

**EFFICACY OF POST-OPERATIVE ANALGESIA PRACTICES FOR SHORT STAY  
OPEN PAEDIATRIC INGUINAL HERNIA REPAIR AT KENYATTA NATIONAL  
HOSPITAL**

**2015**

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OPEN PAEDIATRIC INGUINAL HERNIA REPAIR AT KENYATTA NATIONAL  
HOSPITAL**

A dissertation submitted as part fulfillment of the requirements, for the award of Master of  
Medicine In General Surgery at The University of Nairobi

By

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MBChB(UoN)

2015

## **STUDENT'S DECLARATION**

I hereby declare that this dissertation proposal is my original work and has not been presented in any other university or institution.

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## **DEDICATION**

To my wife Catherine, my children Mark, Ethan and Joe for their patience and encouragement.

To my parents, Solomon and Lydia Mutungi for their overwhelming love and support.

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## **ABBREVIATIONS & ACRONYMS**

**ASA** - American Society of Anesthesiologists

**CHEOPS** – Children’s Hospital of Eastern Ontario Pain Scale

**CNS** – Central Nervous System

**FLACC** - Face, Legs, Activity, Cry, Consolability Scale

**KNH** – Kenyatta National Hospital

**LA** – Local Anesthetic

**NIPS** – Neonatal Infant Pain Scale

**NSAID** – Non-steroidal Anti-inflammatory Drugs

**PPPM** – Parents Postoperative Pain Measure

**UON** – University of Nairobi

**UoN/KNH-ERC** – University of Nairobi/Kenyatta National Hospital Ethics and Research  
Committee

**VAS** – Visual Analog Score

**WHO** – World Health Organization

## **ABSTRACT**

### **Background:**

The paediatric population is at risk of inadequate post-operative pain management due to physiological, psychological, age related factors and poor understanding that exists. Inguinal hernia surgery is among the commonest short stay procedures performed in the paediatric surgical unit at Kenyatta National Hospital (KNH). Currently, no published data exists on adequacy of post-operative pain control and relief following elective short stay open paediatric inguinal hernia repair at KNH.

### **Objective:**

To evaluate the effectiveness of post-operative pain management following elective short stay open inguinal hernia repair in children at KNH.

### **Study design:**

Descriptive prospective study

### **Study population:**

The study included 91 children aged 3 months to 12 years with unilateral inguinal hernias admitted for open elective short stay surgery at the paediatric surgical unit of Kenyatta National Hospital between November 2014 and April 2015.

Selection was by consecutive sampling until the desired sample size was achieved.

### **Methodology:**

Details on type of inguinal hernia, analgesic medications prescribed, and whether dosage given was adequate for weight for children who underwent elective short stay open inguinal hernia repair was recorded. Pain was assessed, using age appropriate scales, on return to the ward after surgery and on the morning of discharge from hospital. The parents were then interviewed by telephone regarding their child's post-operative pain management at home. The interview

comprised the parents' assessment of the child's pain using the Parents Postoperative Pain Measure and an assessment of compliance to prescribed analgesics at home. Data was collected using pre-tested questionnaires, and then entered into an access database. Data analysis was done using SPSS version 22.

## **Results**

The 91 children had a mean age of 3.3 years, with a male to female ratio of 5:1. The most commonly administered group of analgesics intra-operatively was paracetamol and local or regional anaesthetics, which were given to 62 children (68.1%). Intra-operative analgesics were given in the correct dose in 93% of the patients. On arrival to the ward, 74 children (81.4%) reported pain (mild, moderate, or severe). On the morning of the first post-operative day, before discharge, 50 children (55.1%) reported pain. The pain before discharge, from the ward, was not associated with type of post-operative analgesic administered. However there was an association with type of hernia, pulse rate and age of the patient. Twenty nine parents (31.9%) reported 'significant' pain experienced by their children 48 hours after discharge during a telephone interview. Twenty two children (24.2%) were not discharged on any analgesics. Only 40% of patients reported to have received instructions on administration of analgesics at home, from a health worker in the ward, before discharge. Paracetamol was the most prescribed discharge analgesic at 48.4% and it was given in the correct frequency on the two days post-discharge, by only 45% of the parents interviewed.

## **Conclusion:**

The current post-operative analgesia practices for elective short stay paediatric inguinal hernia repair are inadequate at the Kenyatta National Hospital. Improvement in post-operative pain management requires interventions to mitigate current barriers to effective post-operative pain management.

## INTRODUCTION

Post-operative pain may be described as an experience of unpleasant sensory, mental and emotional feelings precipitated by surgical trauma. It manifests with discomfort characterized by behavioral, autonomic and emotional responses which affect the particular part of the body affected with variable extension and involvement of the body of the individual<sup>1</sup>.

It is now known that the nervous system is sufficiently developed to process painful stimuli before birth, and consequently, children should experience pain from birth onward<sup>2</sup>.

The impact of painful experience on the young nervous system is so significant that long-term effects can occur, including a lowered pain threshold for months after a pain-producing event<sup>3</sup>.

Inadequate treatment of pain in children cannot be justified by the lack of easy communication, and certainly not with older children and adolescents<sup>4</sup>. Studies done at the Kenyatta National Hospital (KNH) and elsewhere have shown deficiencies in pain evaluation and treatment are often reported, among health care workers. Ocitti reported that medical staff at KNH prescribed and administered analgesia without considering the patient's post-operative pain response after abdominal and thoracic operations in adult patients. This may result from ignorance of need for adequate pain relief, poor prescription practices, failure to adhere to the prescription and fear of known or imagined adverse effects of drugs used<sup>5, 6 & 7</sup>.

Short stay surgery at KNH entails admission to hospital on the day prior to the surgery, then discharge on the following morning after surgery (1<sup>st</sup> post-operative day). Following short stay surgery, the child's parents or care givers are required and expected to assess and continue administering analgesics to their children at home. Evidence indicates that parents or care givers

tend to administer insufficient doses of analgesia after day surgery. This may be due to misconceptions that the less often analgesics are used the more effective they become, or that the use of analgesic medication by their children predisposes to addiction. Parents may also lack knowledge on how to give the medications due to poor communication from health care providers<sup>8,9</sup>.

The diverse reasons of inadequate treatment of paediatric pain should be understood and provide the basis for professional and parental education, and system changes, that are required to yield to best practices in paediatric post-operative pain control.

Over the past two decades, pain assessment and management in children has greatly improved due to better understanding of pain and development of age-specific pain assessment tools. There has also been a better understanding of the role of adequate analgesia in this population. .

The greatest advance in paediatric pain medicine is the recognition that inadequate pain treatment is a significant cause of morbidity and even mortality after surgical trauma. Therefore adequate post-operative pain control improves psychological, functional recovery as well as enhancing the child and family satisfaction<sup>10</sup>.

## **RESEARCH QUESTION**

Currently, no published data exists on post-operative analgesic practices for elective short stay open inguinal hernia surgery performed in children at KNH. The effectiveness of the analgesic practices used in the hospital and during recovery at home remains largely unknown. The study aimed to elaborate:

- What are the current prescribing practices for analgesics used following short stay surgery for inguinal hernia in children?
- Are the prescribing practices in line with the international recommendations for pediatric post-operative pain control?
- How effective is post-operative pain control following short stay inguinal hernia repair in children?



## LITERATURE REVIEW

Over 20 years ago, a survey reported that 40% of pediatric surgical patients experienced moderate or severe post-operative pain and that 75% had insufficient analgesia<sup>11</sup>. Ocitti, in a study on post-operative pain in adults following major abdominal and thoracic operations at KNH reported 60% of patients had inadequate pain relief 72 hours after surgery<sup>7</sup>.

These findings have prompted development of safe and effective analgesic techniques for management of post-operative pain in children. A pragmatic, practical approach to pediatric post-operative pain management has been developed and used in recent years in most paediatric centers. Realistic aims are to recognize pain in children, to minimize moderate and severe pain safely in all children, to prevent pain where it is predictable, to bring pain rapidly under control and to continue pain control after discharge from hospital<sup>12, 13</sup>.

The guidelines for post-operative pain management in children by the Association of Paediatric Anesthetists (APA) require that post-operative analgesia should be planned and begin prior to the surgical procedure. The analgesics should be given as per the child's age and type of surgical procedure. Post-operative care providers should have knowledge on pain assessment techniques and discuss with patients and their guardians to ensure pain is assessed and suitable ongoing analgesia administered<sup>14</sup>.

Effective and appropriate peri-operative pain management requires a proactive approach using a variety of treatment modalities to obtain an optimal outcome with respect to facilitating rapid recovery. Multimodal analgesia is achieved by combining different analgesics that act by different mechanisms and at different sites in the nervous system, resulting in additive or

synergistic analgesia with lowered adverse effects of sole administration of individual analgesics<sup>15</sup>.

Prevention of pain whenever possible, using multi-modal analgesia, has been shown to work well for nearly all cases and can be adapted for day cases or short stay surgery. Ondieki in a study at KNH showed that a multimodal analgesic protocol of an opioid and NSAID was more effective than the more commonly practiced unimodal approach of an opioid only for post-operative analgesia after major abdominal surgery<sup>16</sup>.

Many acute pain protocols use techniques of concurrent or co-analgesia based on four classes of analgesics, namely local anesthetics, opioids, non-steroidal anti-inflammatory drugs (NSAIDs), and paracetamol<sup>17, 18</sup>. In particular, a local/regional analgesic technique should be used in all cases unless there is a specific reason not to. The opioid-sparing effects of local anesthetics, NSAIDs, and paracetamol are useful. Indeed, for many day-case procedures, opioids may be omitted because combinations of the other three classes provide good pain control in most cases<sup>19</sup>. Adjuvant regional anesthesia is nearly always conducted in anaesthetized children. In addition, some high risk neonates have lower peri-operative morbidity after inguinal surgery when awake spinal anesthesia is used<sup>20, 21</sup>.

Substantial improvement is possible by the establishment of clinical routines and protocols for the assessment and treatment of paediatric post-operative pain. A well-structured protocol for post-operative analgesia with clear instructions for parents is essential following paediatric day-case surgery<sup>22</sup>.

## **Pain Assessment in Infants and Children**

Because children have a limited range of experience and may be unable to use words that adequately express their discomfort, determining just how much pain a child is experiencing can be difficult and involves the use of age appropriate scales. There is no empirical evidence demonstrating the superiority of one assessment tool, but it is recommended that the same scale(s) should be used within an institution<sup>23, 24</sup>. The particular tool chosen is insignificant as long as it is used consistently and applied to the right population<sup>25</sup>.

Behavioral Observational Scales is the primary method of pain assessment for infants, children less than 3 years old<sup>26,27</sup>. The context of distress these behaviors should however be carefully considered. Validated tools include:

1. CRIES: Assesses crying, oxygen requirement, increased vital signs, facial expression, sleep. An observer provides a score of 0-2 for each parameter based on changes from baseline. For example, a grimace, the facial expression most often associated with pain, gains a score of 1 but if associated with a grunt will be scored a 2. The scale is useful for neonatal post-operative pain.

2. NIPS: Neonatal/Infants Pain Scale has been used mostly in infants less than 1 year of age. Facial expression, cry, breathing pattern, arms, legs, and state of arousal are observed for 1 minute intervals before, during, and after a procedure and a numeric score is assigned to each. A score >3 indicates pain.

3. FLACC: Face, Legs, Activity, Crying, Consolability scale has been validated from 2 months to 7 years. It is a simple consistent method of pain assessment in non-verbal or preverbal children. The acronym FLACC (Face, Legs, Activity, Cry and Consolability) facilitates recall of

the categories, each of which is scored from 0-2 with total scores ranging 0-10 similar to other clinical assessment tools. The reliability and validity of this tool has been established in diverse settings and in different populations.

4. CHEOPS: Children's Hospital of Eastern Ontario Scale is validated for children between one and seven years old. It assesses cry, facial expression, verbalization, torso movement, if child touches affected site, and position of legs. A score  $\geq 4$  signifies pain.

Pain is a subjective experience. Self-report measures, therefore, most accurately reflect pain. Self-report is used for children 3 years of age and older who can rank their pain using one of several validated scales<sup>27</sup>. They are divided into faces pain scales for younger children and numerical scales for older children. They include:

### **Faces pain scales**

1. Wong-Baker Faces scale: 6 cartoon faces showing increasing degrees of distress. Face 0 signifies "no hurt" and face 5 the "worst hurt you can imagine." The child chooses the face that best describes pain at the time of assessment.

2. Biering-Modified: Six faces starting from a neutral state and progressing to tears/crying. It is scored 0-10 by the child and used for children above 3 years of age.

### **Numerical pain scales**

3. Visual Analogue Scale (VAS): Uses a 10 cm line with one end marked as no pain and the opposite end marked as the worst pain. The child is asked to make a mark on that line that is then measured in cm from the no pain end.

A Parents Postoperative Pain Measure (PPPM) is a behavioral pain scale which has been validated for children aged upto 12 years. It is an objective report by the parent on their child's pain following surgery. Parents record the presence or absence of each of fifteen (15) behavioral indicators of pain. The score provides a reliable pain assessment. The PPPM has a cut off score of 6, which indicates that the child has significant pain<sup>28</sup>.

Variations in physiological parameters which include heart rate, blood pressure, oxygen saturation and breathing patterns (frequency and irregularity) are frequently used as indicators of pain. Pain causes heart rate and blood pressure to rise, oxygen saturation to decrease and breathing to become more rapid, shallow or irregular. A limitation of physiological indicators is that variations might also be caused by the underlying illness, making them less specific for pain. Increases in heart rate due to acute pain might be short lasting and therefore often remain undetected<sup>29</sup>.

### **Pain relief during and after short stay surgery**

Short stay surgery demands highly efficient pain management, both in the hospital and at home<sup>30</sup>.

Empirical research on non-pharmacologic postsurgical paediatric pain management is sparse, and most of the studies that do focus on non-pharmacologic strategies are anecdotal reports or methodologically flawed<sup>31</sup>. Non-pharmacologic approaches for the treatment of pain in children include psychological strategies, education and parental support. Simple distraction techniques that divert attention away from painful stimuli, or positive incentive techniques which provide a small reward (e.g., stickers or prizes) for attempts at mastery of their responses, can be effective for children undergoing occasional and short procedures. Good contact between the doctor, child

and parent during a pre-operative visit is encouraged. The surgical procedure should be explained in a manner that the child can understand. The parents' fears and misconceptions should also be addressed by honest and clear explanations. The concept of day or short stay surgery also allows the children to recover in their home environment. These techniques are designed to decrease anxiety, but are not adequate as the sole means of pain relief for most pain episodes<sup>32, 33</sup>.

The mainstay of providing analgesia for short stay surgery patients is the extensive use of multimodal analgesia which involves the use of adjuvant regional/ Local Anesthetic (LA) techniques and administration of opioids, NSAIDs and paracetamol<sup>34</sup>.

Pre-emptive analgesia is medication that is initiated before and is active during the surgical procedure in order to reduce sensitization of the nociceptive pathways provoked by surgery. Due to this 'protective' effect on the nociceptive pathway, pre-emptive analgesia may reduce immediate postoperative pain experienced by the patient. Unless contraindicated, a NSAID or paracetamol should be given orally preoperatively or as a suppository under General Anesthesia (GA), before surgery begins.

Wound infiltration with local anesthetic and peripheral nerve blocks are highly effective in the treatment of pain after inguinal surgery in children. However, adjuvant regional anesthesia should be supplemented with an analgesic to ensure continuing pain relief, during the post-operative period<sup>35</sup>. Oral analgesics are the mainstay of continuing pain control at home and it is important to encourage short stay surgery patients to take analgesics preemptively and regularly, starting before the effect of the local anesthetic has worn off<sup>36</sup>.

Simple analgesics such as paracetamol may be sufficient for mild pain. Patients with mild to moderate pain may benefit from combinations of NSAIDs and paracetamol in addition to regional or local anesthesia. Weak oral opioids may be added for severe pain. Patient response to drugs varies, so rescue analgesia for post-operative pain beyond acceptable levels may be needed. Strong opioids are generally avoided in short stay surgery because of their known side effects, including the risk of respiratory depression<sup>37</sup>.

When treating pain in infants it is important to understand that although most of the major organ systems are anatomically well developed at birth, their functional maturity is often delayed. Most analgesics are excreted through the liver or kidney. During the first months of life in both preterm and full-term newborns, these systems rapidly mature, most approaching a functional level similar to adults before 3 months of age. Newborns, and especially premature infants, have diminished ventilatory responses to hypoxemia and hypercarbia<sup>38,39</sup>. These ventilatory responses can be further impaired by Central Nervous System (CNS) depressant drugs such as opioids and benzodiazepines. Whereas monitoring for dosage related adverse effects may be possible for admitted patients, this is a challenge for short stay patients, given that the drugs are administered at home by non-medical personnel who may not notice these effects. Therefore there must be a balance between types and dosages of pharmacological agents used in short stay surgery in the paediatric population and effective pain control.

The guidelines on acute peri-operative pain management of 1992 and 1995 appear to have had little influence on practice patterns or on improved pain control for patients. A retrospective chart review to measure the degree of compliance to post-operative pain protocol by Ceelie et al

concluded that full compliance to the protocol was marginal, possibly leading to inadequate treatment of pain<sup>40</sup>.

Post-operative pain, especially when poorly controlled or under-treated, may produce a range of detrimental acute and chronic effects. The pathophysiology of acute pain includes changes in the neuro-endocrine, respiratory, renal function, gastrointestinal activity, circulatory and autonomic nervous system activity<sup>41, 42</sup>. Good pain control after surgery is important to prevent negative outcomes such as tachycardia, hypertension, myocardial ischemia, decrease in alveolar ventilation, immobility, deep venous thrombosis, sleep disturbance and poor wound healing<sup>43</sup>.



## **STUDY JUSTIFICATION**

Effective post-operative pain management is a key component of comfortable and uncomplicated healing. This requires establishment and adherence to a protocol that effectively addresses pain management in the post-operative period. Effectiveness of a protocol can be determined by scaling against desired outcome of no pain or tolerable pain for the patient. Similarly, adherence to a protocol can be enforced through evaluation of existing practices against set guidelines.

At present, no literature or protocol exists regarding pain management following short stay open paediatric inguinal hernia repair at KNH. The results of this study will be used to make recommendations towards developing an effective postoperative analgesia protocol. Such a protocol could be adapted for post-operative pain management in other pediatric surgical patients.

## **RESEARCH HYPOTHESIS**

Post-operative pain control for short stay inguinal hernia repair in children at K.N.H is not optimal.

## **OBJECTIVES**

### **Main objective:**

To evaluate the effectiveness of post-operative pain management following elective short stay open inguinal hernia repair in children aged between 3 months and 12 years at K.N.H.

### **Specific Objectives:**

1. To document the analgesic medications used and whether the correct dose for weight is prescribed in children following elective short stay inguinal hernia repair at K.N.H.
2. To determine the level of pain control achieved by the analgesics used in the hospital and post discharge at home.
3. To determine the level of compliance to the prescribed analgesics by parents/guardian after discharge.
4. To determine whether instructions are given to parents/guardian by health workers on the use of prescribed analgesics at home.

## **METHODOLOGY**

### **Study area**

The study was conducted in the Paediatric Surgical Unit of Kenyatta National Hospital (a teaching and tertiary referral hospital in Nairobi, Kenya). The paediatric surgical ward is situated on level four of the tower block of KNH. The ward has a capacity of sixty (60) beds and admits children from the age of 0-12 years. The unit has four (4) elective surgical lists in a week, with an average of four patients on each list. On average, four (4) elective short stay open inguinal hernia repairs are done each week.

### **Study population**

All children with unilateral inguinal hernia admitted for open elective short stay surgery at the paediatric surgical unit of Kenyatta National Hospital and who met the inclusion criteria.

### **Study design:**

#### **Descriptive prospective study**

#### **Sample Size**

Sample size was calculated using the formula below.

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

n = is the sample size (91)

P = prevalence of pain among children 40%

$e = 0.05$  (level of precision or margin of error of 5%)

$Z_{\alpha} = 0.974$  (at 67% confidence interval)

Ideally, for a 95% confidence interval and a 5% margin of error, applying the formula above, the sample size is 383. However, because of the length of study and number of patients seen, we assessed 91 patients corresponding to a 67% confidence interval.

### **Sampling procedure**

Non-random progressive recruitment of patients who met the inclusion criteria was done until the sample size was obtained.

### **Inclusion criteria**

All infants and children aged between 3 months and 12 years who were scheduled to undergo elective unilateral open inguinal hernia repair at KNH between November 2014 and April 2015.

### **Exclusion criteria**

1. Parents or guardians who did not provide consent for their children to participate in the study.
2. Patients undergoing redo-surgery for a recurrent hernia.
3. Children undergoing herniotomy and another surgical procedure at the same sitting.
4. Patients with American Society of Anesthesiologists (ASA) morbidity score III – VI.
5. Parent or guardian without a communication device (mobile phone).
6. Patients without an adult available who would look after the child after discharge.
7. Children who suffered chronic pain.

8. Children who were retained in the hospital after the 1<sup>st</sup> postoperative day.

### **Data collection**

Infants and children who met the inclusion criteria and whose parent or guardian consented were recruited into the study. The following data was recorded from the patients' file:

- Demographics – inpatient number, age, weight and sex
- Parent or guardian telephone number
- Type of inguinal hernia
- Preoperative, intra-operative and postoperative analgesic medications given
- Whether the correct analgesic dose for weight was prescribed.

Pain assessment was done on return to the ward after surgery and on the morning of the 1<sup>st</sup> post-operative day before discharge, using age appropriate scientifically validated scales. FLACC score was used for children under 3years of age. Wong Baker faces scale was applied for children between 3 and 7years. The Visual analog score was used for children older than 8 years. If there was doubt that the child clearly understands the concept of assigning a number to describe the degree of their pain, the Wong Baker faces scale or FLACC score were utilized in such situations. All scales graded pain in a standard manner as no pain, mild pain, moderate pain or severe pain. The patients' temperature and pulse were taken and recorded. The child's parent or guardian was questioned on whether they visited the doctor prior to the surgery, during which the procedure was explained and their queries concerning the procedure answered.

Parents/guardians were then contacted (via telephone) on the 3<sup>rd</sup> post-operative day (48 hours after discharge), during which a questionnaire concerning their child's pain management at home was administered. The interview inquired on:

1. Parent's assessment of pain levels experienced by the child at the time of the conversation using the Parents Postoperative Pain Measure (PPPM) scale. The scale is validated for children upto 12 years. It graded pain as 'significant' (score of 6 or above), or 'non-significant' (score less than 6).
2. Whether any pain management information was given by a doctor or nurse in the ward before discharge.
3. Type of analgesic medication given at home and frequency of use on the first and second post-operative day.
4. Wound complications experienced by the child that may have necessitated consultation of a healthcare provider.

The parents were notified before discharge, to expect a telephone call on the morning of the 3<sup>rd</sup> post-operative day. They were also informed that the telephone interview would inquire on their child's post-operative pain and wellbeing at home. The assessment and interviews were conducted by the investigator. All the information obtained was recorded in a predetermined data sheet.

### **Data management**

Data from all patients was entered into an access database. Input data was limited to specific responses hence limiting inaccurate data entry. Data coding and quality control was incorporated in the access database. After entry, the data was exported into SPSS software which was used for

data analysis. Descriptive statistics were used to analyze the various attributes of the sample. Differences in the various attributes were calculated by the  $\chi^2$  or Fisher exact test for categorical variables, the Mann–Whitney  $U$  test for continuous variables, using the SPSS version 22. Spearman’s rank correlation was used to identify relationships between variables.

### **Study limitation**

1. Children of different ages with different levels of communication and understanding were included in the study. Age appropriate pain assessment tools which grade pain in a similar manner, as no pain, mild pain, moderate pain or severe pain were used to mitigate this limitation.
2. Some answers depended on parents’/caregivers’ impressions and memory. Parents were briefed before discharge concerning the telephone interview to follow on the 3<sup>rd</sup> post-operative day. Parents or care-givers were contacted within a short period after discharge hence they were able to easily remember the information requested.
3. Dishonest parents or care-givers (recall bias). Some parents tended to exaggerate when reporting on the child’s pain experience which may give a false impression of inadequate pain control. The scale used asked multiple indirect questions and then summed the total score, hence reducing this bias.

## **ETHICAL CONSIDERATIONS**

The study began after approval by the Department of Surgery of the University of Nairobi and Ethical and Research Committee of Kenyatta National Hospital. Informed consent was sought from the parent/guardian of each patient included in the study. There was effort made to communicate with every child to co-operate with the study. Informed assent was sought from older children, in addition to parent/guardian consent. Participants were allowed to decline participation in the study at will. Confidentiality was maintained at all times, with detailed information revealed to the researcher and those involved in the study. Data was stored in a password protected database.



## RESULTS

Ninety one children scheduled for short stay open elective inguinal hernia repair at KNH between November 2014 and April 2015, were recruited into the study. Their ages ranged between 3 months and 12 years, mean age was 3.3 years (SD  $\pm$  3.3), and median age 2.5 years (IQR 0.5 to 4.1) .

The demographic characteristics of the 91 children are summarized in *Table 1*. Approximately one-third (35.2%, 32/ 91) of the inguinal hernia repairs were performed in children less than one year.

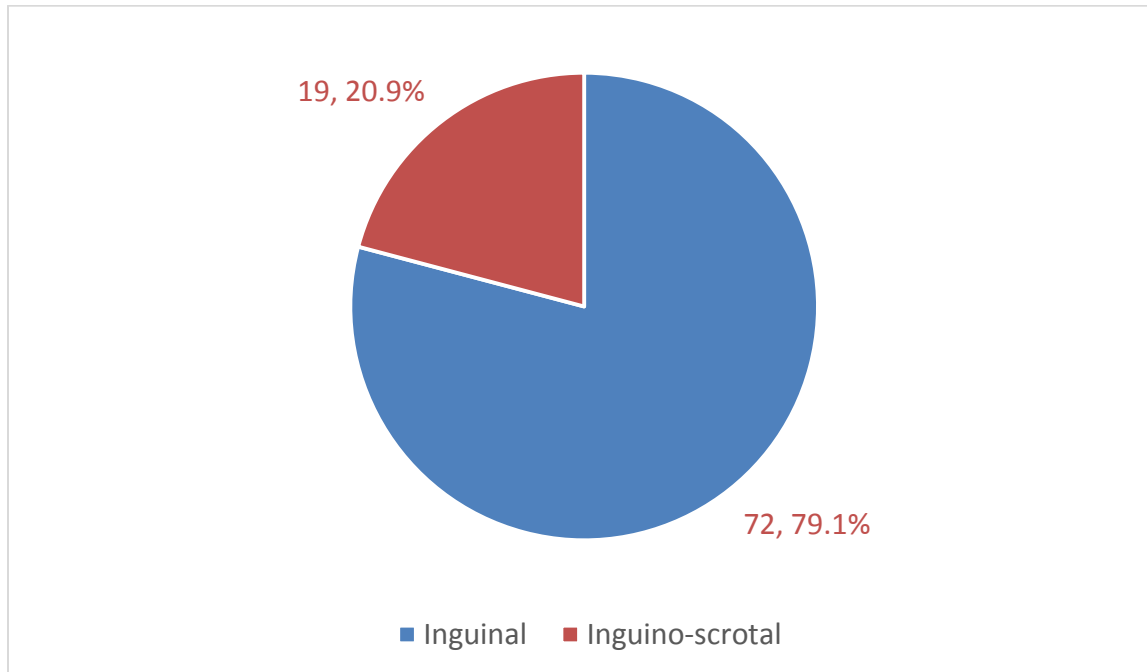
There were 73 males (83%) and 15 females (17%) giving a male-to-female ratio of 5: 1.

**Table 1: Demographic characteristics of children undergoing inguinal hernia repair at KNH**

	<b>Frequency (n)</b>	<b>Percent (%)</b>
<b>Age</b>		
< 1 year	32	35.2
1-2 years	22	24.2
3-4 years	19	20.9
5-12 years	18	19.8
<b>Sex</b>		
Male	73	83
Female	15	17

## Types of hernias

The prevalence of the two main types of inguinal hernias is presented in *Figure 2*. Out of the 91 children, 72 presented with inguinal hernias giving a prevalence of 79.1% (95% CI 69.3% - 86.9%) compared to a prevalence of 20.9% (95% CI 13.1% - 30.7%) for inguino-scrotal hernia.



**Figure 1: Types of inguinal hernia in pediatric patients at KNH**

As shown in *Table 2*, there was no strong association between type of hernia and children's age. The distribution of inguinal hernia across age groups ranged from 72.7% in the 1-2 years age group to 84.4% in infants aged < 1 year. Inguino-scrotal hernias occurred in between 15.6% and 27.3% of children across age groups.

**Table 2: Types of inguinal hernia in paediatric patients at KNH according to age**

	Type of hernia		P value
	Inguinal	Inguino-scrotal	
<b>Age</b>			
< 1 year	27(84.4)	5(15.6)	0.364
1-2 years	16(72.7)	6(27.3)	0.397
3-4 years	14(73.7)	5(26.3)	0.512
5-12 years	15(83.3)	3(16.7)	0.623

### **Peri-operative analgesia**

#### **Preoperative analgesic medication**

All 91 children did not receive any analgesic or anxiolytic premedication prior to surgery.

#### **Intra-operative analgesia**

*Table 3* summarizes intra-operative analgesic drug and dosing practices during elective short stay open inguinal hernia repair in KNH. The most commonly used analgesics were: regional or local anesthesia (using bupivacaine or lignocaine respectively) and paracetamol. Both were administered to 62 (68.1%) children. All the regional or local anesthetics prescriptions were administered in the correct dose, while 90.3% of paracetamol prescriptions were given at the correct dose. Similarly all opioid prescriptions (54, 59.3%) were administered at the correct dose.

**Table 3: Analgesic medications used intra-operatively for elective short stay inguinal hernia repair in children in KNH**

	Yes	No
<b>Analgesic drug administered and dosing</b>		
Opioid	54(59.3)	37(40.7)
Correct opioid dose (n = 54)	54(100)	NA
NSAID	0	91(100)
Paracetamol	62(68.1)	29(31.9)
Correct paracetamol dose (n = 62)	56(90.3)	6(9.7)
Regional/ local anesthesia	62(68.1)	29(31.9)
Correct dose for anesthetic (n = 62)	62(100)	NA
Other analgesic drugs	0	91(100)

#### **Post-operative pain ratings on arrival to the ward**

Pain assessment was conducted using the FLACC and Wong Baker scales administered to 76 (83.5%) children (age range 3 months to 11 years) and 16 (17.5%) children (age range 4 to 12 years), respectively. The levels of pain control on arrival to the ward after surgery are shown in *Table 4*. Thirty-three (36.3%) patients had mild pain, 25 (27.5%) had moderate pain and 16 (17.6%) severe pain. The pain was accompanied by a raised pulse in 47 (53.4%) children and fever in 6 (6.8%) children.

**Table 4: Pain ratings on arrival to the ward**

	<b>Frequency (n)</b>	<b>Percent (%)</b>
<b>Pain severity (FLACC/ Wong Baker scales)</b>		
No pain	17	18.7
Mild pain	33	36.3
Moderate pain	25	27.5
Severe pain	16	17.6
<b>Increased pulse rate</b>		
Yes	47	53.4
No	41	46.6
<b>Raised temperature (&gt; 38 degrees)</b>		
Yes	6	6.8
No	82	93.2

Table 5 shows that the level of pain reported was significantly associated with raised pulse ( $p < 0.001$ ), and type of analgesic used: opioid ( $p = 0.012$ ) and regional or local anesthesia ( $p = 0.003$ ). Patients with a raised pulse were more likely to report moderate (42.6%) or severe (29.8%) pain compared to those without a raised pulse (moderate = 12.2% and severe pain = 4.9%). The children who received opioids were less likely to report severe pain (7.4%) compared to children who did not have an opioid administered (32.4%).(Table 5)

There was no significant association between level of pain and hernia type ( $p = 0.063$ ), age of child ( $p > 0.05$ ), or use of paracetamol ( $p = 0.836$ ) during the intra-operative period.

**Table 5: Comparison of pain levels on arrival to the ward with age, type of hernia, raised pulse and analgesic used.**

	<b>Pain levels</b>				<b>P value</b>
	<b>None</b>	<b>Mild</b>	<b>Moderate</b>	<b>Severe</b>	
<b>Age group</b>					
< 1 year	5(15.6)	12(37.5)	13(40.6)	2(6.3)	0.073
1-2 years	6(27.3)	9(40.9)	4(18.2)	3(13.6)	0.478
3-4 years	4(21.1)	5(26.3)	3(15.8)	7(36.8)	0.072
5-12 years	2(11.1)	7(38.9)	5(27.8)	4(22.2)	0.8
<b>Type of hernia</b>					
Inguinal	17(23.6)	26(36.1)	19(26.4)	10(13.9)	0.063
Inguino-scrotal	0(0.0)	7(36.8)	6(31.6)	6(31.6)	
<b>Raised pulse</b>					
Yes	4(8.5)	9(19.1)	20(42.6)	14(29.8)	<0.001
No	13(31.7)	21(51.2)	5(12.2)	2(4.9)	
<b>Opioid</b>					
Yes	10(18.5)	21(38.9)	19(35.2)	4(7.4)	0.012
No	7(18.9)	12(32.4)	6(16.2)	12(32.4)	
<b>NSAID</b>					
No	17(18.7)	33(36.3)	25(27.5)	16(17.6)	
<b>Paracetamol</b>					
Yes	13(21.0)	21(33.9)	17(27.4)	11(17.7)	0.836
No	4(13.8)	12(41.4)	8(27.6)	5(17.2)	
<b>Regional/ local anesthesia</b>					
Yes	15(24.2)	16(25.8)	16(25.8)	15(24.2)	0.003
No	2(6.9)	17(58.6)	9(31.0)	1(3.4)	
<b>Other analgesic</b>					
No	17(18.7)	33(36.3)	25(27.5)	16(17.6)	

*Table 6* compares the analgesic combinations used intra-operatively with pain level on arrival to the ward. The patients who were on an opioid in combination with local/ regional anesthesia and paracetamol were significantly less likely to report pain compared to the patients receiving the other combinations of analgesic drugs ( $p = 0.044$ ). Forty-four percent of patients in this group reported no pain, none of the patients receiving these drugs reported severe pain, while 11.1% and 44.4% reported experiencing mild and moderate pain, respectively.

**Table 6: Level of pain and analgesic drug combinations administered intra-operatively.**

	Level of pain on day 1				P value
	None	Mild	Moderate	Severe	
<b>Analgesic combinations administered intra-operatively.</b>					
Opioid, local/regional anesthesia and paracetamol	4(44.4)	1(11.1)	4(44.4)	0(0.0)	0.044
Paracetamol and opioid	2(10.0)	10(50.0)	7(35.0)	1(5.0)	0.157
Local/regional anesthesia and paracetamol	7(21.2)	10(30.3)	6(18.2)	10(30.3)	0.069
Opioid and local/regional anesthesia	4(13.8)	12(41.4)	8(27.6)	5(17.2)	0.836

### **Pain ratings before discharge**

Reassessment of pain levels on the following morning before discharge were done using the FLACC and Wong Baker scale and are presented in *Table 7*. 41 (45.1%) patients had no pain, 31 (34.1%) had mild pain, 16 (17.6%) and 3 (3.3%) patients had moderate and severe pain, respectively. The pain was associated with a raised pulse in 35 (38.5%) patients and elevated temperature in 1 (1.1%) patient.

***Table 7: Pain ratings before discharge following short stay open inguinal repair in pediatric patients at KNH***

	<b>Frequency (n)</b>	<b>Percent (%)</b>
<b>Pain severity (FLACC/ Wong Baker scales)</b>		
No pain	41	45.1
Mild pain	31	34.1
Moderate pain	16	17.6
Severe pain	3	3.3
<b>Increased pulse rate</b>		
Yes	35	38.5
No	56	61.5
<b>Raised temperature (&gt; 38 degrees)</b>		
Yes	1	1.1
No	90	98.9

### **Postoperative analgesic medications**

Paracetamol and NSAIDs were the most commonly administered analgesics postoperatively, with 87 (95.6%) and 62 (71.3%) patients receiving the medications, respectively (*Table 8*). Out of these patients 62 (71.3%) received the correct dose of paracetamol and 51 (56%) received the correct dose of NSAIDs. Opioids were administered to 14 (15.4%) patients with 6 (42.9%) receiving the correct dose.



**Table 8: Post-operative analgesic medications following elective short stay inguinal hernia repair in children at KNH.**

	Yes	No
<b>Analgesic drug administered and dosing</b>		
Opioid	14(15.4)	77(84.6)
Correct opioid dose (n = 14)	6(42.9)	8(57.1)
NSAID	51(56)	40(44)
Correct NSAID dose (n = 51)	27(52.9)	24(47.1)
Paracetamol	87(95.6)	4(4.4)
Correct paracetamol dose (n = 87)	62(71.3)	25(28.7)
Regional/ local anesthesia	0	91(100)
Other analgesic drugs	0	91(100)

The level of pain reported in the post-operative period was significantly associated with type of hernia ( $p = 0.008$ ), raised pulse ( $p < 0.001$ ) and age ( $p = 0.02$ ). Three patients (15.8%) with inguino-scrotal hernia were still reporting severe pain in the post-operative period while none of the patients with inguinal hernia report that they experienced severe pain in the post-operative period. Moderate and severe pain were reported in 42.9% and 5.7% respectively, in patients with a raised pulse in the post-operative period, compared to 1.8% of children without raised pulse who reported either moderate or severe pain. Children aged 1-2 years were more likely to report no pain (72.7%) compared to children outside this age group and children aged 5-12 years reported moderate pain (61.1%) more frequently compared to children below the age of 5 years.

There was no significant association between type of analgesic administered and level of pain reported before discharge. (Table 9).

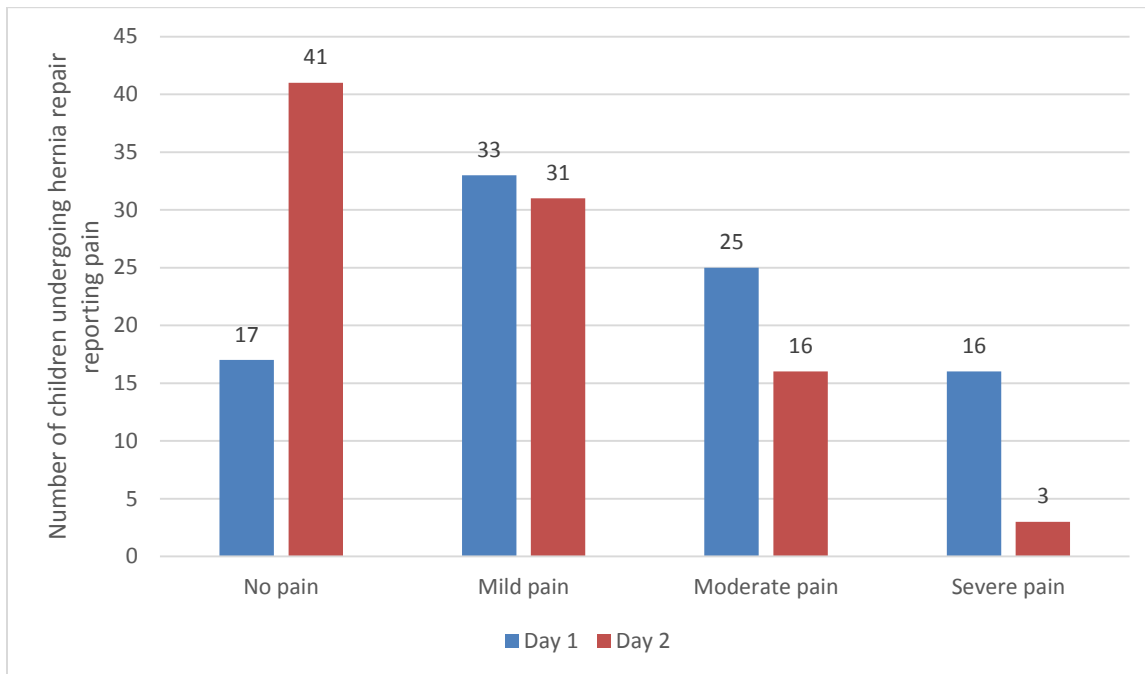
**Table 9: Comparison of pain levels before discharge with age, type of hernia, raised pulse and post-operative analgesics.**

	<b>Pain level (post operation)</b>				<b>P value</b>
	<b>None</b>	<b>Mild</b>	<b>Moderate</b>	<b>Severe</b>	
<b>Age group</b>					
< 1 year	12(37.5)	11(34.4)	7(21.9)	2(6.3)	0.484
1-2 years	16(72.7)	5(22.7)	1(4.5)	0(0.0)	0.02
3-4 years	10(52.6)	4(21.1)	4(21.1)	1(5.3)	0.584
5-12 years	3(16.7)	11(61.1)	4(22.2)	0(0.0)	0.02
<b>Type of hernia</b>					
Inguinal	34(47.2)	25(34.7)	13(18.1)	0(0.0)	0.008
Inguino-scrotal	7(36.8)	6(31.6)	3(15.8)	3(15.8)	
<b>Raised pulse</b>					
Yes	4(11.4)	14(40.0)	15(42.9)	2(5.7)	<0.001
No	37(66.1)	17(30.4)	1(1.8)	1(1.8)	
<b>Opioid</b>					
Yes	7(50.0)	4(28.6)	3(21.4)	0(0.0)	0.82
No	34(44.2)	27(35.1)	13(16.9)	3(3.9)	
<b>NSAID</b>					
Yes	25(49.0)	17(33.3)	7(13.7)	2(3.9)	0.673
No	16(40.0)	14(35.0)	9(22.5)	1(2.5)	
<b>Paracetamol</b>					
Yes	41(47.1)	27(31.0)	16(18.4)	3(3.4)	0.06*
No	0(0.0)	4(100.0)	0(0.0)	0(0.0)	
<b>Regional/ local anesthesia</b>					
No	41(45.1)	31(34.1)	16(17.6)	3(3.3)	NA
<b>Other analgesic</b>					
No	41(45.1)	31(34.1)	16(17.6)	3(3.3)	NA

\* Fisher's exact test

### Effectiveness of post-operative pain management

Figure 2 shows that there was a significant decrease in the levels of reported pain on the first post-operative day compared to the levels of pain reported immediately on arrival to the ward following surgery. Overall, 49 (53.9%) patients reported a reduction in the level of pain felt on the following day before discharge compared to the level of pain on the day of surgery. Thirty-one patients (34.1%) reported no change in pain levels with 12 (13.2%) having no pain on both assessments, 10 (11%) having mild pain, 8 (8.8%) moderate pain and 1 (1.1%) severe pain.



**Figure 2: Effectiveness of postoperative pain management following elective short stay inguinal hernia repair**

### **Preoperative consultation**

49 (53.8%) parents reported being satisfactorily informed about the operation prior to their children undergoing surgery

### **Pain management at home**

A questionnaire concerning the child's pain management at home was administered to all parents of the 91 children via telephone on the morning of the third postoperative day (ie 48 hours after discharge).

### **Pain rating**

The Parents Postoperative Pain Measure (PPPM) scale was used to assess pain levels at home. The parents were questioned on the presence or absence of 15 behavioral pain indicators. A score of 6 and above indicated 'significant pain'. Based on that scale, twenty-nine (31.9%) parents reported that the child was still experiencing 'significant' pain.

### **Instructions on analgesic prescriptions on discharge**

Out of the 91 parents, only 36 (39.6%) reported that they had been given instruction on analgesic administration by a doctor or nurse during discharge (*Table 10*).

**Table 10: Pre-operative consultation and telephone follow-up assessment of pain following hernia repair.**

	<b>Frequency (n)</b>	<b>Percent (%)</b>
Instructions given on administration of analgesic (by doctor or nurse)		
Yes	36	39.6
No	55	60.4
Visit to doctor		
Yes	49	53.8
No	42	46.2
PPPM		
Non-significant pain	62	68.1
Significant pain	29	31.9

### **Analgesic prescriptions**

Paracetamol only, was prescribed on discharge for 44 (48.4%) of the children who had undergone elective hernia repair (Table 11). Twenty two children (24.2%) were not on any analgesics. 15 patients (16.5%) were on a combination of paracetamol and ibuprofen. Other analgesics prescribed on discharge were ibuprofen alone (7.7%) and ibuprofen/diclofenac combination (3.3%).

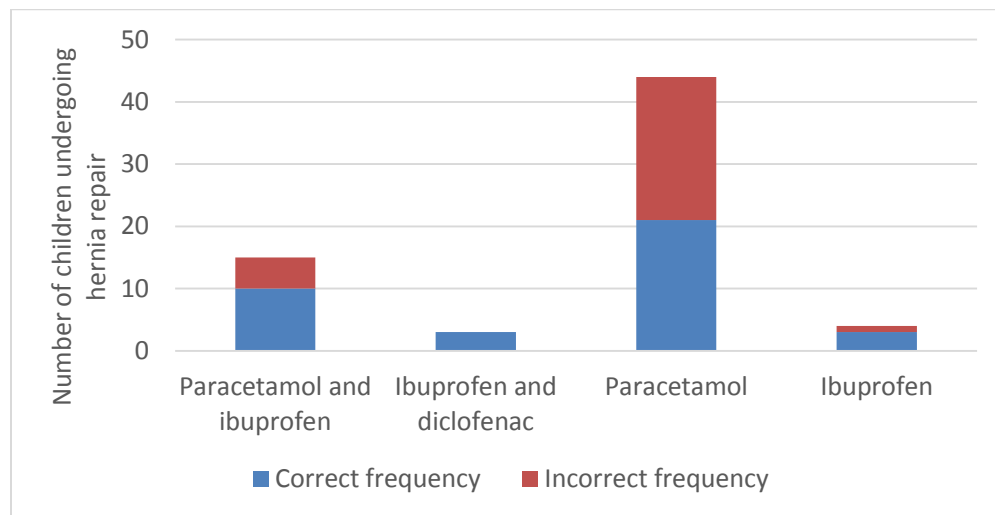
Those parents of the children for whom a combination of ibuprofen and diclofenac were prescribed, administered the medications in the correct frequency on the first and second day post discharge. There were also other children whose prescriptions consisted of paracetamol alone, Ibopruferen alone and a combination of Ibopruferen and Paracetamol. The compliance of the parents of these children were lower. 48% of those meant to administer paracetamol alone on the first day complied. Only 66.7% of those on the combination of Ibopruferen and Paracetamol complied, while 75% of those meant to administer Ibopruferen alone, did so on the first day post

discharge. On the second day post discharge, paracetamol only, paracetamol and ibuprofen combination and ibuprofen alone were given in the correct frequencies in 43%, 66.7% and 50% of the patients respectively. The rates of administration for ibuprofen and diclofenac (100%) and paracetamol and ibuprofen (66.7%) did not change on day 2 post discharge.

**Table 11: Analgesics prescribed on discharge and adherence to analgesic prescriptions in the post discharge period.**

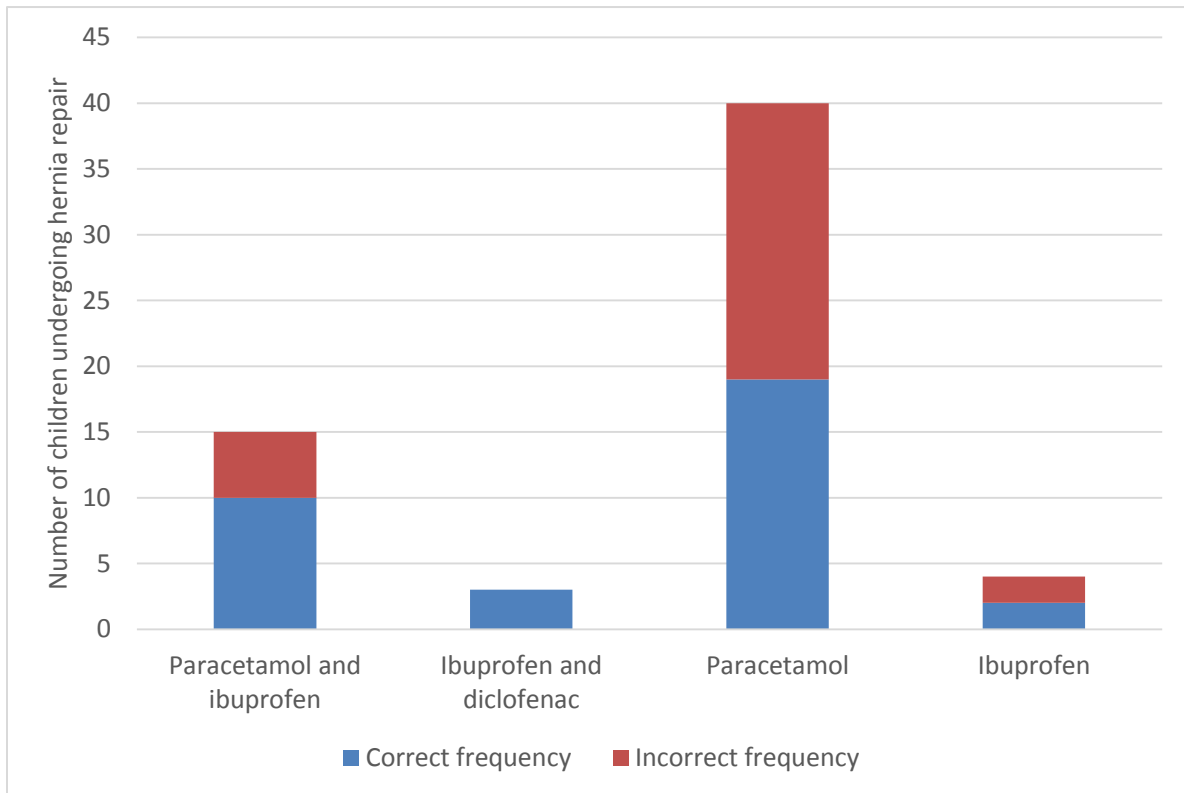
	Drug prescribed on discharge	Drug administered	
		Day 1	Day 2
Paracetamol and ibuprofen	15 (16.5)	10(70)	10(70)
Ibuprofen and diclofenac	3 (3.3)	3(100)	3(100)
Paracetamol	44(48.4)	21(48)	19(43)
Ibuprofen	7 (7.7)	3(75)	2(50)
No analgesic	22(24.2)	NA	NA

Of the four groups of analgesic discharge prescriptions, (paracetamol, ibuprofen, ibuprofen and diclofenac and paracetamol and ibuprofen), parents were less likely to report correct administration of paracetamol by frequency on both days following discharge (*Figure 3*).



**Figure 3: Frequency of administration of analgesics by parents on day 1 post discharge.**

Figure 4 shows that the pattern of incorrect dosing of analgesics in the post discharge period as observed on the first day post discharge (Figure 3), persisted on the second day with parents being less likely to report correct administration of paracetamol by frequency on the second day following discharge (Figure 4).



**Figure 4: Frequency of administration of analgesics by parent on day 2 post discharge.**

*Table 12* compares discharge analgesics with occurrence of ‘significant’ pain. Among those children who experienced ‘significant’ pain, 14 children (48.3%) were on paracetamol alone, 5 children (17.2%) on ibuprofen alone, and 4 children (13.8%) on paracetamol and ibuprofen combination. Six children (20.7%) were not on any analgesics. Children on Ibuprofen and diclofenac combination did not report significant pain.

**Table 12: Discharge analgesics in children with ‘significant’ pain**

<b>Discharge analgesic</b>	<b>Frequency(n)</b>	<b>Percent(%)</b>
Paracetamol	14	48.3%
No analgesic	6	20.7%
Ibuprofen	5	17.2%
Ibuprofen/Paracetamol	4	13.8%
Ibuprofen/Diclofenac	0	0%

### **Post-operative complications**

Two (2.2%) children were reported to have developed complications in the post-operative period. In both cases the complication was related to surgical site swelling (*Table 13*).

**Table 13: Postoperative complications after elective short stay paediatric inguinal hernia repair**

		<b>Frequency (n)</b>	<b>Percent (%)</b>
Complications	Yes	2	2.2
	No	89	97.8
Type of complication	Surgical site swelling	2	100



## **DISCUSSION**

Elective short stay open inguinal hernia repair is a common surgical procedure performed on children at KNH. Effective post-operative pain management is essential for comfortable and uncomplicated healing. This study set out to describe the current pain management practices after elective short stay inguinal hernia repair in children, with a view to making recommendations on improving outcomes.

The 91 children who participated in this study had a mean age of 3.3 years and a male:female ratio of 5:1. Sigmund, in a 35 year review on 6361 paediatric inguinal hernias also found the mean age to be 3.3years and a male to female ratio of 5:1. A study by Adesaji on day case herniotomy in Nigerian children, obtained a mean age of 3.2 years  $\pm$  0.6 years and a male:female ratio of 7.6:1<sup>43, 44</sup>.

Infants and pre-school children (1-4years) were the most commonly diagnosed with inguinal hernia comprising 80.3% of the study population. This finding is comparable with other regional (African) studies<sup>45, 46</sup>. It is possible that more hernias were operated at a younger age due to increased awareness among health care workers of the higher risk of incarceration in early life<sup>47</sup>.

### **Peri-operative Analgesia**

All children did not receive any analgesic or anxiolytic premedication before induction of anaesthesia. Anaesthetic premedication has been shown to reduce anxiety and analgesic requirements in children after surgery. A study by Gomez, on paediatric patients scheduled for surgery, used a combination of midazolam and acetaminophen as premedication. It reported an improved surgical experience for children on this regime<sup>48</sup>.

Intra-operatively, all children were on a combination of two or more analgesics. Most were on regional anaesthesia and paracetamol combination (36.3%) and the minority on an opioid, regional anaesthesia and paracetamol combination (9.9%). No NSAIDs were prescribed intra-operatively. The APA guidelines recommend that all children should be given local/regional anaesthesia, opioids, NSAIDs and Paracetamol in conjunction, not exceeding maximum recommended doses unless there are specific contraindications<sup>14</sup>.

On arrival to the ward, 81.4% of the children reported pain (mild, moderate, or severe). Forty five percent of the children had moderate or severe pain. The arrival of children at different time periods from the last analgesic given in theatre, may partially explain this variation in pain levels. These ratings were high in comparison to studies done from most Western countries. Fortier, in a study on children after short stay surgery reported 41% of children had pain on arrival to the ward from theatre<sup>49</sup>.

The children on the 3 analgesic drug combination (opioid, regional anaesthesia and paracetamol) intra-operatively, were least likely to report pain, compared to the patients who received the other 2 analgesic drug combinations.

### **Pain ratings prior to discharge**

Pain assessment on the first post-operative day (before discharge), revealed 55% of the children experienced pain (mild, moderate or severe). Twenty one percent experienced moderate or severe pain. These pain levels were high, in comparison to a study on children after day surgery in a British Columbia hospital which reported no child experienced moderate or severe pain before discharge<sup>50</sup>. The pain ratings are lower in comparison to those reported locally in adults.

Ocitti, in a study in adults after major abdominal and thoracic operations at KNH reported 90% of the patients experienced pain, 24 hours after surgery<sup>7</sup>.

Overall, there was reduction in pain levels reported on Day 2(before discharge) compared to those obtained on Day 1 (on return to the ward).

There was no significant association between type of analgesic administered postoperatively and level of pain reported before discharge. However, the analgesics prescribed – opioids, NSAIDs and paracetamol were given in incorrect dosage in 57.1%, 47.1% and 28.7% of the children respectively. Other local and regional studies have given these poor prescription practices as some of the reasons for the high post-operative pain levels reported<sup>7,51</sup>.

Children with inguino-scrotal hernias and those aged 5 – 12 years were more likely to report moderate or severe pain before discharge. This may be explained by the fact that inguino-scrotal hernias may involve more extensive tissue dissection compared to inguinal hernias. Children between 5 -12 years are also able to self-report on pain experienced in comparison to those below 4 years where behavioral scales are used. Self reporting is the most reliable indicator of pain<sup>52</sup>.

### **Preoperative Consultation**

Only 53.8% of parents reported retrospectively of having been satisfactorily informed about the surgery their child was to undergo. Preoperative information to patients and their care-givers has been shown to reduce the need for postoperative pain relief by relieving anxiety<sup>53</sup>.

### **Pain rating at home**

Thirty two percent of parents reported that their child was experiencing significant pain, 48 hours after discharge. Shum, in a similar study after day surgery indicated that only 9% of parents reported their child was having significant pain, 48 hours post discharge<sup>50</sup>.

### **Analgesic prescription discharge Instructions**

Sixty percent of parents reported not having received any instruction on administration of analgesics from a health worker in the ward during discharge. Insufficiency of discharge instructions after short stay surgery has been related to children's post-operative pain behaviors at home<sup>9</sup>.

### **Discharge analgesics**

The majority of patients were discharged on paracetamol alone (48.4%) and the minority on Ibuprofen/diclofenac combination (3.3%). Twenty four percent of parents reported that their children were not on any analgesics. On average, Paracetamol alone, ibuprofen alone or paracetamol/ibuprofen combination were given in the correct frequency in 45%, 63% and 70% of the children respectively, on the first and second day post discharge.

The high 'significant' pain rating at home may be explained by the fact that the multimodal analgesic approach was not maintained in all children. A large number of children were not on any analgesia or received it in the wrong frequency. A study of parents perceptions and use of analgesics at home after day surgery in children indicated that parents mostly gave analgesics to children who they assessed as having pain, other than at regular intervals. Some parents also had

misleading perceptions of the nature and adverse effects of analgesics, which were related to giving analgesics to the child<sup>54</sup>.

### **Postoperative Complications**

The rate of complications reported 48hrs post discharge was 2.2%. No mortality occurred. The morbidity rate is similar to that obtained from other regional and Western studies after short stay elective inguinal herniotomy in children<sup>45, 55</sup>.

## **CONCLUSION**

The results of this study, demonstrates that post-operative analgesia practices for short stay paediatric inguinal hernia repair at KNH are suboptimal.

Poor prescription practices, lack of analgesic guidelines, only surgeon based post-operative care and inadequate pre-operative and post-operative information to parents and children concerning post-operative pain management are some of the barriers demonstrated to effective post-operative pain management.

Improvement in post-operative pain management requires interventions that will overcome these barriers to effective pain management.

## **RECOMMENDATIONS**

- A post-operative pain management protocol which includes guidelines on pain assessment, pre-emptive and multimodal analgesia should be instituted as part of standard practice for children undergoing open elective short stay inguinal hernia repair at KNH.
- Health workers should be educated on the analgesia protocol and encouraged to effectively communicate to the patients and their parents, in order to reduce anxiety and improve compliance to analgesic prescriptions.
- A checklist which includes written discharge analgesic instructions for parents may be part of the analgesia protocol after paediatric short stay surgery at KNH.
- A pain management team which constantly evaluates and manages post-operative pain in children after short stay surgery should be constituted at KNH.

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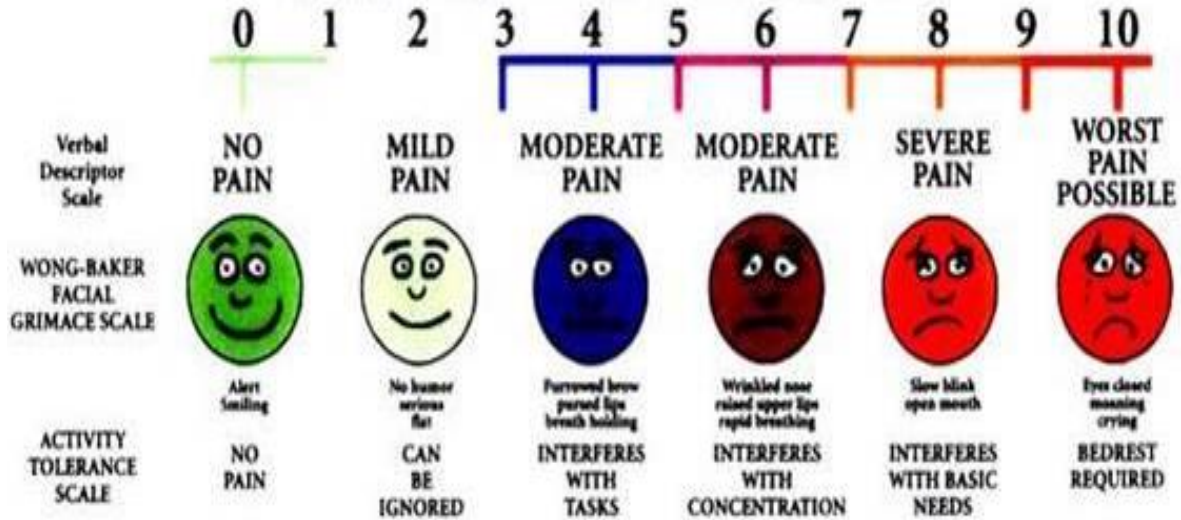
APPENDIX 1 (a) : VISUAL ANALOGUE SCALE

1(a)



## 1(b) UNIVERSAL PAIN ASSESSMENT TOOL

This pain assessment tool is intended to help patient care providers assess pain according to individual patient needs. Explain and use 0-10 Scale for patient self-assessment. Use the faces or behavioral observations to interpret expressed pain when patient cannot communicate his/her pain intensity.



## APPENDIX 2: THE FLACC SCALE

<b>Face</b>		
0	1	2
No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
<b>Legs</b>		
0	1	2
Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
<b>Activity</b>		
0	1	2
Lying quietly, normal position, moves easily	Squirming, shifting back/forth, tense	Arched, rigid, or jerking
<b>Cry</b>		
0	1	2
No cry, awake or asleep	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaints
<b>Consolability</b>		
0	1	2
Content, relaxed	Reassured by occasional touching, hugging, or "talking to," distractible	Difficult to console or comfort

### How to use the FLACC scale

1. Rate patient on each of the five categories (i.e. Face, Legs, Arms, Cry, Consolability). Each category is scored on the 0 to 2 scale.
2. Add the scores together (for a total possible score of 0 to 10).
3. Document the total pain score.

In children who are awake: Observe for 1-5 minutes or longer. Observe legs and body uncovered. Reposition child or observe activity. Assess body for tenseness and tone. Initiate consoling interventions if needed.

In children who are asleep: Observe for 5 minutes or longer. Observe body and legs uncovered. If possible, reposition the child. Touch the body and assess the tenseness and tone.

### Interpreting the score:

<b>0 =</b>	Relaxed and comfortable
<b>1-3 =</b>	Mild pain or discomfort
<b>4-6 =</b>	Moderate pain
<b>7-10 =</b>	Severe pain or discomfort or both



**APPENDIX 3: DATA SHEET 1**

Day	IP Number _____ Data sheet number _____ Age _____ Sex _____ Telephone no. _____																
	Weight _____		Hernia type [Inguinal] _____		[ Inguino-scrotal ] _____												
On return to ward after surgery (Day 0)		Wong Baker facial scale	VAS	FLACC score		Signs	Yes	No	Medications	Pre-op	Correct dose		Intra-op	Correct dose			
											Yes	No		Yes	No		
	1No pain				1Comfortable		High Pulse (>100)			1.Opiod							
	2Mild pain				2Mild discomfort					2.NSAID							
	3Moderate pain				3Moderate pain		High Temp. (>38C)			3.Paracetamol							
	4Severe pain				4severe pain					4.Regional/ LA							
									5Others								

## APPENDIX 4: DATA SHEET 2

Day	IP Number _____ Data sheet number _____ Age _____ Sex _____ Telephone no. _____												
	Weight _____												
Morning of 1st Postop Day		Wong Baker facial scale	VAS	FLACC score		Signs	Yes	No	Medications	Post-op	Correct dose		
											Yes	No	
		1No pain			1Comfortable		High Pulse (>100)			1.Opiod			
		2Mild pain			2Mild discomfort					2.NSAID			
		3Moderate pain			3Moderate pain		High Temp. (> 38C)			3.Paracetamol			
		4Severe pain			4severe pain					4.Regional/ LA			
									5Others				

Did you visit the doctor with your child prior to the surgical procedure, during which the procedure was explained and your queries concerning the same answered?

YES ( )

NO ( )

**APPENDIX 5: DATA SHEET 3 (TELEPHONE INTERVIEW)**

**Study Number**----- **IP Number**----- **Telephone contact**\_\_\_\_\_

1. Date of surgery-----
2. Date of discharge-----
3. Date of interview (morning of 3<sup>rd</sup> postoperative day) -----

**a) Parent postoperative pain measure**

Since discharge, has your child:

1. Whined or complained more than usual? YES ( ) NO ( )
2. Cried more easily than usual? YES ( ) NO ( )
3. Played less than usual? YES ( ) NO ( )
4. Not done the things s/he normally does? YES ( ) NO ( )
5. Acted more worried than usual? YES ( ) NO ( )
6. Acted more quiet than usual? YES ( ) NO ( )
7. Had less energy than usual? YES ( ) NO ( )
8. Refused to eat? YES ( ) NO ( )
9. Ate less than usual? YES ( ) NO ( )
10. Held the sore part of his/her body? YES ( ) NO ( )
11. Tried not to bump the sore part of his/her body? YES ( ) NO ( )
12. Groaned or moaned more than usual? YES ( ) NO ( )
13. Looked more flushed than usual? YES ( ) NO ( )
14. Wanted to be close to you more than usual? YES ( ) NO ( )
15. Taken medication when s/he normally refuses? YES ( ) NO ( )



Day	Analgesic Medication	Frequency
1 <sup>st</sup>		
2 <sup>nd</sup>		

**d) Wound complications**

9. Since discharge from hospital, has your child encountered complications that may have necessitated his/her return to the hospital or health care provider?

YES

NO

If yes, for what reason?

- a) Pain
- b) Wound dehiscence/ breakdown
- c) Wound discharge
- d) Wound bleeding
- e) Surgical site swelling
- f) Other (Specify) .....

## **APPENDIX 6: INFORMED CONSENT FORMS**

### **English version**

This Informed Consent form is for parents/guardians of children hospitalized at the Kenyatta National Hospital paediatric surgical unit who are to have elective unilateral inguinal hernia surgery during the study period. We are requesting these patients to participate in this research project whose title is “Efficacy of analgesia practices for short stay open paediatric inguinal Hernia repair at K.N.H”.

Principal investigator: Dr. Steve M. Mutungi

Institution: School of Medicine, Department of surgery- University of Nairobi

Supervisors: Dr. Francis Osawa, Dr. James Ndungu Muturi and Prof. Peter Odhiambo.

This informed consent has three parts:

1. Information sheet (to share information about the research with you)
2. Certificate of Consent (for signatures if you agree to take part)
3. Statement by the researcher

You will be given a copy of the full Informed Consent Form.

## **Part i: Information sheet**

### **Introduction**

My name is Dr. Steve M. Mutungi, a post-graduate student at the University of Nairobi's School of Medicine. I am carrying out a research on analgesic practices after open short stay elective pediatric inguinal hernia surgery.

I am inviting you to participate in my study on behalf of your child and you are free to either agree immediately after receiving this information or later after thinking about it. You will be given the opportunity to ask questions before you decide and you may talk to anyone you are comfortable with about the research before making a decision. After receiving this information concerning the study, please seek for clarification from either myself or my assistant if there are words or details which you do not understand.

### **Purpose of the Research**

Postoperative pain in children may be ignored by care givers and guardians due to their inability to clearly communicate or other misconceptions that exist. Pain control after surgery is paramount for comfort, and reduces healing complications. The study aims to check the effectiveness of current analgesic practices in the hospital and at home after hernia surgery, with an aim of improving them.

If you agree to participate, you will be asked to provide personal information and other details related to the condition the child is suffering from including the amount of pain experienced.

### **Type of Research Intervention**

Your involvement in this research will be through an interview and clinical evaluation of the child's post-operative pain levels, after undergoing elective short stay inguinal hernia surgery.

### **Participant Selection**

All children undergoing elective inguinal hernia surgery during the study period will be invited to participate. Your participation is voluntary and refusal to participate in the research or withdrawal from it will not affect the treatment the child will receive at this hospital.

## **Study Duration**

Recruitment of patients into the study will take six months from the date approval to conduct the study is given.

## **Risks**

The child will not be exposed to any risks if you consent to participate in this study.

## **Benefits**

There may not be any direct benefit for you or your child but your participation is likely to help us find the answer to the research question; and possibly improve the management of post-operative pain in children after inguinal hernia surgery.

## **Confidentiality**

All the information which you provide will be kept confidential and no one but the researchers will see it. The information about you or the child will be identified by a number and only the researchers can relate the number to you as a person. Your information will not be shared with anyone else unless authorized by the Kenyatta National Hospital/University of Nairobi – Ethics and Research Committee (KNH/UoN-ERC).

## **Cost and Compensation**

You will not incur any cost nor be given any inducements to take part in this research.

## **Right to Refuse/Withdraw**

You or your do not have to take part in this research if you do not wish to do so. You may also stop participating in the research any time you choose.

## **Research Approval**

This proposal has been reviewed and approved by the KNH/UoN-ERC which is a committee whose work is to make sure research participants like you are protected from harm. It was submitted to them through the Chairman, Department of Surgery, School of Medicine, at the



University of Nairobi with the approval of three university supervisors. The contact information of these people is given below if you wish to contact any of them for whatever reason;

- Prof. M. L. Chindia  
Secretary, KNH/UoN-ERC  
P.O. Box 20723 KNH, Nairobi 00202  
Tel 726300-9  
Email: KNHplan@Ken.Healthnet.org
- Prof. S. W. Ogendo  
Chairman, Department of Surgery, School of Medicine– University of Nairobi  
P.O. Box 19676 KNH, Nairobi 00202  
Tel # 0202726300
- University of Nairobi research supervisors  
Dr. Francis Osawa  
Department of Surgery, School of Medicine, University of Nairobi  
P.O. Box 19676 KNH, Nairobi 00202  
Tel # 0202726300  
Dr. James Ndungu Muturi  
Department of Surgery, School of Medicine, University of Nairobi  
P.O. Box 19676 KNH, Nairobi 00202  
Tel # 0202726300  
Prof. Peter Odhiambo  
Department of Surgery, School of Medicine, University of Nairobi  
P.O. Box 19676 KNH, Nairobi 00202  
Tel # 0202726300
- Principle researcher:  
Dr. Steve M. Mutungi  
Department of Surgery, School of Medicine, University of Nairobi  
P.O. Box 19676 KNH, Nairobi 00202  
Mobile phone # 0721213208

**Part ii: Consent certificate**

I.....freely give consent of myself or for my proxy (.....) to take part in the study conducted by Dr. Steve M. Mutungi, the nature of which has been explained to me by him/his research assistant. I have been informed and have understood that my participation is entirely voluntary and I understand that I am free to withdraw my consent at any time if I so wish and this will not in any way alter the care being given to me or my proxy. The results of the study may directly be of benefit to me or my proxy and may improving postoperative pain management after open pediatric inguinal hernia surgery.

.....

Signature/left thumb print (Participant/Next of kin)

Date.....

Day/Month/Year

<p>Thumb print of participant if illiterate (a witness must sign below)</p>
---

**Statement by the witness if participant is illiterate**

I have witnessed the accurate reading of the consent form to the participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness.....

Signature of witness.....

Date.....

Day/Month/Year

**Part iii: Statement by the researcher**

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands the following:

- Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- All information given will be treated with confidentiality.
- The results of this study might be published in a scientific journal.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the parent/guardian of the participant.

Name of researcher or assistant taking consent.....

Signature of researcher or assistant taking the consent.....

Date.....

Day/Month/Year

## **INFORMED ASSENT FORM (FOR MINORS- 8-12 YEARS)**

### **English version**

My name is Dr. Steve Mutungi, a post-graduate student at the University of Nairobi's School of Medicine. I am here about a research project we are doing. The purpose of this research is to understand the effectiveness of post-operative pain control practices after inguinal hernia surgery in children.

If you agree to participate in the research, your details and pain control medicines prescribed after surgery will be recorded. You will then be assessed for post-operative pain, using age appropriate tools upon return to the ward after surgery, and before you are discharged home the next morning. Your parents or guardian will be interviewed through telephone on the morning of the third post-operative day regarding your post-operative pain treatment at home. Participation will not expose you to any risks. Refusal to participate in the research or withdrawal from it will not affect the treatment you will receive at this hospital.

Your parent or guardian must also give permission for you to participate in the research. You have the right to refuse to answer any questions or to withdraw from the study at any time without penalty.

All the information that you give us will be used for this research only. The information about you will be identified by a number and only the researchers can relate the number to you as a person. Your information will not be shared with anyone else unless authorized by the Kenyatta National Hospital/University of Nairobi – Ethics and Research Committee (KNH/UoN-ERC).

My telephone number is 0721213208. You can contact me if you have any questions about the research.

Do you have any questions?

Your signature or initials below will indicate your understanding of this form and agreement to participate. You will be given a copy of this consent form to keep for future reference.

Signature of minor \_\_\_\_\_

Name of minor \_\_\_\_\_

Signature of person obtaining consent \_\_\_\_\_

Name of person obtaining consent \_\_\_\_\_

## **Kiswahili Version**

### **FOMU YA IDHINI**

#### **(i) Sehemu ya kwanza**

##### **Maelezo:**

Mimi ni Dkt Steve M. Mutungi, kutoka shule ya Afya ya upasuaji ya Chuo Kikuu cha Nairobi (University of Nairobi). Ninafanya utafiti kuhusu mitindo ya kutumia madawa ya kuzuia maumivu kwa watoto baada ya upasuaji wa inguinal hernia. Maumivu baada ya upasuaji wa watoto yanaweza sahauliwa na wahudumu na wazazi, kwasababu ya watoto kutoeleza barabara kuhusu maumivu haya. Kudhibiti maumivu baada ya upasuaji ni muhimu, kwa uponaji mwema wa mtoto.

##### **Utafiti:**

Utafiti huu unapanga kujua mitindo hii ya kudhibiti maumivu, kwa nia ya kuiimarisha. Ningependa kukuchagua wewe ama mgonjwa wako katika utafiti huu wangu. Katika utafiti huu utatakiwa kutoa taarifa yako binafsi, taarifa kuhusu mgonjwa wako na pia maumivu anayo hisi. Utafiti huu unatarajia kuchukuwa jumla ya miezi tatu kuaanzia siku idhini ya kufanya utafiti itakapopewa na jopo maalum la utafiti la chuo kikuu cha Nairobi na hospitali kuu ya Kenyatta(KNH/UoN-ERC).

Naomba mimi ama wasaidizi wangu wakuulize wewe ama mgonjwa wako maswali ambayo yatajibiwa kwa fomu maalum.

##### **Taadhima ya siri:**

Habari zote zitakazo kusanywa zitashughulikiwa kwa siri na hazitasambazwa ila tu kwa ruhusa kutoka kwa jopo maalum ya utafiti ya chuo kikuu cha Nairobi na hospitali kuu ya Kenyatta(KNH/UoN-ERC).

**Malipo:**

Kuhusika kwako kwenye utafiti huu hauna malipo yeyote ila ni kwa hiari yako mwenyewe na pia unaweza kujiondoa kwa utafiti wakati wowote bila kuhatarisha matibabu ya mgonjwa wako katika Hospitali Kuu ya Kenyatta.

**Maswali:**

Unaweza kuuliza maswali yeyote kuhusu utafiti huu na ukiridhika tafadhali ijaze fomu ya idhini iliyopo hapa chini. Unaweza pia kuuliza swali lolote baadaye kwa kupiga simu ya mtafiti mkuu ama mkuu wa idara ya upasuaji katika chuo kikuu cha Nairobi ama walimu wanaosimamia utafiti ukitumia nambari za simu zifuatazo;

- Prof. M. L. Chindia, Katibu wa utafiti, Hospitali kuu ya Kenyatta na Chuo kikuu cha Nairobi. Sanduku la Posta 20723 KNH, Nairobi 00202. Nambari ya simu 726300-9.
- Prof. S. W. Ogendo, Mwenye kiti, Idara ya upasuaji katika chuo kikuu cha Nairobi. Sanduku la Posta 19676 KNH Nairobi 00202. Nambari ya simu: 0202726300
- Walimu wasimamizi wa Chuo kikuu cha Nairobi:
  1. Daktari Francis Osawa, Sanduku la Posta 19676 KNH, Nairobi 00202. Nambari ya simu: 0202726300
  2. Daktari James Ndungu Muturi, Sanduku la Posta 19676 KNH, Nairobi 00202. Nambari ya simu: 0202726300
  3. Professor Peter Odhiambo, Sanduku la Posta 19676 KNH, Nairobi 00202. Nambari ya simu: 0202726300

- Mtafiti:

Daktari Steve M. Mutungi, Idara ya Upasuaji ya Shule ya Utabibu – Chuo kikuu cha Nairobi, Sanduku la Posta 2678 KNH Nairobi 00202. Nambari ya simu ya rununu 0721213208

**(ii) Sehemu ya pili - Idhini:**

Mimi (Jina).....kwa hiari yangu ama kwa hiari ya mgonjwa wangu (Jina la Mgonjwa).....

..... nimekubali kushiriki katika utafiti huu unaofanywa na Daktari Steve M. Mutungi kutokana na hali ambazo nimeelezwa na sio kwa malipo ama shurutisho lolote.

Nimeelewa kwamba nina weza kujiondoa wakati wowote nitakapo na hatua hii haita hatarisha matibabu ninayopata ama anayoipata mgonjwa wangu. Matokeo ya utafiti yaweza kuwa ya manufaa kwangu ama kwa wagonjwa wengine kwa jumla na yaweza kusaidia kupunguza maumivu baada ya upasuaji..

Kidole cha gumba kwa wale wasiojua



.....

Sahihi/ama alama ya kidole cha gumba katika sanduku →

Tarehe.....

Siku/Mwezi/Mwaka

Jina la shahidi.....

Sahihi.....

Tarehe.....

(Siku/Mwezi/Mwaka)

**(iii) Sehemu ya tatu – Dhibitisho la mtafiti**

Hii nikuidhinisha ya kwamba nimemueleza mshiriki ama msimamizi wake kuhusu utafiti huu na nimemipa nafasi yakuuliza maswali. Nimemueleza yafuatayo;

- Kwamba kushiriki ni kwa hiari yake mwenyewe bila malipo.
- Kushiriki hakutasababisha madhara ama kuhatarisha maisha kamwe.
- Anaweza kujiondoa kutoka kwa utafiti huu wakati wowote bila kuhatarisha matibabu anayo ipata katika hospital kuu ya Kenyatta.
- Habari ambazo atapeana hazita sambazwa hadharani bila ruhusa kutoka kwake (mshiriki) na pia kutoka kwa mdhamini mkuu wa utafiti wa hospital kuu ya Kenyatta na chuo kikuu cha matibabu.

Jina la mtafiti ama msimamizi wake.....

Sahihi.....

Tarehe.....

(Siku/Mwezi/Mwaka)

kuwandika (Shahidi  
atie sahihi hapa chini)

### **Fomu ya idhini ya watoto (miaka 8 – 12)**

Mimi ni Dkt Steve M. Mutungi, kutoka shule ya Afya ya upasuaji ya Chuo Kikuu cha Nairobi (University of Nairobi). Ninafanya utafiti kuhusu mitindo ya kutumia madawa ya kuzuia maumivu kwa watoto baada ya upasuaji wa inguinal hernia.

Ukikubali kujiunga na utafiti huu, habari kuhusu dawa za maumivu utakazopewa baada ya upasuaji zitanakiliwa. Maumivu utakayokuwa nayo baada ya upasuaji yatakimwa utakaporudi wadi baada ya upasuaji na kabla ya kupewa ruhusa kurudi nyumbani siku itakayofuata. Wazazi wako watapigiwa simu siku ya tatu baada ya upasuaji kuhojiwa kuhusu maumivu yeyote utakayokuwa nayo nyumbani.

Mzazi wako lazima pia atoe ruhusa, kuidhinisha kushiriki kwako katika utafiti huu. Kuhusika kwako kwenye utafiti huu hauna malipo yeyote ila ni kwa hiari yako mwenyewe na pia unaweza kujiondoa kwa utafiti wakati wowote bila kuhatarisha matibabu yako katika Hospitali Kuu ya Kenyatta. Naomba mimi ama wasaidizi wangu wakuulize wewe maswali ambayo yatajibiwa kwa fomu maalum. Habari yote ambaye utatuarifu ni ya siri kati yako nasi watafiti na haitaenezwa kwa watu wengine.

Nambari yangu ya simu ni 0721213208. Unaweza kuwasiliana nami kuhusu maswali yeyote uliyonayo kuhusu utafiti huu.

Je, una maswali yeyote kuhusu utafiti huu?

Sahihi ama alama zako hapa chini zinaonyesha unaelewa fomu hii na umekubali kushiriki katika utafiti huu.

Sahihi ama alama ya mtoto \_\_\_\_\_

Jina la mtoto \_\_\_\_\_

Sahihi ya anayechukua idhini \_\_\_\_\_

Jina la anayechukua idhini \_\_\_\_\_

## ETHICAL APPROVAL



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Ref: KNH-ERC/A/349

Link: [www.uonbi.ac.ke/activities/KNHUoN](http://www.uonbi.ac.ke/activities/KNHUoN)

21<sup>st</sup> October 2014

Dr. Steve M. Mutungi  
Dept. of Surgery  
School of Medicine  
University of Nairobi

Dear Dr. Mutungi

**RESEARCH PROPOSAL- EFFICACY OF POST-OPERATIVE ANALGESIA PRACTICES FOR SHORT STAY OPEN PAEDIATRIC INGUINAL HERNIA REPAIR AT KENYATTA NATIONAL HOSPITAL (P368/06/2014)**

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 21<sup>st</sup> October 2014 to 20<sup>th</sup> October 2015.

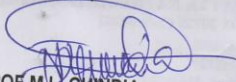
This approval is subject to compliance with the following requirements:

- 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 severe 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) 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*).
- f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- 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.

For more details consult the KNH/UoN ERC website [www.uonbi.ac.ke/activities/KNHUoN](http://www.uonbi.ac.ke/activities/KNHUoN).

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Yours sincerely



**PROF. M.L. CHINDIA**  
**SECRETARY, KNH/UON-ERC**

c.c. The Principal, College of Health Sciences, UoN  
The Deputy Director CS, KNH  
The Chair, KNH/UoN-ERC  
The Assistant Director, Health Information, KNH  
The Dean, School of Medicine, UoN  
The Chairman, Dept. of Surgery, UoN  
Supervisors: Dr. Francis Osawa, Dr. James Ndungu Muturi, Prof. Peter A. Odhiambo

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