ACUTE POST-OPERATIVE PAIN MANAGEMENT AT THE KENYATTA NATIONAL HOSPITAL

A RESEARCH PROPOSAL PRESENTED IN PART FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF A MASTERS DEGREE IN ANAESTHESIA, UNIVERSITY OF NAIROBI.

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ACUTE POST-OPERATIVE PAIN MANAGEMENT AT THE KENYATTA NATIONAL HOSPITAL

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DECLARATION

I declare that this proposal is my original work and has not been submitted for a degree award in any university.

RESEARCHER: SIGNATURE DATE

Dr. Kimani G Mbugua ___________ _______ H58/76364/2009

This proposal has been submitted for the degree of Masters of Medicine in Anaesthesiology with my approval as a university supervisor.

SUPERVISOR: SIGNATURE DATE

Dr. Thomas M. Chokwe ___________ _______

Dr. Timothy M. Mwiti ___________ _______
DEDICATION

To my Parents, Mr. and Mrs. Gichuru

To my siblings Njenga and Gichuru

To my aunt Beatrice.

To the patients without whom this undertaking would not have been possible.
ACKNOWLEDGEMENTS

I would like to sincerely thank the following:

Dr. Muriithi Mwiti, my supervisor for his invaluable input.

Dr. Chokwe, my supervisor and teacher, the human face of anaesthesia.

Mr. Mutai for his invaluable input

The Department of Anaesthesia, University of Nairobi for their suggestions and corrections.

My parents for their support.

Almighty God, for keeping me this entire period.
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LIST OF ABBREVIATIONS

I.V Intravenous

I.M. Intramuscular

I.N. Intranasal

KNH Kenyatta National Hospital

P.R per rectal

PONV post-operative nausea and vomiting

nsNSAIDS non selective non-steroidal anti-inflammatory drugs

NRS Numerical Rating Scale

PCA Patient Controlled Analgesia

S.C subcutaneous
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SUMMARY

Background

The under-treatment of pain has been associated with delayed patient recovery and prolonged hospital stay. In addition, it is associated with significant emotional distress and physiological consequences, especially in the immediate post-operative period. Poorly managed post-operative pain, among other factors, has been identified as a predictive factor for the development of chronic pain after surgery. Even with the acknowledgement of the importance of effective post-operative pain management, a good number of patients (up to 70%) still complain of moderate to severe post-operative pain.

Objective

The aim of this study was to evaluate success of current intraoperative pain management in patients undergoing surgery under general anaesthesia at the Kenyatta National Hospital.

Methods

The study was designed as a Cross sectional observational survey. 166 patients underwent surgery under general anaesthesia. Following completion of surgery, the patients anaesthetic records were analyzed and the postoperative pain score taken using the Numerical Rating Scale.

Results

In this study 10.8% of patients complaining of severe post-operative pain, 29.9% complaining of moderate pain and 46.1% of patients complaining of mild post-operative pain. 13.2% of patients did not have any pain.

Conclusion

Post-operative pain following general anaesthesia is still not adequately addressed.
1.0 INTRODUCTION

The Kenyatta National Hospital is the leading teaching and referral hospital in Kenya. About 1500 major operations are performed per month with a majority being done under General Anaesthesia.

General Anaesthesia is administered by three different cadres of practitioners at KNH who include physician anaesthesiologists, clinical officer anaesthetists and senior post graduate students working under the supervision of physician anaesthetists in the Department of Anaesthesia. Currently there are twenty five (25) physician anaesthesiologists working at this institution. These are doctors who have attained a Master’s degree in anaesthesia. There are nineteen (19) clinical officer anaesthetists at KNH. They have attained a Higher National Diploma in the field of anaesthesia. Senior post-graduate students in anaesthesia are seventeen (17). These are doctors undertaking a Master’s degree in anaesthesia and are in the second or third year of their study program. This facility provides the site where post graduate students undertake their Masters level training in anaesthesia.

Analgesia is one of the key tenets of the practice of anaesthesia, and this remains one of the most important goals.

The under-treatment of pain has been associated with delayed patient recovery and prolonged hospital stay. In addition, it is associated with significant emotional distress and physiological consequences, especially in the immediate post-operative period. Poorly managed post-operative pain, among other factors, has been identified as a predictive factor for the development of chronic pain after surgery. Even with the acknowledgement of the importance of effective post-operative pain management, a good number of patients still complain of moderate to severe post-operative pain. In a study published in the American Journal of Surgery in 2001, Huan N, Cunningham and others established that up to 70% of patients still complained of moderate to severe post-operative pain despite the recognition of the importance of effective pain control. In yet another study looking at the prevalence of post-operative pain in a sample of 1490 surgical patients, M. Sommer, J. M. de Rijke et al found that moderate or severe pain was reported by 41% of patients on the first postoperative day.
2.0 LITERATURE REVIEW

2.1 INTRODUCTION

The International Association for the Study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.”

Acute pain is defined as ‘pain of recent onset and probable limited duration. It usually has an identifiable temporal and causal relationship to injury or disease’. Chronic pain ‘commonly persists beyond the time of healing of an injury and frequently there may not be any clearly identifiable cause’.

2.2 PAIN PERCEPTION, NOCICEPTIVE PATHWAYS

The ability of the somatosensory system to detect noxious and potentially tissue-damaging stimuli is an important protective mechanism that involves multiple interacting peripheral and central mechanisms. The neural processes underlying the encoding and processing of noxious stimuli are defined as ‘nociception’.

The detection of noxious stimuli is dependent upon the presence of peripheral nociceptors (peripheral sense organs) that are located in various parts of the body. Nociceptor activation then requires the transduction of the noxious stimulus into an action potential and conduction to the central nervous system. Nociceptive afferents comprise the medium diameter lightly myelinated A delta fibres and the unmyelinated slow conducting C fibres.

Tissue damage, such as that associated with infection, inflammation or ischaemia, produces disruption of cells, degranulation of mast cells, secretion by inflammatory cells, and induction of enzymes such as cyclo-oxygenase-2 (COX-2).

Ranges of chemical mediators act either directly via ligand-gated ion channels or via metabotropic receptors to activate and/or sensitize nociceptors. Endogenous modulators of nociception, including proteinases, pro-inflammatory cytokines (e.g. TNFα, IL-1β, IL-6), anti-inflammatory cytokines (e.g. IL-10) and chemokines (e.g. CCL3, CCL2, CX3CL1), can also act as signaling molecules in pain pathways.
2.3 PSYCHOLOGICAL ASPECTS OF PAIN

It is important to note that pain is an individual, multifactorial experience influenced, among other things, by culture, previous pain experience, belief, mood and ability to cope. Pain may be an indicator of tissue damage but may also be experienced in the absence of an identifiable cause. The degree of disability experienced in relation to the experience of pain varies; similarly there is individual variation in response to methods to alleviate pain.  

Psychological factors that influence the experience of pain include the processes of attention, other cognitive processes (e.g. memory/learning, thought processing, beliefs, mood), behavioral responses, and interactions with the person's environment. In relation to pain, attention is viewed as an active process and the primary mechanism by which nociception accesses awareness and disrupts current activity. The degree to which pain may interrupt attention depends on factors such as intensity, novelty, unpredictability, degree of awareness of bodily information, threat value of pain, catastrophic thinking, presence of emotional arousal, environmental demands (such as task difficulty), and emotional significance. Of particular note experimental studies have demonstrated that anxiety sensitivity and pain catastrophising may also influence the interruptive qualities of pain on attention. Pain catastrophising may be described as perceiving progressively worse and worse outcomes to a specific worry, in this case the worry being pain.  

Anxiety sensitivity refers to a person's tendency to fear anxiety-related symptoms due to the belief that there will be some negative physical, social, or mental outcome as a result of having those symptoms.

The contribution of psychosocial factors to the pain experience is important in acute and chronic pain settings as well as in the transition from acute to chronic pain.  

Preoperative anxiety has been shown to be associated with higher pain intensities in the first hour after a variety of different operations, including abdominal, coronary artery bypass, gynaecological and varicose vein surgery, and after laparoscopic tubal ligation. Recent studies have suggested a link between acute and chronic pain.
### Table 1 Risk factors for chronic postsurgical pain

#### Preoperative Factors

<table>
<thead>
<tr>
<th>Risk Factor</th>
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<tbody>
<tr>
<td>Pain, moderate to severe, lasting more than 1 month</td>
</tr>
<tr>
<td>Repeat surgery</td>
</tr>
<tr>
<td>Psychological vulnerability (e.g. catastrophising)</td>
</tr>
<tr>
<td>Preoperative anxiety</td>
</tr>
<tr>
<td>Female gender</td>
</tr>
<tr>
<td>Younger age (adults)</td>
</tr>
<tr>
<td>Workers’ compensation</td>
</tr>
<tr>
<td>Genetic predisposition</td>
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<tr>
<td>Inefficient diffuse noxious inhibitory control (DNIC)</td>
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</tbody>
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#### Intraoperative Factors

<table>
<thead>
<tr>
<th>Risk Factor</th>
</tr>
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<tbody>
<tr>
<td>Surgical approach with risk of nerve damage</td>
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</table>

#### Postoperative Factors

<table>
<thead>
<tr>
<th>Risk Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain (acute, moderate to severe)</td>
</tr>
<tr>
<td>Radiation therapy to area</td>
</tr>
<tr>
<td>Neurotoxic chemotherapy</td>
</tr>
<tr>
<td>Depression</td>
</tr>
<tr>
<td>Psychological vulnerability</td>
</tr>
<tr>
<td>Neuroticism</td>
</tr>
<tr>
<td>Anxiety</td>
</tr>
</tbody>
</table>
2.4 PRE-EMPTIVE & PREVENTIVE ANALGESIA

In laboratory studies, administration of an analgesic prior to an acute pain stimulus more effectively minimizes dorsal horn changes associated with central sensitization than the same analgesic given after the pain state is established. This led to the hypothesis that pain relief prior to surgery may enhance postoperative pain management – that is, ‘pre-emptive preoperative analgesia’. However, individual clinical studies have reported conflicting outcomes when comparing ‘pre-incisional’ with ‘post-incisional’ interventions.

There is evidence that some analgesic interventions have an effect on postoperative pain and/or analgesic consumption that exceeds the expected duration of action of the drug, defined as preventive analgesia.

2.5 ADVERSE EFFECTS OF PAIN

2.5.1 PHYSIOLOGICAL

Clinically significant injury responses can be broadly classified as inflammation, hyperalgesia, hyperglycaemia, protein catabolism, increased free fatty acid levels (lipolysis) and changes in water and electrolyte flux. In addition, there are cardiovascular effects of increased sympathetic activity and diverse effects on respiration, coagulation and immune function.

Pain from injury sites can activate sympathetic efferent nerves and increase heart rate, inotropy, and blood pressure. As sympathetic activation increases myocardial oxygen demand and reduces myocardial oxygen supply, the risk of cardiac ischaemia, particularly in patients with pre-existing cardiac disease, is increased. Enhanced sympathetic activity can also reduce gastrointestinal (GI) motility and contribute to ileus. Severe pain after upper abdominal and thoracic surgery contributes to an inability to cough and a reduction in functional residual capacity, resulting in atelectasis and ventilation-perfusion abnormalities, hypoxaemia and an increased incidence of pulmonary complications. The injury response also contributes to a suppression of cellular and humoral immune function and a hypercoagulable state following surgery, both of which can contribute to postoperative complications such as deep venous thrombosis and an increased risk of infection. Patients at greatest risk of adverse outcomes from unrelieved acute pain include very young or elderly patients, those with concurrent medical illnesses and those undergoing major surgery.
2.5.2 PSYCHOLOGICAL EFFECTS

Psychological changes associated with acute pain have received less attention than those associated with chronic pain, however they are no less important. Sustained acute nociceptive input, as occurs after surgery, trauma or burns, can also have a major influence on psychological function, which may in turn alter pain perception. Failure to relieve acute pain may result in increasing anxiety, inability to sleep, demoralization, a feeling of helplessness, loss of control, inability to think and interact with others — in the most extreme situations, where patients can no longer communicate, effectively they have lost their autonomy.27

2.6 PHARMACOGENOMICS & ACUTE PAIN.

Pharmacogenomics deals with the influence of genetic variation on drug response in patients. As an example, genetic factors regulating opioid pharmacokinetics (metabolizing enzymes, transporters) and pharmacodynamics (receptors and signal transduction elements) contribute to the large inter-patient variability in postoperative opioid requirements.28

Drug-metabolizing enzymes represent a major target for identifying associations between an individual’s genetic profile and drug response. The cytochrome P450 enzymes metabolize numerous drugs and show inter-individual variability in their catalytic activity.

2.7 PAIN ASSESSMENT

The definition of pain underlies the complexity of its measurement. Pain is an individual and subjective experience modulated by physiological, psychological and environmental factors such as previous events, culture, prognosis, coping strategies, fear and anxiety. Therefore, most measures of pain are based on self-report. These measures lead to sensitive and consistent results if done properly.29

There are no objective measures of ‘pain’ but associated factors such as hyperalgesia (E.g. mechanical withdrawal threshold), the stress response (e.g. plasma cortisol concentrations), behavioral responses (e.g. facial expression), functional impairment (e.g. coughing, ambulation) or physiological responses (e.g. changes in heart rate) may provide additional information.

Recording pain intensity as ‘the fifth vital sign’ aims to increase awareness and utilization of pain assessment and may lead to improved acute pain management.30
2.7.1 Categorical Scales

Categorical scales use words to describe the magnitude of pain or the degree of pain relief. E.g. verbal descriptor scale (VDS) is the most common example (e.g. using terms such as none, mild, moderate, severe and excruciating or agonizing) typically using four or five graded descriptors.

There is a good correlation between descriptive verbal categories and visual analogue scales, but the VDS is a less sensitive measure of pain treatment outcome than the VAS. Pain relief may also be graded as none, mild, moderate or complete using a VDS.

Categorical scales have the advantage of being quick and simple and may be useful in the elderly or visually impaired patient and in some children. However they have a disadvantage in that there is a limited number of choices in categorical compared with numerical scales may make it more difficult to detect differences between treatments. Other limitations include personal, cultural or linguistic differences in interpretation of the specific words chosen as descriptors both between patients and also between patients and their clinicians.

2.7.2 Numerical Rating Scales

These have both written and verbal forms. Patients rate their pain intensity on the scale of 0 to 10 where 0 represents ‘no pain’ and 10 represents ‘worst pain imaginable’. The Verbal NRS (VNRS) is typically administered using a phrase such as: ‘On a scale of 0 to 10, with 0 being no pain at all and 10 being the worst pain you could imagine, where would you rate the pain you are experiencing right now?’.

It is important that scales are consistent, and it is recommended that the ‘no pain’ point be represented as zero (0) rather than one (1). Pain relief may be measured in the reverse direction with 0 representing ‘no relief’ to 10 representing ‘complete relief’. A visual form of the 11-point NRS with tick marks on a line or boxes with numbers may also be used.
Numerical scales are widely used but they have the disadvantage in that some patients may have difficulty in representing their pain in numerical terms and may be better suited to a categorical scale.

2.7.3 Visual Analogue Scales

These consist of a 100 mm horizontal line with verbal anchors at both ends and no tick marks. The patient is asked to mark the line and the ‘score’ is the distance in millimetres from the left side of the scale to the mark. They include words ‘no pain’ at the left end and ‘worst pain imaginable’ at the right. Pictorial versions also exist.

Instruct the patient to point to the position on the line between the faces to indicate how much pain they are currently feeling. The far left end indicates ‘No pain’ and the far right end indicates ‘Worst pain ever’.
Assessment of pain immediately after surgery can be more difficult and lead to greater inter-patient variability in pain scores because of transient anaesthetic-related cognitive impairment and decreases in visual acuity. A ‘pain meter’ (PAULA) which used five coloured emoticon faces on the front of a ruler and corresponding VAS scores on the back, and allowed patients to move a slider to mark the pain they were experiencing, resulted in less variance than pain scores obtained from a standard VAS.\textsuperscript{36}

VAS ratings of greater than 70 mm are indicative of 'severe pain' and 0 to 5 mm 'no pain', 5 to 44 mm 'mild pain' and 45 to 74 'moderate pain'. These scales have the advantage of being simple and quick to use, allow for a wide choice of ratings and avoid imprecise descriptive terms. However, the scales require more concentration and coordination, need physical devices, are unsuitable for children under 5 years and may also be unsuitable in up to 26\% of adult patients.

\textbf{2.7.4 Verbal numerical rating scales (VNRS)}
These are often preferred because they are simpler to administer, give consistent results and correlate well with the VAS.\textsuperscript{37}

\textbf{2.7.5 Faces Rating Scale}
Designed for children aged 3 years and older, the Wong-Baker Faces Pain Rating Scale is also helpful for elderly patients who may be cognitively impaired. If offers a visual description for those who don’t have the verbal skills to explain how their symptoms make them feel.
The patient is asked to choose the face that best describes how they feel. The far left face indicates 'No hurt' and the far right face indicates 'Hurts worst'. The face chosen is then documented.

2.7.6 Behavioral Rating Scale

The behavioral pain assessment scale is designed for use with non-verbal patients unable to provide self-reports of pain. Each of the five measurement categories is scored (0, 1 or 2). These are then added together and the total pain score out of 10 is documented. Other scales include the FLACC (face, legs, activity, cry, consolability) and the CRIES (crying, oxygenation, vital signs, facial expression and sleeplessness) scales. The former is used commonly used for children aged 2 to 7 while the latter is commonly used for infants 6 months and younger.
<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Face</td>
<td>Face muscles relaxed</td>
<td>Facial muscle tension, frown, grimace</td>
<td>Frequent to constant frown, clenched jaw</td>
<td>Face score:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Restlessness</td>
<td>Quiet, relaxed appearance, normal movement</td>
<td>Occasional restless movement, shifting position</td>
<td>Frequent restless movement may include extremities or head</td>
<td>Restlessness score:</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscle tone*</td>
<td>Normal muscle tone</td>
<td>Increased tone, flexion of fingers and toes</td>
<td>Rigid tone</td>
<td>Muscle tone score:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vocalization**</td>
<td>No abnormal sounds</td>
<td>Occasional moans, cries, whimper and grunts</td>
<td>Frequent or continuous moans, cries, whimper and grunts</td>
<td>Vocalization score:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONSOL ability</td>
<td>Content, relaxed</td>
<td>Reassured by touch, distracible</td>
<td>Difficult to comfort by touch or talk</td>
<td>Consolability score:</td>
</tr>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

Behavioral pain assessment scale total (0–10) /10
2.8 ACUTE PAIN SERVICES (APS)

In the past two decades, enthusiasm among anaesthesiologists in major hospitals all over the world has led to the establishment of acute pain services to provide pain relief to patients in the postoperative period. These include ‘low-cost’ nurse-based, others are anaesthetist-led but rely primarily on APS nurses as there may not be daily clinical participation by an anaesthetist, and some are comprehensive and multidisciplinary services with APS nursing staff, sometimes pharmacists or other staff, and daily clinical input from, and 24-hour cover by anaesthetists.\(^{38-40}\). A review of publications (primarily audits) looking at the effectiveness of APSs (77% were physician-based, 23% nurse-based) concluded that the implementation of an APS is associated with a significant improvement in postoperative pain and a possible reduction in PONV, but that it was not possible to determine which model was superior\(^ {41}\). Possible benefits of Acute Pain Services include better pain relief, a lower incidence of side effects, lower post-operative morbidity/mortality and management of analgesic techniques that may reduce the incidence of persistent pain after surgery.

2.9 PHARMACOLOGICAL MANAGEMENT OF PAIN

2.9.1 SYSTEMICALLY ADMINISTERED ANALGESIC DRUGS

a) OPIOIDS

Opioids remain the mainstay of systemic analgesia for the treatment of moderate to severe acute pain. All full opioid agonists given in appropriate doses produce the same analgesic effect and therapeutic index\(^ {42}\). However, accurate determination of equi-analgesic doses is difficult due to inter-individual variability in kinetics and dynamics.\(^ {43}\) However, for pharmacokinetic and other reasons, some opioids may be better in some patients\(^ {44}\).

The term opioid refers broadly to all compounds related to opium. Opiates are drugs derived from opium and include the natural products morphine, codeine, and thebaine, semisynthetic congeners e.g. heroin and synthetic compounds such as fentanyl, remifentanil, sufentanil among others.

Opioids are administered primarily for their analgesic effect, which results from complex interactions at discrete sites in the brain, spinal cord, and under certain conditions, peripheral tissues at one or more opioid receptors.

Opioids can be administered systemically by a number of different routes. The choice of route may be determined by various factors, including the aetiology, severity, location and type of pain, the patient’s overall condition and the characteristics of the chosen administration technique.
Additional factors to consider with any route of administration are ease of use, accessibility, speed of analgesic onset, reliability of effect, duration of action, patient acceptability, cost, staff education and supervision available.

Oral opioids can be as effective in the treatment of acute pain as opioids given by other more invasive routes if equianalgesic doses are administered. Both immediate-release (IR) and controlled release (CR) formulations have been used. IV opioids are more effective in the management of pain than the same dose given orally. For example IV tramadol is more effective in relieving pain than an equal dose taken orally. IM and SC injections of analgesic agents (usually opioids) are still commonly employed for the treatment of moderate or severe pain. Absorption may be impaired in conditions of poor perfusion (e.g. in hypovolaemia, shock, hypothermia or immobility), leading to inadequate early analgesia and late absorption of the drug depot when perfusion is restored.

IM injection of opioids has been the traditional mainstay of postoperative pain management, despite the fact that surveys have repeatedly shown that pain relief with prn IM opioids is frequently inadequate. Although IM opioids are often perceived to be safer than opioids given by other parenteral routes, the incidence of respiratory depression reported in a review ranged from 0.8 (0.2 to 2.5) % to 37.0 (22.6 to 45.9) % using respiratory rate and oxygen saturation, respectively, as indicators.

A comparison of the same dose of morphine given as either a single SC or IV injection, showed that use of the IV route resulted in more rapid onset of analgesia (5 minutes IV; 20 minutes SC) and better pain relief between 5 minutes and 25 minutes after injection, but also led to higher sedation scores up to 30 minutes after injection, and higher PCO2 levels. In most instances similar doses of rectal and oral opioids are administered, although there may be differences in bioavailability and the time to peak analgesic effect. The stratum corneum of the epidermis forms a major barrier to the entry of drugs. However, drugs such fentanyl and buprenorphine are available as transdermal preparations. Transdermal fentanyl patches are currently specifically contraindicated for the management of acute or postoperative pain in many countries and their use cannot be recommended.

A variety of drugs can be administered by the IN route, including analgesic drugs. The human nasal mucosa contains drug-metabolizing enzymes but the extent and clinical significance of human nasal first-pass metabolism is unknown. Fentanyl had similar analgesic efficacy when given by the IN or IV routes as did butorphanol and morphine. IN pethidine was more effective than SC injections of
pethidine. Administered by the sublingual or buccal routes, their efficacy will in part depend on the proportion of drug swallowed.
Adverse effects of opioids include cognitive and fine motor impairment, miosis, pruritus, respiratory depression, depression of the cough reflex, nausea and vomiting, slowing of gastric emptying, constipation, urinary retention and histamine release.

b) **PARACETAMOL, NON-SELECTIVE ANTI-INFLAMMATORY DRUGS & COXIBS**

**Paracetamol**

There is considerable evidence that the analgesic effect of paracetamol is central and is due to activation of descending serotonergic pathways, but its primary site of action may still be inhibition of PG synthesis.

Paracetamol (acetaminophen) is the only remaining para-aminophenol used in clinical practice and is an effective analgesic and antipyretic. Single doses of paracetamol are effective in the treatment of postoperative pain. Paracetamol is also an effective adjunct to opioid analgesia, opioid requirements being reduced by 20% to 30% when combined with a regular regimen of oral or rectal paracetamol. The use of oral paracetamol in higher daily doses (1 g every 4 hours) in addition to PCA morphine lowered pain scores, shortened the duration of PCA use and improved patient satisfaction.

The combination of paracetamol and NSAID has been shown to be clearly more effective than paracetamol alone, but evidence for superiority relative to the NSAID alone is more limited and of uncertain clinical significance. The oral bioavailability of paracetamol is good at between 63% and 89%. However, early postoperative oral administration can result in plasma concentrations that can vary enormously after the same dose and may remain sub therapeutic in some patients. In the same doses, orally administered paracetamol was less effective and of slower onset than paracetamol given by IV injection, but more effective and of faster onset than paracetamol administered by the rectal route. Adverse effects may include rash, thrombocytopenia, leucopenia, hypotension (when given as an infusion) and hepatotoxicity and nephrotoxicity at high dosages.

**NSAIDs**

The term NSAIDs is used to refer to both nsNSAIDs and coxibs (COX-2 selective inhibitors). NSAIDs have a spectrum of analgesic, anti-inflammatory and antipyretic effects and are effective analgesics in a variety of acute pain states. Many effects of NSAIDs can be explained by inhibition of prostaglandin synthesis in peripheral tissues, nerves, and the CNS. However, NSAIDs and aspirin
may have other mechanisms of action independent of any effect on prostaglandins, including effects on basic cellular and neuronal processes.

Single doses of nsNSAIDs are effective in the treatment of pain after surgery\textsuperscript{49}. However, while useful analgesic adjuncts, they are inadequate as the sole analgesic agent in the treatment of severe postoperative pain. When given in combination with opioids after surgery, nsNSAIDs resulted in better analgesia, reduced opioid consumption and a lower incidence of PONV and sedation\textsuperscript{50}. Perioperative use of NSAIDs is associated with a number of side effects, including decreased hemostasis, renal dysfunction, gastrointestinal hemorrhage, and deleterious effects on bone healing and osteogenesis. Many of these side effects are related to inhibition of COX and the formation of prostaglandins, which mediate many diverse processes throughout the body. In general, there is no good evidence that nsNSAIDs given parenterally or rectally are more effective, or result in fewer side effects, than the same drug given orally for the treatment of postoperative pain. Only in the treatment of renal colic do IV nsNSAIDs result in more rapid analgesia. Rectal administration of nsNSAIDs provides effective analgesia.

**Cyclo Oxygenase Inhibitors (Coxibs)**

Coxibs are as effective as nsNSAIDs in the management of postoperative pain\textsuperscript{51}. Preoperative coxibs reduce postoperative pain and opioid consumption and increase patient satisfaction\textsuperscript{52}. When given in combination with opioids after surgery, coxibs are opioid-sparing.\textsuperscript{53}

### 2.10 NON PHARMACOLOGICAL PAIN MANAGEMENT

This is the management of pain without medications. There are a number of methods and these include transcutaneous nerve stimulation (TENS), cognitive and behavior therapy, heat and cold, physical and occupation therapy, rehabilitation, progressive muscle relaxation, psychotherapy, complimentary medicine (massage, acupuncture, acupressure), exercise therapy and lifestyle changes.

### 2.11 PREVALENCE OF POST-OP PAIN

The under-treatment of postoperative pain has been recognized to delay patient recovery and discharge from hospital. Despite recognition of the importance of effective pain control, up to 70\% of patients still complain of moderate to severe pain postoperatively.\textsuperscript{54}
The incidence of moderate to severe pain with cardiac, abdominal, and orthopedic inpatient procedures has been reported as high as 25% to 50%, and incidence of moderate pain after ambulatory procedures is 25% or higher.\textsuperscript{55}

In a study looking at the prevalence of post-operative pain in a sample of 1490 surgical patients, moderate or severe pain was reported by 41% of patients on day 0, the prevalence being higher in the abdominal surgery group (30-55%).\textsuperscript{56}

Moderate to severe acute postoperative pain occurs frequently after a variety of surgical procedures. Incidences of up to 50% in inpatients and 40% in outpatients (patients undergoing ambulatory surgery) have been reported in yet another study.\textsuperscript{57-60}

A local study done at the Kenyatta national Hospital by E. F. Ocitti and J. A. Adwok titled post-operative management of pain following major abdominal and thoracic surgery concluded that the standard of post-operative pain relief is poor. 56% of the patients experienced moderate to severe pain, with 34.4 % experiencing mild pain. In addition, the study showed that over 97% of the patients received pethidine with 2.8% receiving morphine.
Surgical procedures conducted in patients of the Amsterdam cohort, ordered by increasing incidence of severe acute post-operative pain. (defined as >6 on the numerical rating scale)\(^1\)

<table>
<thead>
<tr>
<th>Surgical procedure</th>
<th>Incidence %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lowest expected pain</strong></td>
<td></td>
</tr>
<tr>
<td>Endoscopic urology</td>
<td>26</td>
</tr>
<tr>
<td>Testicular surgery (including orchidopexy, biopsy, prosthesis implantation,</td>
<td>27</td>
</tr>
<tr>
<td>vasoepididymostomy, testis-scrotum exploration)</td>
<td></td>
</tr>
<tr>
<td>Eye surgery (including strabismus)</td>
<td>37</td>
</tr>
<tr>
<td><strong>Low expected pain</strong></td>
<td></td>
</tr>
<tr>
<td>Pharyngo- and laryngoscopy plus biopsy</td>
<td>40</td>
</tr>
<tr>
<td>Ear nose throat surgery</td>
<td>47</td>
</tr>
<tr>
<td>Diagnostic laparoscopy</td>
<td>48</td>
</tr>
<tr>
<td>Gynecologic surgery (nonabdominal nonlaparoscopic)</td>
<td>49</td>
</tr>
<tr>
<td>Minor rectal surgery</td>
<td>49</td>
</tr>
<tr>
<td>Oral soft tissue surgery</td>
<td>55</td>
</tr>
<tr>
<td>Carotid endarterectomy</td>
<td>56</td>
</tr>
<tr>
<td><strong>Moderate expected pain</strong></td>
<td></td>
</tr>
<tr>
<td>Skin surgery or lymph node biopsy</td>
<td>58</td>
</tr>
<tr>
<td>Peripheral vascular procedures (including varicose veins)</td>
<td>59</td>
</tr>
<tr>
<td>Minor breast surgery</td>
<td>61</td>
</tr>
<tr>
<td>Procedures on muscle and/or ligaments of extremities</td>
<td>63</td>
</tr>
<tr>
<td>Upper abdominal surgery with epidural, including hepato-biliary, esophageal,</td>
<td>63</td>
</tr>
<tr>
<td>pancreatic and intestinal surgery</td>
<td></td>
</tr>
<tr>
<td><strong>High expected pain</strong></td>
<td></td>
</tr>
<tr>
<td>Major breast surgery</td>
<td>67</td>
</tr>
<tr>
<td>Bone procedures, including cranial/facial, oral, spine, orthopedic/traumatology</td>
<td>68</td>
</tr>
<tr>
<td>procedures on clavicle, extremities, hip and pelvis</td>
<td></td>
</tr>
<tr>
<td>Instrumentation or removal of instrumentation, including spine, hip,</td>
<td></td>
</tr>
<tr>
<td>jaw/denture, hand/wrist, clavicle, elbow, ankle/foot or knee</td>
<td></td>
</tr>
<tr>
<td>Arthroscopy of shoulder, hip/pelvis and extremities</td>
<td></td>
</tr>
<tr>
<td>Procedures for abdominal wall herniation</td>
<td>69</td>
</tr>
<tr>
<td>Nephrectomy</td>
<td>69</td>
</tr>
<tr>
<td><strong>Highest expected pain</strong></td>
<td></td>
</tr>
<tr>
<td>Therapeutic laparoscopic procedures, including laparoscopic cholecystectomy,</td>
<td>76</td>
</tr>
<tr>
<td>gynecologic laparoscopy and other therapeutically laparoscopy</td>
<td></td>
</tr>
<tr>
<td>Intraabdominal surgery without epidural, including colon, bladder, prostate,</td>
<td>80</td>
</tr>
<tr>
<td>vascular and gynecological surgery</td>
<td></td>
</tr>
<tr>
<td>Tonsillectomy (in patients over 16 years)</td>
<td>80</td>
</tr>
<tr>
<td>Hemilated disc surgery</td>
<td>84</td>
</tr>
<tr>
<td>Bone procedures including shoulder, thoracotomies, elbow, ankle/foot</td>
<td>85</td>
</tr>
<tr>
<td>(excluding instrumentation or removal of instrumentation)</td>
<td></td>
</tr>
<tr>
<td>Thyroid procedures</td>
<td>86</td>
</tr>
<tr>
<td>Peripheral nerve reconstruction</td>
<td>92</td>
</tr>
<tr>
<td>Vaginal hysterectomy</td>
<td>100</td>
</tr>
</tbody>
</table>
The prevalence of moderate to severe pain varies according to the surgical procedures conducted. In a cohort of patients undergoing surgery in Amsterdam, it was noted that certain surgical procedures were associated with a higher incidence of severe post-operative pain. Highest pain scores were seen in major breast surgery, laparoscopic abdominal surgery, orthopaedic procedures, and nephrectomies among others. Lowest pain scores are expected in testicular and eye surgeries among others.

It has been cited that ‘the knowledge deficit’ of professionals as the most prevalent cause of poor pain management, with poor prescriptions by doctors and inadequate administration by nurses being key issues. Another compounding factor is teaching. Teaching on pain control for medical students in the past has and in some cases, remain poor. Marcer and Deighton in 1998 found that teaching on pain amounted to an average of 3.5 hours being delivered in a 4 year course. More recently, Clarke et al (2003) reported that little has changed in this regard and medical house officers receive 1-5 hours of formal training in pain management.
3.0 JUSTIFICATION OF THE STUDY

Despite modern advances in the management of pain, post-operative pain still remains a challenge that in many cases is yet to be adequately dealt with. Indeed a good number of patients (up to 70%) still complain of moderate pain in the post-operative period. The under treatment of pain has been associated with delayed patient recovery and with increased duration of hospital stay. Apart from the emotional distress that acute pain causes there can be serious physiological consequences for patients in the immediate postoperative period.

Poorly managed post-operative pain has also been shown to be a predictive factor for the development of chronic pain after surgery. Despite advances in pain management techniques and increased nursing knowledge, many patients are still waking up in the recovery room in severe pain.

In 1997 the Audit Commission proposed a standard that fewer than 20 per cent of patients should experience severe pain after surgery, ideally reducing to fewer than five per cent by 2002 (Audit Commission, 1997).

The aim of this study was therefore to determine the local prevalence of moderate to severe post-operative pain and thus the adequacy of intra-operative pain management following surgery under general anaesthesia.

It also sought to determine the adequacy of intra-operative pain management among the different surgical disciplines.

The most commonly used analgesic agents were determined.

Following the outcome of the study, appropriate recommendations are made geared towards the improvement of post-operative pain management, all to the ultimate betterment of the patient experience.
4.0 OBJECTIVE OF THE STUDY

4.1 General Objective
To evaluate success of current intraoperative pain management in patients undergoing surgery under general anaesthesia at the Kenyatta National Hospital.

4.2 Specific Objectives
1. To assess pain scores in patients undergoing surgery under general anaesthesia in the immediate post-operative period.
2. To establish a relation between the timing of administration of analgesia and observed pain scores.
3. To establish the most commonly used analgesic agents for the management of pain intra-operatively.
4. To compare the success of intraoperative pain management among different surgical specialties.
5.0 METHODOLOGY

5.1 Study design

This was a cross-sectional study.

5.2 Study area

KNH is a National Referral and Teaching Hospital in Kenya. It has a total bed capacity of 1800. It has 50 wards, 22 Out-patient clinics, 24 theatres (16 specialized) and Accident & Emergency Department.

The main operative theatre suite comprises of 12 theatres, 11 elective and one emergency theatre. In addition there are satellite theatres which include, maternity, Ear Nose and Throat, Burns and Trauma theatre. The main study area was the main theatre’s Post Anaesthesia Care Unit (PACU). In addition, recovery areas in the satellite theatres also formed part of the study area.

5.3 Study population

The population was consenting adult patients who underwent elective and emergency surgery under general anaesthesia in KNH theatres. The questionnaire was then administered and anaesthetic record analyzed in the immediate post-operative period during the period of study.

5.4 Sample size

The sample size adequate for this study was calculated as follows:

\[ n = \frac{Z_{1-\alpha/2}^2 P (1-P)}{d^2} \]

\[ Z_{1-\alpha/2} \text{ - Two-sided significance level (1-alpha) - 95% } = 1.96 \]

\[ P \text{ - Estimated proportion of patients complaining of moderate to severe post-operative pain = 70% } \]

\[ d \text{ - Precision error } = \pm 7\% \]

Substituting into the formula

\[ n = 165 \]
5.5 Sampling procedure

The patients were selected from the theatres after surgery using systematic sampling procedure. Selection was done from theatre lists. Theatre lists for any particular day are sequentially arranged and pinned together in main theatre starting from theatre one up to theatre twelve. This list of all theatre lists is then pinned up in the theatre patient receiving area and at the main theatre reception. In this way, the twelve individual theatre lists are in a sense merged into one. Every third patient on this master was enrolled based on the eligibility criteria. The eligible patients were consecutively enrolled into the study until the desired sample size was achieved. The study duration was 2 months.

Inclusion Criteria

1. All patients aged 18 years and above undergoing elective surgery under general anaesthesia, in main or satellite theatres that consented to participate in the study.
2. All patients aged 18 years and above undergoing emergency surgery under general anesthesia, in main or satellite theatres that consented to participate in the study.

Exclusion Criteria

1. All patients aged below 18 years.
2. All patients undergoing surgery via regional anaesthesia, where general anaesthesia was not used.
3. All patients who did not consent to participate in the study.
4. Any patient unable to communicate with the investigator due to language barrier or any other reason

5.6 DATA COLLECTION PROCEDURE

Before surgery, the eligible patients were approached to seek their consent to participate in the study. Informed consent was administered explaining the purpose and the procedure of the study
as well confidentiality of the information obtained from the patient. Once the patients understood the study, they were asked to consent and confirm their participation in the study by signing an informed consent form provided by the investigator. Following completion of surgery, files of the consenting patients were reviewed to collect information on bio data, type of surgery done and surgical specialty, start and end time of the surgery, type of analgesia administered, the dosage and route of administration, timing of administration of analgesia and whether or not premedication was administered. The patient was then asked to score their pain using the Verbal Numerical Rating Scale from 0 to 10. The administration of the questionnaire was done at least one hour following completion of surgery, and before the patient was transferred out of the the Post Anaesthesia Care Unit.

Prior to the commencement of the data collection, research assistant underwent training to ensure that data was collected in a standard manner and thus minimized person to person variability.

5.7 DATA COLLECTION

Data was obtained from the patient’s anaesthetic record and from a questionnaire administered by the researcher. The Verbal Numerical Rating Scale was used and for the purpose of this study, ‘0’ represented no pain and ‘10’ corresponded to the worst pain possible. In addition, a score of ‘0’ will meant no pain, a score of 1 to 3 was taken as mild pain, a score of 4 to 6 moderate pain and a score of 7 to 10 severe pain.

In addition to the Pain Score the following were obtained:

- Date
- Patient initials
- Age of the patient
- Sex of the patient
- The type of surgery performed and the sub-specialty
- Time of start of surgery
- Time surgery ended
- Patient initials
- Analgesics administered, dose, route and time of administration
- Whether premedication was administered, and if so, the agent used, its route of administration and time it was given.

5.8 DATA MANAGEMENT AND ANALYSIS

At the end of data collection, data was coded and entered into Microsoft Access database. Data cleaning was performed before the data was exported to SPSS version 17.0 for analysis. Using SPSS statistical software, data was analyzed in which the categorical and the continuous variables were summarized into proportions and means/medians respectively. Statistical tests were performed appropriately using Chi-square test of association. All tests of significance were interpreted at p value of ≤0.05 (95% confidence interval).

The output variables included mean age, gender distribution, mean duration of surgery, the degree of post-operative pain (mild, moderate or severe) i.e. the pain score, the degree of postoperative pain by surgical specialty. In addition, pain scores were compared in the group of patients who received analgesia at the beginning of surgery and those at the end of surgery and the use of analgesic premedication. The findings of the study are presented using tables and graphs.

5.9 ETHICAL CONSIDERATIONS

This protocol was reviewed by the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee. The participants of the study were enrolled after giving informed consent. Confidentiality policy on the information concerning the participants were strictly adhered to at all levels. The study was purely observational and did not include invasive procedures.

In the collection of data, the principal investigator was assisted by a research assistant, who was trained in administration of the questionnaire and obtaining other relevant data from the anaesthetic record. The research assistant was a Registered Clinical Officer Student pursuing a
Higher National Diploma in Anaesthesia. He was therefore be able to administer the questionnaire together with or in the absence of the principal investigator.

Approval to carry out the study was sought and obtained from the Kenyatta National Hospital/UON Ethics and Research Committee. There were no additional costs or incentive for participating in the study.

Findings from the study will be availed to the Ethics Committee of KNH and the University of Nairobi. Patients found to have severe pain with pain scores greater than 7 had their primary anaesthetists informed with a view of having additional medication administered. Information on the primary physicians was obtained from the anaesthetic record.
6.0 RESULTS

This was a study to evaluate success of current intraoperative pain management in patients undergoing surgery under general anaesthesia at the Kenyatta National Hospital. A total of 166 patients were recruited in this study. Following completion of the surgery, the anaesthetic record was examined and the immediate post-operative pain score taken using the verbal numerical rating scale. The following are the results that were obtained.

Age ranged from a minimum of 17 years to a maximum age of 71 years. The mean age was 38.1 years. Figure 1 gives a summary of the sex distribution.

**Figure 1: Pie Chart Showing the Sex Distribution of patients included in the study.**

The age distribution of the patients in this study is as shown below.

**Figure 2: Figure showing the age distribution**
Duration of surgery ranged from less than 30 minutes to 3 hours in duration, majority of them falling into 90 – 120 minutes bracket, as shown in figure 3 below:

**Figure 3: Figure showing the duration of surgery**
The number of patients according to the different surgical specialties was also analyzed and the following was the distribution according to the different surgical specialties. Most of the patients in this study underwent general surgical procedures (43 patients) while ophthalmology had the fewest number of patients (5 patients) as shown in table 1 below.

**Table 1: Table showing number of patients by Surgical Specialty**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstetrics</td>
<td>12 (7.2)</td>
</tr>
<tr>
<td>Gynecology</td>
<td>24 (14.4)</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>5 (3.0)</td>
</tr>
<tr>
<td>Urology</td>
<td>16 (9.6)</td>
</tr>
<tr>
<td>General surgery</td>
<td>43 (25.7)</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>15 (9.0)</td>
</tr>
<tr>
<td>Cardiothoracic</td>
<td>10 (6.0)</td>
</tr>
<tr>
<td>Orthopaedic</td>
<td>24 (14.4)</td>
</tr>
<tr>
<td>Maxillofacial</td>
<td>7 (4.2)</td>
</tr>
<tr>
<td>E.N.T</td>
<td>11 (6.6)</td>
</tr>
</tbody>
</table>

The median duration of surgery was 90 minutes.

The following were the findings of the study regarding the agents used for the provision of analgesia. Diclofenac was the commonest used analgesic, being used in 129 patients (77.2%), followed by pethidine which was used in 110 patients (65.9%). Ketamine was the least employed analgesic, being used in only 3 patients (1.8%). In this study we noted that in most cases more than one mode or class of analgesia was used.
Table 2: Table showing Mode of analgesia administered

<table>
<thead>
<tr>
<th>Drug name</th>
<th>n (%)</th>
<th>Dose (Median)</th>
<th>Route</th>
<th>IM</th>
<th>IV</th>
<th>SC</th>
<th>PR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine 1</td>
<td>17 (10.2)</td>
<td>7.5mg</td>
<td>1 (5.9)</td>
<td>16 (94.1)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Morphine 2</td>
<td>4 (2.4)</td>
<td>5mg</td>
<td>1 (25.0)</td>
<td>2 (50.0)</td>
<td>1 (25.0)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Pethidine 1</td>
<td>110 (65.9)</td>
<td>50mg</td>
<td>15 (13.6)</td>
<td>95 (86.4)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Pethidine 2</td>
<td>31 (18.6)</td>
<td>50mg</td>
<td>22 (71.0)</td>
<td>9 (29.0)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tramadol</td>
<td>75 (44.9)</td>
<td>100mg</td>
<td>1 (1.3)</td>
<td>74 (98.7)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>129 (77.2)</td>
<td>75mg</td>
<td>110 (85.3)</td>
<td>3 (2.3)</td>
<td>-</td>
<td>13 (10.1)</td>
<td>-</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>6 (3.6)</td>
<td>1g</td>
<td>-</td>
<td>6 (100)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Fentanyl 1</td>
<td>62 (37.1)</td>
<td>50mcg</td>
<td>6 (9.7)</td>
<td>56 (90.3)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Fentanyl 2</td>
<td>2 (1.2)</td>
<td>50mcg</td>
<td>-</td>
<td>1 (50.0)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Remifentanil</td>
<td>8 (4.8)</td>
<td>-</td>
<td>-</td>
<td>6 (75.0)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ketamine</td>
<td>3 (1.8)</td>
<td>100mg</td>
<td>-</td>
<td>3 (100.0)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

In this study, only 3 patients (1.8%) received some form of analgesic premedication. Of these, 2 received pethidine and the remaining patient received diclofenac. This is shown in the table below.
Table 3: Table Showing Analgesic Premedication:

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-medication</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3 (1.8)</td>
</tr>
<tr>
<td>No</td>
<td>164 (98.2)</td>
</tr>
<tr>
<td>Premedication drugs</td>
<td></td>
</tr>
<tr>
<td>Diclofenac</td>
<td>1</td>
</tr>
<tr>
<td>Pethidine</td>
<td>2</td>
</tr>
<tr>
<td>Premedication route</td>
<td></td>
</tr>
<tr>
<td>IM</td>
<td>2</td>
</tr>
<tr>
<td>PR</td>
<td>1</td>
</tr>
</tbody>
</table>

The intramuscular route was used for pethidine in 2 of the 3 patients while diclofenac was administered via the rectal route.

Information on the timing of administration of the analgesic agents used was also recorded. Analgesia was either administered at the beginning of surgery, at the end of surgery or both at the beginning and at the end of surgery. It was noted however that a sizable proportion of anaesthetic records, the timing of the administration of analgesia was not indicated. This is shown in table 4 below.
Table 4: Table Showing the Timing of the administration of analgesia

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timing of administration of analgesia</td>
<td></td>
</tr>
<tr>
<td>At the beginning of surgery</td>
<td>88 (52.7)</td>
</tr>
<tr>
<td>At the end of surgery</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>Both (beginning and end)</td>
<td>29 (17.4)</td>
</tr>
<tr>
<td>Not indicated</td>
<td>48 (28.7)</td>
</tr>
</tbody>
</table>

The post-operative pain score was taken using the verbal numerical rating scale. The mean pain score in the study population was 3.3. The mean pain score ranged from 0 to a score of 10, with a median score of 3. The vast majority of patients complained of mild pain (77 patients, 46.1%) with 68 patients (40.7%) reporting moderate and severe pain. This is presented in table 5 below.

Table 5: Table showing Post-operative pain score

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-operative pain score</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>3.3 (2.4)</td>
</tr>
<tr>
<td>Median</td>
<td>3.0 (1.0-5.0)</td>
</tr>
<tr>
<td>Range</td>
<td>0-10</td>
</tr>
<tr>
<td>Degree of pain</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>18 (10.8)</td>
</tr>
<tr>
<td>Moderate</td>
<td>50 (29.9)</td>
</tr>
<tr>
<td>Mild</td>
<td>77 (46.1)</td>
</tr>
<tr>
<td>None</td>
<td>22 (13.2)</td>
</tr>
</tbody>
</table>
The number of patients who reported no pain was 22, representing 13.2% of the study population.

Cardiothoracic surgery had the highest mean pain score (5), while ophthalmology had the lowest mean pain score (1). Neurosurgical, orthopaedic and maxillofacial patients reported mean pain scores of 4. This is presented in figure 2 below.

Figure 4: Figure showing the Mean Pain score by surgical specialty
Table 6: Table showing number of patients with pain vs. no pain by surgical specialty

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pain assessment (Severe+Moderate+Mild)</th>
<th>No pain (None)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical specialty</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obstetrics</td>
<td>12 (8.3)</td>
<td>0</td>
<td>0.102</td>
</tr>
<tr>
<td>Gynaecology</td>
<td>20 (13.9)</td>
<td>3 (13.6)</td>
<td></td>
</tr>
<tr>
<td>Ophthalomology</td>
<td>3 (2.1)</td>
<td>2 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Urology</td>
<td>11 (7.6)</td>
<td>5 (22.7)</td>
<td></td>
</tr>
<tr>
<td>General surgery</td>
<td>36 (25.0)</td>
<td>7 (31.8)</td>
<td></td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>15 (10.4)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Cardiothoracic</td>
<td>10 (6.9)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Orthopaedic</td>
<td>21 (14.6)</td>
<td>3 (13.6)</td>
<td></td>
</tr>
<tr>
<td>Maxillofacial</td>
<td>7 (4.9)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>E.N.T</td>
<td>9 (6.3)</td>
<td>2 (9.1)</td>
<td></td>
</tr>
</tbody>
</table>

There was no statistically significant association between the observed pain score and the surgical specialty. (p value 0.102)

The patients in this study received analgesia either at the beginning of surgery, at the end of surgery or at both the beginning and at or towards the end of surgery. The table below shows the mean post operative pain score for each of the 3 groups of patients mentioned above.
Table 7: Table showing the mean Post operative pain score in patients by the timing of administration of analgesia.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean pain score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timing of administration of analgesia</td>
<td></td>
</tr>
<tr>
<td>At the beginning of surgery</td>
<td>3</td>
</tr>
<tr>
<td>At the end of surgery</td>
<td>4</td>
</tr>
<tr>
<td>Both</td>
<td>3</td>
</tr>
</tbody>
</table>

Patients in this study fell into one of 3 categories depending on the timing of administration of analgesia. The number of patients who reported pain versus the number who reported no pain are presented in the table below.

Table 8: Table showing the number of patients with pain against those with no pain in depending on the timing of administration of analgesia

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pain assessment</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pain</td>
<td>No pain</td>
</tr>
<tr>
<td>Timing of administration of analgesia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At the beginning of surgery</td>
<td>77 (72.0)</td>
<td>11 (91.7)</td>
</tr>
<tr>
<td>At the end of surgery</td>
<td>2 (1.9)</td>
<td>0</td>
</tr>
<tr>
<td>Both</td>
<td>28 (26.2)</td>
<td>1 (8.3)</td>
</tr>
</tbody>
</table>

P value = 0.426
7.0 DISCUSSION

Effective pain control following surgery is important. Inadequate treatment of pain has been shown to delay patient recovery and discharge from hospital thereby increasing cost to the patient. In addition, it is associated with significant emotional distress and physiological consequences, especially in the immediate post-operative period.

In this study, we found an incidence of moderate and severe pain of 40.7%. This compares with the study done by M. Sommer in 2008. This compares with yet other studies such as the one done by Chauvin M in which he found a prevalence of pain of up to 50% of inpatients following surgery.\(^{57}\)

In 1997, the UK Audit Commission proposed a standard that fewer than 20% of patients should experience severe pain after surgery, ideally reducing to less than 5% by the year 2002. Pyati S and Gan TJ found that the incidence of moderate and severe post-operative pain was as high as 70%.\(^{54}\)

M. Sommer et al in 2008 looked at the prevalence of postoperative pain in a sample of 1,490 surgical inpatients and found that the incidence of moderate and severe pain was 41%.\(^{51}\) A previous study at KNH found that 56% of patients experienced moderate and severe pain following major thoracic and abdominal surgery. In this study 34.4% experienced mild pain.\(^{62}\)

From this study, we see that the standard of post-operative pain management at KNH is poor, falling far below proposed standards such as the UK Audit Commission cited above. This is despite the vast analgesic armamentarium at our disposal which includes opioids, NSAIDs, acetaminophen, ketamine among others which are available for administration in a variety of routes. E. F. Ocitti and J. A. Adwok in their study done at KNH also came to a similar conclusion.\(^{62}\) Thus from the finding of this study, and reinforced by the findings of the other study done at KNH, there is clearly a need to improve the standard of current post – operative pain management. This might involve coming up with a set standard or goals towards which anesthesia providers can aim to achieve. A number of possible reasons have been advanced as to the high incidence of post-operative pain. Griepp identified “the knowledge deficit” among professionals as the most prevalent cause of poor pain management. This has been a repeatedly reported factor in pain literature.\(^{65}\) Education is probably the most important tool in improving pain management.\(^{66}\) Another possible reason is the fear of respiratory depression and delayed reversal from general anaesthesia associated with opioid use resulting in sub-optimal dosing and consequently, inadequately managed pain. From this study we see that acute postsurgical pain at KNH is still inadequately managed with room for improvement.
A multimodal approach to the management of pain has been advocated for as it maximizes the benefits of the agents used while minimizing on the adverse effects of the individual agents.

In this study, we looked at the various analgesics used for the management of pain. The most commonly used agent was diclofenac which was used in 77.2% of patients in the study. It is an effective agent in the management of pain that in addition has anti-inflammatory properties. It has the advantage of being relatively inexpensive, no effect on time to waking and delayed emergence from anaesthesia while having minimal respiratory and cardiovascular effects. However, like other NSAIDs, it has a ceiling effect and thus is unsuitable as the sole means of anaesthesia where moderate to severe pain is expected, a more prudent approach being to combine it with another modality e.g. an opioid. We noted in this study that diclofenac was given in over 85% of cases via the IM route with a modest 2.3% receiving it via the IV route. This can be explained by the fact that diclofenac supplied at KNH is in 2 main formulations, for IM use and for PR use as suppositories. From this, we see that diclofenac remains a mainstay of management of postoperative pain. We however note that it was not used in all patients, and although the reason for this was beyond the scope of this study, we can venture to say that this may be due its unsuitability in certain patients owing to its adverse effect profile. These include impaired haemostasis, renal dysfunction, gastrointestinal haemorrhage, and deleterious effects on bone healing and osteogenesis. In this study we see that diclofenac was given only once with no additional dose given, in contrast to opioids for example where in some instances an additional dose was given. It is important to note that diclofenac is typically given every 12 hours, and since none of the surgeries went beyond 12 hours, this is yet another reason why it was unlikely to have been administered as an additional dose.

In this study, the use of opioids was limited to a relatively small range, i.e. morphine, pethidine, remifentanil and fentanyl, these being the opioids that are available in KNH. Of these, pethidine was the most commonly used, being employed in almost two thirds of patients in this study. One possible reason for its popularity is its ease of administration. Compare this with remifentanil, which is a little more resource intensive, requiring an infusion pump to administer. Familiarity may also explain pethidine’s popularity. For a long time pethidine has been the most popular opioid in
clinical practice. Morphine on the other hand was much less used, being used in only 5.9% of the study population. On the one hand, morphine may have been considered a preferable opioid to pethidine on account of its longer duration of action which would allow for more prolonged and sustained pain relief extending into the post-operative period. On the other hand, pethidine whilst having a shorter duration of action, has a faster onset of action. However, the exact reasons for choice of one opioid over another were beyond the scope of this study. For both pethidine and morphine, the IV route of administration was favoured. This may be due to the fast onset of action with this route compared with other routes. However, when we look at these agents when they were administered at the end of surgery, most anaesthesia providers gave it via the IM route. This may reflect a concern of these agents ability to cause respiratory depression, and hence the IM route were delayed and slower absorption associated with reduced risk. Tramadol in this study was commonly used, in up to 45% of patients, predominantly via the IV route. Tramadol is a relatively safe agent effective agent that is not typically associated with the profound respiratory depression of the other opioids and this may explain its popularity. Remifentanil was not commonly used in this study. This may be related to the need for infusion pumps and is typically used in long procedures such as those of the spine and in neurosurgery. Regarding the use of ketamine, it was used in only 1.8% of patients in this study. Whereas it is a potent analgesic, it may have been used as an induction agent rather than an analgesic. Its use as an analgesic may not be common owing to its adverse side effects such as psychoactive properties and increased lacrimation. From this study we see that paracetamol was underutilized, being used in only 3.6% of patients. Given its safety profile, paracetamol should be utilized more often. Paracetamol is also an effective adjunct to opioid analgesia, opioid requirements being reduced by 20% to 30%. 

From this study, we see pre-emptive analgesia or analgesic premedication was the exception, occurring in only 3 patients. The reason for this may very well be that the effectiveness of pre-emptive analgesia is a controversial topic, with many studies suggesting that only certain forms of pre-emptive analgesia are effective while others like NSAID premedication showing no improvement in post-operative pain scores.

This study also looked at the timing of administration of analgesia and the observed pain scores following surgery. The average pain score in the different groups did not differ much, being 3, 4 and 3 for those who received analgesia at the beginning, at the end of surgery and both at the beginning and at the end of surgery respectively. The higher mean pain score observed in the group of patients that received analgesia solely at the end of surgery may not mean much considering that
the numbers involved was small (2 in number). From this study it seems that the timing of administration of analgesia was not significant when related with the postoperative pain score observed. A p value of 0.426 suggests that the occurrence of pain in this study was not significantly related to the timing of administration. Therefore the time a particular analgesic was administered to a patient did not have a significant bearing on the pain score observed.

This study also looked at the various surgical disciplines and the postoperative pain scores in patients by the various specialties. The highest pain score was cardio thoracic surgery. This may be related to the type of surgical procedures performed that include thoracotomies that are associated with significant amounts of pain. The least mean pain score in this study was found in patients that underwent ophthalmology procedures. The findings of this study compare to a cohort study in Amsterdam suggested that certain procedures were more likely to be associated with severe post-operative pain scores. An example include eye surgery which in that study were associated with lowest post-operative pain scores, a finding that is replicated in this study. However, analysis of the relation between the surgical specialty a patient fell under and the observed mean pain score revealed it was not statistically significant. (p value 0.102). This means that a patient is not necessarily likely to obtain a particular post-operative pain score depending on the surgical specialty he happens to fall under. Many more factors are likely to contribute. These include the surgical procedure itself, patient factors such as anxiety among others.

8.0 CONCLUSION

This study was designed to evaluate the success of current post-operative pain management in patients undergoing general anaesthesia at the Kenyatta National Hospital. From the study, it is concluded that:

1. Pain is still not been adequately addressed with a high proportion of patients still experiencing moderate to severe post operative pain.
2. Opioids and NSAIDs, chiefly diclofenac, remain the mainstay of intraoperative pain management at KNH.
3. There is no relation between the post operative pain score observed and the time analgesia is given.
4. There was no significant correlation between the pain observed at the end of surgery and the surgical discipline.

LIMITATIONS

1. Incomplete anaesthetic record keeping. Especially in regard to recording the time when a particular drug is administered or an intervention made.

9.0 RECOMMENDATIONS

1. Clinicians need to put in place measures to reduce the number of patients that experience moderate to severe pain following surgery. This may include the routine taking down of pain score and taking appropriate and timely interventions, education to clinicians with the view of better pain prescriptions and regular audits to review progress towards the reduction of severe pain.

2. Paracetamol as an analgesic should be utilized more to achieve a more balanced approach to the management of pain. As it stands now, paracetamol is still not used as much as it might be.

3. Anaesthesia record keeping needs to be improved with the particular time a drug is given or an intervention is made recorded.
10.0 REFERENCES


54. Pyati, Srinivas; Gan, Tong J., CNS Drugs 2007;21 (3): 185 - 211


61. International Anaesthesia Research Society Vol. 107, No 4, October 2008


64. Cliff K.-S. Ong, DDS, Philipp Lirk, MD, Robin A. Seymour, PhD and Brian J. Jenkins, MD, The Efficacy of Preemptive Analgesia for Acute Postoperative Pain Management: A Meta-Analysis

Appendix I

Letter to respondents

Dear Sir/Madam,

I am a Senior House Officer currently undertaking a Masters of Medicine (M.Med) degree in anaesthesiology at the University of Nairobi.

I am conducting a survey titled ‘ACUTE POST-OPERATIVE PAIN MANAGEMENT AT THE KENYATTA NATIONAL HOSPITAL’.

The objective of this study is to assess pain scores in patients following surgery under general anaesthesia, to determine the most commonly used analgesic agents, assess the success of pain management among the different surgical specialties and to establish a relation between the timing of administration of analgesia and the observed pain score.

This is in part fulfillment of the M.Med program requirements.

I am requesting you to take a few minutes of your time to fill out the attached consent form and respond to the questions that will be put to you. Please answer all questions. Confidentiality will be maintained.

This is a voluntary exercise. Thank you for your co-operation

Dr. Kimani Mbugua

NB: In case of an illiterate person, the nature of the study, the consent form and consent explanation shall be explained to the patient in a language they understand, and a translator used if necessary.
Appendix II

CONSENT FORM

ACUTE POST-OPERATIVE PAIN MANAGEMENT AT THE KENYATTA NATIONAL HOSPITAL

CONSENT BY PATIENT

I ........................................... of ........................................... do hereby give consent for myself to participate in the above study whose nature, benefits and risks have been fully explained to me by the researcher. I have not been coerced or enticed to participate and voluntarily gave permission. I have been assured of my/my relative’s confidentiality and that am free to withdraw from the study at any stage and this will in no way influence treatment.

CONSENT BY RESEARCHER

I ........................................... have explained the nature of the study to the participants detailing the benefits and risks of the study and have not withheld any information. I have assured the participants of their confidentiality and the right to withdraw from the study at any stage and that this will in no way influence the patient’s treatment.

Signature.............................................

Witnessed by:    Name: ...........................................

Signature: .............................................
FOMU YA IDHINI KUSHIRIKI

ACUTE POST-OPERATIVE PAIN MANAGEMENT AT THE KENYATTA NATIONAL HOSPITAL.

KUKUBALI KWA MGONJWA/JAMAA WA MGONJWA.

Mimi………………………………..kutoka mji wa ………………………….nimetoa kibali changu/jamaa wangu kushiriki katika utafiti huu.Nimeelezwa juu ya manufaa ya utafiti huu vilevile kuhusu madhara yanayoweza kutokea na nimekubali kushiriki kwa hiari yangu.

Nimeahidiwa kuwa habari zozote nitakazotoa zitabakia siri na nina uhuru wa kujiondoa kwenye utafiti huu wakati wowote na kufanya hivi hakutabadili kwa vyovyote vile, matibabu nitakayopokea.

Sahihi …………………………………………………………………………………..

KUKUBALI KWA MTAFITI

Mimi mtafiti nimemweleza mshiriki kwa kina kuhusu utafiti huu,manufaa na madhara yote bila kuficha habari zozote.Pia nimemweleza kuwa habari zozote atakazozitoa zitabakia siri na kwamba ana uhuru wa kujiondoa kwenye utafiti huu wakati wowote bila dhuluma na kufanya hivi hakutabadili kwa namna yoyote matibabu atakayopokea.

Sahihi ya mtafiti…………………………………………………………………………..

Shahidi  Jina : ………………………………………………..

Sahihi : ……………………………………………..

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CONSENT EXPLANATION

ACUTE POST-OPERATIVE PAIN MANAGEMENT AT THE KENYATTA NATIONAL HOSPITAL

Introduction

My name is Dr Kimani Gichuru Mbugua, MBchB, a post graduate student in anesthesia at the University of Nairobi. I am conducting a study on acute post-operative pain management at the Kenyatta National Hospital in patients undergoing surgery under general anaesthesia. I will be assisted by Kwameh Wafula, a Clinical Officer pursuing a Higher National Diploma in Anaesthesia. The study will take about 2 months and will take place in the Post Anaesthesia Care Unit in main theatre or in one of the satellite operating theatres.

Purpose of the study

The aim of this research is to assess our local practice in pain management and compare it to the international guidelines with the intention of identifying weaknesses and strengths and come up with recommendations on how to improve our practice and help improve patient outcomes. The data generated will be used strictly for research purposes.

Interventions.

The study will involve an interview with the patient during which he/she will be asked to quantify the pain they feel at the time of the interview. This interview will take place at least one hour after the end of surgery and will be carried out in the Post Anaesthetic Care Unit. This tool is called the Verbal Numerical Rating Scale. Data will be collected using questionnaire. Information will also be obtained from the patient record on the pain medication administered and the timing of the same.

Voluntary participation.

Your participation in this study is entirely voluntary. You reserve the right to withdraw from the study at any stage. In the event you decide to decline participation or to pull out at any stage, this will in no way influence the treatment that you will receive.
**Risks and benefits.**

You are not exposed to any risks by participating in this study. The data collected will be used to come up with recommendations on the adequacy of current pain control strategies in use at the Kenyatta National Hospital.

**Confidentiality.**

Confidentiality and research ethics will be guaranteed throughout the research. Serial numbers instead of names will be used to identify participants.

**Contacts.**

For any questions or clarifications you can contact the following people:

Dr Kimani G Mbugua- 0721621104 or kimmbugua@live.com

Dr. Thomas M. Chokwe -0722528237 or tchokwe@yahoo.com

Dr. Timothi M. Mwiti -0721366294 or mtmwiti@yahoo.com

In case of any query, clarification or complaint, you may contact The Kenyatta National Hospital/University of Nairobi Ethics and Research Committee: uonknh_erc@uonbi.ac.ke
Appendix III

QUESTIONNAIRE

Date of interview __ __/ __/ __ __ __ __ Study number ____________
    dd    mm    yyyy

I. SOCIO-DEMOGRAPHIC FACTORS
1. Patient Initials: __________
2. Patient’s age? ________ years
3. Gender    Male ☐    Female ☐

II. SURGERY
4. Surgical procedure information
   a. Operation/Procedure _________________
   b. Surgical specialty
      - Obstetrics ☐
      - Gynaecology ☐
      - Ophthalmology ☐
      - Urology ☐
      - General surgery ☐
      - Neurosurgery ☐
      - Cardiothoracic ☐
      - Orthopaedic ☐
      - Maxillofacial ☐
      - E. N. T ☐
   c. Duration of surgery
      i. Start time ________
      ii. End time ________
III. POST-OPERATIVE PAIN ASSESSMENT

5. Pain management

   a. Type of analgesia administered

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Time given</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>IM</td>
<td>IV</td>
</tr>
<tr>
<td>Morphine</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pethidine</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tramadol</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diclofenac</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paracetamol</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fentanyl</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remifentanil</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

b. Did the patient receive pre-medication
c. If yes in 5 (b) above, state the form in which it was administered

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. Indicate the post-operative pain score of the patient

```
0 1 2 3 4 5 6 7 8 9 10
No pain Moderate pain Worst possible pain
```
## Appendix IV

### Budget

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<thead>
<tr>
<th>ITEM</th>
<th>UNIT COST (KSh)</th>
<th>NUMBER OF UNITS</th>
<th>TOTAL COST (KSh)</th>
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</thead>
<tbody>
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<td>Printer/copier</td>
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<td>5000</td>
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<td>Paper</td>
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<td>Internet hours</td>
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<td>Statistician</td>
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<td>Document binding</td>
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<td>8</td>
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</tr>
<tr>
<td>ERC fee</td>
<td>1000</td>
<td>1</td>
<td>1000</td>
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</table>

**Sub total**

Contingency @ 5% of sub total

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Contingency @ 5% of sub total</td>
<td>1950</td>
</tr>
</tbody>
</table>

**Grand Total**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Grand Total</td>
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</tbody>
</table>
## Appendix V

### Work Plan

<table>
<thead>
<tr>
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<th>Dec</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
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<td>Presentation to Ethical Review Committee</td>
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<td>Pilot Study</td>
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<td></td>
<td></td>
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</tr>
</tbody>
</table>
Appendix VI: Copy of the Ethics and Research Committee Approval

Dear Dr. Kimani,

RESEARCH PROPOSAL: ACUTE POST-OPERATIVE PAIN MANAGEMENT AT THE KENYATTA N.HOSPITAL

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and approved your above revised proposal. The approval periods are 6th December 2012 to 5th December 2013.

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/KNH/UoN
Yours sincerely

[Signature]

PROF. A.N. GUANTAI
SECRETARY, KNH/UON-ERC

cc. The Deputy Director CS, KNH
    The Principal, College of Health Sciences, UoN
    The Dean, School of Medicine, UoN
    The Chairman, Dept. of Surgery, UoN
    The HOD, Records, KNH

Supervisors: Dr. Thomas M. Chokwe, Dept. of Surgery, UoN
             Dr. Timothy M. Mwiti, Dept. of Surgery, UoN
Appendix VII

DECLARATION OF ORIGINALITY FORM

Name of student _________________________________
Registration Number_____________________________
College_________________________________________
Faculty/School/Institute__________________________
Department_____________________________________
Course Name____________________________________

DECLARATION

1. I understand what plagiarism is and I am aware of the University's policy in this regard.
2. I declare that this __________________________ (Thesis, project, essay, assignment, paper, report, etc.) is my original work and has not been submitted elsewhere for examination, award of a degree or publication. Where other people’s work, or my own work has been used, this has properly been acknowledged and referenced in accordance with the University of Nairobi’s requirements.
3. I have not sought or used the services of any professional agencies to produce this work.
4. I have not allowed, and shall not allow anyone to copy my work with the intention of passing it off as his/her own work.
5. I understand that any false claim in respect of this work shall result in disciplinary action, in accordance with University Plagiarism Policy.

Signature___________________________
Date_____________________________

Signed by University Supervisor

Dr. Thomas Chokwe__________________________Date_________________

Dr. Timothy Mwiti__________________________Date_________________