% between 1983 and 1997. This was attributed to KNH being a tertiary level referral centre serving the whole country (4)

2.2 Classification and categorization of emergency Caesarean Section

The increasing rates of CS rate have been a major public concern worldwide. Appropriate classification of CS has been proposed as one of the measures to better understand the drivers of this trend and reduce the

CS rate where needed. According to WHO a good classification system for CS should be simple, clinically applicable, accountable, replicable, and verifiable (2).

Torloni et.al did a systematic review in 2010 and reviewed 27 existing classification systems as illustrated in table 1. Their analysis and comparison were based on an essential criterion that an international panel of experts had recognized as essential for comparing the merits and demerits of each system. Women based classification in particular the 10 group (Robson's) scored highest, followed by the urgency based iclassification, which can be attributed to disparities in mutually exclusive categories, total inclusivity, and the ability to identify prospective victims. Urgency based classification mainly focuses on emergency CS hence was faulted for not being totally inclusive and lacking clear definitions of categories. It was however seen to be conceptually easy, could improve communication between health professionals leading to improved maternal-perinatal outcomes (5)

Table 1. Classifications of caesarean section

	Main Characteristics*								Case-scenarios (N = 12)#		
Classifications	Easy[1]	Clarity[2]	Mutually exclusive[3]	Totally inclusive[4]	Prospective identif. categories[5]	Reprod-ucibility[6]	Impleme-ntability[7]	Overall score (max. 14)	% disagr-eement between raters	% cases class-ified in >1 category	% cases not included in any category
Indication based											
Althabe 2004 [15]	2	2	0	2	1	1	1	**9**	17	8	8
Anderson 1984 [7]	2	0	2	2	0	1	2	**9**	8	8	0
Calvo 2009 [16]	2	2	0	2	1	0	1	**8**	58	58	0
Pytherch 2007 [22]	2	2	0	0	1	0	2	**7**	33	8	58
RCOG 2001 (a) [4]	2	0	0	2	1	0	2	**7**	42	50	0
NICE 2004 [20]	2	1	0	0	1	1	2	**7**	-	-	-
Gregory 1994 [18]	1	0	2	0	1	1	1	**6**	25	8	0
Nico 1990 [21]	1	1	0	2	1	0	0	**5**	83	17	0
Stanton 2008 [23]	2	0	0	0	1	0	2	**5**	50	58	8
Unmet needs network 2000[24]	2	0	0	0	1	0	2	**5**	42	28	33
Cisse 1998 [17]	1	0	0	0	1	0	2	**4**	83	42	42
Kushtagi 2008 [19]	1	0	0	0	0	0	1	**2**			
Degree of urgency based											
Van Dillen 2009 (a) [14]	2	0	2	2	1	0	2	**9**	33	0	0
Nicopoullos 2003 (a) [13]	2	1	1	2	0	0	2	**8**	67	42	8
Lucas 2000 [26]	2	0	1	2	0	0	2	**7**	58	42	0
Van Dillen 2009 (b) [14]	2	0	2	0	1	0	2	**7**	17	0	17
Huissoud 2009 [25]	2	0	2	0	0	0	2	**6**	50	17	25
Women based											
Robson 2001 [6]	2	2	2	2	2	2	2	**14**	0	0	0
Denk 2006 [28]	2	2	2	2	2	2	1	**13**	8	8	0
Cleary 1996 [27]	2	2	2	0	2	2	2	**12**	8	0	0
Lieberman 1998 [29]	1	0	0	1	1	1	1	**5**	33	25	0
Other types											
RCOG 2001 (b) [4]	2	1	0	0	2	1	2	**8**	-	-	-
RCOG 2001 (c) [4]	2	1	0	0	1	1	22	**7**	-	-	-
Nicopoullos 2003 (b) [13]	2	1	-	0	-	1	1	**5**	-	-	-
ICD 10 1992 [32]	1	0	1	2	0	0	1	**5**	50	8	0
WHO 2004 [30]	2	0	0	2	0	0	1	**5**	42	8	0
Guidotti 2008 [31]	2	0	0	0	1	0	0	**3**	-	-	-

Code: 2 = good, = regular, 0 = poor, : - = not applicable.
1-Easy: how much effort or time it takes to understand main concepts, logic and rules of the classification.
2-Clarity: clear, objective, precise and unambiguous definitions given for each category.
3- Mutually exclusive: each unit being classified by the system (e.g. woman or CS) can only be placed in a single of the existing categories.
4- Totally inclusive: Each and every unit being classified can be placed in at least one of the categories.
5- Prospective identification of categories: allows classification of the patient into one of the categories before she is taken to the operating theater.
6- Reproducibility: probability that the same case would be classified in the same category by different raters.
7- Implementability: human and material requirements needed to introduce and maintain the classification in continuous use.
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Adapted from classification of Caesarean Section. A systematic review by Torlani et al, PLoS ONE 2011. VOL 6

Due to the decreased number of categories proposed for CS, classifications based on scale of urgency were also found to be theoretically easy to comprehend and enforce (Table 2). An improved communication between health professionals (nurses, obstetricians, anaesthesiologists) could result from this type of classification that determines "when" (or how quickly) CS is necessary. These classifications are limited by

a lack of clear and unambiguous definitions for their categories, which could make inter-rater reproducibility, comparability, and interpretation difficult(2).

AVan Dillen (2009) urgency of classification based on clinical definitions with interpretations was found to be more inclusive amongst the urgency-based classifications where he included four categories (table 2):

Category 1 Caesarean Section: Situations where there is maternal and fetal compromise at the time of delivery and whose lives are in immediate danger.

Category 2 Caesarean Section: Deliveries in which there is no immediate threat to a woman's life or the baby's life, but maternal and foetal compromise exists.

Category 3 Caesarean Section: For cases in which there is no compromise to the mother or foetus, but the delivery must be undertaken as soon as possible

Category 4 Caesarean Section: When both mother and doctor agree that no maternal or foetal compromise exists, the delivery can be performed whenever it is convenient for the mother and the doctor.

According to his comparative study in 2009, Van Dillen found the 4 grade system with interpretation had relatively low inter-observer variability compared to the traditional binary system after asking 212 obstetricians to classify 18 different obstetrics scenarios(3)

Huissoud, (2009) colour codes for emergency CS had three categories and employed use of colours green, yellow and red to better define his categories where green was non urgent CS, yellow was urgent CS and red represented extremely urgent cases of CS (4)(table 2). In 2008 O. Dupuis et al did a study using the 3 colour code system and found that it significantly reduced the DDI in emergency cases(5).

Table 2. Classification of caesarean section based on the degree of urgency

Author, year	Major categories/subcategories: Description of major categories	Special Characteristic
Van Dillen 2009 (a) Urgency of CS classification based on clinical definition with interpretation	**4/0** • 1: immediate threat to the life of mother or fetus • 2: Maternal or fetal compromise but not immediately life threatening • 3: The mother needs early delivery but there is no maternal or fetal compromise • 4: Delivery timed to suit the mother or the staff	Relatively easy and an improvement over simple binary classification. Could improve if more detailed definitions were given for each of the categories, along with examples. A total of 79 doctors tested it on 18 theoretical case-scenarios.
Nicopoullos 2003, Priority of delivery by CS	**4/0** • Crash (10–20 min) • Urgent (up to 30 min) • Emergency (up to 2 h) • Elective (no time limit)	Simple, few and well defined categories. However, offers no evidence to support the cut-offs proposed for each category. Tested on real patients.
Lucas 2000, Urgency of CS classification based on clinical definition	**4/0** • emergency • urgent • scheduled • elective	Same as Van Dillen but with less definitions and guidelines for use. Conceptually easy but needs to exemplify better the clinical situations that would be classified under each category. Tested on real patients.
Van Dillen 2009 (b) Traditional Binary System for Degree of Urgency	**2/1** • 1ary: if vaginal delivery was not intended • 2ary: if vaginal delivery was attempted	Simple and easy, but offers very limited amount of information. Could improve if more detailed definitions were given for each of the categories, along with example. A total of 79 doctors tested it on 18 theoretical case-scenarios.
Huissoud, 2009 Color codes for emergency CS	**3/0** • green: non-urgent CS (up to 1 h interval) • yellow: urgent (<30 minutes) • red: extremely urgent (<15 minutes)	Conceptually easy and simple. Could improve communication between staff and ultimately improve maternal and perinatal outcomes. Tested on real patients.

Adapted from classification of Caesarean Section. A systematic review by Torlani et al, PLoS ONE 2011. Vol 6.

In 2010 RCOG published a guideline; Good practice no 11 'classification of Caesarean Section-a continuum of risk' incorporating a modified version of the classification proposed by *Lucas et al*(6) indicating the use of a colour scale that emphasizes the need to recognize that a continuum of risk applies to CS(7)

Table 3. A classification relating the degree of urgency to the presence or absence of maternal or foetal compromise.

Urgency	Definition	Category
Maternal or fetal compromise	Immediate threat to life of woman or fetus	1
	No immediate threat to life of woman or fetus	2
	Requires early delivery	3
No maternal or fetal compromise	At a time to suit the woman and maternity services	4

Adapted from classification of Caesarean Section-a continuum of risk, good practice no. 11 RCOG Guidel. 2010;(11):1–4.

2.3 Decision to delivery time interval

An interval of time between deciding to perform a Caesarean section and delivering the newborn is called a decision-to-delivery interval (DDI) (12). It is recommended that DDI time in category 1 caesarean sections should not be more than 30 minutes. To meet this requirement, emergency obstetric care units must be equipped to perform Caesarean sections within 30 minutes of making the decision to do so (12).

In Anoxia over 10 minutes causes irreversible cerebral damage in monkeys, according to Faro and Windle (13). In their report, Bujold and Gauthier described three infants who were born 15, 16, and 23 minutes after foetal bradycardia began, all of whom proceeded to develop ischemic encephalopathy (10,14). Bloom and Leveno reported that an infant delivered 33 minutes after an emergency C-section decision died of ischemic encephalopathy (15). A decision to delivery time interval has consequences, as these findings show.

In its bulletin number 256, ACOG stated that Caesarean delivery can be started within 30 minutes after the decision was made if anaesthesia and surgical personnel are available (16). Several studies have shown that

up to 29–61% of cases do not meet the 30-minutes rule (17)(18)(19)(20). Study results also showed that very urgent CS has a significantly shorter decision-to-delivery interval (DDI) than urgent CS, and that mean DDIs have a wide range (11.4–42.9 minutes) (10)

Hirani BA and Mchome Et Al conducted a retrospective cross-sectional study in a referral hospital in Northern Tanzania in 2014. This study reviewed 598 emergency CSs, with a median time to diagnosis 60 minutes. Most of them were handled within 30 minutes, with 12% being treated within 15 minutes. Cephalo Pelvic Disproportion (CPD) and uterine rupture were the two conditions associated with the shortest DDI, which lasted 40 & 45.5 minutes, respectively. The was no significant association between DDI and the first and fifth minutes of the Apgar score (P0.05) (21).

In a study conducted by Hussein A.H in 2012 in KNH and Pumwani Maternity Hospital (PMH) and involved 130 women at KNH and 121 women at PMH respectively. In KNH and PMH, the median DDI was 178 minutes and 290 minutes, respectively. A DDI of 30 minutes was achieved by < 1% of the participants, and a 31–60-minute DDI by 4% of women (20). The study found that 37% of women had DDIs of more than five hours in his study. At 6%, wound sepsis was the most common complication. Nevertheless, the study concluded that prolonged DDI did not significantly raise maternal complications risk.

With so many professionals working in the labour unit (senior obstetrician, registrar obstetrician, anaesthesiologist, midwives, and anaesthesia nurse), the findings raise the question of whether communication quality affects team performance.

3.0 CONCEPTUAL FRAMEWORK

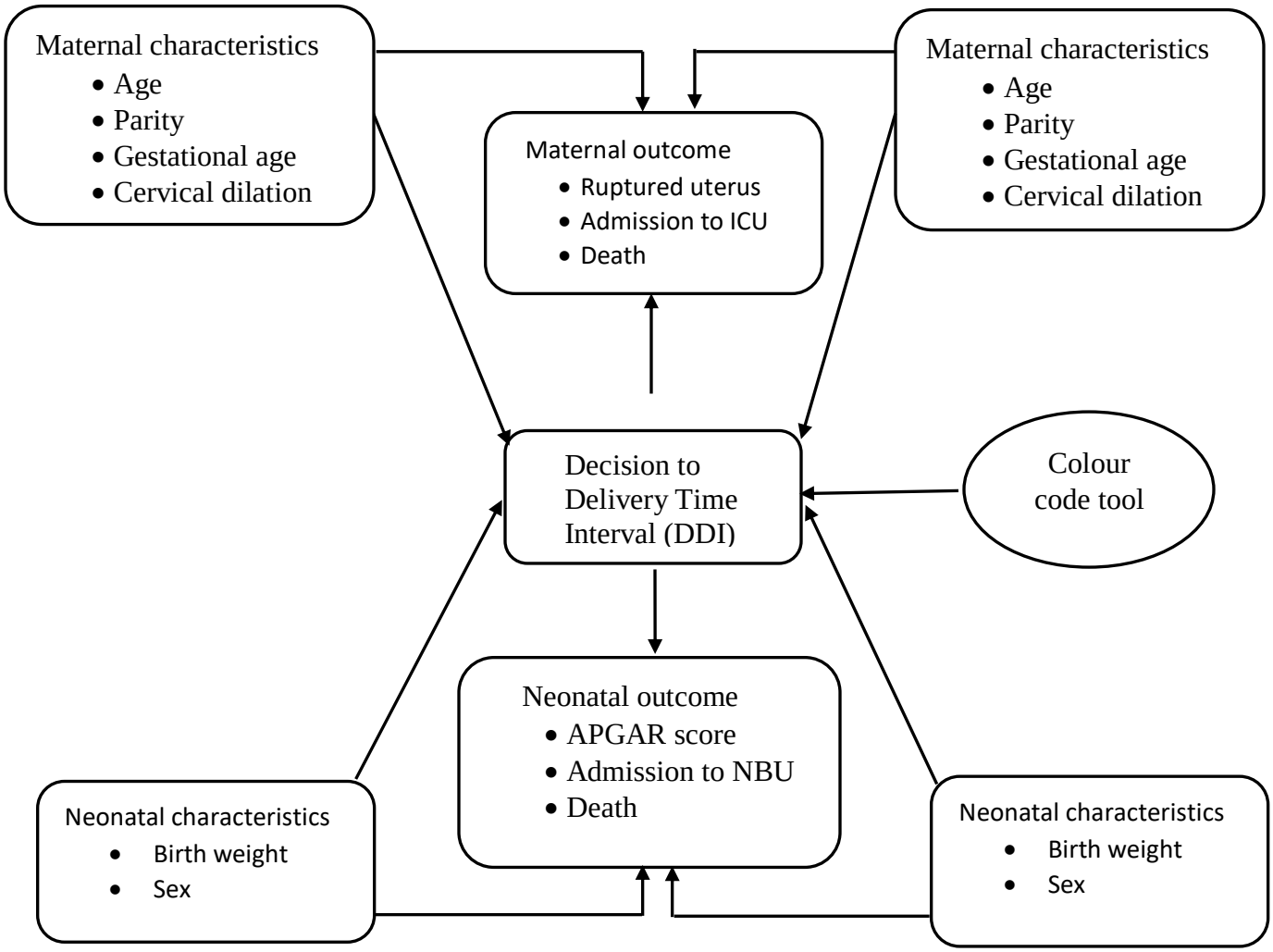
3.1 Narrative

The conceptual framework demonstrates the interconnection between the independent and the dependent variables. From the literature review, it shows that there is a linkage between maternal characteristics (age, parity, gestational age, previous Caesarean Section, and cervical dilation), neonatal characteristics (birth weight and APGAR score) and pregnancy outcome. In addition, there could be an association with the decision to delivery time interval (DDI) in both phases for emergency Caesarean. Interlinkage of patient socio-demographics, obstetric and neonatal characteristics and pregnancy outcome in phase II with introduction of a novel colour code tool may shorten the DDI significantly in emergency CS improving the pregnancy outcome. This has been attributed to improved communications among different cadres, improved responsiveness to emergency and prompt decision making. Categorizing CS will also enable easy data collection for audit of obstetrics and anaesthetics outcomes, thereby improving the quality of healthcare.

3.2 Figure 1: Diagrammatic Representation of conceptual framework

Phase I (without colour code): Independent variables

Phase II (with colour code): Independent variables



4.0 JUSTIFICATION OF THE STUDY

Due to the rising rates of Caesarean Section in both high income and low and middle income, countries with majority being emergency section there is need to categorize emergency CS in busy maternity settings. This will contribute to a lower decision to delivery time interval and improved maternal and neonatal outcome. Categorizing CS also enables easy audit of obstetrics and anaesthetics outcomes.

Kenyatta National Hospital receives many referrals from across the country of mothers requiring emergency CS. KNH conducts about 10,000 deliveries each year with a caesarean section rate of 30 to 40 %. Despite this data, there exists no tool for categorization of emergency CS.

This study aimed at introducing a colour code tool to enable categorization of emergency Caesarean Sections by degree of urgency to bridge this gap. It will therefore influence policy if shown to reduce decision to delivery time interval and improve maternal and neonatal outcomes.

It is also imperative to note that no such study has been done in the Sub-Saharan Africa

5.0 RESEARCH QUESTION

Does introduction of a colour code tool to prioritize emergency Caesarean Section affect the decision to delivery time interval and pregnancy outcomes at Kenyatta National Hospital, between August 2020 and October 2020.

6.0 NULL HYPOTHESIS

Introduction of a colour code tool to prioritize Caesarean Section at Kenyatta National Hospital does not result in reduction of decision to delivery time interval and improvement of pregnancy outcomes.

7.0 STUDY OBJECTIVES

7.1 Broad Objective

To determine the effect of a colour code tool on the decision to delivery time interval and pregnancy outcome for emergency caesarean section among parturient attending Kenyatta National Hospital between August 2020 and October 2020.

7.2 Specific Objectives

Among parturient undergoing emergency CS at Kenyatta National Hospital, between August 2020 and October 2020, before and after introduction of the colour code tool, to compare the:

1. DDI
2. Maternal outcomes
3. Neonatal outcomes

CHAPTER THREE

8.0 RESEARCH METHODOLOGY

8.1 Study Design

A quasi experimental, before after study design of patients requiring emergency Caesarean Section at Kenyatta National Hospital. The study method is favoured over a randomised control trial because the participants were not randomly selected and the two phases of the study were done at different times hence there were minor differences between the two groups that were controlled for in the analysis.

The study was conducted in two phases each covering one month: phase I and phase II.

Phase I

This phase of the study was conducted in the month of August 2020, before introduction of the colour code tool. The principal investigator and his assistants recruited parturient undergoing emergency CS at KNH during that period and categorized them using Luca's classification based on the level of urgency. As in Lucas classification, cases were categorized into 'very urgent', 'urgent', 'elective' and 'scheduled'. In this phase, the on-call obstetrician/registrar made the decision for Caesarean delivery in his or her on manner and the patient was neither colour coded nor her file labelled but went on to receive routine care. Parturient were followed through and decision time, time of arrival at the operating theatre, time of incision, time of delivery, indication of CS, maternal and foetal outcomes were captured in a structured questionnaire. Elective and scheduled categories of Caesarean Section were excluded.

Phase 11

This phase was conducted in the month of September and October 2020. It began with two weeks of information dissemination to all senior obstetricians, registrars, members of the labour ward (midwives and junior obstetricians) and theatre team (nurses, surgeon, anaesthetist) in three steps; a written step, a visual step and an oral step. The written step was a guideline defining the red, yellow and green code (i.e. category 1, 2 and 3 respectively) that was sent to the head of departments, nursing officer in charge and

theatre in charge. The visual step were posters were placed on notice boards of labour ward, doctor's workstation, nurse's workstation and theatre. Finally, the oral step was a talk by the principle investigator and his assistants to the maternity team during handover meetings defining the red, yellow and green code and explaining when to use each colour code.

After the 2 weeks of sensitization, the principal investigator and his assistant started collecting data using a structured questionnaire. In this phase, the on-call obstetrician/registrar went ahead to inform the rest of the team the Caesarean section category and corresponding colour code as soon he or she decided to operate. The patient was then tagged with an appropriate colour code. The patient file and theatre list were labelled with a corresponding and matching sticker. The patient was then followed through until discharge and the decision time, time of arrival at the operating theatre, incision time, time of delivery, and indication of CS, maternal and foetal outcomes were captured.

8.2 Study Site and Setting

In this study, maternity patients were recruited from Kenyatta National Hospital, a level 6 public referral and teaching hospital in Nairobi, Kenya, with a capacity of 2063 beds. With its wide range of specialist and super specialist services, it has a wide catchment area with referrals coming from all over the country.

Every month, about 1000 deliveries are conducted within the Department of Reproductive Health; that is in labour ward and maternity theatres.

There are three antenatal/post-natal wards and two maternity theatres. Labour ward is covered by two obstetrics and gynaecology junior registrar, 1 senior registrar being 2 nd on call and a consultant obstetrician and gynaecologist as 3$^{rd\ on}$ call. The doctors have trained midwives each allocated to specific patients. Two obstetrics and gynaecology registers, two anaesthetists and a team of nurses cover the two maternity theatres.

8.2.1 Factors that made the site suitable

It is the largest referral facility in the country, easily accessible within the capital city of Kenya and receives referrals of a large number of patients requiring emergency caesarean section. The hospital also has a busy maternity manned by a team of resident obstetrician and gynaecologists, trained midwives with two functional operating theatres within the maternity.

8.2.2 Factors that limit the suitability of the site

KNH being a large referral hospital, the findings may not represent the statistics of other hospitals in the country. It is also important to acknowledge that the KNH is in a low resource country.

8.3 Study Population

The target study population were parturient indicated for emergency caesarean section at Kenyatta National Hospital between the period of August 2020 and October 2020

8.4 Sample Size Calculation

The sample size was calculated using the formula for comparing means as below:

$$n_1 = \frac{(r+1)}{r}\frac{\sigma^2(Z_\beta + Z_{\alpha/2})^2}{\text{difference}^2}$$

Based on a similar study conducted whereby there was a statistically significant difference between the decision to delivery interval for colour coded and non-colour coded patients in a study done by Olivier Dupuis (5)

n_1	= Size of each group	
r	= ratio of exposed to control group	= 1
σ	= standard deviation of the exposed group	= 6.3
Difference = clinically meaningful difference in means of the outcome: 2.3 – 19.1 = 2.2		
Zβ	= corresponds to the power of the study	= 80%
Nα/2	= corresponds to two – tailed significance level	= 1.96 for α = 0.05

Substituting the above values into the equation gives the sample size n_1

$$= \frac{(1+1)}{1} \frac{6.32(0.84 + 1.96)^2}{2.2^2}$$

= 64.3*2=129

With a mark-up of 10%

The recalculated n per arm =

100/90*129 = **142 per arm**

8.5 Sampling technique

Consecutive sampling technique was applied. It is a simple method that aims to sample all accessible subjects without regard to probability

8.6 Eligibility criteria and Recruitment Procedure

8.6.1 Inclusion Criteria

The study was limited to patients who underwent emergency Caesarean Sections at KNH between August 2020 and October 2020, were able and willing to give consent, with;

- Viable foetus at gestational age of 28 weeks to 42 weeks.

8.6.2 Exclusion criteria

- Category 3 ‘elective’ and 4 ‘scheduled’ Caesarean Sections.
- Parturient who presented in advanced labour and were unable to consent

8.6.3 Recruitment procedure

All patients admitted to labour ward were briefed about the study by the principal investigator and the research assistants at the point of triage. Those willing to participate in the study were screened for eligibility and recruited. The eligible participants were then taken through the informed consent and enrolled after signing the consent form. Those in advanced labour (cervical dilation of more than 6 cm) were deemed not fit to consent and therefore excluded.

The enrolled group was followed through labour to determine the ones who required emergency Caesarean Section. It was common for consultants to make this decision during their daily handover rounds twice a day; however, the registrar who covered the ward in between handover rounds was also allowed to decide, either autonomously or after deliberation with the consultant on call. We excluded participants who underwent spontaneous vaginal delivery and assisted vaginal delivery.

Participants were monitored throughout the preparation process for the theatre, in theatre and post operatively up to discharge or 7^{th} post-operative day whichever came earlier, and data collaborated from patient file captured in a structured questionnaire.

The research assistants were two nurses and one medical student with background training on basic data collection processes. Further training was done, and a pilot study undertaken by the principal researcher. Standard clocks were provided in both labour ward and theatre and synchronization done on weekly basis.

8.7 Data Variables

The study variables assessed by the study were:

8.7.1 Dependent variables

The dependent variables in this research included;

i. Decision to Delivery time Interval (DDI)
ii. Maternal outcome (complications, additional interventions, duration of hospital stay)

iii. Foetal outcome (Apgar score, admission to NBU, admission to NICU, duration of admission)

8.7.2 Independent Variable

The independent variables included;

i. Maternal characteristics (age, parity, gestational age, previous caesarean section, parity, cervical dilation, referral and mode of anaesthesia used).

ii. Neonatal characteristics (birth weight, sex, Apgar score).

8.8 Data Collection Procedures

Patients who consented to the study were interviewed using an interviewer-guided questionnaire, that was tested on 15 patients at KNH before commencing the study. Additionally, the file of the patient was used to gather data on the time of decision for emergency Caesarean delivery and documented in the questionnaire. Research assistants documented when the patient was received in the operating room, when anaesthetic agents were administered, when the baby was delivered and when the skin was incised. The participants were further followed up post-operatively and the neonatal and maternal outcomes were recorded up to discharge or day 7 of admission whichever came earlier. Data was abstracted and populated into the abstraction Excel sheet.

8.9 Quality assurance procedures

The principal investigator recruited two qualified nurses and one medical student with background training on basic data collection processes to be research assistants. The research assistants underwent one week training on basic data collection procedures to enable them extract data as well as get informed consent from the study participants. Data captured was keyed into an Excel sheet after thorough scrutiny and validation. All the questionnaires had a unique serial number and a register was maintained. The register was counter-checked on a daily basis for any double entry. Both manual and system backup were done frequently to avoid loss of data.

8.10 Data Validity and Reliability

Three research assistants were trained by the principal investigator to administer the questionnaires and obtain informed consent from study participants. A pre-test of the questionnaire was conducted among 15 patients attending the KNH for delivery services. Methods and procedures were clearly defined in the study. Further, the PI provided clocks in strategic location in labour ward and theatre and synchronised them on a weekly basis. The first two weeks of phase II involved dissemination of information about the new tool to reduce inter-observer variability in classifying different clinical scenarios.

8.11 Data Management

A daily counter check was performed by the PI to ensure that the data collected was complete. Additionally, every twentieth questionnaire was used for quality control. After the questionnaires were filled out, they were locked up before being submitted to a password-protected Excel sheet.

8.12 Data analysis

STATA version 15 was used to analyze the data. In addition to checking for outliers, inconsistencies, missing data, and distribution, the variables were checked for outliers and inconsistencies. To identify outliers and distributions of the data, scatter plots, box plots, and histograms were used to visually inspect all continuous variables. For categorical variables, there were some groupings, especially when the subgroups were small.

The descriptive analysis was carried out to provide a description of the population based on means (standard deviations) and medians (interquartile ranges) and frequencies (percentages). To test for statistical significance, we used the Chi square test and the student T test. We used Wilcoxon rank sum test for non-normally distributed continuous variables, and Fisher's exact test for small frequencies.

A univariate inferential analysis was conducted to determine whether the observed differences between phase I and phase II were due to chance.

9.0 ETHICAL CONSIDERATIONS

Kenyatta National Hospital / University of Nairobi Ethics and Research Committee (KNH/UoN ERC) and Department of Reproductive Health at University of Nairobi granted permission to conduct the study. Labour ward nursing officer in charge and heads of concerned departments were also informed of the study. An informed consent was obtained from participants prior to enrolment. Collected data was coded and made accessible to the principal investigator, research assistants, statistician and supervisors only and utmost confidentiality of subjects observed. The participants were allowed to withdraw from the study and still proceeded to get routine care.

10.0 STUDY LIMITATIONS AND MITIGATION

The designated clocks may not have been used to record the times of interest in some cases despite training and sensitization of doctors and midwives involved in the management of study participants and constant reminders by the investigator and his data collection assistants on the use of designated clocks.

Inter-practitioner variability was observed leading to misclassification of patients in the initial stages, however more posters were availed and sensitization period extended.

The quality of record keeping was poor in some cases with doctors forgetting to indicate the decision time in patients file. This information was obtained from the theatre list register.

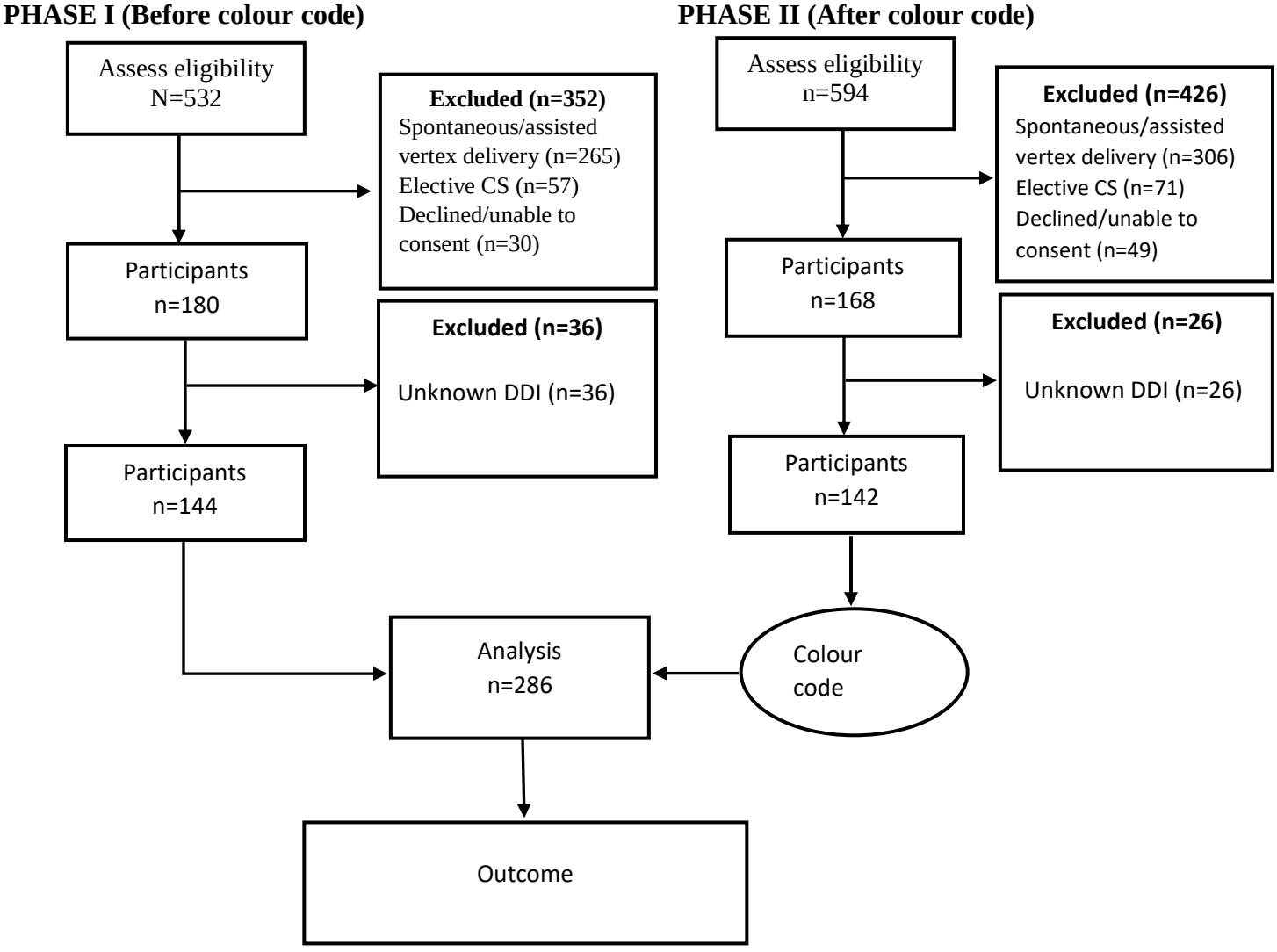
Due to the non-random nature of consecutive sampling, this study was susceptible to selection bias.

CHAPTER FOUR

11.0 RESULTS

There were 532 deliveries during phase I and 594 deliveries in phase II. Of these, participants recruited were 144 and 142 in phase I and phase II respectively as shown in the study flow chart below.

Figure 2: Flow chart of the process of identifying and recruiting participants.



11.1 Patient characteristics

Table 1: Comparison of socio demographics characteristics before and after introduction of the colour code tool.

Participant characteristics		Phase I N=144 (%)	Phase II N=142(%)	p value
Age	(mean/SD)	28.0 (5.9)	27.8 (5.9)	0.78
Age	<18 years	5 (3.5)	5 (3.5)	
categories	19 – 25 years	47 (32.6)	50 (35.2)	
	26 – 30 years	45 (31.3)	35 (24.7)	0.792
	31 – 35 years	32 (22.2)	37 (26.1)	
	>36 years	15 (10.4)	15 (10.6)	
Marital	Single	20 (12.9)	21 (14.8)	0.828
	Married	124 (86.1)	121 (85.2)	
Occupation	Employed	42 (29.2)	40 (28.2)	0.852
	Unemployed	102 (70.8)	102 (71.8)	
Education	Primary	35 (24.3)	30 (21.1)	
	secondary	69 (47.9)	69 (47.9)	0.805
	College	40 (27.8)	40 (27.8)	
Referral	No	92 (63.9)	81 (57.0)	
	Yes	52 (36.1)	61 (43.0)	0.236

Table one above shows that the most of women in the study population were aged between 19 and 35 years of age, married and had some level of formal education. About two third (70%) of them were not in formal employment and less than half of the parturient studied were referred from another healthcare facility, 36% and 43% in phase I and phase II respectively. The demographic characteristics were comparable between the two groups.

Table 2: Comparison of the obstetric characteristics, rank of operation and mode of anaesthesia before and after introduction of the colour code tool.

Participant characteristics		Phase I N=144 (%)	Phase II N=142(%)	p value
Parity	0	44 (30.6)	44 (31.0)	0.974
	1	43 (29.9)	43 (30.3)	
	2	36 (25.0)	38 (26.8)	
	3	13 (9.0)	10 (7.0)	
	≥4	8 (5.6)	7 (4.9)	
Previous live births	0	48 (33.3)	51 (35.9)	0.227
	1	51 (35.4)	44 (31.0)	
	2	28 (19.4)	39 (27.5)	
	3	11 (7.6)	5 (3.5)	
	≥4	6 (4.2)	3 (2.1)	
Previous abortions	0	133 (92.4)	131 (92.3)	0.208
	1	9 (6.3)	5 (3.5)	
	≥2	2 (1.4)	6 (4.2)	
Gestation (weeks)	<34 weeks	4 (2.8)	10 (7.0)	0.247

	34 – 40 weeks	64 (44.4)	61 (43.)	
	>40 weeks	76 (52.8)	71 (50.0)	
Phase of labour	Latent	92 (63.9)	81 (57.0)	0.236
	Active	52 (36.1)	61 (43.0)	
Rank of operation	Primary	93 (64.6)	89 (62.7)	0.737
	Repeat	51 (35.4)	53 (37.3)	
Mode of anaesthesia	General	9 (6.3)	5 (3.5)	0.285
	Spinal	135 (93.8)	137 (96.5)	
Birth weight in grams	Mean (SD)	3159 (584)	3165 (752)	0.923

Table 2 above describes the obstetric and neonatal characteristics, and mode of anaesthesia of the study population. As shown in the table, majority of the patients were of low parity. There was no significant difference noted in both phases of the study. The highest parity included was para five which formed 4.2% and 2.1 % in phase I and phase II respectively. Majority of the multiparous in the study had a good obstetric history with 92 % reporting no prior history of abortion in both phases. Amongst the parturient with a history of two or more abortions a majority were in phase II (4.2%) compared to phase I (2.1%) even though not statistically significant (p value 0.208). The gestational age of women in the study range between 34 - 42 weeks with 95% of them being term. The population recruited below 34 weeks was 2.8% in phase I and 7.0% in phase II. Despite this difference, the results of the two groups were comparable. Intrapartum emergency Caesarean Sections were predominant in both phases of the study (60%). There were more women in active phase of labour at the time of decision in phase II (43%) than in phase I (36%) even though this was not statistically significant (p value 0.236). Spinal anaesthesia was the preferred mode of anaesthesia for emergency caesarean section in both groups. The mean birth weight was comparable between the two groups.

11.2 Interval time

Figure 2: Box plot representing the median decision to delivery time

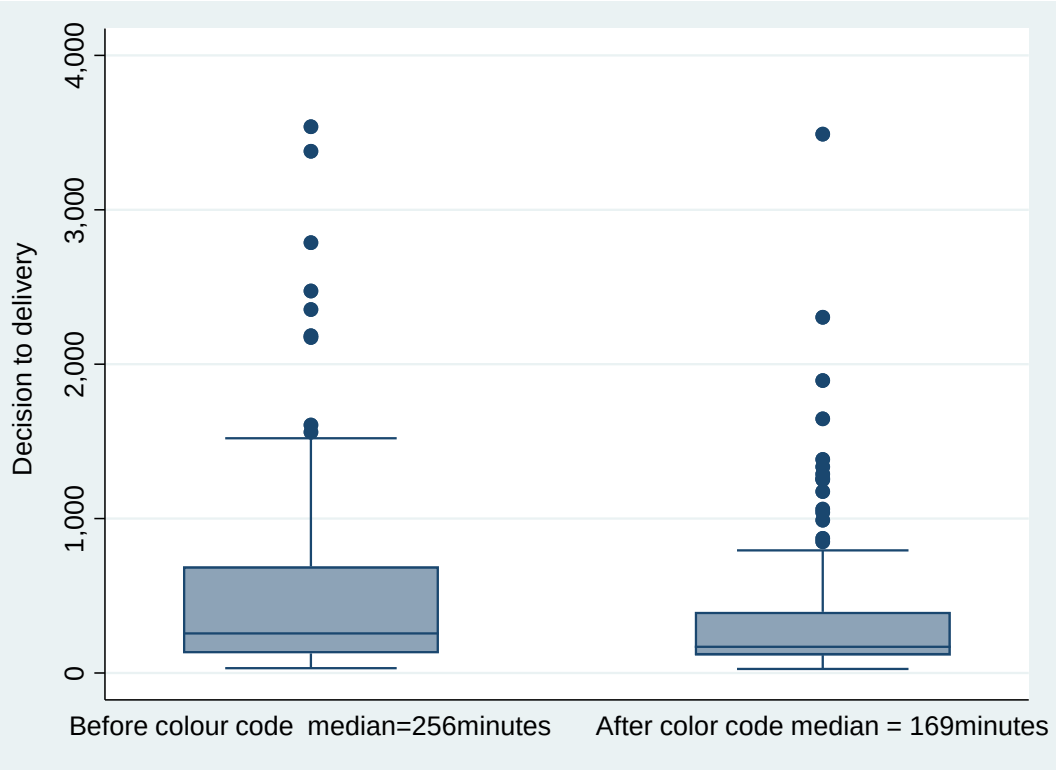


Table 3: Comparison of time intervals within DDI before and after introduction of the colour code tool.

Time interval (minutes)	Phase I median (IQR)	Phase II median (IQR)	P value*
Decision to operating theatre (median/IQR)	195 (574.5)	121 (280)	0.02
OT to administration of anaesthesia	15 (8)	14 (8)	0.92
Administration of anaesthesia to delivery	20 (10)	20 (10)	0.621
Incision to delivery	5.5 (4)	5 (5)	0.73
Decision to delivery	256.0 (563)	169.5 (281)	0.012

*Wilcoxon rank-sum test was used to determine significance

Table 3 compares median time intervals between phase I and phase II of the study. The median DDI was 256 minutes and 169 minutes in phase I and phase II respectively with a p value of 0.012. The change being attributed to reduction in the median decision to operating theatre time interval from 195 minutes in phase I to 121 in phase II with a p value of 0.02. The theatre to anaesthesia time interval, anaesthesia to delivery time interval and incision to delivery time interval remained relatively the same between the two phases.

11.3 Neonatal outcome

Table 4: Comparison of neonatal outcomes before and after introduction of a colour code tool.

Neonatal outcome		**Phase I** **N=144 (%)**	**Phase II** **N=142(%)**	**p value**
Baby condition at birth	Alive	143 (99.3)	138 (97.2)	0.212*
	FSB	1 (0.7)	4 (2.8)	
APGAR score	>7/10	138 (95.8)	129 (92.1)	0.218
	<7/10	6 (4.2)	11 (7.9)	
NBU admission	Not admitted	122 (84.7)	110 (77.5)	0.078
	admitted	22 (15.3)	32 (22.5)	
Duration of admission	0-3 days	131 (91.0)	117 (82.4)	0.09*
	4-7 days	3 (2.1)	7 (4.9)	
	>7 days	10 (7.9)	18 (16.7)	
Condition at day 7 of life	alive and well	140 (97.2)	116 (81.7)	-
	admitted	0 (0.0)	18 (12.7)	
	deceased	4 (2.8)	8 (5.6)	

*fishers exact was used to determine significance.

Table 4 above focuses on the neonatal outcome before and after introduction of the colour code. Low APGAR score and slightly more stillbirth were observed in phase II compared to phase I. There were also more NBU admissions at 22% in phase II compared to 15% in phase I. This was also accompanied with prolonged hospital stay and higher neonatal mortality for the majority of new-borns admitted to NBU in

phase II of the study. However, all the above differences between the two groups were not statistically significant with p values >0.05.

11.4 Maternal outcome

Table 5: Comparison of maternal outcomes before and after introduction of the colour code tool.

Maternal outcome		Phase I N=144 (%)	Phase I N=142(%)	p value
Complications	None	138 (95.8)	136 (95.8)	0.606
	Yes	6 (4.2)	6 (4.2)	
Additional interventions	Admission to ICU	1 (0.7)	2 (1.4)	0.809
	Blood transfusion	3 (2.1)	1 (0.7)	
	Secondary GA	1 (0.7)	1 (0.7)	
Duration of hospital stay	<3 days	130 (90.3)	137 (96.5)	0.093
	>3 days	14 (9.8)	5 (3.5)	

Table 5 shows parameters comparing maternal outcomes in both phases of the study. Only 4.2% of the participants developed complications in each phase of the study. About 3.5% in phase I required additional interventions compared to 2.8% in phase II of the study. The additional interventions included admission to ICU, blood transfusion and secondary GA. There was an improvement in the duration of hospital stay with those requiring more than 3 days of hospital stay reported as 9.8% and 3.5% in phase I and phase II respectively.

Table 6: Univariate analysis comparing the DDI and specific participant's characteristics to depict associations.

Participant characteristics		**DDI >180 154 (53.8%)**	**DDI <180 132 (46.2%)**	**AOR (95%CI)**
Phase of study	Before	85 (59.0)	59 (41.0)	Ref
	After	69 (48.6)	73 (51.4)	1.63 (1.02 to 3.14)
Colour code	Green	89 (69.0)	40 (31.0)	Ref
	Orange	57 (44.5)	71 (55.5)	9.85 (3.21 to 30.31)
	Red	8 (27.6)	21 (72.4)	1.51 (0.85 to 2.67)
Referral status	No	103 (59.5)	70 (40.5)	Ref
	Yes	51 (45.1)	62 (54.9)	1.42 (0.81 to 2.50)
Dilatation (cm)	0 – 2	84 (77.1)	25 (22.9)	Ref
	3 – 4	40 (57.1)	30 (42.9)	2.94 (1.47 to 5.91)
	5 – 7	20 (34.5)	38 (65.5)	5.64 (2.62 to 12.09)
	8 – 10	10 (20.4)	39 (79.6)	14.76 (6.00 to 36.32)
Maternal hospital stays	<3 days	140 (52.4)	127 (47.6)	Ref
	>3 days	14 (73.7)	5 (26.3)	0.29 (0.08 to 1.06)
APGAR	>7/10	146 (54.7)	121 (45.3)	Ref
	<7/10	8 (47.1)	9 (52.9)	0.74 (0.35 to 1.68)
NBU admission	No	126 (54.3)	106 (45.7)	Ref
	Yes	28 (51.9)	26 (48.2)	0.74 (0.35 to 1.68)

Table five shows inferential univariate analysis carried out to determine whether the observed differences between the two groups was due to chance by comparing the DDI to patent's characteristics. It was observed that after introduction of the colour code in phase II a participant was 1.63 times more likely to achieve a DDI of less than 180 minutes than in phase I. Code orange and red groups as well as referred cases were more likely to achieve a shorter DDI compared to code green and non- referrals respectively. Advanced cervical dilatation was associated with shorter DDI. Having a prolonged DDI was not associated with likelihood of getting a new-born with a low APGAR score and admission to NBU.

CHAPTER FIVE

12.0 DISCUSSION

The introduction of the colour code tool for emergency caesarean section at Kenyatta National Hospital maternity unit allowed the understanding of several things. There was significant improvement in the median decision to delivery time interval with introduction of the colour code tool from 256 minutes to 169 minutes in phase I and phase II respectively. It is however important to note that none of these intervals was good enough and fell below the ACOG recommended global target of 30 minutes aimed at reducing significant morbidity and mortality. Despite the overall improvement in the DDI there no associated statistically significant improvement in the maternal and neonatal outcomes.

Participant's characteristics

As shown in table 1 above, women in this study were generally young, the majority being between 18 – 35 years of age, which is the optimum for child bearing. This is comparable to the findings of an earlier study by Habib et al (8) and The Nairobi Birth Survey (9). The pattern of age distribution was similar in both phases of the study. Majority of the women were married and with a formal education level. However, a predominant number were unemployed (71%) pointing towards low socioeconomic status. Among the women recruited, those that were referred from other health facilities formed a large portion in both phases; 64% and 57 % in phase I and II respectively. This was mainly attributed to the fact that Kenyatta National Hospital is a level 6 facility and receives referrals from Nairobi and neighbouring counties. Further, they were several industrial strikes experienced in County hospitals in Nairobi and neighbouring Kiambu County during the study period. Post-operative maternal morbidity was greater in the referred group with a relatively longer hospital stay. Referred patients generally present in a poorer condition with prolonged

labour, prolonged rupture of membranes, high risk of obstructed labour, hence are likely to develop complications.

With reference to table 2, majority of the patients were of low parity in both groups. This is in keeping with the findings of earlier studies(8)(10)(11)(12)(13). The gestational age of women in the study range 34 -42 weeks (95%), majority being term. Similar patterns were observed in studies by Habid et al(8) in Kenya and a Norwegian study involving 24 maternity units which was conducted over a period of 7 months(14). Intrapartum emergency caesarean sections were predominant in both phases of the study (60%). There were more women recruited in active phase of labour in phase II (43%) than in phase I (36%) even though this was not statistically significant (p value 0.236). This meant that women in phase II were more likely to have laboured for long and more prone to poor maternal and neonatal outcome. Repeat caesarean sections accounted for 35% in phase I and 37% in phase II with an overall of 36%. This figure was lower than the 51.2% reported at KNH by Karanja et al in 1982 (13). However its comparable to 30% reported by Habid (8) in 2010. This can be explained by the increasing caesarean section rate over the years. Spinal anaesthesia was the preferred mode of anaesthesia for emergency Caesarean section in both groups. This mode of anaesthesia has been shown to be increasingly safe and effective, providing acceptable response times in the majority of urgent cases (15)(16). General anaesthesia is faster than spinal anaesthesia, however the number of Caesarean sections performed under general anaesthesia was very small to make any comparison.

Objective one: DDI

The introduction of the colour code lead to significant reduction in the median decision to delivery time interval from 256 minutes in phase I to 169 minutes in phase II with a p value of 0.012. Benazza et al in 2018 did a similar study in a France secondary healthcare maternity unit and reported a reduction of decision to birth delay for extremely emergency caesarean (p = 0.0769) (17). Two other studies reported

similar findings indicating that the colour code tool ensured improved communication and coordination among the perinatal team(5)(18). It is paramount to note that in this study the change in DDI was attributed to a reduction in the decision to OT time interval from 195 minutes to 121 minutes in phase I and phase II respectively (p value 0.02). The time taken to transfer the patient to the operating room remains critical as it represents approximately half of the interval between decision and delivery by emergency Caesarean Section. Thus, factors that shorten the decision-to-operating theatre time interval or the preparation time should have a large impact on the global DDI (10). The median DDI was short of the ACOG recommended target of 30 minutes (19) for category I CS. A study done locally by Habid AH in 2012 reported median DDIs of 178 minutes and 290 minutes at KNH and Pumwani Hospital respectively(20). This was similar to our findings, thus raising questions on the feasibility of achieving the recommended ACOG target DDI at KNH under the current setup.

Objective two: Neonatal outcome

Despite the improvement of the DDI in phase II compared to phase I there was an increase in the number of stillbirths, low APGAR score, admission to NBU and prolonged hospital stay. However, these findings were not statistically significant and may be attributed to a high rate of referrals and more women presenting in active phase of labour in phase II compared to phase I. We can therefore conclude that there was no association between DDI and neonatal outcomes. Hirani et al (2017) in Tanzania studied 598 women and reported no significant association between DDI and neonatal and maternal outcomes(21). Habib et al (2012) in Kenya also reported similar findings. Similar findings were also reported by Dupuis et al in a French maternity hospital(18) where he reported that the three colour code tool significantly reduced the DDI but a similar effect not seen on maternal and neonatal outcome. On the contrary Benazza et al in 2018 did a retrospective observational study in a French hospital and reported less transfer to neonatology unit (p value 0.004) after introduction of a colour code(17). Tashfeen et al (2016) in Oman reported a DDI>60mins was associated with low APGAR score and increased admission to NBU.

Objective three: Maternal outcome

Less than 5% of the women recruited in both groups developed complications. It was noted that those requiring additional interventions were more in phase I compared to phase II. Moreover, more women experienced a reduced hospital stay in phase II (3.5%) compared to phase I (9.8%). However, none of the above differences was statistically significant. In conclusion, there was no association between DDI and adverse maternal outcomes. Several studies have reported similar findings; Hirani et al in 2017(21), Habib AH in 2012(8), Dupuis et al in 2008(18). On the contrary, Gupta et al did a prospective audit of emergency CS in a tertiary hospital and reported that failure to meet the ACOG recommended DDI was associated with adverse maternal outcomes(22).

Being a prospective experimental study and the first to be done in sub-Saharan Africa it shall inform clinical practice and act as a reference point for more studies. However, this study is also subject to certain limitations; perinatal outcome was assessed using the five-minute APGAR score and admission to NBU which are inferior compared to umbilical code acid base balance and presence of encephalopathy (23), the study was conducted over a short duration and determinants of prolonged DDI were not examined.

13.0 CONCLUSION

With use of the colour code tool, the DDI was significantly shortened due to a reduction in the preparation time. This is very important especially in busy maternity units and is a sign of improved maternal care. However, it was also noted that the median DDI was not optimal and falls below the recommended global target of 30 minutes for emergency CS.

That introduction of the colour code was not associated with significant improvement in maternal and neonatal outcomes.

14.0 RECOMMENDATION

1. Adoption of the three-colour code tool to improve Caesarean Section turnaround time.
2. More studies to be done to look to barriers and feasibility of achieving the recommended target DDI of 30 minutes for emergency CS.
3. Further studies with large samples size and extended duration should be done determine any association between prolonged DDI and adverse neonatal and maternal outcomes.

15.0 FUTURE

This study shall guide clinical practice once the three-colour code is adopted leading to improved patient care. It also opens an avenue for more studies to be done in future.

16.0: STUDY TIMELINE

Projected months	April 2019	Feb 2020	March- July 2020	Aug- Sept 2020	Oct 2020	Nov 2020	Dec 2020
Proposal development							
Proposal presentation							
Ethics approval							
Data collection							
Data analysis							
Final presentation							
Thesis write up							
Manuscript development							

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18.0 APPENDIXES

APPENDIX 1: CLASSIFICATION OF CS GUIDELINE

Category		Classification	Additional interpretation
1		Immediate threat to the life of the mother or foetus.	CD is performed for acute life-threatening events. There is an emergency situation; CD should be performed as soon as possible to save the life of mother or foetus.
2		Maternal or foetal compromise, but not immediately life threatening	Delivery of the foetus is urgent, because maternal or foetal compromise is present and is demonstrated at this moment. CD is needed to prevent deterioration of either maternal or foetal condition.
3		No maternal or fetal compromise,but needs early delivery	No maternal or foetal compromise is present at this moment, but compromise may be expected if spontaneous delivery is awaited. CD is needed to prevent compromise.
4		Delivery timed to suit woman or staff	Compromise is not expected if CD is not performed. There is no strict medical indication.

Adapted from classification of caesarean section. A systematic review by Torlani et al, PLoS ONE 2011. V

APPENDIX 2: COLOR CODE PROTOCOL

APPENDIX 3. QUESTIONNAIRE

UNIQUE STUDY NUMBER …….

DATE……

A. Category of caesarean section

- ❑ 1
- ❑ 2

B. Socio-demographic data:

a) Age .....(years)

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

- ❑ YES
- ❑ NO

If yes state the reason for referral ……

D. Obstetric data:

a) What is the parity at the time of delivery: Para …….?

b) What is the number of children previously delivered alive ……...

c) What is the number of stillbirths delivered previously ……

d) What is the number of abortions previously……...

e) Gestational age at the time of delivery …… (Weeks)

f) What was the cervical dilation when the decision for emergency caesarean section made…….

E. Information pertaining to the emergency caesarean section:

a) Rank of emergency caesarean section:

- ❑ Primary
- ❑ Repeat

a) Indication for emergency caesarean section:

- ❑ Non-reassuring foetal status
- ❑ Placenta prevail with haemorrhage
- ❑ 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.....

b) Mode of anaesthesia administered:

- ❏ Primary General anaesthesia
- ❏ Primary Spinal anaesthesia
- ❏ Secondary general anaesthesia

c) Seniority of the surgeon:

- ❏ Registrar
- ❏ Consultant
- ❏ Medical officer

F. The decision-to-delivery interval:

a) What time was decision to operate made ……. (Hrs.)

b) What time was patient received in theatre ……. (Hrs.)

c) What time was anaesthesia administered …… (Hrs.)

d) What time was incision made……... (Hrs.)

e) What time was baby delivered……? Hrs. (in case of twin delivery, refer to first twin)

f) What was the time interval between (minutes)?

(I) Decision making and arrival in theatre ……. (b-a)

(ii) Arrival in theatre and administration of anaesthesia ……. (C-b)

(iii) Administration of anaesthesia and delivery of the baby ……. (D-c)

(iv) Incision and delivery of the baby…… (e-d)

(v) Decision making and delivery of the baby ……. (e-a)

G Maternal outcome (Tick where applicable/appropriate)

a) What maternal complication occurred (tick where appropriate):

Complication	Yes	No
Raptured uterus		
Acute renal failure		
Postpartum haemorrhage		
Severe anaemia		
Congestive cardiac failure		
Pulmonary oedema		
Fever		
Infection (incision, endometritis, pelvic abscess)		
Poor reversal from General anaesthesia		
Death		

b) What additional intervention(s) were undertaken (tick where appropriate):

Intervention	Yes	No
Blood transfusion		
Repeat surgery		
Subtotal hysterectomy		
Secondary general anaesthesia		
Admission to ICU/HDU		

c) What was the duration of postoperative hospitalization ……Days

d) 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 anaemia/CCF
- ❑ Cardiac disease
- ❑ Wound/Puerperal sepsis
- ❑ Other……

G. New-born outcome:

a) What was the condition of the baby at delivery:

- ❑ Alive
- ❑ Fresh stillbirth
- ❑ Macerated stillbirth

b) What was the sex of the baby

- ❑ Male
- ❑ Female
- ❑ Ambiguous

c) What was the birth weight of the baby …… Grams

d) What was the Apgar score at 5 minutes?

- ❑ Less than 7
- ❑ More than or equal to 7

e) Was the Baby admitted to NBU?

- ❑ Yes (if yes indicate duration in days…….)
- ❑ No

f) Was the Baby admitted to NICU?

- ❑ Yes (if yes indicate duration in days…….)
- ❑ No

g) What was the status of baby at day 3/discharge?

- ❑ Alive and well
- ❑ Admitted
- ❑ Deceased

APPENDIX 4. INFORMED CONSENT FORM

UNIVERSITY OF NAIROBI (UoN)

COLLEGE OF HEALTH SCIENCES

P O BOX 19676 Code 00202

Telegrams: varsity

(254-020) 2726300 Ext 44355

KNH-UoN

ERC

Email: uonknh_erc@uonbi.ac.ke Website: http://www.erc.uonbi.ac.ke

Facebook: ttps://www.facebook.com/uonknh.erc

Twitter: @UONKNH_ERC

ttps://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL (KNH)

P O BOX 20723 Code 00202

Tel: 726300-9

Fax: 725272

Telegrams: MEDSUP, Nairobi

PARTICIPANT INFORMATION AND CONSENT FORM ADULT CONSENT

FOR ENROLLMENT IN THE STUDY

(To be administered in English or any other appropriate language e.g. Kiswahili translation) Title of Study:

THE EFFECT OF A COLOR CODE TOOL TO PRIORITIZE EMERGENCY CAESERIAN SECTION

ON DECISION TO DELIVERY TIME INTERVAL AND PREGNANCY OUTCOME AT KENYATTA NATIONAL HOSPITAL Principal Investigator\and institutional affiliation: DR SAMUEL GATEI NGATIA, OBSTETRICS AND GYNECOLOGY DEPARTMENT AT THE UNIVERSITY OF NAIROBI

Co-Investigators and institutional affiliation: DR KIREKI, DR GWAKO, DR IKOL Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal

iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES ☐ NO ☐

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. P166/03/2020

WHAT IS THIS STUDY ABOUT?

This study aims to assess the effect of introducing a colour code tool to prioritize emergency caesarean section on decision to delivery time interval (DDI) and pregnancy outcomes at KNH maternity unit. The study comes amidst the rising rate of caesarean section that has been a concern worldwide. It will ensure rational use of CS as a mode of delivery. Further it may contribute to reduction in the decision to delivery time interval and improve the outcome of the mother and the baby. Categorizing CS also enables easy data collection for audit of pregnancy outcomes and recovery from anaesthesia after surgery thereby improving the quality of healthcare.

Kenyatta National Hospital receives many referrals from across the country of mothers requiring emergency CS. KNH conducts about 10,000 deliveries each year with a caesarean section rate of 30 to 40 % with its limited resources. Despite this data, there exists no tool for categorization of emergency CS.

Similar studies have been done in other countries like France and England and resulting in positive outcomes with significant reduction of the DDI.

The researchers listed above are interviewing individuals who are eligible for the study. The purpose of the interview is to find out the impact of introduction of a colour code tool to prioritize emergency caesarean section on DDI and pregnancy outcomes. Participants in this research study will be asked questions about their personal and social characteristics and their history of pregnancy relevant to the study. There will be approximately 284 participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen: You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately five Minutes. The interview will cover topics such as previous pregnancy outcomes, personal and social characteristics.

After the interview has finished, you shall be a given a coloured tag and your file labelled with a corresponding-coloured sticker. We shall follow you through the surgery and recovery up to discharge. We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include: _ follow up after surgery

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you. Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview. We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews. Also, some questions may be stressful (e.g. event recalls).

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may benefit by receiving health information. We will refer you to a hospital/other department for care and support where necessary. Also, the information you provide will help us better understand caesarean delivery. This information is a contribution to science and research.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

(Explain) you will not incur any financial cost by undertaking in this study.

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

(Enter statement) no monetary benefits will be given for participating in the study.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page. For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke. The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counsellor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

I agree to provide contact information for follow-up: Yes No

Participant printed name:

Participant signature / Thumb stamp Date

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: Date:

Signature

Role in the study: *[i.e. study staff who explained informed consent form.]*

For more information contact at from

To

Witness Printed Name (*If witness is necessary, a witness is a person mutually acceptable to both the researcher and participant)*

Name Signature /Thumb stamp:

Contact information Date

CONSENT FORM: FOMU YA IDHINI

MADA: THE EFFECT OF A COLOR CODE TOOL TO PRIORITIZE EMERGENCY CAESERIAN SECTION ON DECISION TO DELIVERY TIME INTERVAL AND PREGNANCY OUTCOME AT KENYATTA NATIONAL HOSPITAL.

MTAFITI MKUU: DR SAMUEL GATEI NGATIA

WASIMAMIZI:

Dr. Kireki Omanwa

Dr. George Gwako

Dr. Allan Ikol

KITANGULIZI

Ningependa kukuambia kuhusu utafiti unaofanywa na watafiti juu waliotajwa. Madhumuni ya fomu hii ya idhini ni kukupa taarifa unahitaji kukusaidia kuamua kama kuwa mshiriki katika utafiti. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, kile kinachotokea kama wewe kushiriki katika utafiti, hatari ya uwezekano na manufaa, haki yako kama kujitolea, na kitu kingine chochote kuhusu utafiti au fomu hii ambayo si wazi. Wakati tutakapo jibu maswali yako yote kwa kuridhika kwako, unaweza amua kuwa katika utafiti huu au la. Utaratibu huu inaitwa 'utoaji idhini. Mara baada ya kuelewa na kukubali kuwa katika utafiti, utie sahihi na jina lako kwa fomu hii. Lazima uelewa kanuni za jumla zinazotumika na washiriki wote katika utafiti wa matibabu: i) Uamuzi wako wa kushiriki kabisa ni kwa hiari ii) Unaweza kuondoka kutoka utafiti wakati wowote bila lazima kutoa sababu ya kujitoa yako iii) Kukataa kushiriki katika utafiti hakutaathiri huduma zilizo haki yako katika kituo hiki cha afya au vifaa vingine. Tutawapa nakala ya fomu hii kwa kumbukumbu zako.

Ninaweza kuendelea? NDIO ☐ LA ☐

Utafiti huu umeidhinishwa na komitee ya utafiti ya hospitali kuu ya Kenyatta na Chuo kikuu cha Nairobi (KNH-UoN ERC).

Namabari ya Utafiti …….

MALENGO YA UTAFITI HUU

malengo haya ya utafiti kutathmini matokeo ya kuanzisha kodi ya rangi kuweka kipaumbele upasuaji wa dharura kati ya muda wa uamuzi wa wakati wa kujifungua (DDI) na matokeo ya ujauzito katika kitengo cha uzazi KNH. Hali ya upasuaji imekuwa ikiongezeka katika nchi zote na imkekuwa na matokeo mabaya kwa afya ya mama na motto. Hii imefanya utafiti huu uwe na maana ili kuweza kuweka upasuaji wa dharura kipaumbele. Utafiti huu utahakikisha matumizi bora ya CS kama taratibu ya kuzalisha. Zaidi ya hayo, unaweza kuchangia kupunguza uamuzi wa wakati wa kujifungua muda na kuboresha matokeo ya wajawazito na wanao. Upasuaji wa CS ukiwekwa kwa aina baina kulinganana na kiwango cha dharura itawezesha ukusanyaji data kwa ajili ya ukaguzi wa masuala ya uzazi matokeo kwa hivyo kuboresha huduma za afya. Hospitali kuu ya Kenyatta hupokea wagonjwa wengi kutoka nchini kote,kati yao wakiwa akina mama wanaohitaji upasuaji wa dharura . KNH husaidia wanawake 10, 000 kujifungua kila mwaka na upasuaji huwa kati 30% na 40%. Licha ya taarifa hii, hakuna chombo cha kubainisha CS kulingana na hatari kwa mama na mtoto. Tafiti nyingine kama hiziziumefanyika katika nchi nyingine kama Ufaransa na Uingereza na kuwa na matokeo mazuri kwa kupunguza DDI.

Watafiti waliotajwa hapo juu ndiyo watahoji watu ambao wanastahiki utafiti. Madhumuni ya mahojiano ni kutafuta matokeo ya kuanzishwa kwa chombo kodi ya kuweka kipaumbele CS ya dharura kwa DDI na matokeo ya ujauzito. Washiriki katika utafiti huu watatakiwa kujibu maswali kuhusu historia yao ya uzazi Kutakuwa takriban washiriki 284 katika utafiti huu. tunakuomba idhini ya kuzingatia ushiriki wako katika

utafiti huu.

ITAKUWAJE UKIAMUA KUSHIRIKI KWA UTAFITI HUU?

Ukikubali kushiriki katika utafiti huu, mambo yafuatayo kutokea: Utahojiwa na mtafiti katika eneo binafsi ili uwe na starehe ndiyo ujibu masawalli vizuri. mahojiano ya tachukua dakika tano. mahojiano yatafikia mada kama vile matokeo ya mimba ya awali na historia yako.

Baada ya mahojiano ya kumalizika, utapewa kitambulisho cha rangi na faili yako iwekwe lebo sambamba kulingana na kitambulisho cha rangi. Tutakufuaya kupitia upasuaji na kupona hadi usaha.

tutakuomba namba ya simu ambapo ili tuweze kuwasiliana na wewe kama ni lazima. Ukikubali kutoa taarifa ya anwani yako,iyatumika na watafiti pekee kwa ajili ya utafiti na haitapewa kwa watu wasiokuwa ka utafiti huu. Tutataka kuwasiliana na wewe ili kukujulia hali baada ya upasuaji.

JE, KUNA HATARI, NA USUMBUFU KUHUSISHWA NA UTAFITI HUU?

utafiti wa matibabu una uwezo wa kuanzisha hatari ya kisaikolojia, kijamii, kihisia na kimwili . Juhudi lazima iwe imewekwa ili kupunguza hatari. Moja ya hatari kukosa faragha. Tutaweka kila kitu unachotuambia kama siri kama iwezekanavyo. Tutatumia kodi kukutambua. Na rekodi za faili zitawekwa katika kabati ilifungwa vizuri. Hata hivyo, hakuna mfumo wa kulinda usiri yako inaweza kuwa salama kabisa, hivyo bado inawezekana kwamba mtu anaweza kujua ulishiriki katika utafiti huu na anaweza kujua kuhusu wewe.

Pia, kujibu maswali katika mahojiano inaweza kuletea wasiwasi . Kama kuna maswali yoyote hataki kujibu, unaweza kuyaacha. Una haki ya kukataa kuhojiwa au maswali unayoulizwa wakati wa mahojiano. Sisi tutaufanya kila kitu tunaweza ili kuhakikisha kwamba hii itafanyika kwa siri. Zaidi ya hayo, kila wafanyakazi wa utafiti na watafiti ni wataalamu walio na mafunzo maalum katika haya mahojiano.

JE, KUNA FAIDA KUWA KATIKA UTAFITI HUU?

Unaweza kufaidika na kupokea taarifa za afya?

Tutakuelekeza kwa hospitali ama idara nyingine ya huduma kwa msaada unaokufaa. Pia, kutoa taarifa

itatusaidia kuelewa upauaji wa CS. Habari hii itachangia kwa sayansi na utafiti.

UTAHITAJIKA KULIPA KATIKA UTAFITI HUU?

Kushiriki kwa utafiti huu ni bure na hufai kulipa chochote.

UTAPATIWA PESA KWA UTAFITI HUU?

Hakutakuwa na pesa zitakazopewa kwa washiriki watakao kuwa kwa utafiti huu.

MAWASILIANO UKIWA NA MASWALI

Kama una swali lolote kuhusu utafiti tafadhali wasiliana mwenye kiti wa KNH-UoN ERC, nambari ya simu. 2726300 Ext. 44102 barua pepe: uonknh_erc@uonbi.ac.ke.

KUJITOA KUTOKA KWA UTAFITI

Kushiriki katika utafiti huu itakuwa ni kwa hiari yako na ni sehemu ya tathamini yako katika uchunguzi wa maabara na unaweza kujiondoa wakati wowote bila kupoteza faida yoyote ambayo ni haki yako katika taasisi hii.

FOMU YA IDHINI

Nimesoma fomu hii ya idhini au habari ya utafiti huu kusoma na kwangu . nimekuwa na nafasi ya kujadili utafiti huu na mshauri wa utafiti. Maswali yangu yamejibiwa kwa lugha ya rahisi na nikaelewa. Pia, amenielezea hatari na faida za utafiti huu. Naelewa kwamba ushiriki wangu katika utafiti huu ni kwa hiari na ninaweza kujiondoa wakati wowote. Ninakukubali kushiriki katika utafiti huu utafiti.

Naelewa kwamba juhudi zote zitafanywa ili kuweka maelezo kuhusu utambulisho wangu ya kibinafsi kwa faragha.

Kwa sahihi fomu hii ya idhini, sijakataa haki zozte za kisheria ninazo kama mshiriki katika utafiti.

Ninakubali kushiriki kwa utafiti huu **NDIO** ☐ **LA** ☐

Ninakubali kupeana anuani zangu ili kuwa na mawasiliano **NDIYO** ☐ **LA** ☐

Jina la mshiriki ……

Sahihi ya Mshiriki ..... Tarehe .....

Kauli ya mtafiti mkuu

Nimemwelezea mshiriki aliyetajwa na kumpa habari yote muhimu kuhusu utafiti huu na kuamini kuwa mshiriki ameelewa na kupeana idhini kwa hiari

Sahihi ya mtafiti …… Tarehe ……

Jukumu katika utafiti …….

Mshahidi ……. Anuani ……

Sahihi ……. Tarehe ……

APPENDIX 5: ETHICS REVIEW COMMITTEE (ERC) APPROVAL

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
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Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
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Tel: 726300-9
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Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/191

26th June 2020

Dr. Samuel Gatei Ngatia
Reg. No. H58/69375/2016
Dept. of Obstetrics and Gynecology
School of Medicine
College of Health Sciences
University of Nairobi

APPROVED
26 JUN 2020
KNH/UoN-ERC

Dear Dr. Ngatia,

RESEARCH PROPOSAL – EFFECT OF COLOUR CODE TOOL TO PRIORITIZE EMERGENCY CAESARIAN SECTION ON DECISION TO DELIVERY TIME INTERVAL AND PREGNANCY OUTCOMES AT KENYATTA NATIONAL HOSPITAL; A QUASI EXPERIMENTAL STUDY (P166/03/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 26th June 2020 – 25th June 2021.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

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For more details consult the KNH- UoN ERC websitehttp://www.erc.uonbi.ac.ke

Yours sincerely,

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