FACTORS INFLUENCING CHOICE OF INGUINAL HERNIA REPAIR TECHNIQUE AMONG SURGEONS AND SURGICAL TRAINEES: A DESCRIPTIVE CROSS-SECTIONAL STUDY IN KENYATTA NATIONAL HOSPITAL, NAIROBI-KENYA

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A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE (GENERAL SURGERY), UNIVERSITY OF NAIROBI

2015
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I hereby certify that this dissertation is my original work and has not been submitted for the award of a degree in this or any other institution.

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DEDICATION
To Lorina – the reason why I do what I do.
To the outstanding students and teachers of the discipline of surgery at the University of Nairobi – past, present and future.
ACKNOWLEDGEMENTS

Special appreciation goes to my supervisors, Dr Awori, Mark Nelson and Dr Ojuka, Kinyuru Daniel whose contribution has been invaluable in the development of this proposal.
To Dr Bernard Ndung’u, thank you for believing that this idea could grow into what it is today.
Deep gratitude goes out to my wife and family for their unwavering support and encouragement; and to the Almighty God for this wonderful opportunity to pursue my dreams.
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<table>
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<th>Description</th>
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<tbody>
<tr>
<td>GPRVS</td>
<td>Giant Prosthetic Reinforcement of the Visceral Sac</td>
</tr>
<tr>
<td>KNH</td>
<td>Kenyatta National Hospital</td>
</tr>
<tr>
<td>LHR</td>
<td>Laparoscopic Hernia Repair</td>
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<tr>
<td>OHR</td>
<td>Open Hernia Repair</td>
</tr>
<tr>
<td>PHS</td>
<td>Prolene Hernia System</td>
</tr>
<tr>
<td>P&amp;P</td>
<td>Plug and Patch Repair</td>
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<tr>
<td>SPSS</td>
<td>Statistical Package for the Social Sciences</td>
</tr>
<tr>
<td>TAPP</td>
<td>Transabdominal Preperitoneal Repair</td>
</tr>
<tr>
<td>TEP</td>
<td>Totally Extraperitoneal Repair</td>
</tr>
<tr>
<td>TIPP</td>
<td>Trans-Inguinal Preperitoneal Mesh Hernioplasty</td>
</tr>
<tr>
<td>USA</td>
<td>United States of America</td>
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<tr>
<td>USD</td>
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ABSTRACT

Background: Inguinal hernia repair surgery is one of the most frequently performed surgical procedures worldwide. Tension-free mesh repair has become a standard procedure in the developed world due to the proven lower complication rates associated with this technique. Clearly-defined structures for inguinal hernia repair training are present in the West. However, in our setting, it is not known what factors influence surgeons and surgical trainees’ choice with respect to operative technique, and whether this choice is influenced by the evidence-base. This study sought to highlight factors that may influence decisions concerning inguinal hernia repair techniques at Kenyatta National Hospital (KNH).

Objective: To establish the factors that influence the choice of inguinal hernia repair technique among surgeons and surgical trainees at KNH.

Study design: This was a descriptive cross-sectional study

Study duration: One (1) month

Setting: Kenyatta National Hospital General Surgical Unit

Study Population: Surgeons and surgical trainees

Methodology: Data was collected through printed pre-tested questionnaires. Data collected included: qualification of the operating doctor, level at which practical training on inguinal hernia repair occurred, awareness of the surgeons and surgical trainees of the various inguinal hernia repair methods, inguinal hernia repair method(s) used for the past three (most recent) inguinal hernia operations and reasons for using that /those repair method(s).

Data from all the doctors was entered into an MS access database, and exported to EpiData and Stata software for analysis. Frequency tables and graphs have been used to present the analyzed data.

Approval to carry out the study was sought from the KNH and University of Nairobi Ethics and Research Committee.
**Results:** Fifteen (15) consultant surgeons and sixty (60) surgical trainees were recruited. The modified Bassini is the repair method majority have been trained in (98.67% of the respondents); followed by the Lichtenstein method. Training by an experienced peer (both outside and during residency) is the most common way these two methods were learned by the respondents. The most frequently used hernia repair method is the Lichtenstein method (38.22%). The laparoscopic hernia repair methods (TAPP, TEP) – as opposed to the suture and mesh repairs - are the least used (less than 3%). Some of the most frequently cited reasons influencing choice of repair technique include: training on the technique, ease of the technique, availability of repair material and equipment and decreased recurrent rate.

**Conclusion:** Training on the technique plays a big role in the choice of technique to use. Residency is a critical time period for training in hernia surgery. Most trainees are trained by their fellow peers. Limited resources act as a hindrance to the use of tension free hernia repair methods (both open and especially laparoscopic).
INTRODUCTION

1.1 Magnitude of hernia pathology

Inguinal hernia is a common pathology encountered by general surgeons; comprising of approximately 75% of all abdominal wall hernias. Inguinal hernia repair is the second most common general surgical operation worldwide (after appendectomy) accounting for 10 to 15% of all surgical procedures.

1.2 Repair techniques in current use

Since Bassini published his original description of inguinal hernia repair in 1887, many techniques for hernia repair such as Shouldice, Darning, Desarda, Modified Bassini, Lichtenstein mesh repair and laparoscopic mesh repair have been published. Laparoscopic and Lichtenstein mesh repair are becoming popular in recent days as they are associated with rapid return to normal activities with low recurrence rates. These repair methods have come to replace the traditional suture repairs of Bassini and McVay in many developed nations.

Some strong recommendations exist in favor of Lichtenstein repair. American College of Surgeons chose this technique as the “gold standard”, while the National Institute of Clinical Excellence [NICE] from UK and The National Agency for Accreditation and Evaluation in Health [ANAES] from France recommended it for inguinal hernia repair. It is easy to learn and perform. The Lichtenstein Hernia Institute and the British Hernia Centre reported very low recurrence rates in thousands of cases. It is also suitable for outpatient surgery using local anesthesia.

Laparoscopic repairs provide very good results where surgeons have expertise. They result in very low postoperative pain, fewer wound infection, and quick return to daily activity. A mesh is placed either with a totally extraperitoneal technique (TEP) or a transabdominal preperitoneal approach (TAPP). A Cochrane review found these two approaches equivalent regarding duration of operation, hematoma, length of stay, time to return to usual activity and recurrence.
However, because of poor socioeconomic status, non-affordability to patients and non-availability of mesh and laparoscopy in most centres in developing countries, these inguinal hernia repair techniques are not popular in these countries. As a result traditional suturing techniques such as Shouldice, Darning, Desarda and Modified Bassini are still practiced widely in this part of the world\textsuperscript{10}. The management of inguinal hernia poses therapeutic challenges to general surgeons practicing in resource-limited countries. Late presentation of the disease coupled with lack of modern therapeutic facilities such as laparoscopy and mesh are among the hallmarks of the disease and its management in developing countries\textsuperscript{11}. In many parts of Africa many patients develop large inguinoscrotal herniation as a result of delayed presentation, and the need for emergency surgery with its attendant morbidity is common. In these countries, approximately 65\% of inguinal hernias are repaired as emergencies, with a bowel resection rate of 24\% and mortality of 87\% in those not reaching hospital\textsuperscript{12}. Early presentation and elective repair of inguinal hernia have been reported to eliminate the morbidity and mortality associated with this very common problem.

In a 5-year retrospective study of adult inguinal hernia patients at KNH, 17.9\% of these patients had emergency surgery; while the repair method employed for all the hernias was the modified Bassini repair\textsuperscript{13}.

1.3 Learning process for doctors in inguinal hernia repair

Hands-on instruction is an integral component of surgical education in the West\textsuperscript{6}. Graduate surgical education in the United States, for example, follows a model of graded clinical responsibility and operative experience, with continuous evaluation, throughout a residency program\textsuperscript{14}. The program requirements for Residencies in Surgery, as defined by the Accreditation Council for Graduate Medical Education, state:

“Operative skill is essential and can be acquired only through personal experience and training. The program must provide for sufficient operative experience to train qualified surgeons, taking into account individual capability and rate of progress.”\textsuperscript{14}

Charged with the responsibility for instructing, supervising, and evaluating surgery residents are attending surgeons who have both an ethical and a legal responsibility for overall care of each patient and supervision of the resident involved in that care. Residents are required to be provided with adequate opportunities to learn techniques and skills. Safeguarding patient
welfare is guaranteed by appropriate supervision by more experienced surgeons. This redundancy in patient care, implicit in teaching hospitals, may be the basis for outcomes of surgical care that are at least as good as those in nonteaching institutions. There are a number of studies that compare outcomes of procedures done at teaching hospitals by residents and those procedures performed by attending surgeons\textsuperscript{15}. Almost uniformly, these studies show no negative effect on outcome when patients are operated on at hospitals with residents involved in patient care. It has been reported that, when surgical procedures were performed with low levels of attending surgeon supervision, complication levels and mortality were raised\textsuperscript{16}.

1.4 Research Question

There is paucity of published data on surgical management of inguinal hernias in our environment. The frequencies of the various surgical repair techniques and the bases for different technique preferences remain largely unknown. Data on hernia surgery training is also lacking.

This study aimed to tackle these questions:

1. Who performs inguinal hernia repair at Kenyatta National Hospital?
2. Which are the most common inguinal hernia repair techniques currently used in this institution?
3. What factors influence the choice of inguinal hernia repair technique?
LITERATURE REVIEW

2.1 Hernia Disease Burden
In Africa the incidence inguinal hernias is 175 per 100,000 people each year, but only 25 are repaired\textsuperscript{17}. There has been difficulty accessing elective surgery and a large number of patients present as emergencies with obstruction and/or strangulation. This has led to a disproportionately large number of giant hernias compared with the developed world\textsuperscript{17}.

It is estimated that 30 patients per 100,000 in Africa need surgery for strangulated hernia; and only four actually receive an operation\textsuperscript{17}. The mortality rate of patients who have a strangulated hernia and do not reach a hospital is over 85%. Even for those who reach a hospital, the majority have had strangulation lasting longer than 72 hours and the overall mortality rate is 40\%\textsuperscript{18}. In Sudan, an assessment of 64 patients with strangulated hernia found that more than half presented to hospital greater than 24 hours after the onset of symptoms\textsuperscript{19}. They subsequently had a 37.5\% rate of bowel resection and a 6.25\% chance of mortality. In Nigeria, 20.6\% of hernia patients present with an acute abdominal emergency and prophylactic repair has been recommended\textsuperscript{11}. In Ghana, it was found that out of 552 patients presenting with intestinal obstruction, 59.8\% were caused by hernias\textsuperscript{20}. These patients had an overall mortality of 9.4\%.

2.2 Repair Methods – A Brief History
The repair of groin hernias is one of the most common and important surgical procedures. It has been said that the history of groin hernias is the history of surgery itself. Abrahamson\textsuperscript{21} and Read\textsuperscript{22} give a comprehensive account of the development of the different hernia repair techniques as detailed subsequently. In the mid to late 1800’s, groin hernia repair recurrence rates after 1 year were 30 - 40\% and most recurred within 4 years. Mortality rates were reported between 5 - 10\%. The late 1800’s brought significant change with outcome improvements in patients undergoing groin hernia repairs. Aseptic surgery was introduced. And the realization that a successful groin hernia repair required more than just manipulation of the hernia sac; it also required repair of the underlying fascial defect.

Bassini, an Italian surgeon, is credited as the father of modern herniorrhaphy as he was the first to describe clear anatomical dissection and reconstruction of the inguinal canal. As such,
inguinal hernia repairs began as suture repairs, all being modifications of the Bassini repair. The two main principles of a suture repair include repair of the transversalis fascial defect and tightening of the internal ring. The McVay repair is a modification of the Bassini repair that enables closure of the femoral canal in the event of a femoral hernia. The Shouldice repair was introduced in Canada in the 1950’s and it too is based on principles established by Bassini\textsuperscript{22}. This technique involves tightening the internal ring and a continuous 4 layer repair of the posterior wall of the inguinal canal to repair the transversalis fascia defect. Recurrence rates from specialized hernia centres using the Shouldice technique are reported to be less than 1\%\textsuperscript{22}.

2.3 Tension-Free Repair

The nylon darn repair is a suture repair that introduced the concept of a tension-free repair. In the beginning of the 1900’s, various surgeons used pedicled strips of the external oblique aponeurosis or fascial grafts from the thigh for their repairs. This led to the idea of a lattice or darn suture repair. The plication – darn technique was formally described by Maloney in the 1950’s. The technique was revised and further popularized by Abrahamson in the 1980’s. In his reported series of 100 patients, his recurrence rate was also less than 1\%.

By now the notion of minimizing tension in a groin hernia repair, to reduce the risk of recurrence, was becoming more popular. This eventually led to mesh repair techniques. The difficulty was finding the appropriate material. Metal sheets were first introduced, but they were fraught with complications. PTFE (polytetrafluoroethylene) results were also disappointing. Credit for the successful introduction of mesh should be attributed to Usher. He initially used polyethylene and later substituted it with polypropylene mesh in the 1950’s. Rives (1960’s) and Stoppa (1980’s) made significant contributions in this area of surgery. While Newman was first to use mesh for anterior repair, Lichtenstein popularized this approach (1980’s). Gilbert introduced the Prolene Hernia Repair system based on input from Usher.

Since the 1970’s, the use of polypropylene meshes have become increasingly popular. The most popular open mesh repairs today include a flat patch, plug and patch, and the prolene hernia system. The reported advantages of mesh repairs include low recurrence rates, less postoperative pain, and quicker return to regular activities. The advent of laparoscopy has also resulted in the introduction of the TAPP and TEP mesh repairs.
2.4 Mesh vs. Non-mesh Repair
A review of twenty trials comparing open mesh with non-mesh techniques for groin hernia repairs concluded that mesh repair has less of recurrence with similar rates of complication as non-mesh repair. However they also conclude that Shouldice is the technique with the lowest recurrence rate among all tissue repairs. In a prospective randomized trial comparing Lichtenstein technique with four layer Shouldice procedure the author concludes that both techniques are effective. The Lichtenstein technique is more favored because it is easy to master, the recurrence rate is lower, and can be performed under local anesthesia. Many reviews have confirmed that Shouldice is certainly associated with a higher recurrence rate compared to mesh based repair.

In a comparison of Lichtenstein technique with Prolene Hernia Repair system (PHS) and Plug and Patch repairs, the outcomes were similar though PHS and P&P can be performed faster than Lichtenstein’s.

2.5 Laparoscopic Hernia Repair
Laparoscopic surgery for cholecystectomy gained widespread acceptance very quickly. The same has not been the case with laparoscopic intervention for hernia. While a lot of comparisons are available in the literature the Veterans Affairs Co-operative Study is very often quoted. In this study, the 2 year recurrence rate was significantly higher in the laparoscopic hernia group: 10.1% vs. 4.9%. The complication rates were also higher with laparoscopic group. Return to activity was almost same in both groups (39 vs. 33.4%). In a multicenter randomized trial from Sweden with a follow up of 5 years, the authors initially report a recurrence rate of 3.5 % with LHR. With the exclusion of one surgeon who was responsible for most cases of recurrence in LHR, the recurrence rate fell to 2.4% as opposed to 1.2% for Lichtenstein in the same trial. The authors also mention that in the Swedish hernia register the number hernia cases attempted laparoscopically has decreased from 20% in 1990’s to 9% in 2006. It is possible that the increased operating time and the long learning curve have prompted surgeons to choose open mesh repair.

In a Cochrane review of 41 trials involving more than 7000 patients the authors conclude that patients in the laparoscopic arm returned earlier to usual activities and reported less pain. This came at the expense of slightly prolonged operative time and visceral injuries. The review concludes that irrespective of the method, it is the use of mesh that reduces the recurrences.
reurrence. In a similar meta-analysis appearing in the American Journal of Surgery\textsuperscript{8} the authors state that with the advent of the open mesh posterior technique there has been no significant difference between LHR and OHR with regard to post-operative recovery and recurrence rate. These authors also hint that it is the presence of the mesh that alters the outcome and not the method by which it is placed.

2.6 Regional Picture

Papers on hernia repair at conferences and publications on hernia repair in journals are made by herniologists who work in ideal conditions in developed countries. In Africa, inguinal hernias present in a different manner than in developed countries. It is reported that 65\% of all hernia repairs in Kumasi, Ghana, are emergencies\textsuperscript{29}. Seventy-one percent of these are inguinal hernias, 10\% femoral hernias. The bowel resection rate was 24\% and the mortality for strangulated inguinal hernias was 6\%. These statistics differ fundamentally from the developed world where strangulated hernias represent only 1-3\% of the total repairs. In another study from Sierra Leone, strangulated hernias represented 25\% of all emergency operations with a resection rate of 33\%\textsuperscript{30}.

In Odula’s\textsuperscript{31} study of groin hernia from Uganda, 76\% of repairs were emergencies. Fifty-five percent of cases were said to show strangulation, but unfortunately the rate of bowel resection was not indicated. There were wound infections in 7\% of cases. Bassini repairs were performed in 68\% of cases. In Nigeria, obstructed hernias were said to represent 26\% of all abdominal wall hernias\textsuperscript{32}. The resection rate was 13\% and the wound infection rate 20\%. Hernia incarceration rate was found to be 25\%\textsuperscript{33}. A review from Dakar, Senegal, on 100 uncomplicated adult groin hernias treated with non-mesh repairs reported a 21\% complication rate, including bladder injury; urinary retention; scrotal hematoma; intestinal occlusion and immediate recurrence\textsuperscript{10}.

Passionate discussions occur when medical doctors are asked what influences their choice of technique to fix a groin hernia. The different epidemiology seen above has significant implications on the choice of technique a medical doctor opts for. Mesh OHR will not be appropriate in more than 30\% of cases due to the presence of contamination or risk of infection. In the presence of infection rates of around 10\% or more the use of mesh might be considered ill advised.
The next issue is that of infrastructure. Although Pallas\textsuperscript{34} mused over the possibility of laparoscopy, this is a limited choice under present conditions in Africa. A more realistic question is whether African hospitals and patients can afford even the prosthetic material in mesh OHR. Rutkow\textsuperscript{6}, discussing the costs of hernia surgery in the USA, placed more emphasis on time spent in theatre and time to recovery than on differences in material costs. In hospitals in Canada a plug repair system costs USD126 (Ksh.10, 710) per case and a package of polypropylene mesh which might do for 12 cases costs USD45 (KShs. 3, 825) or less than USD4 (KShs. 340) per case. In Africa the cost of mesh, not to mention its acquisition, might present a formidable barrier and therefore influence choice of technique used. Although mesh repair (Lichtenstein’s) has proven to be effective with decreased risk of recurrence, it has not been used frequently in Africa due to the expense of the mesh and fear that using a mesh will increase the already high rate of complications\textsuperscript{35}.

2.7 Training on Hernia Surgery

The final issue is that of training. The Bassini repair is still the standard in Africa and can be taught in a structured training program\textsuperscript{36}. Shouldice repair is considered difficult to learn, but it has been shown that it can be successfully taught\textsuperscript{37}. Mesh repairs are also easily taught\textsuperscript{38}. Direct supervision for junior trainees with all techniques is emphasized\textsuperscript{39}.

As mentioned earlier, graduate surgical education in the USA uses a model of graded clinical responsibility and operative experience, with continuous evaluation, at the level of residency\textsuperscript{14}. Residency is the equivalent of the post-graduate level of training in our setting.
3.1 STUDY JUSTIFICATION

Inguinal hernias are common throughout the world but particularly in Africa where they comprise a greater percentage of the surgical volume and account for more morbidity\(^{20}\). The repair of groin hernias is one of the most common and important surgical procedures\(^3\). In KNH, a glance at the health records for the past 5 years shows that around 400 hernias are repaired yearly.

In Kenya, like the rest of Africa, there is paucity of data on the epidemiology of groin hernias and their management. The frequency of use of the various surgical repair techniques and the bases for different technique preferences remain unknown. It is not established at what point in their training doctors learn how to conduct hernia surgery and how this influences technique preferences.

Knowing what inguinal hernia repair techniques are used, the factors that influence choice of these techniques and whether these choices are evidence-based is important in informing decisions later on in terms of training of postgraduate students of surgery and laying emphasis on the correct repair techniques. Additionally, no clear guidelines on inguinal hernia management exist in this institution (KNH). The results of this study may help if and when such a protocol is later developed.

3.2 STUDY OBJECTIVES

3.2.1 Main Objective

- To establish the factors that influence choice of inguinal hernia repair technique among surgeons and surgical trainees in Kenyatta National Hospital

3.2.2 Specific objectives

- To establish the awareness level of surgeons and surgical trainees at Kenyatta National Hospital on the different inguinal hernia repair techniques
- To establish what inguinal hernia repair techniques are used by surgeons and surgical trainees at Kenyatta National Hospital
- To determine the rationale behind the choice of inguinal hernia repair technique among surgeons and surgical trainees at Kenyatta National Hospital
- To establish at what level surgeons and surgical trainees at Kenyatta National Hospital had practical training on inguinal hernia repair
RESEARCH METHODOLOGY

4.1 Study Design
This was a descriptive cross-sectional survey study investigating the factors which influence choice of inguinal hernia repair techniques among surgeons and surgical trainees at KNH. A cross-sectional study design was chosen because the study involved a one-time interaction with the subjects.

4.2 Study Area
The study was conducted at the Kenyatta National Hospital General Surgical Unit.

4.3 Study Population
The study targeted the entire population of surgeons and surgical trainees at the General Surgical Unit of KNH.

4.4 Study Duration
The study duration was one (1) month.

4.5 Sample Size
The census approach to determining sample size was employed. The total number of surgeons and surgical trainees who do inguinal hernia surgery at KNH (at the time of the study) was 75. This entire population formed the sample.

4.6 Data Collection Techniques
Self-administered printed questionnaires were used for data collection. These questionnaires were pretested and adjustments made before the actual study. The principal researcher recruited a research assistant who was a medical officer intern. He was trained in the study design and the questionnaire format and helped the principal researcher administer consent and distribute (and collect) the questionnaires.

4.7 Consenting Process
Written informed consent was obtained before administering the questionnaire. The consultants and surgical trainees were approached at a time and place convenient to them by the principal researcher or his assistant. There was full disclosure of the nature of the research and the participant’s involvement using the informed consent document as a guide. The discussion included all the required elements of informed consent, such as, the purpose of the research, the fact that participation is voluntary, protection of confidentiality and the
name and contact of the principal researcher to be contacted for questions or problems related to the research. The potential subjects were then given an opportunity to ask questions and had them answered by the principal researcher or his assistant. Once the potential participants had read the consent document and their questions were answered, if they agreed to participate in the research, they signed and dated the informed consent document. When need arose, the potential participants were allowed to carry the informed consent document to read carefully and consult with family, friends or colleagues before signing. They were given 24 hours to consider participation in the research. Those who consented were given ample time to fill in the questionnaire which was then collected by the principal researcher or his assistant.

The data that was collected included: qualification of the operating doctor, level at which practical training on inguinal hernia repair occurred, awareness level of the surgeons and surgical trainees on the various inguinal hernia repair methods, inguinal hernia repair method(s) used for the past three inguinal hernia operations (the most recent) and reasons for using that /those repair method(s).

4.8 Eligibility criteria

4.8.1 Inclusion Criteria

• Consultants and surgical trainees at KNH General Surgical unit who conduct inguinal hernia repairs on patients older than 12 years

4.8.2 Exclusion criteria

• Consultants and surgical trainees who did not consent to be included in the study
• Consultants and surgical trainees who conduct inguinal hernia repairs on patients 12 years and younger
• Inguinal hernia operations done during hernia projects
• Surgical trainees who had not performed at least 3 inguinal hernia operations

4.9 Data analysis and presentation

The collected data was entered into a password-protected customized MS Access database with in-built checks to minimize on data entry error. Once data entry was complete, the principal researcher compared the entered data with the hard copy forms to check for errors, inconsistencies, missing entries and duplicate entries to ensure high quality data.
Descriptive statistics were used to analyze the various attributes of the sample. Differences in the various attributes were calculated by the $\chi^2$ test for categorical variables using Stata software.

Data is presented in the form of graphs and tables.

**4.10 Study Limitation**

This was a single-institution study and hence the results may be difficult to generalize to medical doctors countrywide.

Recall bias may have affected validity of the results.

**4.11 Ethical Consideration**

Approval to carry out the study was sought from the Department of Surgery, and the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee. The purpose of the study was explained by the principal researcher or his assistant to all potential participants so as to get a signed informed consent. All information obtained was treated with confidentiality to protect the source and participants were at liberty to leave or terminate the filling of the questionnaire at will.
RESULTS PRESENTATION AND INTERPRETATION

5.1 Questionnaire Completion Rate
Data was collected from 15 surgeons and 60 surgical trainees at KNH General Surgical Unit. Of the 75 questionnaires administered, all were completed. None of the questionnaires had questions left unanswered. Thus the questionnaire completion rate was 100%.

5.2 Surgical Trainee Demographics
The surgical trainees’ demographics are as shown in table 1 below:

<table>
<thead>
<tr>
<th>Year of training</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2\textsuperscript{nd}</td>
<td>7</td>
<td>11.67</td>
</tr>
<tr>
<td>3\textsuperscript{rd}</td>
<td>16</td>
<td>26.67</td>
</tr>
<tr>
<td>4\textsuperscript{th}</td>
<td>21</td>
<td>35.00</td>
</tr>
<tr>
<td>5\textsuperscript{th}</td>
<td>11</td>
<td>18.33</td>
</tr>
<tr>
<td>&gt;5</td>
<td>5</td>
<td>8.33</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100</td>
</tr>
</tbody>
</table>

5.3 Awareness Level on Hernia Repair Methods

5.3.1 Awareness Level Among Consultant Surgeons
Respondents were asked about their theoretical knowledge on 12 different hernia repair techniques. 100% of the consultants knew about the Bassini and Lichtenstein repair techniques. The Maloney darn and Marcy repair methods were the least known among the consultants – only 27% (4 out of a total of 15) of the respondents knew about each of those two methods.

5.3.2 Awareness Level Among Surgical Trainees
Respondents were asked about their theoretical knowledge on 12 different hernia repair techniques. 100% of the surgical trainees knew about the Bassini and Lichtenstein repair techniques. Only 3 surgical trainees (5%) knew about the Marcy method of hernia repair. Significantly, 58% of the surgical trainees (35 out of a total of 60) knew about the trans-abdominal pre-peritoneal (TAPP) laparoscopic hernia repair compared to 86% (13 out of a total 15) of the consultants. An almost similar percentage knew about the totally extra-peritoneal (TEP) laparoscopic hernia repair (48% of the surgical trainees and 86% of the consultants).
5.4 Practical Training on Hernia Repair Techniques

Practical training on the various hernia repair techniques was highest in the modified Bassini and Lichtenstein methods (among both the consultant surgeons and surgical trainees). None of the respondents was trained in the McVay repair technique. The results are as summarized in figure 1 below:

![Figure 1: Practical Training in Hernia Repair](image)

5.5 Levels at Which Practical Training on Inguinal Hernia Repair Occurred

The modified Bassini technique was taught to most surgical trainees by an experienced peer outside of residency (57.63%). This is as depicted below:

![Figure 2: Level at which practical training occurred – modified Bassini (surgical trainees)](image)
Thirty-three percent (33%) of the consultants were taught the modified Bassini technique as undergraduates. This is shown below:

![Figure 3: Level at which practical training occurred – modified Bassini (consultants)](image)

On the other hand, the Lichtenstein method was taught to most surgical trainees by an experienced peer during residency:

![Figure 4: Level at which practical training occurred – Lichtenstein (surgical trainees)](image)

An equal number of consultants learned the Lichtenstein method through workshops/conferences and through an experienced peer during residency:
Figure 5: Level at which practical training occurred – Lichtenstein (consultants)

Most surgical trainees (44.68%) were taught the PHS/plug method by a consultant surgeon during residency. Workshops and conferences played a big role in the skills acquisition by the consultants for the laparoscopic hernia repair methods (90% and 87.50% for TAPP and TEP methods respectively).

5.6 Hernia Repair Methods Used

All the 75 respondents were asked about the hernia repair methods they had used for their last 3 inguinal hernia operations. This translated into 225 operations in total. Out of these, 173 (76.89%) were elective operations while 52 (23.11%) were emergencies. The 3 most commonly used repair methods were the Lichtenstein, PHS/plug and modified Bassini respectively. The modified Bassini was the commonest method used in emergency cases while the Lichtenstein method was preferred by most for the elective repairs.
Table 2: Hernia Repair Methods Used

<table>
<thead>
<tr>
<th>Hernia Repair Method</th>
<th>Surgery Type</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Elective cases</td>
<td>Emergency cases</td>
</tr>
<tr>
<td>Modified Bassini</td>
<td>15 (9%)</td>
<td>37 (71%)</td>
</tr>
<tr>
<td>Shouldice</td>
<td>0</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Lichtenstein</td>
<td>77 (44%)</td>
<td>9 (17%)</td>
</tr>
<tr>
<td>PHS/plug</td>
<td>75 (43%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>TIPP</td>
<td>1 (1%)</td>
<td>0</td>
</tr>
<tr>
<td>TAPP</td>
<td>4 (2%)</td>
<td>0</td>
</tr>
<tr>
<td>TEP</td>
<td>1 (1%)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>173 (100%)</strong></td>
<td><strong>52 (100%)</strong></td>
</tr>
</tbody>
</table>

None of the respondents used the Maloney Darn, Desarda and GPRVS repair methods despite some of them having practical training on these methods.

Overall, using the Pearson’s chi-squared test, a statistically significant value between the types of hernia surgery (whether emergency or elective) and the repair method used was found (p-value = 0.000).

Similarly, for the 3 most common methods (modified Bassini, Lichtenstein and PHS/plug), there was statistical significance between the use of these methods and the type of hernia surgery – whether elective or emergency (p-value = 0.000). The modified Bassini is preferred in emergency as opposed to elective surgery. Conversely, the open mesh repairs (Lichtenstein and PHS/plug) are preferred in elective, as opposed to emergency, surgery (p-value =0.000).

5.7 Reasons for Picking on the Hernia Repair Methods Used

Various reasons were cited by the respondents as a basis for their choices in the different hernia repair techniques. The most common reasons for 4 of the repair techniques are depicted below:

Table 3: Reasons for Picking on the Various Repair Techniques

<table>
<thead>
<tr>
<th></th>
<th>Training on Technique</th>
<th>Ease of Technique</th>
<th>Availability of Repair Material</th>
<th>Early Return to Work</th>
<th>Decreased Recurrent Rate</th>
<th>Perceived Reduced Risk of Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modified Bassini</td>
<td>44%</td>
<td>49%</td>
<td>19%</td>
<td>10%</td>
<td>2%</td>
<td>33%</td>
</tr>
<tr>
<td>Lichtenstein</td>
<td>77%</td>
<td>60%</td>
<td>72%</td>
<td>27%</td>
<td>62%</td>
<td>12%</td>
</tr>
<tr>
<td>PHS</td>
<td>77%</td>
<td>36%</td>
<td>82%</td>
<td>27%</td>
<td>62%</td>
<td>24%</td>
</tr>
<tr>
<td>TAPP</td>
<td>75%</td>
<td>25%</td>
<td>75%</td>
<td>100%</td>
<td>50%</td>
<td>75%</td>
</tr>
</tbody>
</table>
DISCUSSION

6.1 Background
Inguinal hernia ranks as one of the commonest pathologies encountered by general surgeons worldwide¹; and the repair of inguinal hernias is one of the most commonly performed surgical procedures³. Thus surgeons must endeavor to master the most relevant of the inguinal hernia repair techniques. This study set out to look at how a teaching hospital in a developing country fares in terms of inguinal hernia surgery compared to the rest of the world.

6.2 Knowledge in Hernia Repair Techniques
All the respondents in the study had a theoretical understanding of the Bassini and Lichtenstein repair methods. The Bassini method of hernia repair was described in the late 19th Century²¹. The principles behind this repair method (and its modifications) remain relevant even in the present day. It is no surprise then that all the respondents were familiar with it. The Lichtenstein repair, on the other hand, is the most popular mesh repair worldwide.

It is important to note that though the Shouldice method has been described as being complex, theoretical understanding among the respondents was quite high (92%). The PHS/plug method of repair was also understood by a sizeable number of the respondents (88%).

More consultants (87% for both methods) had a theoretical understanding of the TAPP and TEP repair methods compared to surgical trainees (58% for TAPP and 48% for TEP).

The less common suture repair methods such as McVay, Maloney darn and Desarda were not widely known by the respondents. No other study has looked at awareness of the various hernia repair techniques per se.

6.3 Hernia Repair Technique Training
The majority of the respondents were trained in the modified Bassini technique (followed by Lichtenstein). A higher proportion of consultants were conversant with the laparoscopic methods of repair compared to the surgical trainees.

This trend does show that knowledge and skills transfer in laparoscopic hernia repair may not be adequate. This may be due to the fact that resources/ infrastructure needed to adequately train in this form of surgery are not that readily available in KNH – just as in many public facilities in developing countries. This argument is supported by the fact that most of the
consultants honed their skills in laparoscopic hernia surgery during workshops and conferences (90% and 88% for TAPP and TEP methods respectively) and not in medical school (as undergraduate students or as residents). It is also possible that most of the consultants were surgical trainees at a time when laparoscopic hernia repair was not used widely – hence they were not exposed to it during their time in school. These avenues of learning (workshops and conferences) are yet to be fully exploited by the surgical trainees.

An interesting observation is that while theoretical understanding of the Shouldice method is quite high (92%), only 28% of the respondents can practically perform it. This does underline the complexity of this suture repair method that has exceptionally good outcomes in the hands of the experienced surgeon²².

The majority of the surgical trainees acquired practical skill in the modified Bassini method outside of residency. This is the period when the trainees worked as medical officers in various hospitals across the country. The modified Bassini technique is used extensively in many peripheral hospitals due to resource limitation in the adaptation of the mesh repair techniques. Hence the method of hernia repair that the surgical trainees are more likely to learn prior to residency is the modified Bassini. Very little practical training in surgery occurs in medical school undergraduate. Only 20% of the respondents learned the modified Bassini technique as undergraduates. None of them learned any other technique at that level of their training.

The Lichtenstein method is the repair method majority learn while in residency. Experienced peers at this level of training do play an important role in passing on skills to the less experienced surgical trainees. This is underlined by the fact that 23 out of 53 (43%) and 11 out of 47 (23%) surgical trainees learned the Lichtenstein and PHS/plug repair methods respectively from an experienced peer during residency.

Of the 225 operations sampled, 173 operations were elective cases (77%). This is not in keeping with the literature that states that majority of the hernia operations done in most African institutions are emergencies²⁹, ³¹, ³³. This may be because the study was done at a Level 6 facility. Facilities downstream may give a different picture altogether. Lichtenstein, PHS/plug and modified Bassini are the three most common repair methods used in KNH (96% of the 225 operations sampled). The modified Bassini technique is the procedure of choice in most emergency hernia surgeries as it was used in 71% of all emergencies. This may be informed by the fact that use of mesh material in the presence of contamination is not recommended due to the risk of infection with detrimental consequences. Hence the
respondents preferred using a suture-based method in patients presenting with bowel strangulation/perforation.

6.4 Reasons for Picking on the Repair Methods

Various reasons were forwarded for picking on one repair method as opposed to the other. In the modified Bassini method, respondents cited ease of technique (49%), training on the technique (44%) and perceived reduced risk of complications (33%) as the most common reasons for picking it. This is in keeping with the emergency nature of the surgeries the technique is mainly employed in – due to the time factor one would pick on the technique they are most comfortable performing and reduced risk of complications is based on evidence that mesh use in the presence of contamination greatly increases risk of surgical site infection.

As for the open mesh repair methods (Lichtenstein and PHS/plug) the three most commonly cited reasons for their use were: training on the technique (77% for both methods), availability of repair material and equipment (72% for Lichtenstein and 82% for PHS), and decreased recurrent rate (62% for both methods). These were the two methods commonly used in elective hernia surgery. Studies have consistently shown the supremacy of these repair techniques to the suture-based ones – particularly in terms of hernia recurrence. Hence the respondents were justified to use them since their actions were backed by evidence. The only limitation to the use of these methods was the availability of mesh material. Even in a tertiary teaching institution like KNH, there are times when meshes are unavailable and hence one cannot use a repair method that they would have preferred.

Of the laparoscopic mesh repair methods, TAPP was preferred to TEP (though they were only employed in 5 of the 225 operations – 4 TAPP repairs versus 1 TEP repair). Patient early return to work (100%), training on the technique (75%), availability of repair material and equipment (75%), and perceived reduced risk of complications (75%) were some of the reasons cited for using the laparoscopic repair methods. Not many among the respondents were trained in laparoscopic hernia repair compared to open repair. Laparoscopy equipment may also not be readily available at KNH. Interestingly, the evidence available does not support superiority of laparoscopic mesh hernia repair in terms of early return to work and low complication rate – even though less post-operative pain has been demonstrated with the use laparoscopy as opposed to open mesh repair. To a large extent, the choice of inguinal hernia repair is evidence-based as detailed above. The greatest limitation to following this through though is lack of appropriate expertise and
material/equipment. A study done in Poland\textsuperscript{41} showed that all respondents were familiar with and able to perform tension-free techniques. Forty-four percent were influenced by their individual professional skills in selecting the technique. Another 44\% based their decision on trends in their hospital, and only 22\% considered the patient's preferences. None of the respondents in our study cited trends in their hospital or patient preference as a factor influencing what repair technique they used.
6.5 Conclusion and Recommendations

This study set out to tackle the following questions:

1. Who performs inguinal hernia repair at Kenyatta National Hospital?
2. Which are the most common inguinal hernia repair techniques currently used in this institution?
3. What factors influence the choice of inguinal hernia repair technique?

Inguinal hernia surgery is carried out by both the surgical trainees and consultant surgeons at KNH. The surgical trainees – due to their superior numbers – do the bulk of the operations. The modified Bassini method is the most common method employed in emergency hernia surgery. The open mesh repair methods (Lichtenstein and PHS/plug) are the methods most commonly used in elective hernia repair.

Training on the technique plays a big role in the choice of technique to use. Most trainees are trained by their peers. The consultant surgeons should play a bigger role in training the senior residents, not just in inguinal hernia surgery but in all types of surgery, since they - the senior residents - do play an important role in imparting practical skill to the junior surgical trainees. The surgical trainees should also take a keener interest in workshops and conferences as an important avenue of learning (as demonstrated by the consultants). Training in laparoscopic hernia repair is wanting. A solution may lie in incorporating external rotations in the surgical curriculum so that the surgical trainees can go to centers where they get exposed to this skill. But is should be emphasized that as at the present moment, no evidence has been adduced to the superiority of laparoscopic mesh hernia repair to open mesh hernia repair.
REFERENCES


APPENDICES

Appendix 1: Consent form

This informed consent form is for surgeons and surgical trainees performing inguinal hernia repair surgery at KNH. We are requesting these doctors to participate in this research project whose title is: “Factors Influencing the Choice of Inguinal Hernia Repair Technique Among Surgeons and Surgical Trainees: A Case Study in Kenyatta National Hospital.”

Principal investigator: Dr S.D.J. Osilli
Institution: School of Medicine, Department of Surgery - University of Nairobi
Supervisors: Dr Awori, Mark Nelson and Dr Ojuka, Kinyuru Daniel

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. Sikodah D.J. Osilli, a Post-Graduate student at the University of Nairobi’s School of Medicine. I am carrying out a study to determine, Factors Influencing the Choice of Inguinal Hernia Repair Technique Among Surgeons and Surgical Trainees: A Descriptive Cross-sectional Study in Kenyatta National Hospital.

I am inviting you to participate in this study 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**
Inguinal hernia repair operations are frequently performed at Kenyatta National Hospital. However, there is paucity of data on the frequencies of the various surgical repair techniques and what factors influence a doctor to pick one technique over the other. It is not established at what point in their training doctors learn how to conduct inguinal hernia surgery and how this influences technique preferences.

This study aims to look at these diverse aspects of hernia management in our local set-up and may eventually influence our mode of hernia surgery training.

If you agree to participate, you will be asked to provide information regarding your experiences in hernia surgery as detailed in the questionnaire.

**Type of Research Intervention**
This research will involve a one-time filling of a self-administered questionnaire and you will not expose yourself to any risks if you consent to participate.

**Participant Selection**
All doctors actively performing inguinal hernia repair surgery are invited to participate in this study. Your participation is entirely voluntary. You may change your mind later and stop participating even if you agreed earlier.

**Study Duration**
The study will be carried out over a period of one (1) month.

**Risks**
You will not be exposing yourself to any risk by participating in this study.

**Benefits**
There may not be any direct benefit for you but your participation is likely to help us find the answer to the research question; and possibly influence the training of future generations of medical doctors in surgical management of inguinal hernias.

**Confidentiality**
All the information which you provide will be kept confidential and no one but the researchers will see it. The information about you will be identified by a number instead of your name 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 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 at 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 two university supervisors. The contact information of these people is given below if you wish to contact any of them for whatever reason:

Secretary, KNH/UoN-ERC,
P.O. Box 20723- 00202,
KNH, Nairobi.
Tel: 020-726300-9
Email: KNHplan@Ken.Healthnet.org

• University of Nairobi research supervisors;
  • Dr. Awori, Mark Nelson
    Department of Surgery, School of Medicine - University of Nairobi,
    Tel: 020-2726300
  • Dr. Ojuka, Kinyuru Daniel
    Department of Surgery, School of Medicine - University of Nairobi,
    Tel: 020-2726300

• Principle researcher:
  Dr. Osilli, D.J. Sikodah
  Department of Surgery, School of Medicine, University of Nairobi
  P.O. Box 19676-00202,
  KNH, Nairobi.
  Mobile phone: 0722 481913
Part ii: Consent Certificate
I………………………………………………………………freely give consent of myself to take part in the study conducted by Dr. Osilli, D.J. Sikodah, 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.

……………………………………………………………………………………………………………………………..
Signature                                                                               Cadre
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:

• Participation is voluntary and the participant can withdraw from the research at any time
• All information given will be treated with confidentiality
• The results of this study might be published to facilitate training in inguinal hernia surgery

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 participant.

Name of researcher or assistant taking consent …………………………………………………

Signature of researcher or assistant taking consent …………………………………………………

Date……………………………………………………………………………………………………
                                      Day/Month/Year
Appendix 2: Study Questionnaire

FACTORS INFLUENCING CHOICE OF INGUINAL HERNIA REPAIR TECHNIQUE AMONG SURGEONS AND SURGICAL TRAINEES: A DESCRIPTIVE CROSS-SECTIONAL STUDY OF KENYATTA NATIONAL HOSPITAL, NAIROBI-KENYA

Questionnaire no.: ___________________________ (Pre-filled by researcher)

1. What is your professional qualification (Tick one)
   - Surgical trainee/Registrar
   - Consultant Surgeon
   
   If a consultant, proceed to Question 3.

2. Year of study
   - Year 1
   - Year 2
   - Year 3
   - Year 4
   - Year 5
   - > 5 years

3. Which of the following hernia repair methods do you theoretically know about? (Tick all that apply)
4. What inguinal hernia repair methods have you been practically trained in? (Tick all that apply)

**Suture:**

- Bassini
- Marcy
- Shouldice
- McVay
- Maloney Darn
- Desarda

**Mesh:**

- Modified Bassini
- Shouldice
- Other (specify)

**Laparoscopic:**

- TAPP
- TEP

5. Level at which practical training on inguinal hernia repair occurred? (list the method trained)

**Level of training**

- Hernia repair method

- Medical school (undergraduate)
- Through an experienced peer (outside residency)
- Through an experienced peer (during residency)
- Through a consultant surgeon (outside residency)
- Through a consultant surgeon (during residency)
- Workshops and conferences
6. What type of hernia repair did you perform in your last 3 inguinal hernia operations over the last one year({\it Operation 1 being the most recent})? (Operations done during hernia projects are not included)

**Operation 1**

Elective

Emergency

Tick the method that you used in operation 1: -

**Suture:** -

- Modified Bassini
- Shouldice
- Other (specify)..............

**Mesh:**–

- Lichtenstein
- PHS/Plug
- TIPP
- GPRVS

**Laparoscopy:** -

- TAPP
- TEP

**Operation 2**

Elective

Emergency

Tick the method that you used in operation 2: -

**Suture:** -

- Modified Bassini
- Shouldice
- Other (specify)..............

**Mesh:**–

- Lichtenstein
- PHS/Plug
TIPP
GPRVS

*Laparoscopy:* -

TAPP  □  TEP  □

**Operation 3**

Elective  □
Emergency  □

Tick the method that you used in operation 3: -

*Suture:* -
Modified Bassini  □
Shouldice  □
Other (specify)……………□

*Mesh:*–
Lichtenstein  □
PHS/Plug  □
TIPP  □
GPRVS  □

*Laparoscopy:* -
TAPP  □
TEP  □
7. What are the reasons for picking on the above repair methods?

<table>
<thead>
<tr>
<th>Reason</th>
<th>Operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training on the technique</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Ease of technique</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Availability of repair material and equipment</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Affordability</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Less time consuming</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Patient early return to work</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Less post-operative pain</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Decreased recurrence rate</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Perceived reduced risk of complications</td>
<td>☐ ☐ ☐</td>
</tr>
<tr>
<td>Other (specify)</td>
<td>☐ ☐ ☐</td>
</tr>
</tbody>
</table>

………………………………………………………………

………………………………………………………………

………………………………………………………………

………………………………………………………………
KNH/UoN-ERC APPROVAL LETTER

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19767 Code 00202
Telegram: vsuri
(Tel. 020) 3789890 Ext 44355

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 7263099
Fax: 726272
Telegram: MEDSUP, Nairobi

Ref: KNH-ERC/A/243

Link: www.sonobi.ac.ke/activities/KNHUoN

Dr. Sikodah D.J. Osili
Dept. of Surgery
School of Medicine
University of Nairobi

Dear Dr. Osili

RESEARCH PROPOSAL: FACTORS INFLUENCING CHOICE OF INGUINAL HERNIA REPAIR TECHNIQUE AMONG SURGONS AND SURGICAL TRAINEES: A DESCRIPTIVE CROSS-SECTIONAL STUDY IN KENYATTA NATIONAL HOSPITAL, NAIROBI-KENYA (PS47002014)

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 30th July 2014 to 29th July 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.

Protect to Discover
Yours sincerely

[Signature]

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

C.c.
The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chairperson, KNH/UoN-ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chairman, Dept. of Surgery, UoN
Supervisors: Dr. Mark Nielso Awori, Dr. Ojuka Kinyuru Daniel

Protect to Discover