EVALUATION OF THE PRACTICE AND ADEQUACY OF CURRENT PAIN MANAGEMENT FOLLOWING CAESAREAN DELIVERY IN PATIENTS AT KENYATTA NATIONAL HOSPITAL BETWEEN MARCH & MAY 2019
A DESCRIPTIVE COHORT STUDY

A research dissertation submitted as partial fulfilment of the degree of Master of Medicine in Obstetrics and Gynaecology,
University of Nairobi.

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DECLARATION

I declare that this dissertation is my original work, carried out with the guidance of my supervisors, and references to work done by others are indicated.

This dissertation is not presented in any other university for the award of a degree.

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This is to certify that this dissertation is the original work of Dr. Kituku Joyce Mbithe, H58/80955/2015, a masters degree student in the Department of Obstetrics and Gynaecology, School of Medicine, University of Nairobi. It has been written under the guidance and supervision of Professor Koigi Reuben Kamau and Dr. Okutoyi Lydia.

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OPERATIONAL DEFINITIONS

***Pain*-**unpleasant sensory and emotional experience associated with actual or potential tissue damage (1)

In this study's context, it is defined as "the unpleasant physical perception of hurt in and around the surgical incision" (2)

***Acute pain*-**results from damaged tissue following injury, usually lasting for a short period, and is associated with a temporal reduction in intensity as healing takes place.

***Adequate/effective pain control*-**pain management/control resulting in mild pain; corresponding to levels below 40mm on a VAS of 0-100mm.

Satisfaction-difference between the expectation of level of care(pain relief) and perception of actual care received ('Expectation-performance theory')

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

ACOG	American College of Obstetricians and Gynaecologists
APMS	Acute Pain Service
APS	American Pain Society
ASA	American Society of Anaesthesiologists
CS	Caesarean Section
ERC	Ethics and Research Committee
GA	General Anaesthesia
IASP	(European Federation of) International Association for the Study of Pain
IM	Intramuscular
IV	Intravenous
ISO	International Organisation for Standardisation
JC	Joint Commission- formerly known as Joint Commission on Accreditation of Healthcare Organisations (JCAHO)
KNH	Kenyatta National Hospital
MOH	Ministry Of Health
NICE	National Institute for Health and Care Excellence
NSAIDS	Non-steroidal Anti-inflammatory Agents
PCA	Patient Controlled Analgesia
PO	Per Oral
POP	Post Operative Pain
PR	Per Rectal
PRN	Pro re nata (as needed)
RCoA	Royal College of Anaesthesiologists
RCOG	Royal College of Obstetricians and Gynaecologists
RCTs	Randomised Controlled Trials
SC	Subcutaneous
SOP	Standard Operating Procedures
UON	University Of Nairobi
VAS	Visual Analogue Scale
VRS	Verbal Rating Scale
WHO	World Health Organisation

ABSTRACT

TITLE: EVALUATION OF THE PRACTICE AND ADEQUACY OF CURRENT PAIN MANAGEMENT FOLLOWING CAESAREAN DELIVERY IN PATIENTS AT KENYATTA NATIONAL HOSPITAL BETWEEN MARCH AND MAY 2019

Introduction: The global increase in caesarean deliveries is associated with a rise in the burden of postoperative pain which is ranked highest among undesirable clinical outcomes. Acute post operative pain remains under-treated. Adequate pain control in post CS patients has many benefits including early mobilisation averting the risk of thromboembolism and prompt recovery that enables the mothers to breastfeed, bond and generally take care of the newborn. There is a paucity of local data on incidence of acute postoperative pain and adequacy of pain management in patients undergoing CS.

Objectives

Broad objective: To determine the practice and adequacy of current pain management following caesarean delivery in patients at Kenyatta National Hospital between March and May 2019.

Specific objectives: To describe the type(s) of analgesics prescribed by the attending physicians and their dosing schedule; to determine the proportion of analgesics administered to post caesarean delivery patients; to evaluate level of pain control & physical function limitation and to establish patients' satisfaction with post cesarean delivery pain management.

Methodology: Approval to carry out a descriptive cohort study at the labor and postnatal wards of Kenyatta National Hospital was granted by the KNH-UoN ethics & research committee. 246 post CS patients who gave informed consent were enrolled following recruitment through consecutive sampling.

Independent variables were postoperative analgesics and patients' sociodemographic & reproductive/surgical characteristics. Dependent variables were pain levels 24, 48 & 72 hours postoperatively, limitation of function and patients' satisfaction.

Data was collected using a structured questionnaire. Review of records (daily birth register and patients' files) was done. Adequacy of pain management was inferred from Visual Analogue Scale scores where a cut off pain score of 40mm on a scale of 0-100 was used. Data on limitation of function was obtained on a ten-point likert scale whereas data on satisfaction was obtained on a two-point scale.

Data analysis was performed using SPSS version 23.0. Descriptive and inferential statistics were computed. Mean was used to summarise continuous variables like age. Categorical variables were analysed using frequencies. Data on pain scores were used to create binary variables where <40mm was coded as mild pain and >40mm as moderate-severe pain. Primary and secondary independent variables were analysed against outcome variables using multivariate analysis. Chi square test was used to determine relationship between post CS pain and independent variables, as well as satisfac-

tion status and pain scores. T-tests were used to compare limitation of function and pain scores. Tables and graphs/charts were used to present these statistics.

Results: Intermittent IM administration of post CS analgesics was the commonest mode of treatment. Morphine was the commonest opioid prescribed (97.9%). Diclofenac was the commonest co-analgesic prescribed (94.3%). Acetaminophen was prescribed by 91.2%. Multimodal analgesia prescription was practised by 84% of doctors.14.8% of Morphine prescription orders were adhered to whereas 74% of prescribed Diclofenac was administered accordingly. 100% of paracetamol prescription orders were adhered to. Of the QID/TID morphine prescription orders, 100% were administered at an OD frequency. Majority (51.2%) of the morphine prescription orders were at 8-hourly intervals, followed by QID at 10.1%, BID at 9.3%, PRN at 4% and OD at 3.6%. Tramadol was given in combination with Morphine in 28.5% of the patients and as monotherapy in 4%. Incidence of post CS pain was 95.9%. Moderate-severe pain levels were reported in 85.7% of patients while 14.3% reported mild pain levels 24 hours post operatively. On day 3 post operatively 83.7% reported mild pain levels while 16.3% reported moderate-severe pain levels. Associations between age, parity, type of CS, type of anaesthesia and 24-hour pain scores were not significant. >60% reported physical function limitation scores corresponding to insignificant interference. 85% of the patients were satisfied with post CS pain management.

Conclusion: The current practice of post-cesarean delivery pain management at Kenyatta National Hospital is not standardised.

Actual administration of post CS pain medications does not match the prescription orders. Orders on less labor-intensive routes of administration were adhered to more.

Based on the 2012 RCoA Audit Recipes recommendations, post CS pain management is inadequate despite the percentage of patients satisfied.

Recommendations: Standardization of post CS pain management through SOPs, sensitisation of healthcare providers on post CS pain management as well as investigation of barriers to adequate pain management following CS including adherence to prescription orders are recommended based on the study's findings.

Key words: Caesarean section, post-operative pain management, current practice, adequacy, patient satisfaction.

1.0 INTRODUCTION

1.1 Background

Caesarean section is the most common major surgical procedure worldwide, according to the Healthcare Cost and Utilisation Project United States Report of 2011. The recent global increase in caesarean sections has been accompanied by a rise in the burden of postoperative pain. (3–5)

The term pain is derived from the French and Latin words 'Peine' and 'Poena' respectively which means 'punishment' or 'penalty'. Pain is ranked highest among undesirable clinical outcomes associated with caesarean section. (6) However, despite recognition of pain as a significant public health problem, increasing understanding of its pathophysiology, advances in pain research and management, development of new treatment modalities, establishment of new guidelines, recommendations & educational efforts and recognition of pain relief as a basic human right, management of post operative pain remains a significant challenge and patients continue to experience severe and intolerable levels of pain. (7,8)

According to the Royal College of Anaesthesiologists, one of the proposed standards for best practice is that 100% of post CS patients should report their worst pain score below 30mm on the Visual Analogue Scale i.e. all post operative patients should either report mild pain or should not be in pain; however, studies have found a prevalence of moderate-to-severe post operative pain of 20-80%. (7) . This prevalence mirrors the prevalence of similar pain intensity in Africa, of 13.7% - 79.6% (9-12) Pain is so important that in the mid 90s the American Pain Society pushed for it to be treated as the 'fifth vital sign' during post operative pain assessment in order to solve the global problem of gross under treatment of pain. (13)

Article 43 of the 4th chapter of the Constitution of the Republic of Kenya states that "Every person has the right to the highest attainable standard of health, which includes the right to healthcare services …." (14) Also, embodied within the Hippocratic oath is the declaration that healthcare givers will keep their patients from harm. Indeed, healthcare givers have a legal, moral and ethical duty towards relief of pain experienced by those under their care. According to Brennan et al, "under treatment of pain is poor medical practice that results in many adverse effects and is an abrogation of a fundamental human right." (15) Inadequate pain control after CS results in a number of short and long term risks including, poor wound healing, pneumonia, insomnia, increased financial risk due to readmissions & long hospital stays as well as lack of satisfaction with pain management. Ineffective post operative pain management has also been shown to be associated with development

of chronic conditions such as persistent severe pain interfering with infant care as well as postnatal depression. (16) Furthermore, poor pain control interferes with a patient's ability to make choices regarding their care hence contravening the bioethical principle of autonomy, such that, patients end up not making reasonable requests for pain relief whenever necessary. (17)

Effective pain management is a key element of post-operative care, more so in post CS mothers, owing to their unique circumstances-the need for immediate ambulation to avert the risk of developing thromboembolic events, the need to breastfeed and bond with their newborns as soon as possible and provision of general newborn care. These requirements are also regarded as non-pharmacological methods of pain relief, therefore they provide synergistic analgesic effect. Effective post operative pain control is not determined by adoption of sophisticated technologies and acquisition of expensive drugs but on the optimal utilisation of available resources. Therefore, is KNH utilising the available analgesic modalities to the maximum benefit of its post cesarean section patients?

2.0 LITERATURE REVIEW

An understanding of the pain pathways and pathophysiology of pain caused by CS is paramount in achieving optimal control in the post operative period.

2.1 Pathophysiology of caesarean section pain

Pain due to CS is a form of acute nociceptive, surgical or clinical pain subsequent to an inflammatory reaction caused by transection of tissues. It is categorised into visceral or somatic pain. (18) Inflammation of aforementioned tissues leads to activation and peripheral sensitisation of nociceptors and resultant release of mediators including, neuropeptides like Substance P & calcitonin-gene related peptide (CGRP), bradykinin, leukotrienes, prostaglandins, interleukins, serotonin, neurotrophins, potassium, & histamine. (18,19) The noxious impulse is transmitted to the central nervous system for interpretation as pain. (18)

Modulation of the painful stimulus may occur through release of endogenous opioids failure to which the perception of pain persists. On the other hand, heightening of the response to painful stimulus may occur resulting in hyperalgesia. These responses are affected by inter-individual variabilities brought about by difference in genetic make-up, psychological, ethnocultural, socio demographic factors and neurohumoral mechanisms. (20,21)

2.2 Analgesic options post cesarean delivery

To date, there is no ‘‘gold standard’’ regimen for post-cesarean pain management. Generally, factors that influence the choice of analgesic regimen in the post operative context include, drug availability, institutional protocols, individual preferences, the experience of the prescribing practitioner, available resources, financial considerations, history of drug allergies, patient choices & expectations, anticipated challenges and duration of the surgery. (22,23) Most of the regimens used incorporate opioids, NSAIDS and/or paracetamol, and peripheral nerve blocks as adjuncts. Post CS pain management options are progressively increasing with new research and the preexisting methods are also being advanced. (22) “An ideal method of pain relief after caesarean section should be cost effective, safe for the mother, require minimal monitoring and use drugs that are not secreted into breast milk. The mother should not be sedated or hampered by equipment that prevents her from moving freely and caring for the new-born.” (24)

According to the RCoA 2012 Audit Recipes, there is little evidence on what constitutes appropriate, achievable parameters in best practice for the provision of post caesarean section analgesia (25);

however, studies done demonstrate that multimodal analgesia including opioids, paracetamol and NSAIDS(if no contraindication), provides superior pain relief when compared to a single analgesic (opioid) approach, following caesarean section. (26,27) A multimodal approach to analgesia is important for optimising post-operative pain control and decreasing the requirements of oral or intravenous opioids (28,29) The Clinical Practice Guidelines on the management of post operative pain, approved by the APS in conjunction with the American Society of Anaesthesiologists, recommend the use of multimodal analgesia in post operative patients. (30,31)

An adaptation of the 1986 WHO analgesic ladder for treatment of cancer pain was made for treatment of intense acute pain as well as breakthrough pain. A step down approach is recommended including starting at step three of the ladder, with a strong opioid plus a non opioid (NSAID and acetaminophen) and tapering down as pain intensity reduces. (32)

Opioids and paracetamol provide adequate analgesic cover against somatic pain, whereas NSAIDS alleviate the visceral component. This property makes the combination of these drugs an excellent choice in post cesarean patients where the two main components of pain are experienced. The co-analgesic drugs/ adjuvants i.e. NSAIDS & paracetamol are reported to possess an excellent opioid-sparing effect in that when combined with opioids they facilitate use of lower opioid doses without compromising on their analgesic effectiveness. They also potentiate the analgesic effect of opioids . (22,28,30) Owing to the synergistic effects of NSAIDS and paracetamol, it is recommended that both are prescribed in the postoperative period. (33,34) “There is no clear evidence for the clinical superiority of an individual NSAID for post operative use... the choice may therefore depend on the desired route of administration, duration of effect, side effect profile and cost.” However, meloxicam has been shown to have pronounced anti inflammatory activity with a large therapeutic margin compared with other standard NSAIDs. (35)The American Academy of Paediatrics considers the use of NSAIDs in lactating mothers safe. (36) Acetaminophen (Paracetamol) is an effective analgesic drug, has few side effects and minimal rates of transfer to breastmilk. It is also an affordable option. (28) There is lack of clear evidence to support the prescription and administration of intravenous paracetamol which results in escalated costs and intensity of labour; hence, the use of oral paracetamol is recommended in patients who can tolerate oral medication. (28) Most studies indicate no clear differences in post operative pain reduction between oral and intravenous paracetamol or NSAIDs, save for the faster onset of action with the intravenous route.(37,38) Scheduled aceta-

minophen results in decreased opioid use and more consistent acetaminophen intake compared to pro re nata administration. (39)

2.3 The burden of post operative pain and the practice of post-caesarean pain management

In spite of the aforementioned recommendations, unstandardised practice has been shown to be widespread, particularly in low and middle income countries.(9,12,43) In 2009 at the '4th All Africa Anaesthesia Congress' in Nairobi, Kenya, a call was made to African countries to develop and institutionalise standardised protocols for the assessment and treatment of pain.To date, the Ministry of Health has not formulated guidelines on post operative pain management, what is available are guidelines on cancer pain treatment. (40)

Many patients still suffer from moderate to severe postoperative pain, advances made in the understanding of pathophysiology of pain and availability of recommendations/guidelines notwithstanding. (18,41)

Most patients who undergo cesarean section do not receive adequate analgesia (10,12,42,43)Consequently, these patients are predisposed to the untoward effects of inadequate post-operative analgesia, including discomfort, delayed restoration of function, increased risk of thromboembolism, inability to breastfeed and take care of their newborns, persistent pain resulting in hampered functional recovery, increased opioid use, increased risk of postpartum depression and reduced patient satisfaction (28,44) The highest incidence of post operative pain has been shown in the obstetric population compared to other surgical procedures (gynaecological, orthopaedic, Cardiothoracic, urological, breast ophthalmological, Ear Nose and Throat, plastic/reconstructive, vascular and general surgeries.) (11)

Some of the reasons contributing to the high incidence of inadequate post operative analgesia include unavailability of pain medicines, prohibitive legal measures against access to opioids, unstandardised pain practice resulting in infrequent & insufficient doses of analgesics, lack of adherence to prescription instructions & treatment guidelines and poor knowledge & attitude amongst professionals. (45-47) Lack of knowledge to evaluate and manage POP pain is a significant barrier to adequate POP control. An IASP survey by Bond M et al revealed that among the common barriers, 91% was attributed to this in developing countries. (48) Under assessment and under treatment of post operative pain appears not to be a preserve of the developing world. More than 80% of patients

experience pain in the post operative period, with an incidence of moderate to severe pain of more than 75%. (7,49,50)

The severity of acute post operative pain varies according to factors including, analgesic technique(lower incidence reported in patient controlled and epidural analgesia compared with IM analgesia, analgesic/anaesthetic intervention, age, sex, preoperative pain, size of incision and time after surgery(the longer the period, the lower the incidence of moderate-to-severe pain. (41,51)

In most facilities, the approach employed in post operative pain management is usually doctor-prescribed & nurse-administered analgesia.

Regionally, studies demonstrate that postoperative pain is under treated in patients who undergo caesarean section. According to a prospective study done in South Africa by Adriaan Albertus et al, caesarean section stood out as the procedure with the highest incidence of moderate-to-severe pain during the first 24 hours post operatively and also in the immediate post operative period compared to gynaecological, orthopaedic, Cardiothoracic, urological, breast ophthalmological, Ear Nose and Throat, plastic/reconstructive, vascular and general surgeries. Some of the possible reasons cited were young age, female gender and nature of the procedure (a high incidence was reported for abdominal surgeries). (11) A discrepancy between morphine prescriptions and administration was found, such that the patients did not receive their medication regularly enough and some did not receive at all. Only 46% of prescribed morphine was administered. Furthermore, the mean dose interval of administered morphine was much longer than the prescribed dose. (11)

Another prospective descriptive study conducted at Ilorin teaching hospital in Nigeria in 1999-2000 by Kolawole et al (12), found a high incidence of moderate to severe pain of more than 79% in the immediate post operative period as well as on the first POD. Ineffective post operative analgesia was mainly attributed to erroneous prescription practices due to lack of knowledge on pharmacology of drugs, clinician attitude and late initiation of analgesia following surgery. Potent opioids recommended for use in treatment of moderate-to-severe acute POP e.g morphine were not used in this study, instead weak opioids such as Tramadol & Pentazocine dominated the prescriptions; this was mainly due to reduced access to strong opioids due to government restrictions on their acquisition and use. Intermittent IM administration of analgesics was the main mode of practice, common in developing countries because it's convenient, affordable, relatively safe and it was the method that the clinicians were most familiar with. Use of the IM route has been discouraged since it adds on to

the effects of pain, and it is associated with varied pharmacokinetic properties, hence commonly results in inadequate pain control. The IM drug may also precipitate at the injection site resulting in low blood drug concentration. This practice is mirrored in other African countries. (9,10,52) Satisfaction with pain management was paradoxically high similar to other studies done globally & regionally. (10,42)

A South African study done by Dlamini at Chris Hani Baragwanath Academic hospital in 2016, established partial adherence to post caesarean section pain treatment guidelines resulting in relatively high incidence of moderate to severe pain. (10) Availability of pain management protocols has been shown to result in improved post caesarean section pain scores. (53)

Response to patients' requests for rescue analgesia has been shown to be wanting causing higher post operative pain scores. According to a prospective study done by Tewodros et al at a university teaching hospital in Ethiopia in 2012, majority of the patients (70%) never requested for rescue analgesics, 14% had their requests overlooked and a good number (22%) had to wait for 1 hour to receive it; this reflects a poor patient participation in pain management and a poor attitude from the caregivers towards patients' pain. (52)

Locally, in Kenya, Dr Mbuba et al carried out a prospective study in 2007 at KNH on maternal satisfaction with post operative pain management.(54)The commonest post CS analgesic regime in the first 24 hours post operatively was found to be IM Pethidine and IM Diclofenac . This mirrors the regional & global post operative picture of prescription of pethidine and IM analgesic administration (33,48), a practice that is no longer recommended by WHO. Limited analgesic options were cited as one of the reasons. Dosing schedules were erratic for the same drug prescribed. This was a reflection of knowledge and treatment standardisation gap in the institution. This study seeks to establish whether this practice is still in place, and possibly contributing to inadequate pain control. In addition, Dr Mbuba et al's study,(54) like many others did not establish pain intensities beyond 24 hours post operatively thus missed out on the effect of transition from intensive analgesic therapy(parenteral medication) to oral analgesics. Our study aims at bridging this gap. In Dr Mbuba et al's study, level of satisfaction was proportional to severity of pain.(54) This is in contrast with most of the studies done that show satisfaction levels of >80% despite significant post operative pain levels. (10,12,42). The study also recommended adoption of PCA whose benefits are well known and demonstrated in post CS patients. Our study also aims to establish whether the recommendation was adopted.

There is a huge knowledge hiatus in Kenya on management of post operative pain as demonstrated in a 2009 Eldoret survey by Kituyi WP et al where 57% of healthcare practitioners who work with patients in the peri-operative period indicated that they lacked the knowledge to manage postoperative pain. (40)

2.4 Assessment of outcomes of postoperative pain management

"**The ECHO model** assumes that the outcomes of medical care can be classified along three general dimensions: clinical, economic and humanistic outcomes". (55) Assessment of these components was used to evaluate the effectiveness of pain treatment. In this study, clinical outcomes (pain) and humanistic outcomes (satisfaction with pain management after cesarean section) were assessed. Assessment of the two aforementioned outcomes is a reflection of the quality of care given to the patients. Assessment of pain helps in determining whether care is adequate, whether analgesic dose changes are required, whether additional interventions are warranted and whether specialty consultations are required in case of pain that is difficult to manage. (56)

Pain assessment ought to be done on a regular basis using a standard format. In addition, every assessment should include the pain intensity measure because the choice of drug and dosing are based on it. The RCoA 2012 audit recipes mention documentation of hourly observations of pain intensity for 24 hours in patients who have received morphine as an indicator of good practice. (25,31) Since the experience of pain is inherently subjective, patient self-report is the primary and most accurate basis of all pain assessments. (25) This is important so as to enable tailoring of analgesic requirements to individual patient needs. Reliance on patient behaviour and vital signs is discouraged, except in patients who are not able to self-report because of circumstances such as cognitive deficits and excessive sedation, since they are not objective measures of pain assessment. (31)

In this study, clinical outcomes were measured via rating of pain intensities and drug-related problems (including number of patients missing essential prescriptions and medication administration errors) and humanistic outcomes featuring patient satisfaction with pain management. Combined assessment of satisfaction with pain scores minimises the chances of ignoring inadequately treated post operative pain. (57)

In the IASP's declaration of 2010–2011 as a global year of acute pain it was emphasised that when acute pain is treated optimally it results in better patient satisfaction with care. (58) However, several studies have demonstrated a paradoxical satisfaction with pain management among post opera-

tive patients who report high pain intensity scores. This may be explained by the fact that significant improvement in other measures of quality of life such as sleep and general activity may be made even though improvement in pain intensity is not present.(59,60) Another possible reason for the discrepancy between satisfaction and report of moderate to severe pain is the measure of satisfaction used. Most of the authors of these studies measured satisfaction at a global level e.g 'satisfaction with pain management' and 'satisfaction with care' but these global measures are too general and less specific so patients respond to the questions while putting into consideration confounding factors like how their caregivers communicate to them and time taken to receive pain medication, which are unrelated to their pain level. (61,62) Studies that measured satisfaction through use of specific measures demonstrated a reduction in the satisfaction level in patients who had higher pain scores, they did not establish this paradoxical relationship like the other studies. (63)

Evaluation of patient satisfaction is an important tool for monitoring the quality of pain management and can generate areas of improvement in order to achieve better outcomes.

3.0 CONCEPTUAL FRAMEWORK

3.1 Narrative

Cesarean section results in acute somatic and visceral pain due to surgical trauma to tissues together with associated inflammatory reaction and neurohumoral response. Pain following Caesarean section is also a consequence of uterine contraction during involution.

The type(s) of analgesic drugs prescribed/administered and their dosing affect the level of pain experienced by patients who undergo Caesarean section.

Post caesarean section pain levels, physical functional status and degree of satisfaction with pain management are influenced by a number of factors including gender, level of preoperative pain, length of surgery, type of surgery I.e whether emergency or elective and prior exposure to surgical pain.

3.2 Diagrammatic representation

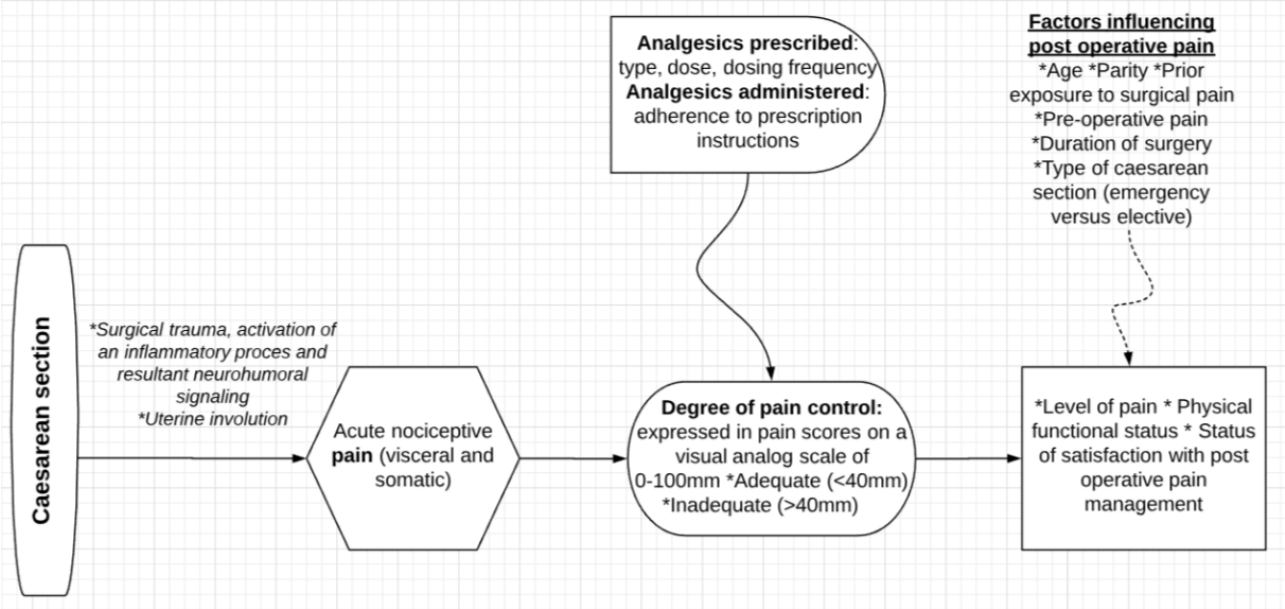

Figure 1 : Conceptual Framework

4.0 JUSTIFICATION

- Management of acute postoperative pain remains inadequate in low and middle income countries & unstandardised practice of post operative analgesia is still rampant.
- Globally, there is a knowledge hiatus in effective post CS pain management. This is worse in low and middle income countries.
- Postoperative pain is poorly studied in developing countries.
- Most studies have evaluated effectiveness of post CS pain management in the first 24 hours. This study evaluated management beyond 24 hours. Essentially, it provided information on the treatment and pain outcomes between the initial intensive therapy on the first postoperative day and transition to oral drugs or less potent drugs from 24 hours to 72 hours postoperatively.
- A similar study on the subject was conducted thirteen years ago. This informed the need to research the current impact of pain treatment following caesarean section due to changes in practice including increased use of regional anaesthesia techniques
- It is a practice-impacting study/research.Strengths and gaps revealed in the study will inform clinicians' training needs regarding post caesarean delivery pain management and implementation of a local treatment protocol which will ensure standardisation, safety and quality of care. Standardisation promotes safety, repeatability and consistent quality of care.

5.0 RESEARCH QUESTION

What is the practice and adequacy of current pain management following caesarean delivery in patients at Kenyatta National Hospital between March and May 2019?

6.0 OBJECTIVES

6.1 Broad Objective

To determine the practice and adequacy of current pain management following caesarean delivery in patients at Kenyatta National Hospital between March and May 2019

6.2 Specific Objectives

Among post cesarean section patients receiving care in Kenyatta National Hospital between March and May 2019;

1. To describe the types of analgesics prescribed and dosing.

2. To determine the analgesics administered.

3. To evaluate level of pain control and limitation of function.

4. To establish satisfaction with pain management.

7.0 METHODOLOGY

7.1 Study Design

To achieve the objective, a Descriptive Cohort study design was employed. In this type of study design, identification of a group (cohort) with the exposure of interest in a given population is done. These 'group' members are followed up within a specified time limit and outcomes of interest are analysed at the end of the study period. Usually data are collected at multiple intervals, and there is no control. In this study, a group of post cesarean delivery patients who are exposed to post operative pain and analgesics thereafter, were followed up over a period of 72 hours post operatively, during which data was obtained at 24 hour intervals since the time of the operation. The outcomes of interest in this study were as follows: Pain intensities at rest and on movement, limitation of physical function and patients' satisfaction with the pain management.

7.2 Study Setting

The study was carried out at Kenyatta National Hospital. It is a public national referral hospital located in Nairobi county, Kenya that offers specialised care to clientele from different parts of the country with varied sociodemographic characteristics. It also serves as a tertiary teaching hospital to the students of University of Nairobi, school of Health Sciences, Faculty of Medicine and Kenya Medical Training College students. Currently, It has an average general bed capacity of 2,000 and serves an average of 70,000 inpatients and 500,000 outpatients on an annual basis. The Obstetrics and Gynaecology department is one of the specialist units within the hospital. The Obstetrics unit has a bed capacity of 145 with an average bed capacity of 40 in the antenatal/post natal wards. Approximately 15,800 deliveries (average of total number of deliveries between 2014 and 2017) are conducted per year and the department is linked to two operating theatres, where about 6,600 cesarean sections are conducted annually contributing 42% of all deliveries. With such figures and the enormity of the catchment area, the setting was suitable for this study whose findings are likely to be generalisable to other parts of the country. Eligible study participants were drawn from the post-natal wards namely,1A, GFA & GFB.Data were collected between April and May 2019.

7.3 Study Population

The Study population included post cesarean delivery patients admitted for at least 72 hours after surgery, and received post surgical/post natal care at the KNH.

7.4 Eligibility Criteria

7.4.1 Inclusion criteria

●Mothers who were able and willing to give consent;

●Mothers who delivered via CS

7.4.2 Exclusion criteria

Participants who were unable/unwilling to give consent such as;

●Those who developed intra-operative/post-operative complications(PPH, sepsis)

●Those whose babies were stillborn.

●Those with known neurological/psychiatric disorder.

●Intensive Care Unit/High Dependency Unit admissions(maternal).

●Those whose files were missing.

●Those who were on chronic opioid use.

7.5 Sample Size Determination

This study used ***Cochran's formula*** at a precision level of 5% and 95% confidence interval (Singh & Masuku, 2014) as shown below. (64)

$$n = \frac{Z^2_{1-\alpha} \times P(1-P)}{\partial^2}$$

n = Desired sample size when population is > 10,000

α = level of significance (5%)

Z = Standard normal deviate corresponding to 95% confidence level (1.96).

P = Assumed proportion of target population (50% since unknown)

∂ =Degree of accuracy desired at 5%

Upon substitution, the study sample size was 384.

Since the target population was <10,000, the study sample was proportionally adjusted as follows:

$$nf = \frac{n}{1 + \frac{(n-1)}{N}}$$

Where,

nf= is the proportionally adjusted sample size since population was < 10,000

n =is the desired sample size when population is greater than 10,000

N =is the population

Upon substitution, and considering monthly average of 545 CS deliveries, the sample size was **226** patients. 10% mark up was done to cater for errors like incomplete documentation, resulting in ***247.***

7.6 Data Collection Procedure

7.6.1 Sampling Method/Procedure

Study participants were selected according to the Consecutive sampling technique, where post caesarean section patients who fit the inclusion criteria and were available in the wards of interest were issued with the questionnaire. This type of sampling technique obviates bias during selection of participants. Available participants were enrolled into the study until the desired sample size was achieved.

7.6.2 Sources and Methods of Recruitment

Recruitment of study participants was done by the principal investigator and two research assistants. The research assistants were trained by the principal investigator on proper study procedures and supervised in the first week of data collection.

Study participants were identified in labour ward initially and followed up in the post-natal wards (post cesarean section rooms) once admitted from theatre via labour ward observation rooms.

A pilot test of the questionnaire was done using five potential participants and unclear areas were sorted in the final questionnaire. Thereafter participants were approached and invited to take part in the study. An information document (Annex 2 Part I & Annex 3) was issued to each patient, in the language of their choice i.e. either english or kiswahili, and the principal investigator or research assistant explained the objective of the study. Subsequently, the patients were offered a chance to ask questions or seek clarifications on the study. Those who agreed to participate in the study were assessed for eligibility. Those who fit in the inclusion criteria and did not fit in the exclusion criteria were requested to give informed consent in the form of a signature or a left thumb print on the consent form provided (Annex 2 Part II). The principal investigator or research assistant placed their signature and date on the consent form. The principal investigator or research assistant visited the appropriate wards daily after the doctors' ward round, and got information from the participants who consented. According to the 2015 APS and ASA guidelines on the management of post operative pain, there is no sufficient evidence on the appropriate timing and frequency of pain assessment in the post operative setting; however, timing of pain assessment should be guided by the time taken for the peak analgesic effects to be achieved, which is usually 15 to 30 minutes for parenteral medication and 1 to 2 hours for orally administered drugs. (65)

The initial pain scores were obtained within a maximum of four hours post operatively and the timing of subsequent scores were guided by the drug's route of administration as mentioned earlier.

Enrolment of participants continued until the desired sample size is achieved.

7.7 Data Variables

The primary independent/exposure variables included analgesics and their dosing schedule. The secondary independent variables included patients' sociodemographic, clinical & surgical characteristics including age, parity, number of previous surgeries (CSs) and their indication, duration of surgery, intra-operative analgesia given, pain before the CS, type of current CS (emergency/elective)

The dependent/outcome variables included pain levels at 24, 48 and 72 hours postoperatively at rest & on movement and patients' satisfaction with the pain management.

7.8 Data collection procedure

Data were collected using a structured questionnaire and review of records described below;

Daily ward register: This was used to identify the study participants who were eligible. On each day of data collection, after the ward round, the principal investigator or research assistant request ed this register from the matron in charge of each of the three postnatal wards i.e. GFA, GFB & 1A and identified patients who underwent delivery via cesarean section.

Antenatal clinic attendance card: Obstetric data (CS order)

*Patients' files***:** Herein, information from the treatment charts, theatre procedure notes, and anaesthetic chart, was obtained.

Nursing kardex: This provided information on analgesics administered, frequency of administration and presence or absence of assessment of pain and its treatment.

The principal investigator and/or trained research assistants administered the structured questionnaires to eligible participants (who gave consent) admitted to labour ward and post natal wards of KNH after CS. For each questionnaire, a unique patient identifier was provided.

7.9 Filling of the questionnaire

The questionnaire (Annex 5) was in seven parts and contained a series of closed and a few open-ended questions, with check off options for each that facilitated answering by the participants.

Following enrolment and obtaining of consent from study participants, a unique study number was allocated to the participant.

The principal investigator or research assistant filled in appropriate responses from the participant, on age, parity, history of previous CS, indication for previous CS if there was any, indication for CS undergone immediately prior to recruitment. For the pain scores, a VAS was administered to the study participants, as a 100mm line, with the descriptions 'no pain' and 'worst possible pain' affixed on either end, to the left and right side respectively. The participant was asked to make a vertical mark on the scale indicating the intensity of the pain they were experiencing at that particular time. The pain score was measured from the zero anchor to the patient's mark using a ruler with millimetre markings. Adequate pain control was considered to be pain levels corresponding to ≤40mm on the VAS and vice versa. Twenty four-hour cumulative pain scores were obtained at 24, 48 and 72 hours post operatively. A human pictorial illustration was included in order to obtain information on the location of the pain.

The APS and ASA 2015 Practice Guidelines on post operative pain management recommend assessment of pain during activity in addition to 'at rest pain' because pain on movement, for example coughing or moving about, is more severe and difficult to manage; furthermore, it guides decisions on on going pain management and at the time of discharge thereby contributing positively to return to normal function. (31) Control of pain at rest is important for comfort and during movement it is important for function and reduction of risk of postoperative complications. (31)

Information related to the type of CS, type of anaesthesia, analgesics prescribed & their dosages and frequency of administration was obtained from the patient's file while that regarding analgesics administered, was obtained from the nursing kardex.

Data on limitation of function due to pain experienced was on obtained on a 10-point Likert scale.

Patients's satisfaction with pain management was assessed on the second post operative day using a 2-point scale 'satisfied' or 'not satisfied'.

7.10 Validity & Reliability

Pain rating scales are clinical indicators that are used as a basis for selection of treatment alternatives or treatment modification. A number of validated and reliable tools for assessing pain intensity are available and these include, visual analogue scale, numerical rating scale, verbal rating scale and FACES rating scale. According to the expert panel that contributed to the 2015 APS/ASA recommendations on acute post operative pain management, there is inadequate evidence on which specific tool to use, but clinicians should use a validated tool that is reliable, sensitive and simple to administer. (31,56)

The VAS is a 100mm long unidirectional scale, with the descriptions ‘no pain’ and ‘worst possible pain’ affixed on either end, to the left and right side respectively. It was validated in 1983 by Price et al whose study showed that the scale is valid and reliable in measuring both the intensity and unpleasantness of human pain. It has been considered a valid and reliable tool in measurement of acute pain as well as chronic pain. A 2001 study by Bijur et al established that the VAS is an extremely reliable instrument for measuring acute pain, such that in case it is used to measure a patient’s change in level of pain, a change of 10mm or more is likely to be a true change in the pain intensity for most patients. Although it has a shortcoming of the need for an investigator to have equipment, either electronic or on paper, when administering it, it has more pain response categories compared to other pain measurement tools, thus increased sensitivity. (66-69)

The VAS has also been shown to demonstrate sensitivity to effects of analgesics. (68)

7.11 Data Quality Assurance

Quality of the data collected was maintained throughout the study through a number of means or processes including use of a reliable and validated pain rating scale, VAS, for the pain scores, pre-test of the structured questionnaire to be able to ascertain appropriateness of questions and respondents' level of comprehension (to avoid bias, misinterpretations and ambiguities) especially on how to use the VAS. Pilot testing of the questionnaire was done and it provided an opportunity to identify further training needs of the research assistants; this ensured reliability of data collected and also their consistency. The research assistants were trained by the principal investigator on the study methodology including how to conduct the interview and retrieval of information.

During the first week of data collection, the research assistants worked under the guidance and supervision of the principal researcher and this ensured attainment of relevant and complete information.

7.12 Data Management and Analysis

Data tools were pretested and Cronbach Alpha coefficient of 0.7 was used to ascertain internal validity and reliability of the data extraction tool (partly adopted from the American Pain Society Patient Outcome Questionnaire) in testing pain levels and degree of limitation of function in the study. Cronbach alpha is used to test the reliability of a tool used to measure latent variables like 'satisfaction' and 'pain level'. An alpha score of 0.7 or more validates the use of the tool used to measure the latent variable of interest. Collected data was coded, processed and cleaned off any inconsistencies and outliers. Statistical Package for Social Sciences (SPSS Version 23) was used to analyse quantitative data from the questionnaires. The data were analysed using descriptive and inferential statistics. Sample characteristics were summarised using mean (SD) for continuous variables e.g. age. For categorical variables tables of frequencies containing numbers of participants within each level of the variables was counted and corresponding percentage calculated. The main outcomes were post CS pain at 24, 48, and 72 hours. Data collected from VAS ranging from 0 to 100 mm at each time point was used to create binary variables with VAS score below 40 mm coded as minimal pain and VAS > 40 mm coded as moderate to severe pain. Chi square tests of association, and logistic regression was used to determine the relationship between post CS pain and independent variables including type of CS, type & combinations of drugs prescribed and type of anaesthesia. The association between pain and independent variables were presented using Odds Ratios (95% CI). The limitation of functions in the post CS period was compared between patients with mild and

moderate to severe pain using t-tests. Satisfaction status was compared between patients with mild and moderate-severe pain using Chi square tests. Statistical significance was determined using a p-value < 0.05. Findings were presented in the form of text, charts/graphs and tables.

7.13 Ethical Considerations

Permission to conduct the study was sought from the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (Annex 1). Nurse-in-charges of labour and postnatal wards were informed of the study prior to commencement of data collection.

An information letter (Annex 2 Part I) was issued to the study participants and written and verbal informed consent (Annex 2 Part II) was obtained prior to enrolment.

Confidentiality was maintained by use of unique identifiers on every questionnaire instead of patients' names and hospital in-patient numbers. Collected data were accessible to the principal investigator, research assistants, statistician and supervisors only.

The participants had the right to withdraw from the study without affecting their care regarding pain control adversely.

For participants with moderate-to-severe pain at the time of interview, the nurse or doctor on duty was notified and appropriate action taken.

7.14 Study Strengths

1) The prospective nature of the study allowed for real time data collection under routine circumstances.
2) Generalisability plausibility due to varied sociodemographic characteristics of participants.
3) The study bridged the gap between the transition from strong analgesics to oral formulations by collecting data beyond 24 hours post operatively, unlike other studies.

7.15 Study Limitations

1) Since pain is a subjective phenomenon, variations in the pain scores for a similar intensity of pain perceived by the study participants were anticipated. The study mitigated this through multivariate analysis of the secondary independent variables vis a vis pain scores and no significant differences in pain scores between the groups were found.

2) This was a prospective study; therefore, a possibility that overestimation of practice by the prescribers may have occurred. Also the study may not have captured the true practice on the ground since health care providers particularly the ones responsible for drug administration were cognisant of the audit and therefore they may have modified their behaviour.

3) Study participants may have given incorrect information regarding pain scores due to fear of victimisation. This was mitigated by provision of adequate information concerning the objectives, and reassuring them on the maintenance of the usual standard of care. Cooperation and transparency from all cadres was accorded.

4) Incomplete patient records/documentation. One questionnaire had missing pain scores; thus, it was omitted during analysis.

5) Due to the descriptive nature of the study, it lacked a control group.

6) Lack of correlation between drugs administered and degree of pain control

8.0 RESULTS

The study period was from 28th March 2019 to 10th May 2019. A total of 260 mothers were screened. 247 were eligible to participate in the study based on the eligibility criteria; therefore, were enrolled into the study. However, data on pain scores from one participant were missing; thus, were not included in the analysis.

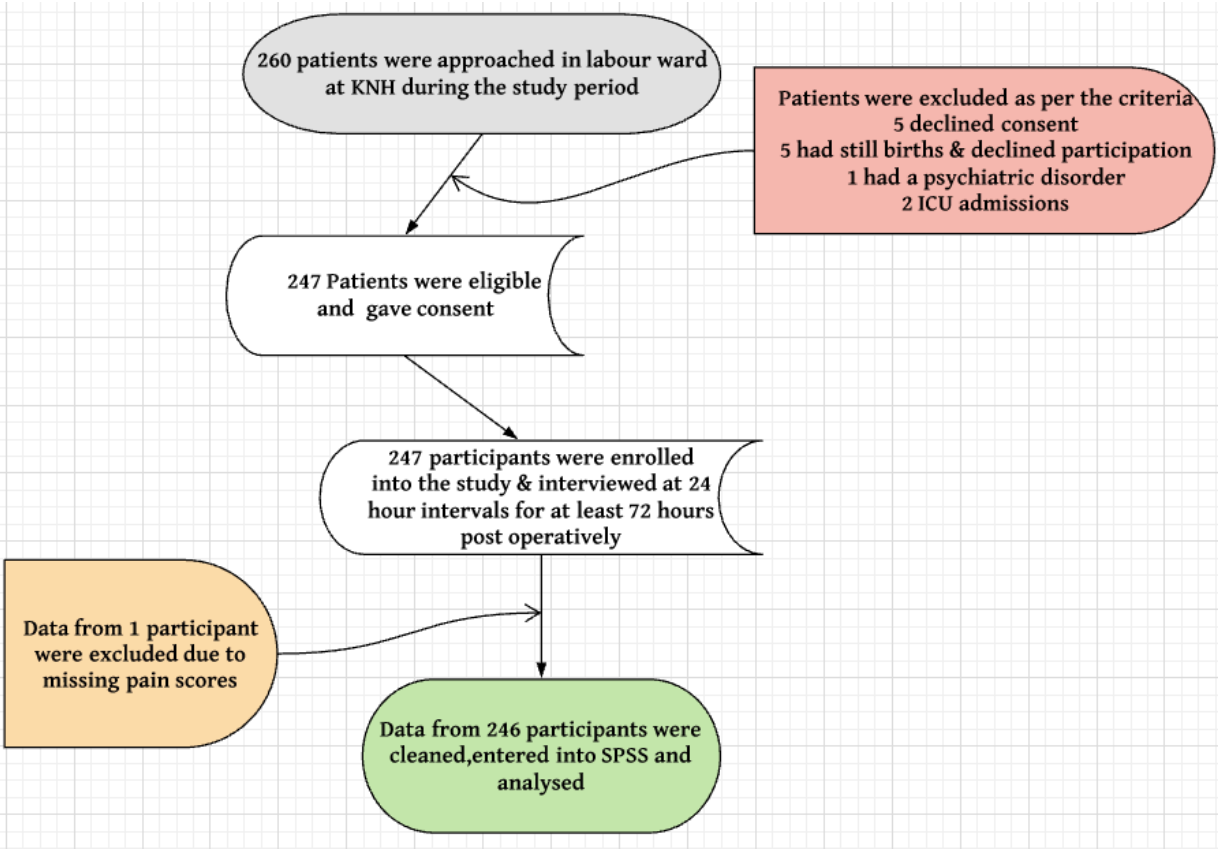

Figure 2: Flow chart of data collection procedure

Objective 1: Types of analgesics prescribed and their dosing schedule in post CS patients at Kenyatta National Hospital.

Table 1: Socio-demographic and reproductive characteristics of Post CS mothers at Kenyatta National Hospital (N=246)

Characteristic	n (%)
Socio-demographic	
Age	
<35	207 (84.2)
≥35	39 (15.9)
Marital status	
Married	212 (86.2)
Single	34 (13.8)
Religion	
Christian	237 (96.3)
Muslim	9 (3.7)
Reproductive & Surgical	
Type of CS	
Emergency	235 (95.5)
Elective	11 (4.5)
Parity	
Primiparous	80 (32.5)
Multiparous	166 (67.5)
Number of previous CS	
None	193 (78.5)
≥1	53 (21.5)
Type of anaesthesia	
Spinal	235 (95.5)
General	11 (4.6)

Table 1 shows that majority of the patients (84.2%) were aged below 35 years and were married (86.2%). A large number (96.3%) professed the christian faith and a significant number (95.5%) underwent emergency caesarean section. Based on parity, majority (67.5%) had more than one live births. Majority (78.5%) had not undergone CS previously and few (21.5%) underwent a CS prior. 95.5% received spinal anaesthesia while 4.6% received general anaesthesia.

Table 2: Frequency of prescribed analgesics in post caesarean delivery patients at Kenyatta National Hospital on the first post operative day (N=246)

Analgesic	n (%)
Morphine	242 (97.9)
Tramadol	50 (20.3)
Diclofenac	232 (94.3)
Acetaminophen	225 (91.2)

Table 2 shows the frequency of prescribed analgesics by drug type. Morphine was prescribed in 97.9% of the patients, while tramadol was prescribed in 20% of the patients. Diclofenac was prescribed in 94.3% of the patients whereas acetaminophen was prescribed in 91.2%.

Table 3: Frequency of prescribed Opioid analgesics and their dosing in post caesarean delivery patients at Kenyatta National Hospital (N=246)

Analgesic	Prescription Mode (range)	n (%)
Morphine		
Modal dose	10mg (5-10mg)	242 (97.9)
Modal frequency	TID	160 (65.1)
Modal route	IM	183 (74.4)
Modal duration	1 day	134 (57.3)
Tramadol		
Modal dose	100mg (50-100mg)	50 (20.3)
Modal frequency	BID	37 (55.2)
Modal route	IM	35 (47.3)
Modal duration	3 days	55 (88.7)

Table 3 shows that morphine was the most frequently prescribed opioid (97.9%) at a dose and frequency of 10mg and 8-hourly doses respectively. The commonest route of administration and prescription duration was intramuscular and 1 day respectively. Tramadol was either given in combination with morphine most commonly (28.1%) or less frequently (4.1%) as monotherapy.

Table 4: Frequency of prescribed Co-analgesics and their dosing in post caesarean delivery patients at Kenyatta National Hospital (N=246)

Analgesic	Prescription	n (%)
Diclofenac		
Modal dose	100mg	152 (61.8)
Modal frequency	BID	149 (60.6)
Modal route	PR	126 (51.2)
Modal duration	2 days	103 (41.9)
Paracetamol		
Modal dose	1g	225 (91.2)
Modal frequency	TID	126 (51.2)
Modal route	PO	154 (62.6)
Modal duration	3 days	185 (75.5)

Table 4 shows that diclofenac (NSAID) was prescribed at a dose of 100mg, at 12-hourly intervals most frequently. The commonest route of administration and prescription of Diclofenac were Per rectal and 2 days respectively; whereas those of paracetamol were Per oral and 3 days respectively.Paracetamol was commonly prescribed at a dose of 1g (91.2%) at 8-hourly intervals.

Figure 3: Frequency of multimodal prescriptions in post CS patients at Kenyatta National Hospital

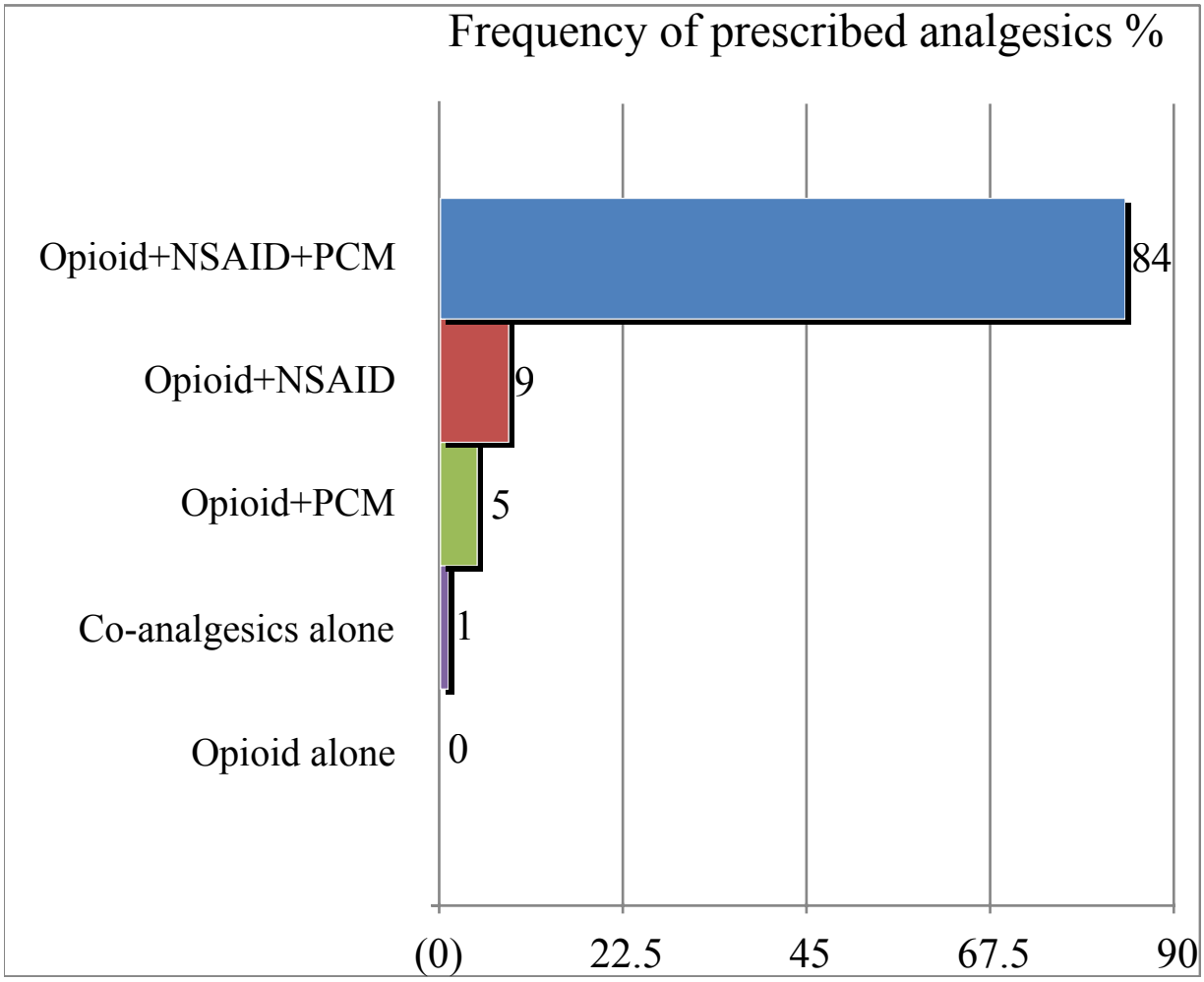

Figure 3 shows prescribed post CS analgesic combinations in comparison to international recommendations (WHO,IASP,ASA).84.6% of the prescriptions comprised of the multimodal regimen. 1.2% of the prescriptions comprised of diclofenac & paracetamol alone, while 0.41% comprised of an opioid alone.

Objective 2: Proportion of analgesics administered to post CS patients at Kenyatta National Hospital.

Figure 4: Frequency of administered analgesics in post caesarean delivery patients at KNH

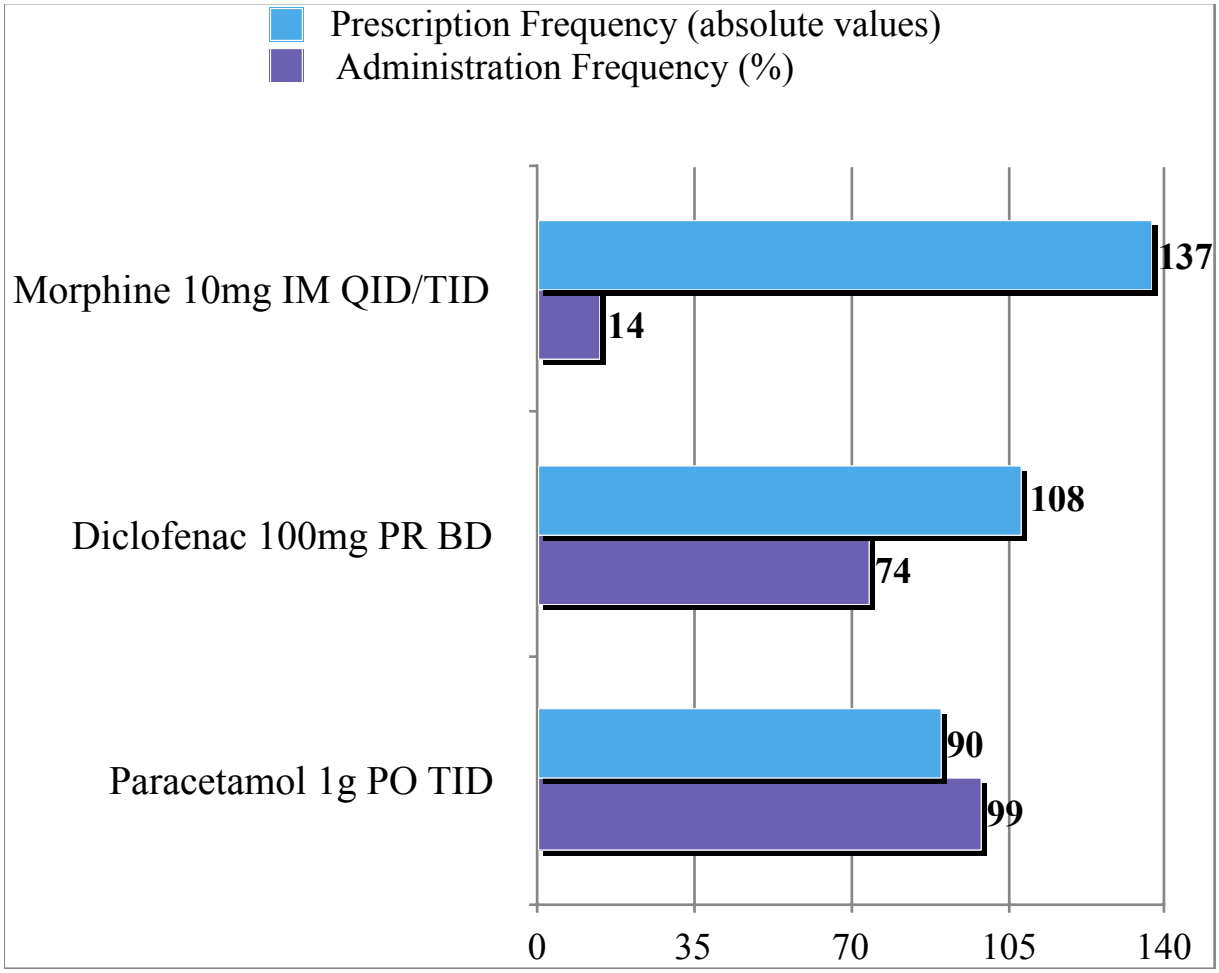

Figure 4 shows proportion of prescribed post CS analgesics that were administered. Of 137 morphine prescriptions 14.8% were administered. Out of 108 per rectal diclofenac prescriptions 74% were administered. 98.9% of per oral paracetamol prescription orders were adhered to . Cumulatively 22.8% of the drugs were not administered.

Objective 3: Severity of pain following post CS pain management in patients at Kenyatta National Hospital.

Table 5: Frequency of pain scores at rest and on movement by post operative period in post caesarean delivery patients at Kenyatta National Hospital (N=246)

Pain score	24h- n(%)	48h- n(%)	72h- n(%)
At rest			
<40	82(33.3%)	143(58.1%)	230(93.5%)
>40	164(66.7%)	103(41.9%)	16(6.5%)
Mild	82(33.3%)	143(58.1%)	230(93.5%)
Moderate	127(51.6%)	96(39%)	13(5.3%)
Severe	37(15%)	7(2.8%)	3(1.2%)
On movement			
<40	35(14.2%)	82(33.3%)	206(83.7%)
>40	211(85.8%)	164(66.7%)	40(16.3%)
Mild	35(14.2%)	82(33.3%)	206(83.7%)
Moderate	128(52%)	147(59.8%)	35(14.2%)
Severe	83(33.3%)	17(6.9%)	5(2%)

Table 5 shows the frequency of pain scores by post operative day at rest and during movement. 24 hours and 72 hours post operatively, 66.7% and 6.5% of the patients had moderate-severe pain at rest, respectively. During movement, 85.8% and 16.3% of the patients had severe pain 24 hours and 72 hours post operatively.

Figure 5: Distribution of pain scores (on movement) by post operative day among post CS patients at Kenyatta National Hospital (N=246

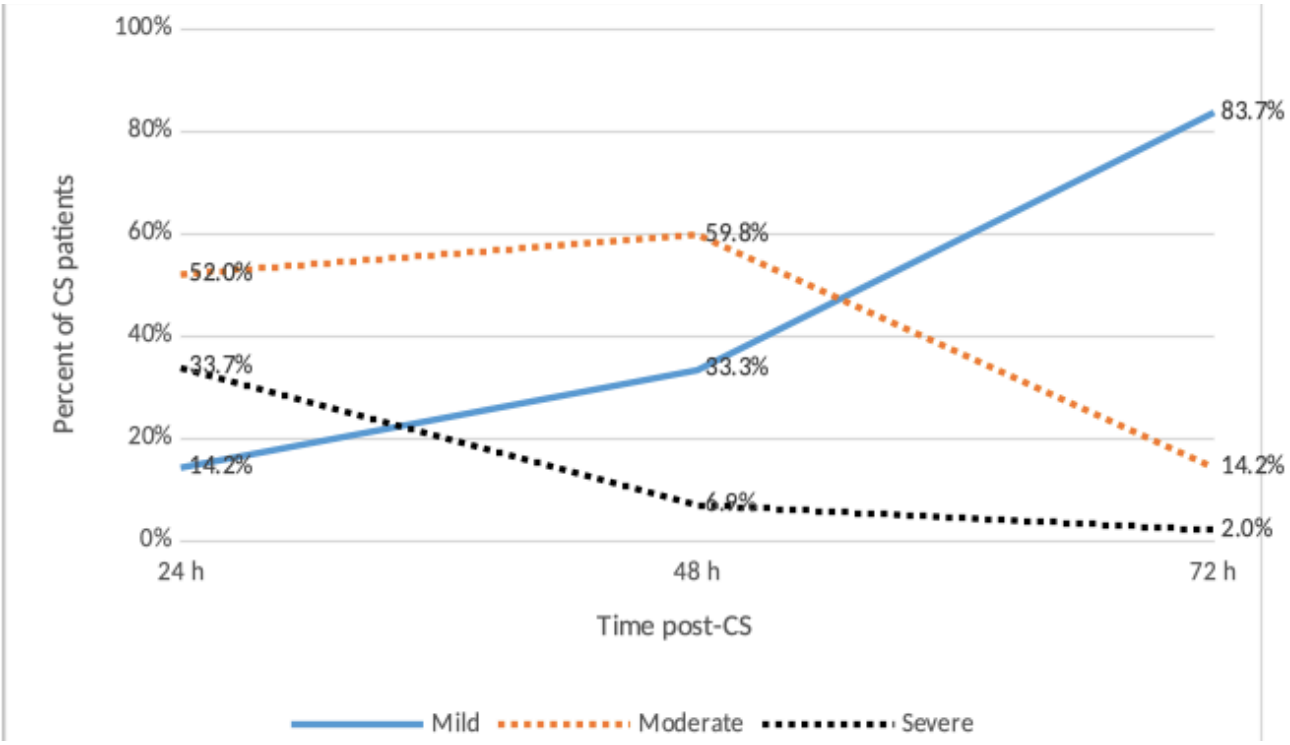

Figure 5 shows the trend in relative post CS pain scores over a 72-hour period. 85.7% of the participants reported moderate-severe pain levels 24 hours post operatively. 14.2% reported mild pain levels during the same time interval. There was an increase and decrease in the number of participants reporting mild and severe pain levels respectively in the subsequent 48 hours post operatively. However, the number of participants who reported moderate pain levels increased by 7.8% 48 hours post operatively before declining to 14.2% on the third post operative day.

Table 6: Association between sociodemographic, reproductive, surgical characteristics and pain scores at 24 hours post CS at Kenyatta National Hospital (N=246).

	Pain on movement (24 hours)			
Characteristic	**Yes (>40)**	**No (<40)**	**OR (95% CI)**	**P value**
Age				
<35	180(85.3)	26(74.3)	1.0	
≥35	30(14.2)	9(25.7)	0.48(0.21-1.13)	0.092
Parity				
Primiparous	70(33.2)	10(28.6)	1.0	
Multiparous	141(66.8)	25(71.4)	0.81(0.37-1.77)	0.591
Type of CS				
Emergency	201(95.3)	34(97.1)	1.0	
Elective	10(4.7)	1(2.9)	1.69(0.21-13.64)	0.622
Type of anaesthesia				
Spinal	202(95.7)	33(94.3)	1.0	
General	9(4.3)	2(5.7)	0.74(0.15-3.55)	0.702

Table 6 depicts multivariate analysis of secondary independent variables and 24-hour pain scores post caesarean delivery.It revealed no significant differences in the pain scores between the groups. P value of <0.05 was considered as statistically significant.

Objective 3: Limitation of physical function following CS in patients at Kenyatta National Hospital.

Figure 6: Distribution of limitation of function scores by activity among post CS delivery patients on pain management at Kenyatta National Hospital. (N=246)

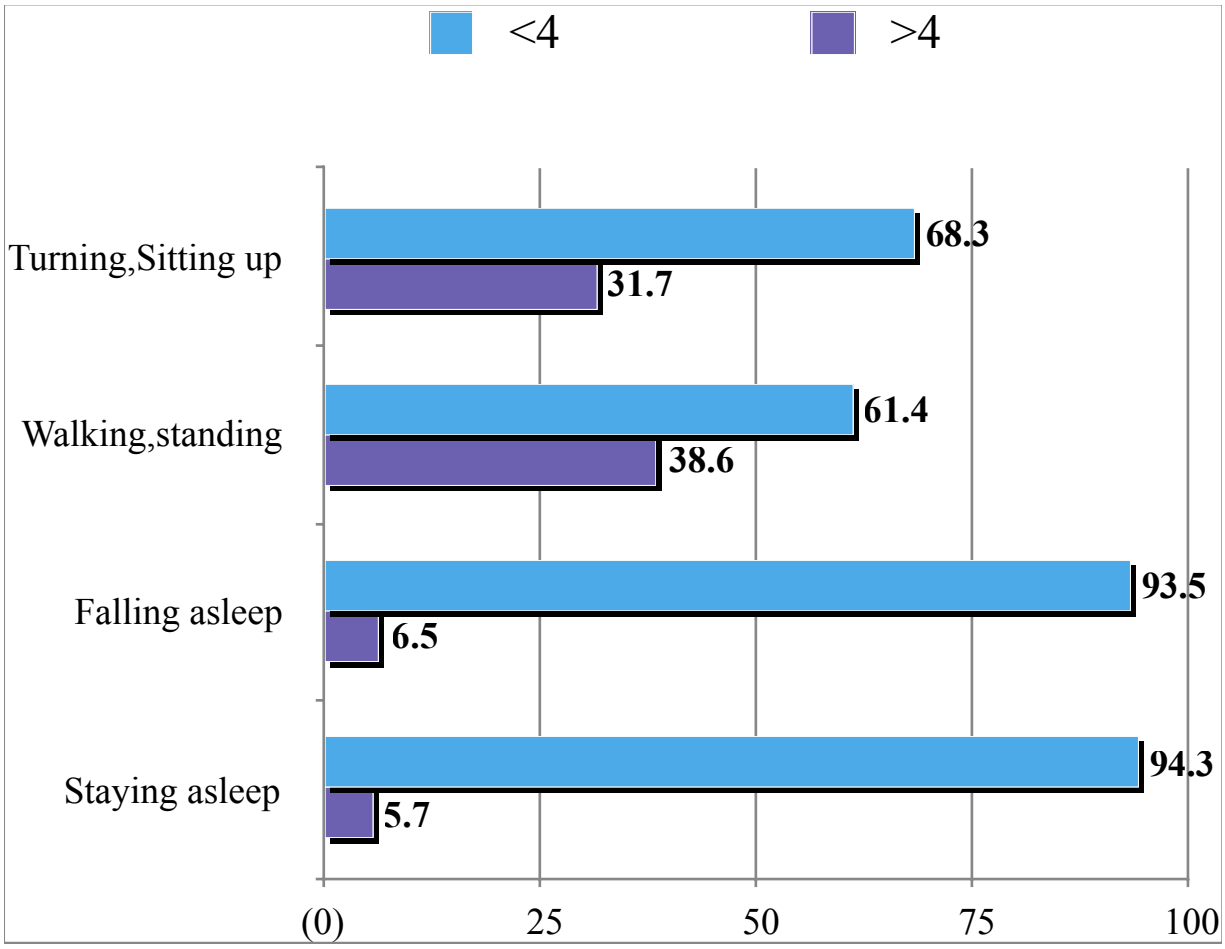

Figure 6 demonstrates distribution of limitation of function scores following CS. Majority (68.3%) reported scores below 4 for activities of daily living such as turning in bed and sitting up. 31.7% reported scores above 4 for aforementioned activities. Regarding falling and staying asleep, 93.5% and 94.3% respectively, reported limitation scores below 4.

Table 7:Association between limitation of function and pain scores during movement 72 hours post CS in patients at KNH

Activity	Pain >40 Mean (SD)	Pain <40 Mean (SD)	P value
Activity in bed	5.25(2.07)	3.30(1.82)	<0.001
Activity out of bed	6.03(1.97)	3.39(1.87)	<0.001
Falling asleep	2.22(2.34)	1.62(1.50)	0.12
Staying asleep	2.33(2.30)	1.08(1.23)	0.002

Table 7 shows the comparison between degree of limitation of performance of activities of daily living and pain scores. Participants who reported moderate-severe levels of pain had mean limitation functional scores of above 4 while those who reported mild pain levels had mean limitation functional scores of below 4 for performance of activities in and out of bed. All participants had mean limitation functional scores below 4 for both sleep activities regardless of the severity of pain experienced. P value of <0.05 was considered as statistically significant.

Objective 4: Satisfaction with post CS pain management in patients at Kenyatta National Hospital.

Figure 7: Frequency distribution of Status of satisfaction with pain management in post caesarean delivery patients at Kenyatta National Hospital (N=246)

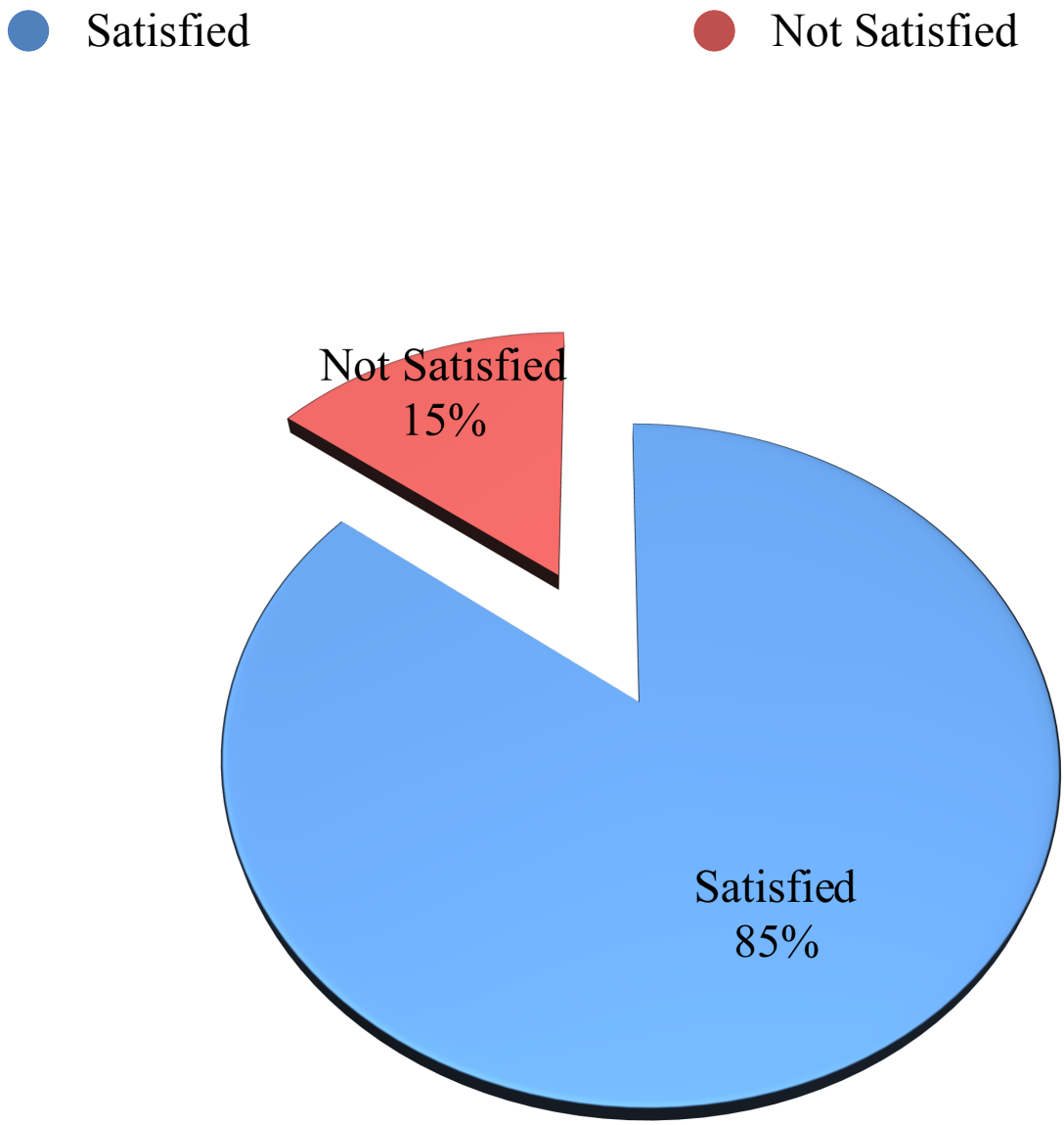

Figure 7 shows frequency distribution of satisfaction with pain management following CS. Generally, 85% were satisfied while 15% were not satisfied with the pain management. Regarding global pain management, 87.4% of the participants were satisfied while 12.6% were dissatisfied. Regarding staff behaviour related to post CS pain management, 88.2% were satisfied whereas 11.8% were dissatisfied.

Table 8:Association between satisfaction status and pain status(on movement) in post CS patients at KNH

Time interval	Satisfied	Not Satisfied	OR(95% CI)	P value
24 hours				
No pain	33(15.3)	2(6.5)	1.0	
Pain (yes)	182(84.7)	29(93.5)	0.38(0.09-1.67)	0.201
48 hours				
No pain	76(35.3)	6(19.4)	1.0	
Pain (yes)	139(64.7)	25(80.6)	0.44(0.17-1.12)	0.084
72 hours				
No pain	189(87.9)	17(54.8)	1.0	
Pain (yes)	26(12.1)	14(45.2)	0.17(0.07-0.38)	<0.001

Table 8 shows the comparison between satisfaction status and pain status categories i.e. those who reported pain scores equivalent to mild pain levels/no pain and those who reported scores that corresponded to moderate-severe levels of pain. On the first post operative day, 84.7% of those who had moderate-severe pain were satisfied compared to 15.3% of those who had mild pain whereas 93.5% of those who were in moderate-severe pain were dissatisfied with the pain management following CS compared to 6.5% who reported scores equivalent to mild pain levels. On the second post operative day, the outcomes were similar to those of day one post CS. On the day of discharge (72 hours post CS), 87.9% of those who were in mild pain were satisfied compared to 12.1% who were in moderate-severe pain. P value of <0.05 was considered as statistically significant.

9.0 DISCUSSION

Intermittent intramuscular administration of analgesics was the commonest mode of post CS pain treatment. This was prevalent despite the fact that it is bad practice which has been discouraged by several pain management bodies & associations.(31) This practice is not unique to Kenya, it has been demonstrated in regional studies as well. (12,43) On the other hand, this finding differed from other studies in the African region and outside Africa where most of the analgesics were prescribed in and administered through the IV (infusion) route. (42,52)

The dominant prescription pattern was scheduled while a few were on an as needed basis, similar to other related studies. (10,12,42,52)

Majority of the doctors practised multimodal analgesia prescription, a few prescribed dual analgesics (opioid & NSAID or opioid & acetaminophen), while a very small number practiced monotherapy prescriptions (co-analgesics only or opioid only).

During the study period, although in suboptimal doses, Morphine was the most prescribed opioid, through the intramuscular route. This is unlike related studies where weak opioids including Meperidine and Tramadol dominated the treatment charts. (9,42,52) This can be explained by the fact that the use of meperidine (pethidine) was phased out in KNH. There were varied opioid dosing schedules for both opioids for all characteristics including dose, route of administration, frequency and duration. Studies have shown that errors in opioid dosing are frequent in clinical management. (8)The commonest co-analgesic prescribed was acetaminophen through the oral, route also in contrast to aforementioned studies where NSAIDs (diclofenac) was the commonest co-analgesic prescribed. (12,42,52) Akin to opioids, the co-analgesic dosing schedule varied greatly.

Discrepancies between post CS analgesic prescriptions and their administration thereof were established. Less than a fifth of the commonest morphine dose prescribed was administered as per the prescription. About a quarter of all prescribed analgesics were not administered. This figure was higher than other related studies. (52) In addition, the modal frequency of administration was significantly less than the prescribed morphine frequency. Maximum prescribed doses of tramadol, diclofenac and acetaminophen were not administered either. These findings mimic those of Mark and Sachar et al, Murray et al, Kolawole et al study. (11,12,49) On the other hand a significant proportion of patients received diclofenac as per the prescription and almost all patients received acetaminophen (paracetamol) as prescribed. These findings can be explained by the fact that the

commonest mode of route of administration of prescribed morphine was intramuscular which is labor intensive and painful for the patient, as well as a small nurse-to-patient ratio; however, diclofenac and paracetamol were prescribed in less labor intensive routes of administration hence easier to administer. All the analgesics were prescribed and administered in suboptimal doses similar to other studies. (12,52)

Majority of the patients reported having pain following CS. Similar post operative pain incidence has been reported in other studies. (12,43,52) There was a high incidence of moderate-severe pain following caesarean section twenty hours post operatively, mirroring related global and regional studies. (7,10-12,42) A smaller number reported mild pain levels during the same time interval. There was a consistent increase and decrease in the number of participants reporting mild and severe pain levels respectively in the subsequent 48 hours post operatively. On the third post operative day, most of the participants experienced mild pain while few had moderate-severe pain. This finding falls short of the 2012 RCoA Audit Recipes recommendations where 100% of patients should reports VAS pain scores corresponding to mild pain levels or no pain.(25) The increasing percentage of patients with mild pain with time reflected the natural temporal reduction in intensity of acute pain; however, the presence of moderate-severe pain in some patients on day 3 post operatively could also be a result of the erratic administration patterns of post CS analgesia.

Assessment of functional outcomes reflects on the adequacy of pain control following CS. All the participants were able to fall and stay asleep with ease as confirmed by physical function limitation scores below 4 which corresponded to minimal interference of activity; this was regardless of the level of pain experienced. Regarding performance of activities in and out of bed, those who reported moderate-severe pain levels had significant limitation of function compared to those who reported pain scores corresponding to mild pain. This finding was statistically significant and mirrors that of a 2013 study done in Ethiopia. (52) The combination of assessment of satisfaction with pain scores reduces the chances of inattention to inadequately controlled post operative pain. (57) Generally, majority of the patients were satisfied with post CS pain management despite a large proportion reporting moderate to severe pain levels demonstrating a paradoxical relationship between levels of pain and satisfaction as seen in most studies. (9,10,12,42,52) High level of satisfaction vis a vis proportion of participants with moderate-to-severe pain can be attributed to other aspects of care including patients' expectations, good caring attitude of the healthcare professionals and an environment that fosters communication between the patients and caregivers This was observed in patients twenty four and forty eight hours post operatively. However, a proportional relationship

between satisfaction status and level of pain was observed on the third post operative day and this outcome was statistically significant. Those who were dissatisfied cited ineffectiveness of analgesics administered, late administration of requested rescue analgesics as well as clinicians overlooking requests for unscheduled analgesics and lack of administration of scheduled doses as reasons.

Multivariate analysis of secondary independent variables and severity of pain revealed differences in the pain scores between the groups, these differences were not statistically significant. This was similar to studies which showed that parity, age and type of CS do not influence the severity of pain reported in the post operative period.(10,70,71) This finding however, contrasts that of Solehati et al which demonstrated that primiparous women reported significantly higher pain scores compared to multiparous women.(71) Possible reasons for the difference in outcomes include differences in study design, sample size and study population.

CONCLUSION

- Based on the study's findings, the current practice of post-cesarean delivery pain management at Kenyatta National Hospital is not standardised.

- The study's findings highlighted the mismatch between the prescribed and actual administration of post CS pain medications, where prescription orders on less labor-intensive routes of administration were adhered to more.

- The practice of post CS pain management at Kenyatta National Hospital is inadequate both at rest and during movement, using the 2012 RCoA Audit Recipes as a gold standard. This is despite the fact that a significant percentage of patients were satisfied.

11.0 RECOMMENDATIONS

Based on the study's findings, the following recommendations were made;

- Standardisation of post CS pain management through implementation of a local protocol/guidelines.
- Sensitisation of healthcare providers on post CS pain management and care processes through avenues such as Continuous Medical Education sessions. This was inferred from unstandardised and erroneous dosing practice depicted in the study's results
- Investigation of barriers to adequate post CS pain management including adherence to

prescription orders.

- Efficacy or effectiveness trials on multimodal analgesia.

12. 0 STUDY TIMELINE

ACTIVITIES	Jan-Aug 2018	Sep 2018	Oct 2018	Nov 2018	Dec 2018	Jan 2019	Feb 2019	March April 2019	May 2019	June 2019
PROPOSAL DEVELOPMENT										
PRESENTATION & CORRECTIONS										
ETHICS										
DATA COLLECTION										
DATA COLLECTION & ANALYSIS										
RESULTS PRESENTATION										
SUBMISSION										

13.0 STUDY BUDGET

Components	Unit of measure	Duration or number	Unit cost (Kshs)	Total cost (Kshs)
Personnel				
Research assistants	**1 pax**	**32 days**	**1,500.00**	**48,000.00**
Statistician	-	**1**	**-**	**30,000.00**
Printing				
Consent form	**1 copy**	**10 pages**	**10.00**	**100.00**
Questionnaires	**1 copy**	**10 pages**	**10.00**	**100.00**
Final report	**1 copy**	**100 pages**	**10.00**	**1,000.00**
Eligibility Criteria	**1 copy**	**1 page**	**10.00**	**10.00**
Photocopying				
Consent form	**250 copies**	**5 pages**	**3.00**	**3,750.00**
Questionnaires	**250 copies**	**10 pages**	**3.00**	**7,500.00**
Eligibility Criteria	**1 page**	**250 copies**	**3.00**	**750.00**
Final report	**5 copies**	**100 pages**	**3.00**	**1,500.00**
Final report binding	**6 copies**	**1**	**500.00**	**3,000.00**
Miscellaneous				
ERC Fees	-	-	-	**2,000.00**
Poster printing	**1 copy**	**1**	**2,500.00**	**2,500.00**
Rulers (mm)	**3**	**1**	**50.00**	**150.00**
Box Files	**2**	**1**	**220.00**	**440.00**
Pens	**6**	**1**	**30.00**	**180.00**

Notebooks	**3**	**1**	**50.00**	**150.00**
TOTAL				**101,130.00**

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15.0 ANNEXES

Annex 1: Letter to ERC

Dr Kituku Joyce Mbithe

H58/80955/2015.

Date……..

The Chairperson,

Ethics, Research and Standards Committee,

Kenyatta National Hospital and University of Nairobi,

P.O. Box 20723,

NAIROBI

Thro'

The Dean,

College of Health Sciences

Thro'

The Chairperson,

Department of Obstetrics and Gynaecology

Dear Sir/Madam,

RE: SUBMISSION OF MASTERS DEGREE RESEARCH PROPOSAL FOR APPROVAL

I wish to submit my research proposal for approval by your committee. I am a second year student currently undertaking a Master's Degree in Obstetrics and Gynaecology at the University of Nairobi, College of Health Sciences.

Yours Sincerely,

Dr. Kituku Joyce Mbithe,

Department of Obstetrics and Gynecology,

College of Health Sciences,

University of Nairobi.

Annex 2: Patient Information and Consent for Enrolment in The Study

STUDY IDENTIFICATION NUMBER:……...DATE:____/____/2019

This informed consent form has two parts:

1. Consent explanation form (to inform you about the research)

2. Certificate of consent (for your signature if you agree to participate in the study)

PART I: PATIENT INFORMATION SHEET/CONSENT EXPLANATION FORM

TITLE OF THE STUDY: EVALUATION OF THE PRACTICE AND ADEQUACY OF CURRENT PAIN MANAGEMENT FOLLOWING CAESAREAN DELIVERY IN PATIENTS AT KENYATTA NATIONAL HOSPITAL BETWEEN MARCH AND MAY 2019

INVESTIGATOR'S STATEMENT:

My name is Dr Kituku Joyce Mbithe, a postgraduate student in the Department of Obstetrics & Gynaecology, College of Health Sciences at the University of Nairobi.

As part of my course work, I am conducting research on the practice and adequacy of the current pain management in patients undergoing cesarean section at Kenyatta National Hospital.

I would like to invite you to participate in this study. The aim of this consent form is to assist you in making a decision on whether to participate or not.

The research is guided by my supervisors, Professor Koigi Kamau & Dr Lydia Okutoyi and is funded from my own resources.

The KNH-UoN Ethics and Research Committee has approved the study as evidenced by the protocol number -**P773/11/2018**

A member of the research team (principal investigator/research assistant) will be present for any questions or clarifications that you may have.

The results of the study will be analysed and published in a peer reviewed journal and a copy will be availed to the College of Health Sciences Library and the Department of Obstetrics & Gynaecology, UoN.

Please read through this information carefully.

Thank you for choosing to participate in this study.

Brief description and purpose of the study

The aim of the study is to establish the type of drugs for pain control provided to mothers who deliver via cesarean section at Kenyatta National Hospital, and treatment outcomes. This will facilitate proper post operative pain care, improved mother and baby outcomes and reduction of short and long term risks associated with inadequate pain control.

Study procedure/ what will happen if you choose to take part in the study?

In the event that you decide to participate in this study you will be required to append your signature on the consent form. A copy of the completed form will be made and kept in your file. You will then respond to a series of questions in the questionnaire administered by the investigator or research assistant. These questions will entail personal information, information related to your medical, obstetric, and surgical history, interference of function, side effects experienced, if any, response of caregivers to pain requests made by you, and your satisfaction with post operative pain management. You will then be provided with a Visual Analogue Scale for rating your pain, which is a 0-10cm horizontal line in the questionnaire to make a vertical mark on it indicating the level of pain you will be experiencing at the time of the investigator's or research assistant's visit, at rest and on movement e.g coughing or walking to the toilet, for example. 0 means no pain and 10 means the worst possible pain you can imagine. These pain levels/intensities will be obtained on three consecutive days from the day of operation. Once filled, the questionnaire will be in the custody of the principal investigator.

Are there any risks/harm associated with this study?

There are no anticipated risks associated with this study. However you may be concerned about your privacy, and denial of treatment due to disclosure of pertinent information related to your pain

management. Utmost confidentiality will be maintained as outlined below and I want to assure you about your right to receive pain medication in case you report pain.

Are there any benefits associated with taking part in this study?

This study aims to establish the type of pain medication offered to you and extent to which it is effective. This will facilitate better care for you by enabling quick recovery and mobility; thus, immediate and optimal care for your newborn, and also avert risks such as development of clots within your blood vessels, and persistent pain in future. In case pain control is not effective, appropriate correspondence will be enabled among the relevant caregivers, in order to achieve adequate control.

What will happen to the information I provide?

The information you provide will be confidential. Anonymity shall be maintained by ensuring no names and hospital numbers are used, instead, each participant will be assigned a unique identification number. Only the principal investigator, research assistants and my supervisors will have access to the information provided, which will be kept under lock and key. Once the study is completed, results will be shared only to the relevant parties.

Will taking part in the study cost me anything?

This study will take a few minutes of your time for three consecutive days after the operation, while admitted in the postnatal ward. There will be no monetary costs on you.

What if I have questions in future?

For any queries or clarifications concerning the study, feel free to call or send a message to the contacts provided in the consent form.

You have a right as a research participant to contact the Ethics and Research Committee on the same. The contact person is **Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone number (254-020) 2726300 Extension 44102, P.O Box 19679-00202, Nairobi, email uonknh_erc@uonbi.ac.ke**. The research team will refund the costs you shall incur while making the phone call or for messages sent.

Right to decline/withdraw

Participation in the study is purely voluntary, therefore, you do not have to take part if you do not wish to. You may decide to withdraw from the study at any time. Refusal to participate or withdraw from the study will not influence your current management and all your rights will be safeguarded.

PART II: CONSENT FORM (STATEMENT OF CONSENT)

PARTICIPANT'S STATEMENT:

I have read this consent explanation form or it has been read out to me. I have understood the information outlined therein and explained to me by the principal investigator/research assistant. I have had an opportunity to ask questions that have been answered to my satisfaction. I understand that part of the information will be collected from my file and will be kept confidential. I understand that my name and hospital number will not be part of the information collected for the study, and therefore no information used will be traced back to me. I have agreed to take part in this study voluntarily and reckon that I can withdraw from the study at any time.

Participant's name:

Participant's Signature: ----------OR Thumb print_ _ _ _ _ _ _ _ _ _ _ _

Date: ----------

STATEMENT BY RESEARCHER/RESEARCH ASSISTANT

I have explained the relevant details of the study to the participant. I have given the participant an opportunity to ask questions relevant to the study, and I have answered correctly to the best of my abilities. I have confirmed the participant has given consent voluntarily.

Name of Researcher/research assistant: ----------

Signature: ----------

Date: ----------

Who to contact for more information;

For any questions or clarifications about the study, feel free to contact: Dr Kituku Joyce Mbithe, on mobile: 0738346651, email: **jyckituku@gmail.com** or at the Department of Obstetrics and Gynecology, University of Nairobi, or my supervisors listed below.

Professor Koigi Kamau (Superviser)

Obs / Gyn Consultant University of Nairobi

P.O. Box : 19676-00202

Nairobi

Tel:0722714402

Email: koigikamau@kenyaweb.com

Dr Okutoyi Lydia(Supervisor)

Obs / Gyn Consultant Kenyatta National Hospital

P.O. Box:19676-00202

Nairobi

Tel: 0721814381

Email: lydiakinyuru08@yahoo.com

Prof Mark L. Chindia,

Secretary, KNH-UoN ERC

P.O Box 19679-00202 Nairobi.

Tel: (254-020) 2726300-9, Email: uonknherc@uonbi.ac.ke

Annex 3: Ridhaa Ya Mafunzo Au Maelezo

Sehemu Ya Kwanza: Maelezo

Mada ya Utafiti: Tathmini ya mbinu (ikiwemo aina ya madawa) za kutibu maumivu kwa wagonjwa yanayotokana na kujifungua kupitia njia ya upasuaji, na matokeo yake katika hospitali kuu ya Kenyatta kutoka mwezi wa tatu hadi wa tano katika mwaka wa elfu mbili na kumi na tisa.

Mtafitii Mkuu: Daktari Kituku Joyce Mbithe, Mwanafunzi katika idara ya uzazi na magonjwa ya wanawake/njia ya uzazi.

Utangulizi

Daktari Joyce Mbithe Kituku ni mwanafunzi wa Chuo Kikuu cha Nairobi katika idara ya mafunzo ya uzazi na afya ya wanawake. Ninafanya uchunguzi kuhusu aina ya madawa yanayotumika kulegeza au kuondoa maumivu kwa wagonjwa wanaojifungua kupitia njia ya upasuaji na matokeo yake katika hospitali kuu ya Kenyatta.

Maudhui ya ridhaa hii ni kukupa maelezo utakayohitaji kutumia katika uamuzi wa kushiriki au kutoshiriki katika uchunguzi huu. Uwe huru kuuliza maswali yoyote yatakayohusu lengo la utafiti huu, nini kitakachotokea iwapo utashiriki katika utafiti huu, faida na hasara ya kushiriki, haki zako kama mshirika, na chochote kile ambacho hakieleweki vizuri. Baada ya maelezo utaamua kushiriki kwenye utafiti huu au kutoshiriki. Unakaribishwa kushiriki katika uchunguzi huu na unaweza kuchukua muda wowote unaohitaji kufanya uamuzi . kushiriki katika utafiti huu ni kwa hiari yako na sio kwa kushurutishwa. Kama kuna maswali yoyote au ufafanuzi utakaohitajika, kuwa huru kuwasiliana na mdadisi mkuu au manaibu wake.

LENGO LA UTAFITI/UTAFITI HUU UNAHUSU NINI?

Lengo la utafiti huu ni kuchunguza aina ya madawa yanayotumika kulegeza au kuondoa maumivu kwa wagonjwa wanaojifungua kupitia njia ya upasuaji na matokeo yake katika hospitali kuu ya Kenyatta. Utafiti huu una nia ya kuboresha matibabu ya wanawake wanaojifungua kwa njia ya upasuaji sana sana katika maswala ya kupunguza au kumaliza maumivu baada ya operesheni. Maumivu yanapokingwa au kupunguzwa mama anapona upesi hivyo basi anaweza kumnyonyesha mwanawe ipasavyo, kumtunza na kuwa karibu naye. Pia upungufu wa maumivu baada ya upasuaji unakinga madhara ya mwili kama kuganda kwa damu ya mama anayejifungua na hata kukinga madhara ya siku za usoni kama maumivu yasiyo

isha na unyogovu yaani ‘depression'. Washiriki katika utafiti huu wataulizwa maswali kuhusu miaka yao, kazi wanazofanya, dini, maswala ya uzazi kama nambari ya watoto au operesheni wakati wa kujifungua na kama kuumewuwa na matumizi ya dawa za kupunguza maumivu kwa muda mrefu. Zaidi ya hayo, jumbe kuhusu madawa yanayotumika wakati wa operesheni na baada ya operesheni, na huduma ambayo wagonjwa watapata kwa kijumla inayoangazia upungufu wa maumivu zitachukuliwa.

Tunaomba kujumuika kwako katika utafiti huu na idhini yako.

NI NINI KITAKACHOTOKEA UKISHIRIKI KWENYE UTAFITI HUU?

Iwapo utakubali kushiriki katika utafiti huu, utahitajika kuweka saini na tarehe katika idhini. Utapewa nakala ya idhini ili utie saini yako. Timu ya utafiti itakusanya ujumbe unaohitajika kutoka kwa rekodi zako za hospitali. Pia utahojiwa kuhusu maswala ambayo hayatapatikana katika rekodi zako na kiwango cha maumivu utakayohisi wakati wa mahojiano. Mahojiano yatafanyika kwenye chumba cha wagonjwa baada ya upasuaji. Utaendelea kupata huduma ya kawaida.

HASARA INAYOTARAJIWA

Utafiti huu hauna hasara yoyote. Taarifa itakayochukuliwa kutoka kwako itawekwa kisiri na kufungiwa pahali pa siri. Wakati wa mahojiano ndio utachukua muda wako wa dakika chache.

Hakuna utaratibu utakaofanywa mbali na huduma za kimsingi au za kawaida.

FAIDA INAYOTARAJIWA

Utafiti huu utakufaidi kwa namna hii; matibabu yanayolenga au kuangazia maswala ya upungufu wa maumivu kwa kutumia madawa baada ya kujifungua kwa njia ya operesheni yatachunguzwa, hivyo basi matokeo ya uchunguzi huu utanuia kuboresha matibabu ya akina mama wajawazito ili kusababpisha kupona kwa haraka na uleaji wa watoto wanaozaliwa kwa njia bora. Pia itasaidia idara husika kuboresha matumizi ya madawa ya kupunguza maumivu baada ya operesheni kwa akina mama kupitia kutengenezwa kwa itifaki au miongozo ambayo itawezesha kuwa na huduma sawa kwa wagonjwa wote.

USIRI

Ujumbe utakaochukuliwa kutoka kwako na kwa rekodi zako za hospitali utaonwa na kutumiwa na mtafiti mkuu na manaibu wake pamoja na wasimamizi na mtakwimu peke yake. Nambari yako ya hospitali au faili haitatumika ila nambari maalum itatumika kukutambulisha wewe kama mshiriki.

JE, KUSHIRIKI KWENYE UTAFITI HUU KUTAKUGHARIMU CHOCHOTE?

La, kushiriki kwako katika utafiti huu hautakugharimu chochote ila muda wako wakati wa mahojiano.

HAKI YA KUKATAA/ WAWEZA KUJIONDOA KWENYE UTAFITI?

Kukubali kushiriki au kuhusika kwenye utafiti huu ni kwa hiari ila sio kwa kushurutishwa. Una haki ya kukataa kushiriki kwenye utafiti huu. Ila utaendelea kupata matibabu ipasavyo bila ubaguzi.

SEHEMU YA PILI: MAKUBALIANO (IDHINI YA KUJUMUISHWA KWENYE UTAFITI)

Taarifa ya mshirika/mhusika.

Nimesoma na nikaelewa ujumbe ulionukuliwa hapo juu. Nimeelezwa kikamilifu kuhusu utafiti huu na nilipata nafasi ya kuuliza maswali yaliyojibiwa kikamilifu kupitia lugha ninayoielewa. Nimeelezwa kuhusu faida na hasara ya utafiti. Nimekubali kushiriki katika utafiti huu bila kulazimishwa ama kupewa hongo, na naweza kuamua au kuchagua kutoshiriki wakati wowote. Naelewa kwamba juhudi zote zitawekwa ili kuhakikisha usiri kuhusu habari yangu ya kibinafsi na ile itakayotoka kwa rekodi zangu za hospitali.

Nimekubali kushiriki kwenye utafiti : NDIO……HAPANA/LA……..

Jina la Mhusika:…… au Alama ya Kidole…….

Saini ya Mhusika: …….

Tarehe: ……..

Saini ya Shahidi: …….….

Tarehe: …….

Taarifa ya Mtafiti

Nimewaeleza wahusika kuhusu utafiti na nikawapa nafasi ya kuuliza maswali. Nimeyajibu maswali yote niwezavyo. Nimehakikisha kuwa wanaohusika wamekubali kwa hiari yao.

Jina la mdadisi/mtafiti: ……..……

Saini: ……..

Tarehe: ……

Mawasiliano zaidi

Kwa maswali yoyote au ufafanuzi wowote wasiliana na mtafitu mkuu: Daktari Kituku Joyce Mbithe, nambari ya simu: 0738346651, anwani ya barua pepe: jyckituku@gmail.com, au wasimamizi wangu kama walivyoorodheshwa hapa chini;

Professor Koigi Kamau (Msimamizi wa utafiti)

Sanduku la Posta: 19676-00202

Nairobi.

Nambari ya Simu: 0722714402

Barua pepe: koigikamau@kenyaweb.com

Dr Okutoyi Lydia (Msimamizi wa utafiti)

Sanduku la Posta: 19676-00202

Nairobi.

Nambari ya Simu: 0721814381

Barua Pepe: lydiakinyuru08@yahoo.com

Prof Mark L. Chindia,

Katibu, KNH-UoN ERC

Sanduku la Posta: 19676-00202

Nairobi.

Nambari ya simu: (254-020)2726300-9

Barua Pepe: uonknh_erc@uonbi.ac.ke

Annex 4: Data Abstraction Tool

Eligibility Criteria Checklist

Eligibility requirements	Tick if satisfactory
Caesarean mode of delivery	
No complications causing reduction of level of consciousness including PPH, sepsis	
No known neurological or psychiatric disorder	
Baby was stillborn and is willing to participate in the study	
No chronic opioid use	
File available with relevant data sources	

Structured Questionnaire/Data extraction form-adopted in part (and modified) from 'Pain Audit Tools', 'The Controlling Pain Vignettes Survey' by City of Hope Medical Centre and the APS-POQ(American Pain Society Patient Outcome Questionnaire)

We value your comfort and appreciate your voluntary participation in this study aimed at improving post cesarean section pain relief services. Your responses will remain confidential.

Annex 5: Study Questionnaire

EVALUATION OF THE PRACTICE AND ADEQUACY OF CURRENT PAIN MANAGEMENT FOLLOWING CAESAREAN DELIVERY IN PATIENTS AT KENYATTA NATIONAL HOSPITAL BETWEEN MARCH AND MAY 2019: A DESCRIPTIVE COHORT STUDY

Date…….. Identification number……

SECTION A: PATIENT DATA

PART I: BIODATA AND SOCIO-DEMOGRAPHIC CHARACTERISTICS

1. Age in (completed) years……..Y.O.B…….

2. Marital status

[ ]Single [ ]Married [ ]Separated [ ]Divorced [ ]Widowed

3. Religion

[ ]Christian [ ]Muslim [ ]Others (specify)……..

4. Nationality……

5. Residence…….

6. Occupation……...

7. Parity……

8. How many cesarean sections have you undergone?…….

[ ] 1 [ ] >1

a) If yes to above question, what was the indication(s)…….

[ ] Maternal (specify)……

[ ] Fetal (specify)……..

[ ] Feto-maternal (specify e.g CPD)……..

b) What type of CS did you undergo?

[ ] Emergency [ ] Elective

c) What was the indication for the current CS…….

9. Are you on any longterm pain medication?

[ ] Yes [ ] No

If yes,

a) which one(s)……..b)Diagnosis……...

c) Duration of intake…….

10. Peri-operative Data

a) Type of anaesthesia

[ ] General [ ] Neuraxial (spinal/epidural) [ ] TAP block/local infiltrative techniques

[ ] Other (specify)……..

b) Indicate the time of discharge from post anaesthetic care unit to initiation of post operative analgesia (hours)……..

c) Type of skin incision

[ ] Pfannenstiel [ ] Joel Cohen [ ] Sub umbilical midline incision [ ] Not documented

d) Uterus handling during repair

[ ] Exteriorised [ ] Repaired in situ [ ] Not documented

e) Handling of peritoneum

[ ] Closed [ ] Not closed [ ] Not documented

PART II: ANALGESIC DRUGS AND THEIR DOSING SCHEDULE

a) Analgesics administered intra-operatively(indicate the drug given)…….

b) Post operative prescription of Opioids (**put an X sign where not administered**)

DRUG	Tick appropriately		DOSE (mg)	FREQUENCY (tick appropriately)					ROUTE OF ADMINISTRATION (tick appropriately)					DAYS PRESCRIBED (tick appropriately)		
	Prescribed	Administered		OD	BID	TID	QID	PRN	PR	IM	PO	IV	SC	DAY1	DAY2	DAY3
Morphine																
Meperidine (pethidine)																
Tramadol																
Others(specify)																
None prescribed																

c) Post operative prescription of Co-analgesia(**put an X where not administered**)

DRUG	Tick appropriately		DOSE (mg/g)	FREQUENCY (tick appropriately)					ROUTE OF ADMINISTRATION (tick appropriately)					DAYS PRESCRIBED (tick appropriately)		
	Prescribed	Administered														
NSAIDS				OD	BID	TID	QID	PRN	PR	IM	PO	IV	SC	DAY1	DAY2	DAY3
*Diclofenac																
*Ketorolac																
*Others(specify)																
Acetaminophen																
NSAID+ Acetaminophen																
None prescribed																

KEY:

PR =per rectal PO=Per oral. OD=Once daily IM=Intramuscular

IV=Intravenous SC=Subcutaneous. TID=8 hourly BID=12 hourly QDS/QID=6 hourly

d) Rescue analgesia

i) Do you request for pain medication when you experience pain in between the scheduled analgesic doses?

[ ] Yes [ ] No

ii) If no to above, state the reason(s)

[ ] Complaining could distract the doctor/nurse from the general management of my condition

[ ] Good patients avoid complaining or reporting about pain

[ ] It is easier to put up with pain than with the side effects associated with the medication

[ ] I could get addicted to pain medication

[ ] Others (specify)..……

iii)If yes to above,

* Indicate time taken to obtain the rescue analgesia

[ ] <5 min [ ] 5-15 min [ ] 15-30 min [ ] 30-60 min [ ] >60 min

[ ] Asked, never received

* Indicate the drug offered

[ ] Morphine [ ] Meperidine (pethidine) [ ] Tramadol [ ] Acetaminophen (paracetamol)

[ ] Others (specify)……..

PART III: PAIN SCORES

On the Visual Analogue Scale provided below, make a vertical line on it indicating the level of pain you are experiencing, where 0 is 'no pain at all' and 10cm is 'the worst possible pain'.

a) Any pre existing pain before the cesarean section?

[ ] Present [ ] Not present

If present, indicate the intensity on the scale provided below.

---

0 1 2 3 4 5 6 7 8 9 10

No pain **Worst pain possible**

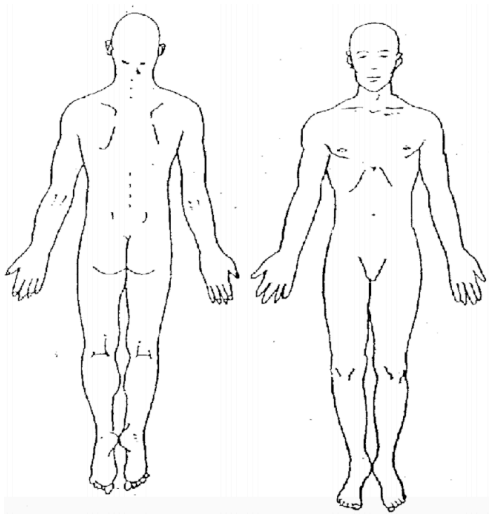
Equivalent score in cm when correlated with a ruler with millimetre markings=

b) Are you in pain now?

[ ] Yes

[ ] No

If yes, please indicate where the pain is felt on the body outline provided below;



If yes, please indicate your worst pain level at this point in time- **24 hours after surgery**

i) Pain intensity at rest

---

0 1 2 3 4 5 6 7 8 9 10

No pain **Worst pain possible**

Equivalent score in cm when correlated with a ruler with millimetre markings=

ii) Pain intensity on movement (e.g walking to the bathroom)

---

0 1 2 3 4 5 6 7 8 9 10

No pain **Worst pain possible**

Equivalent score in cm when correlated with a ruler with millimetre markings=

c) Please indicate your worst pain level at this point in time- **48 hours after surgery**

i) Pain intensity at rest

---

0 1 2 3 4 5 6 7 8 9 10

No pain **Worst pain possible**

Equivalent score in cm when correlated with a ruler with millimetre markings=

ii) Pain intensity on movement (e.g walking to the bathroom)

0 1 2 3 4 5 6 7 8 9 10

No pain **Worst pain possible**

Equivalent score in cm when correlated with a ruler with millimetre markings=

d) Please indicate your worst pain level at this point in time- **72 hours after surgery**

i) Pain intensity at rest

0 1 2 3 4 5 6 7 8 9 10

No pain **Worst pain possible**

Equivalent score in cm when correlated with a ruler with millimetre markings=

ii) Pain intensity on movement (e.g walking to the bathroom)

0 1 2 3 4 5 6 7 8 9 10

No pain **Worst pain possible**

Equivalent score in cm when correlated with a ruler with millimetre markings

PART IV: LIMITATION OF FUNCTION (adopted from APS-POQ)

Tick the box below that best describes how much pain interfered or prevented you from;

a) Doing activities in bed such as turning, sitting up, repositioning

0 1 2 3 4 5 6 7 8 9 10

Does not interfere **Completely interferes**

b) Doing activities out of bed such as walking, sitting in a chair, standing at the sink

0 1 2 3 4 5 6 7 8 9 10

Does not interfere **Completely interferes**

c) Falling asleep

0 1 2 3 4 5 6 7 8 9 10

Does not interfere **Completely interferes**

d) staying asleep (you wake up earlier than your usual time)

0 1 2 3 4 5 6 7 8 9 10

Does not interfere **Completely interferes**

PART V: PATIENT SATISFACTION (to be asked on day 3 post operatively)

Circle the number that best correlates with your level of satisfaction with the pain management you have received while in the hospital

a) Satisfaction with global pain management

[ ] Satisfied [ ] Not satisfied

b) Satisfaction with the staff behaviour concerning post operative pain treatment

[ ] Satisfied [ ] Not satisfied

What are your reasons, if not satisfied? (114,115)

[ ] Analgesic injections (medication) not given.

[ ] Analgesic injections not given promptly when requested.

[ ] Analgesic injections given promptly but not very effective.

[ ] Did not want injections.

[ ] Other (specify)…….

PART VI: EVALUATION OF PAIN-to be confirmed in the kardex/nursing care plan or doctors' notes (tick where appropriate)

a) Documentation (at least one written evaluation in the post natal ward)

[ ] Present [ ] Not present

b) If a) is present,

i) Indicate the evaluator

[ ] Doctor [ ] Nurse [ ] Both doctor & nurse evaluated

ii) Indicate the frequency of evaluation or time between evaluations (in hours)

[ ] [ ] [ ] [ ]

iii) Indicate the evaluation tool used

[ ] Visual analog scale [ ] Numerical scale [ ] Verbal rating scale [ ] Non-numerical tool e.g FACES rating scale [ ] None

THANK YOU VERY MUCH FOR PARTICIPATING IN THIS STUDY

Annex 6: KNH-UoN ERC Approval

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
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KENYATTA NATIONAL HOSPITAL * APPROVED 08 MAR 2019 KNH/UoN-ERC * P. O. BOX 20723 - 00202 NAIROBI *

Ref: KNH-ERC/A/85

8th March, 2019

Dr. Kituku Joyce Mbithe
Reg. No.H58/80955/2015
Dept. of Obs/Gynae
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Mbithe

RESEARCH PROPOSAL: EVALUATION OF THE CURRENT PRACTICE AND OUTCOMES OF POST CAESAREAN DELIVERY PAIN MANAGEMENT IN PATIENTS AT KENYATTA NATIONAL HOSPITAL; A DESCRIPTIVE COHORT STUDY (P773/11/2018)

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 8th March 2019 – 7th March 2020.

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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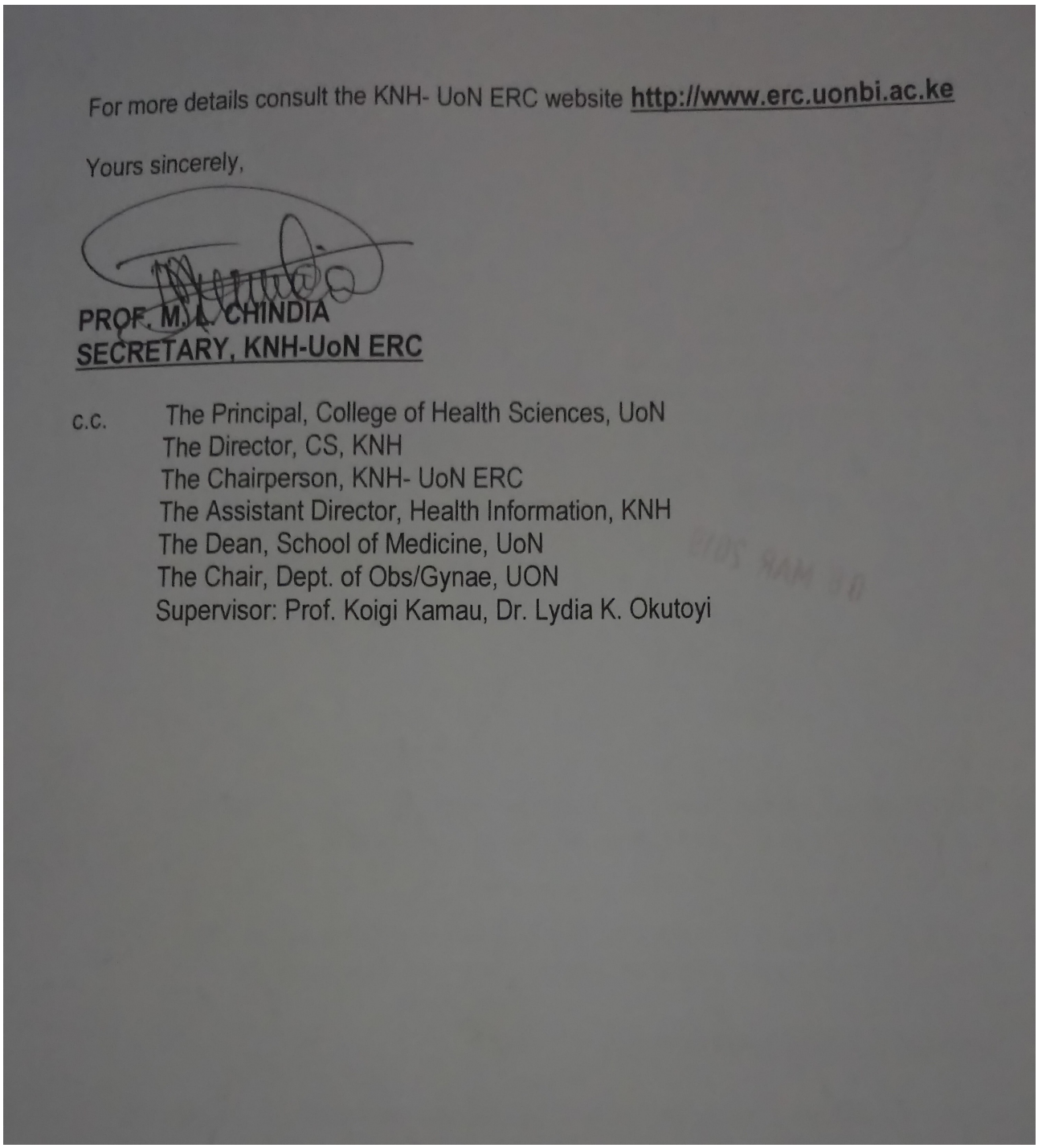
Annex 6: KNH-UoN ERC Approval



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

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Obs/Gynae, UON
Supervisor: Prof. Koigi Kamau, Dr. Lydia K. Okutoyi

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Annex 7: Certificate of Good Clinical Practice-CITI Program

CITI PROGRAM

Completion Date 04-Apr-2016
Expiration Date 04-Apr-2019
Record ID 19159972

This is to certify that:

Joyce Kituku

Has completed the following CITI Program course:

Biomedical Research - Basic/Refresher (Curriculum Group)
Biomedical Research - Basic/Refresher (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

University of Nairobi

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wdb1e376d-d86c-4aac-8fc1-2e6891a25848-19159972

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