A SURVEY OF ICU SETUPS IN THE REPUBLIC OF KENYA

THIS DISSERTATION IS SUBMITTED IN PART FULFILMENT OF THE REQUIREMENT FOR MASTERS IN ANAESTHESIOLOGY AT UNIVERSITY OF NAIROBI

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MAY 2014
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DECLARATION

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

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Signature………………………….           Date…………………………

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DEDICATION

To my beloved father Dr Moses Okech who believed in my ability to become a doctor from high school, my mother Elizabeth Okech who has been encouraging me to work hard ever since childhood and through my medical career, brother Hillary for his moral support and helping put together this dissertation.

To my late grandmother Hilda Jane Ocholla who was happy to see me move to another level of specialization training and knew I would succeed because my hard work.

My mentor into the anaesthesia field, Dr Noah Nganga of Nairobi Hospital.
ACKNOWLEDGEMENT

I sincerely thank the following:

The almighty God, for giving me strength and perseverance

Dr Thomas Chokwe, my supervisor, for his continued support and encouragement since the start of this project.

The ICU staff of the hospitals visited for their good hospitality during data collection and former MMED Anaesthesia Alumni who played their part in helping collect data and supporting this study.

My parents for their love and support.
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<td>BP</td>
<td>Blood Pressure</td>
</tr>
<tr>
<td>CCU</td>
<td>Critical Care Unit</td>
</tr>
<tr>
<td>HDU</td>
<td>High Dependency Unit</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>KNH</td>
<td>Kenyatta National Hospital</td>
</tr>
<tr>
<td>ICU</td>
<td>Intensive Care Unit</td>
</tr>
<tr>
<td>ICP</td>
<td>Intracranial Pressure</td>
</tr>
<tr>
<td>MTRH</td>
<td>Moi Teaching And Referral Hospital</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>USA</td>
<td>United States Of America</td>
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ABSTRACT

Background: Intensive care medicine is a medical specialty which focuses on management of critically ill patients. Critical illness describes a general state which may arise from various medical pathologies which may lead to impairment of vital or single organ function.

The majority of critically ill patients in less developed countries, harboring two thirds of world populations do not have access to intensive care.

In countries like Bangladesh, India and Nepal, there is an increase in availability of intensive care units although shortage in staffing, lack of basic medical supplies, poor maintenance of equipment, interrupted supplies often pose major challenges. These factors inevitably result to lack of recognition of intensive care medicine as a medical specialty in resource poor settings.

Objectives: evaluate the current status of Intensive Care Unit setups & facilities in Kenya.

Methodology: This was an observational; cross sectional survey study. The study was carried out in referral hospitals, provincial level 5 hospitals, mission hospitals and private hospitals with intensive care units. A survey tool was used for collecting data concerning bed capacity, number of working staff in ICU/specialty training, admission patterns for past 1 year, equipment availability & working capacity, availability of essential drugs used in ICU and laboratory support services.

Results: A total of 21 hospitals were surveyed in the republic. The bed capacity of ICUs was low. There is a deficit of equipment, essential drugs and laboratory support services used in patient care. Shortage of workforce in areas of ICU nursing and Specialized ICU Physician. Post operative surgical cases are the leading causes of ICU admissions in Kenya.

Conclusion: There is a deficit of ICUs in the Republic Of Kenya.
CHAPTER 1

1 Introduction and literature Review

In the last few decades there has been a general trend to separate anaesthesiology from critical care. Many professionals recognized the fact that intensive care is a multidisciplinary field of medicine, that the critically ill patient needed more than routine knowledge and skills of only one specialty and that there is a place for improving the patient’s management by involving experts from other fields. Majority of hospitals in high income countries run more than one ICUs, for example medical, paediatric, surgical and cardiac.¹

Critical care medicine refers to the medical specialty that which focuses on the management of critical ill patients. Various medical pathologies e.g. trauma, infection, acute coronary syndrome, stroke can lead to impairment of vital single or multiple organ function. Further more intensive care includes the care of patients after major surgery or the observation of patients in whom critical illness may rapidly occur.

Critical care involves close, constant attention by a team of specially-trained health professionals. It usually takes place in an intensive care unit ICU.

1.1 Brief History Of Intensive Care Units

In Western Countries the first intensive care facilities were setup in 1950’s and 1960’s during the polio epidemic in Europe. In 1950, anaesthesiologist Peter Safar established the concept of “advanced life support” keeping patients sedated and ventilated in an intensive care environment. He is considered the first practitioner of intensive care as a specialty.

Since then the number of intensive care units (ICU) has grown steadily and intensive care medicine has gained importance as a medical specialty on its own right.
1.2 **Intensive Care In Resource Poor Settings/ low Income Countries**

Majority of critically ill patients in less developed countries, harboring around two thirds of the world’s population, still do not have access to ICUs.

Little information exists on the current state of intensive care medicine in less developed countries. There seems to be a wide variability in the availability of ICUs in these countries, ranging from non–existent to sophisticated centres in selected private hospitals catering for few privileged patients.¹

In Zambia for example, only 29 beds ICU beds exist for an entire country of 12.9 million people and only 7% of hospitals providing surgical services run an ICU. Even in those hospitals with ICUs basic equipment is lacking and an oxygen supply is inconsistently available.¹

In countries like Bangladesh, India and Nepal, there has been an important increase in the availability of ICUs although shortage in staffing, lack of basic equipment, poor maintenance of equipment and interrupted supplies pose major challenges.¹

In addition the medical profession in less developed countries is not setup to provide formal training in intensive care. These factors inevitably result in lack of recognition of intensive care medicine as a specialty in resource poor settings.

Disease severity at ICU admission is typically higher at resource poor settings and leads to higher mortality rates in less developed than in high income countries.¹

1.3 **Intensive Care In Kenya**

In Kenya the oldest & largest referral hospital was founded in 1901 then named King George VI in 1952. It was renamed Kenyatta National Hospital in 1964 after Kenya’s first president Jomo Kenyatta. Over that period there was no ICU. The ICU at Kenyatta hospital was established in 1972 with technical assistance from the Japanese. The local expertise in critical care operations was by then quite limited and the Japanese were assigned the duty of training the local medical personnel and appropriately equip the facility.

Currently the critical care unit (CCU) has 21 bed capacity, with 140 nurses deployed, a staffing ratio of 2 nurses for every 3 patients. ICU is managed primarily by consultants in anesthesiology,
senior house officer in anaesthesia. Consultants in other fields with their residents also play their part in care of patients in their respective fields. It is an Open ICU that is not split into different specialties as it admits cases of surgery, paediatrics, medicine and obstetric complication. The CCU at KNH is able to provide mechanical ventilation for each of these 21 beds. In addition patient monitoring is available as well as laboratory support for blood gas analysis, acute hematological and biochemical assays. Access to portable radiologic imaging is possible for patients. Challenges faced include equipment shortage such infusion pumps, ventilator spares, nursing shortage, lack of a full time intensivist. There is long waiting list for admission due to full bed capacity from long stay patients. Despite the above challenges the CCU is still able to provide satisfactory critical care to patients admitted from casualty with various illnesses.

KNH also has satellite critical care facilities in cardiothoracic surgery, burns care, neurosurgery and renal unit. Additional facilities managed under casualty are emergency ward and acute room.

ICU setups are also located in Provincial Hospitals, also referred to as level 5 facilities in the government sector. Provincial hospitals have challenges as lack of basic equipment, inconsistent availability of oxygen supply, poor maintenance of equipment, shortage in staffing and training expertise which reflects in the ICU units. This leads to some critically ill patients being referred all the way to KNH from distant provincial headquarters. As a result KNH is overwhelmed and the backlog of patients awaiting ICU admission increases.

Faith Based hospitals are health care institutions run by the various religious denominations. Very few of them have intensive care units. They mainly rely on donor funding from their denominations to equip the facility. As much as these organizations have invested a lot in primary health care from the lowest level, setting up a major hospital with an ICU that is well equipped still remains a challenge due to funding. 75% of the 1013 faith based institution in Kenya comprise of health centres and dispensaries. The remaining 25% are hospitals. From these hospitals 0.29% have intensive care units. This shows that there is still a deficit in this service. This results in more referrals from these institutions to Kenyatta National Hospital.

Private Hospitals are present in most major towns in Kenya and not all of them have ICU facilities. Those hospitals that have ICUs strive to have well equipped facilities, 1 to 1 nurse ratio, constant drug supplies, good service of equipment & well laid out resuscitation protocols
including a special resuscitation team. In these private hospitals, ICU is general. Some of these hospitals have an intensivist who runs the ICU with help from other medical disciplines. Those that do not have intensivist, ICU care is supported by Medical Officers trained in looking after ICU patients, Consultants of medicine, surgery & pediatrics who have their patients to admit to ICU. In such a scenario, the anesthesiologists may be called upon to intubate, set the ventilator and assist with sedation/paralysis if need be. The bed capacity in these hospitals may range from 3-10. Some have both an ICU and HDU combined, where patients who are critically ill and need close observation are admitted, with an option of shifting a patient for intensive care if patients condition changes.

ICUs in high income countries, despite being well equipped, with good material availability and adequate nurse ratio still face challenges of having full time intensivist for coverage. This was shown in a stratified weighted survey study done by Agnus DC et al in 2006 with the aim of describing the organization and distribution of services and to determine the ICU physician staffing\(^3\) The publication and dissemination of Leapfrog group ICU physician staffing recommendations define an ICU as “high intensity” if \(\geq 80\%\) of patients were cared for by a critical care physician (intensivist) providing some form of in-house physician coverage during all hours. Only \(4\%\) (\(n = 255\)) of all adult ICUs in the United States appeared to meet the full Leapfrog standards (a high-intensity ICU staffing pattern plus dedicated attending coverage during daytime plus dedicated coverage by any physician during nighttime).

A follow up study by Khan JM et al in 2007 looking at the barriers implementing the recommendations for intensivist’s physician staffing found that increased implementation cost to the hospital administration and convincing hospital organizations, medical staff regarding the benefits of adopting the standard in USA hospital ICUs were the barriers.\(^4\)

This however did not hinder efforts of USA ICU hospitals in implementing the leapfrog recommendations and most hospitals—including half of those who publicly resisted the standard-made attempts to change physician staffing in their ICUs, based on the criteria outlined by the Leapfrog Group.\(^5\)

Critical care remains in its infancy in many low income countries.\(^6,11\) In a review and analysis of intensive care medicine in the least developed countries by Dunser MW et al the burden of
critical illness is high in low income countries and little data exists on the current state of intensive care medicine.⁷

Despite these hospitals having ICU, basic equipment is lacking and oxygen supply is inconsistent.¹,⁶,⁸ The net availability falls short of the WHO recommendation that every hospital performing surgery and anaesthesia should have an ICU.⁹

Comparative studies from Asia & Solomon Islands focused on common presentations of critical illness, available hospital resources, and what resources would be helpful in improving the care of critically ill patients in the future. Respondents from this study emphasized the need for basic critical care resources in the region, including equipment such as oximeters and oxygen concentrators; greater access to medications and blood products; laboratory services; staff education; and the need for at least one national critical care facility. Inadequate resources for primary prevention and healthcare affected critical care service delivery in this region.¹⁰

In Sub-Saharan African countries intensive care medicine or critical care services are poorly developed or at most still in infancy. Special intensive care units (ICUs), like neurological and neonatal ICUs, are still a novel concept.¹¹ Medical care has been hampered by economic reversals resulting in low wages, manpower flight overseas, government apathy towards funding of hospitals, and endemic corruption.¹¹

Priority setting favours HIV, TB and malaria interventions. Little is known on the challenges faced to critical care. Kwizera et al found that the national bed capacity in Uganda was very low. There are 33 adult ICU beds in the whole country for a 33 million population.¹²

A study by Tim Baker in low income countries noted that there were three factors contributing weaknesses in critical care.⁶ These were-triage and emergency care; lack of ICU facilities and quality of intensive care.

On triage and emergency care Baker noted that many hospitals lack formal triage system which leads to delays for critically patients to be given emergency care and to be admitted. Many hospitals lack ICUs and seriously ill patients are treated in general wards. The ICU would allow concentration of critical care expertise, drugs and equipment.
There was also lack of expertise in managing ICU facilities in Bakers review. Ideally, a physician trained in anaesthesia and intensive care would be responsible for the ICU. This is not always possible and currently the medical input often comes from non-physician anaesthetic officers, medical assistants or other physicians. Nurses are frequently left to manage the patients themselves as the physicians have more duties elsewhere. Oxygen equipment was not always available. A survey from Tanzania showed that 75% of district hospitals had oxygen supply for < 25% of the year.  

On Quality of Hospital care, Baker noted that lack of resources and less money spent on the total health budget affected quality of care. Other factors affecting quality of hospital care are shortage of staff, inadequate laboratory facilities, lack of Imaging facilities, lack of essential drugs and basic equipment and significantly poor awareness of the principles of critical care.

These weaknesses have also affected critical care service delivery to the paediatric age group. Paediatric emergency and critical care services are often one of the weakest parts of the health system and improving such care has the potential to significantly reduce mortality and would help achieve millennium development goal number 4.

The challenges on critical care in low income countries were also noted to be a barrier in implementing the surviving sepsis campaign guidelines in Sub-Saharan Africa (Baelani I et al 2011). Drugs, equipment, and disposable materials required to implement the Surviving Sepsis Campaign guidelines or sepsis bundles were less frequently available in African than high-income countries. 1.2% (3/248) of the respondents from Sub Saharan countries had the resources available to implement the Surviving Sepsis Campaign guidelines in entirety. The percentage of implementable recommendations was lower in African than in high-income countries, particularly in Sub-Saharan African countries than South Africa, Mauritius, and the Northern African countries.

As a result of these challenges, there is lack of recognition of intensive care as a specialty in low income countries. As a consequence disproportional high mortality rates have been reported in for selected critical illnesses in developing countries (Dunser MW et al 2008).
CHAPTER 2

2 Justification

Little data exists on the current state of intensive care medicine in less developed countries but there seems to be variability in the availability of ICUs, in these countries ranging from nonexistent to sophisticated centres in selected private hospitals catering for few privileged patients.

In Kenya we have no data existing on critical care service provided by referral, provincial hospitals and faith based organization registered by Ministry of Medical Services. The two national referral hospitals, Moi Teaching & Referral Hospital (MTRH) and Kenyatta National hospitals receive patients from district hospitals, provincial, mission and private tertiary hospitals for critical care because of lack of essential support systems in the periphery. This creates a huge load in these referral hospitals because bed capacity is occupied fully most of the time and patients are kept on the waiting list because there is no space available even when urgent admission is required. Acute rooms serve as immediate emergency care areas without close monitoring and the standard ICU care required is not fully effective.

This study will give a better picture of how ICU facilities are setup on the ground at Referral, provincial hospitals, faith based organizations registered by Ministry Of Medical Services. This will also bring out data on bed capacity, staffing and training, equipment and maintenance, essential drugs. If there are deficits noted from results of the study, it can be used by the Ministry Of Medical Services for future planning to improve critical care services in its hospitals. The data also from this study will also assist in addressing challenges faced in low income countries. International organizations dealing with critical care can work with various government organizations on ways of improving critical care services in low income countries by having results such studies because challenges that are faced on ground can be acted upon with strategic planning.
CHAPTER 3

3 OBJECTIVES

3.1 Broad Objectives

To evaluate the current status of ICU setups & facilities in Kenya.

3.2 Specific Objectives

I. To assess the bed capacity.

II. To assess the equipment used in patient care, essential drugs used in patient care, laboratory support service.

III. To assess work force in the intensive care unit.

IV. To assess the case admission pattern over past 1 year.
CHAPTER 4

4 METHODOLOGY

4.1 STUDY DESIGN

This is an observational; Cross Sectional Survey Study.

4.1 STUDY AREA

The study shall be conducted at the Kenyatta National Hospital (KNH), Moi Teaching And Referral (MTRH), 7 Provincial Hospitals, Kisii level 5 hospital and Mission Hospitals; Tenwek, Kijabe, Consolata Mathari and 8 Private Hospitals. The area of study will be the intensive care unit hospital department.

4.2 STUDY POPULATION

The target population will be the two major referral hospitals i.e. KNH, MTRH ICUs, provincial hospitals ICUs (7 in total) Kisii level 5 Hospitals and the Kijabe, Tenwek, Consolata Mathari mission hospitals ICUs and 8 Private Hospitals. Nurses and primary care clinicians who run the ICU are also part of my study population. The above hospitals are those known to have ICU facilities in the country.

4.3 INCLUSION CRITERIA

1) Public and mission hospitals registered with the Ministry Of Medical Services with ICUs.

2) Private Hospitals with ICUs.

4.4 EXCLUSION CRITERIA

1) Public and mission Hospitals registered with Ministry Of Medical Services without ICUs.

2) Private Hospitals without ICUs
3) Hospitals that do not give permission to carry out the study.

4.5 SAMPLING PROCEDURE

In this study the sampling procedure is Purposive. The study is being carried out in hospitals known to have ICUs. As stated in the exclusion criteria: public hospitals, mission hospitals and private hospitals without ICUs are not part of the study and hence not sampled.

4.6 SAMPLE SIZE

In my study the calculation of sample size will not be applicable as I am using purposive sampling procedure. The hospitals facilities mentioned are those available in the country with known ICUs.

<table>
<thead>
<tr>
<th>Hospitals</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referral Hospitals</td>
<td>2</td>
</tr>
<tr>
<td>Mission Hospitals</td>
<td>3</td>
</tr>
<tr>
<td>Provincial Hospitals/level 5 hospitals</td>
<td>8</td>
</tr>
<tr>
<td>Private Hospitals</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
</tr>
</tbody>
</table>

4.7 STUDY PROCEDURE

The study will be undertaken at two major referral hospitals i.e. KNH, MTRH, the seven provincial hospitals, Kisii Level 5 Hospital and 3 mission hospitals with ICUs and 8 private hospitals. Once given permission by the ethics and review committee of KNH and other hospital facilities, a visit to these ICUs facilities will take place.

A survey tool will be used to evaluate aspects of bed capacity, equipment used in patient care, laboratory service, staffing workforce of the intensive care unit and case admissions over a one year period. Data collected from the survey tool will be used for analysis and publishing of results.
CHAPTER 5

5 DATA COLLECTION

I the researcher will conduct the survey in hospitals with ICUs. The data will be collected using a survey tool on visit to the ICU based on aspects from the secondary objectives.

5.1 DATA MANAGEMENT AND ANALYSIS

The data collected from survey tool would be quantitative and electronically captured using Microsoft access database. The data will be validated and then transferred to the Statistical Product Service Solution version 20(SPSS) for analysis.

Descriptive and inferential statistics will be used to analyze the data. To describe characteristics of the population, univariate analysis will be used to extract simple frequencies and various aspects will be presented graphically. To look for association and effectiveness, inferential statistics will be carried out.
CHAPTER 6

6 ETHICAL CONSIDERATION

1) The nature of the study was explained to hospital personnel in charge of the ICUs.

2) A written informed consent was sought from hospital personnel in charge of the ICUs.

3) Confidentiality of participating hospitals was maintained.

4) The study did not constitute harm to staff and patients in ICU.

5) The study was only undertaken upon approval by KNH/MTRH Ethics and review committee, Medical Superintendent of Provincial Hospitals, Mission Hospitals and Hospital Administrators of Private Hospitals.
7 RESULTS

7.1 NUMBER OF HOSPITALS SURVEYED WITH ICUs

A total of 21 hospitals were surveyed in the Republic of Kenya as follows:

a) Referral-2
b) Provincial-5
c) Mission-3
d) Private-11

These hospitals were purposively selected. The study was carried out in hospitals known to have ICUs.
7.2 **BED CAPACITY**

The total bed capacity of the 21 hospitals that were surveyed was 6,551.


*Figure 1: Number of hospital beds expressed as percentage*
7.3 ICU BEDS

The total number of ICU beds from the 21 hospitals surveyed was 130.

Referral hospital I-21 beds, Referral hospital II-6 beds, Provincial hospitals had 22 beds, Mission hospitals-22 beds and private hospitals 59 beds.

![Number of ICU beds](image)

Figure 2: Number ICU beds
7.4 PERCENTAGE OF ICU BEDS TO HOSPITAL BEDS

The percentage of ICU beds to hospital beds was low in most categories of hospitals as shown in the table. It fell short of the required 10-20% of hospital beds as per WHO standards.

<table>
<thead>
<tr>
<th>Type of Hospital</th>
<th>ICU beds</th>
<th>Hospital beds</th>
<th>Ratio of ICU to Hospital beds</th>
<th>% of ICU beds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referral hospital I</td>
<td>21</td>
<td>1455</td>
<td>7 : 485</td>
<td>1.44%</td>
</tr>
<tr>
<td>Referral hospital II</td>
<td>6</td>
<td>734</td>
<td>3 : 367</td>
<td>0.82%</td>
</tr>
<tr>
<td>Provincial hospital</td>
<td>22</td>
<td>2316</td>
<td>11 : 1158</td>
<td>0.95%</td>
</tr>
<tr>
<td>Private hospital</td>
<td>59</td>
<td>1203</td>
<td>59 : 1203</td>
<td>4.90%</td>
</tr>
<tr>
<td>Mission hospital</td>
<td>22</td>
<td>853</td>
<td>22 : 853</td>
<td>2.58%</td>
</tr>
</tbody>
</table>

Table 1: Percentage Of ICU beds to hospital beds
7.5 STAFFING AND TRAINING

There were 414 nurses working in the ICU from the sampled hospitals. Nurses working in ICU per shift were 81 in all hospitals. The nurse to patient ratio was variable in different categories of hospitals. The two referral hospitals had a ratio of 1:2. In the private hospitals 6 had a ratio of 1:1, 3 had a 1:2 ratio and 2 had 1:3 ratio. The 3 mission hospitals surveyed had a ratio of 1:2. Among the 5 provincial hospitals 3 had 1:2 ratios while two others had a ratio of 1:3

<table>
<thead>
<tr>
<th>Type of Hospital</th>
<th>Total nurses working in ICU</th>
<th>Total nurses per shift</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referral hospital I</td>
<td>112</td>
<td>15</td>
</tr>
<tr>
<td>Referral hospital II</td>
<td>20</td>
<td>3</td>
</tr>
<tr>
<td>Provincial hospital</td>
<td>56</td>
<td>10</td>
</tr>
<tr>
<td>Private hospital</td>
<td>179</td>
<td>41</td>
</tr>
<tr>
<td>Mission hospital</td>
<td>47</td>
<td>12</td>
</tr>
</tbody>
</table>

Table 2: Nurses working in ICU and number in shift

7.6 TRAINING EXPERIENCE OF NURSES IN ICU

There were 204 ICU trained nurses, 223 basic trained nurses, 32 renal trained nurses and 6 paediatric trained nurses in the ICU of sampled hospitals. Referral hospital I had 106 trained ICU nurses, Referral hospital II had 6 trained ICU nurses, Provincial hospitals had 24 trained ICU nurses, Private hospitals had 54 trained ICU nurses and Mission hospitals had 10 trained ICU nurses. 3 Private hospitals did not have ICU trained nurses. The Referral hospital I had 1 renal trained nurse while referral hospital II did not have renal trained nurses. The two referral hospitals did not have paediatric nurses.

4 Provincial hospitals did not have renal trained nurses and all lacked paediatric trained nurses. In the private hospitals 4 lacked renal trained nurses and 8 lacked paediatric trained nurses. 2 private hospitals did not have basic trained nurses in their ICUs. All Mission hospitals did not have renal and paediatric trained nurses.

The percentage of ICU trained nurses to other nurses in ICU was highest in Referral hospital I 93.81%, Referral hospital II 50%, Provincial hospitals 41.38%, Private hospitals 23.79% and lowest in Mission hospitals 21.28%.
<table>
<thead>
<tr>
<th>Type of Hospital</th>
<th>Number of trained nurses</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Basic nursing only</td>
<td>ICU further training</td>
</tr>
<tr>
<td>Referral hospital I</td>
<td>6</td>
<td>106</td>
</tr>
<tr>
<td>Referral hospital II</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Provincial hospital</td>
<td>32</td>
<td>24</td>
</tr>
<tr>
<td>Private hospital</td>
<td>138</td>
<td>54</td>
</tr>
<tr>
<td>Mission hospital</td>
<td>37</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 3: Training experience of nurses in ICU
7.7 PRIMARY CARE CLINICIAN IN ICU

- Referral Hospital I-Senior House Officer Anaesthesia, Consultant Anaesthesiologist
- Referral Hospital II-Medical Officer, Consultant Anaesthesiologist
- Provincial Hospitals- Consultant Anaesthesiologist (frequency 5)
- Private Hospitals-Medical Officers (frequency 3), Medical Physician (Frequency 5), Consultant Anaesthesiologist (frequency 7)
- Mission Hospitals-Medical Physician (Frequency 2), Nurse Anaesthetist (Frequency 1), Medical Officer (frequency 1), Clinical Officer Anaesthetist (Frequency 1)

There was Consultant support in other fields of surgery, paediatrics, obstetrics & gynaecology and medicine in all hospitals.
7.8 CASE ADMISSION TO ICU

Post operative surgical cases took a big number of admissions in the past 1 year 1086 (30%) , Trauma cases were 909(26%), Cardiac illness cases were 538(15%), Paediatric illness cases were 345(10%), Cerebral Vascular accident cases were 281(8%), Obstetric complication cases were 228(6%), Poisoning cases were 141(4%) and Neuromuscular disorder cases were 38(1%). However, some records on ICU admission cases were missing in Private and Mission hospitals.

![ICU admission cases in past 1 year](image)

**Figure 4: Percentage Of ICU case admission for the past 1 year (2013) in all ICUs**
<table>
<thead>
<tr>
<th>Type of Hospital</th>
<th>Trauma</th>
<th>Post-Operative Surgery</th>
<th>Paediatric Illness</th>
<th>Obstetric complication</th>
<th>Cerebral Vascular Accident</th>
<th>Cardiac Illness</th>
<th>Neuro-muscular disorder</th>
<th>Poisoning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referral hospital I</td>
<td>189</td>
<td>59</td>
<td>57</td>
<td>47</td>
<td>22</td>
<td>20</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Referral hospital II</td>
<td>70</td>
<td>447</td>
<td>37</td>
<td>31</td>
<td>21</td>
<td>11</td>
<td>13</td>
<td>30</td>
</tr>
<tr>
<td>Provincial hospital</td>
<td>197</td>
<td>249</td>
<td>52</td>
<td>95</td>
<td>26</td>
<td>15</td>
<td>2</td>
<td>23</td>
</tr>
<tr>
<td>Private hospital</td>
<td>435</td>
<td>298</td>
<td>194</td>
<td>53</td>
<td>200</td>
<td>482</td>
<td>12</td>
<td>68</td>
</tr>
<tr>
<td>Mission hospital</td>
<td>18</td>
<td>33</td>
<td>5</td>
<td>2</td>
<td>12</td>
<td>10</td>
<td>1</td>
<td>12</td>
</tr>
</tbody>
</table>

*Table 4: ICU cases admission in different categories for the past 1 year (2013)*
7.9 CASES ASSOCIATED WITH EACH ICU BED IN THE PAST 1 YEAR

Trauma cases carried a high number in Referral hospital I. Post Operative surgical cases carried a high number in Referral hospital II, Provincial hospitals and Mission hospitals. Cardiac illness cases carried a high number in Private hospitals.

<table>
<thead>
<tr>
<th>Type of Hospital</th>
<th>Trauma</th>
<th>Post Operative surgical</th>
<th>Paediatric illness</th>
<th>Obstetric complication</th>
<th>Cerebral Vascular Accident</th>
<th>Cardiac illness</th>
<th>Neuro-muscular disorder</th>
<th>Poisoning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referral hospital I</td>
<td>9.00</td>
<td>2.81</td>
<td>2.71</td>
<td>2.24</td>
<td>1.05</td>
<td>0.95</td>
<td>0.48</td>
<td>0.38</td>
</tr>
<tr>
<td>Referral hospital II</td>
<td>11.67</td>
<td>74.50</td>
<td>6.17</td>
<td>5.17</td>
<td>3.50</td>
<td>1.83</td>
<td>2.17</td>
<td>5.00</td>
</tr>
<tr>
<td>Provincial hospital</td>
<td>8.95</td>
<td>11.32</td>
<td>2.36</td>
<td>4.32</td>
<td>1.18</td>
<td>0.68</td>
<td>0.09</td>
<td>1.05</td>
</tr>
<tr>
<td>Private hospital</td>
<td>7.37</td>
<td>5.05</td>
<td>3.29</td>
<td>0.90</td>
<td>3.39</td>
<td>8.17</td>
<td>0.20</td>
<td>1.15</td>
</tr>
<tr>
<td>Mission hospital</td>
<td>0.82</td>
<td>1.50</td>
<td>0.23</td>
<td>0.09</td>
<td>0.55</td>
<td>0.45</td>
<td>0.05</td>
<td>0.55</td>
</tr>
</tbody>
</table>

*Table 5: Cases associated with each ICU bed in the past 1 year (2013)*

7.10 EQUIPMENT

All types of sampled hospitals had ventilators, monitors, suction machines and piped oxygen. Infusion pumps were fully available in all referral, private and mission hospitals but missing in one provincial hospital. Defibrillators were fully available in all referral, provincial and private hospitals but missing in one mission hospital.

Oxygen concentrators as an additional source to piped oxygen were seen in 1 private hospital, 1 mission hospital and 1 provincial hospital. Hemodialysis equipment in the ICUs was not available in the referral, mission, 3 private hospitals and 4 provincial hospitals. It was mainly available in the remaining 8 private hospitals and 1 provincial hospital. Invasive monitoring for blood pressure/intracranial pressure (BP/ICP) was absent in 2 private hospitals, all provincial hospital and 2 mission hospitals. Only 2 private hospitals could perform both BP/ICP.
7.11 WORKING AND NON WORKING EQUIPMENT

In terms of percentage of equipment performance in the different hospital categories it was found that private and mission hospitals reached 95-100% as compared to other hospital group. These figures demonstrates how different hospitals were equipped in their capacity.

Figure 5: Percentage of equipment performance in Referral hospital I
Figure 6: Percentage of equipment performance in Referral hospital II
Figure 7: Percentage of equipment performance in Provincial hospitals
Figure 8: Percentage of equipment performance in Private hospitals
Figure 9: Percentage of equipment performance in Mission hospitals

7.12 ESSENTIAL DRUG SUPPORT

Resusitation drugs (Adrenaline, atropine), sedatives (benzodiazepines) and analgesics (Opiods/NSAID) were fully available in all types of hospitals. Anticonvulsants were fully available in referral, private, mission and partly available in provincial hospital (missing in 1 provincial hospital). Penicillins, Amioglycosides were fully available in all types of hospitals. Cephalosporins, tetracyclines antibiotics were fully available in referral, mission and partly available in provincial (missing in 1 hospital), private (missing in 1 hospital). Carbapenems and Flouroquinolones antibiotics were fully available in referral and private hospitals, partly available in mission hospitals (missing in 1 hospital) and unavailable in all provincial hospitals.
Adrenaline inotropes were fully available in all types of hospitals whereas Dopamine and Dobutamine were fully available in referral, private and mission hospitals and not available in provincial hospitals. Antiarrythmic (Amiodarone) was fully available in all referral, private and mission hospitals and unavailable in provincial hospitals.

7.13 LABORATORY

Biochemistry Investigation (Kidney Function Test, Blood Electrolytes, Liver Function Test), Microbiology Hematological investigations were available in all types of hospitals. Blood Gas Analyses were fully available in referral hospitals, most private hospital (1 hospital missing) and partly mission hospitals (2 hospitals missing) and absent in all provincial hospitals. Coagulation Profile was fully available in all types of hospitals apart from 1 provincial hospital. Portable X-ray was available in all types of hospitals. Portable ultrasound was fully available in all referral hospitals, present in 2 mission hospital and absent in 1 private hospital. Provincial hospitals lacked portable ultrasound services.
CHAPTER 8

8 DISCUSSION

The findings in this survey demonstrate the status of critical care services in Kenya. Only 11% of hospitals in Kenya provide ICU services. The WHO states that every hospital performing surgery and anaesthesia must have an ICU. On the aspect of bed capacity comparing between ICU beds and hospital beds in the hospitals surveyed it fell short of the required 20-40% of total hospital beds recommended by Society of Critical Care Medicine. From the hospitals surveyed known to have ICUs we found a total of 130 beds in the whole country for a population of 44,000,000 million. If this is broken down to ICU beds per 100000 populations it would be 0.29. This means there is a shortage of ICU beds to serve the Kenyan population. This finding is similar to Kwizera et al who did a study on the national bed capacity in Uganda which he found 33 adult ICU beds for a 33 million population. Having fewer ICU beds can lead to delayed admission of critically ill patients.

The nurse to patient ratio varied in different hospitals but it was noted that there were shortages as some hospitals, seen from my data had ratios of more than1:2. The ideal 1:1 ratio recommended by the European Society of intensive Care medicine could only be met in 6 private hospitals surveyed. Inadequate nursing staff leads to increased burn out and can affect quality of nursing care. Referral hospital I had 93% of its of nurses working in ICU specialized in critical care nursing. There was an equal number of ICU trained and basic trained nurses in Referral hospital 2. The provincial hospitals, private hospitals and mission hospitals showed an imbalance between ICU trained nurses and nurses who had a basic training. This meant that there were more nurses who had only undergone basic training working in ICUs as opposed to those who had gone further to do training in ICU. In 2 private hospitals there were no ICU trained nurses. This demonstrates a shortage of nurses specialized in ICU. These findings are similar to a study by Dunser M.W et al. where he noted one of the challenges facing ICUs in low income countries was a shortage of staff. Baker T et al also noted this problem in their study on the aspect of quality of care being affected by acute shortage and burnout. There was also shortage in of nurses in fields of paediatric and renal nursing who could add valuable care to these cases on ICU admission.
Anesthesiologists were noted to be main primary care clinician in ICUs compared to other medical staff specialties. This could be related to critical care exposure during their post graduate training. The nurse anaesthetists were seen to play a role in managing ventilated patients in one mission hospital due to critical care exposure and working in a rural setting where physicians of any speciality are very few. Medical Officers and Medical Physician also played part in ICU management. In all hospitals there was Consultant support from other fields together with the primary clinician in patient management. This shows that in Kenya ICUs are open. Comparing this status with leap Frog criteria of ICU physician staffing it falls short. The standard set by this group of having high intensity ICUs where 80% of patients were cared for by a critical care physician (intensivist) providing some form of in-house physician coverage during all hours. This is currently being taking up in most ICUs in the USA as dicussed in a study by Pronovost P et al. In Closed ICUs an intensivist principally responsible for the care of all patients admitted in the ICU. Organization of ICUs as closed units, including the presence of an intensivist, has been shown to result in lower mortality, less complication, a reduce length of stay and lower costs as compared to open ICUs (Topeli et al).1

It was noted that post operative surgical cases were the leading cause of admission in 2013. Main factors influencing admission were slow/failed recovery from anaesthesia and close monitoring depending on the nature of surgery. In the private hospitals cardiac illness took the lead in cases per bed. This could be explained by patient culture groups and lifestyle factors compared to public facilities. These cases were mainly Acute Myocardial Infarction with its complications. The numbers of obstetric complications admitted were higher in provincial hospitals compared other hospital groups. Contributing cases were patients who had Severe Pre-eclampsia, Severe Obstetric hemorrhage and post partum sepsis. Trauma had more cases per bed in Referral Hospital I which is the largest in country and has the highest number of ICU beds compared to other hospitals. Most of the referrals to this hospital were from its home county and neighboring county facilities that don’t have ICUs. The findings of post operative surgical admissions taking lead admissions in 2013 are similar to a study by Ray Towey in Uganda at St Marys Hospital Lacor,Gulu Towey noted that this surgical emphasis was also present in published data from Burkina Faso,Nigeria,Malawi, Zambia, Tanzania and Democratic republic of Congo. In western countries most frequent pathologies leading to ICU admission are cardiovascular, major surgery,
sepsis and respiratory failure. ICUs in Western countries are specialized into medical ICUs, surgical ICUs, cardiac and Paediatric ICUs.

Equipment was another challenge in these ICUs. The mission and private hospitals had the best equipped facilities, followed by Referral hospitals. The Provincial hospitals had equipment shortage and problems with maintenance. The number of ICU beds in these hospitals ranged between 3-8. Not all beds had ventilators. The number of ventilators ranged between 2-4. Infusion pumps were also few in number to match the patients demand. Only 1 provincial hospital out the 5 was able to provide hemodialysis within the ICU for patients who required it. Mission hospitals lacked hemodialysis service within ICU. All provincial hospitals and 2 mission lacked invasive haemodynamic monitoring equipment. Hemodialysis service within the ICU was best carried out at Private hospitals. The two major referral hospitals could not carry out hemodialysis within the ICU. Patients had to be transferred to the renal unit of the hospital to get this service. Essential equipment like a defibrillator was missing in 1 hospital sampled. These challenges in equipment were also brought out by Baker T et al, Jochberger et al when reviewing critical care in low income countries. Intensive care units in low income should strive to have basic resource requirements to support the patients and ICU work staff as discussed by Martin W Dunser. These include monitors, suction machines, mechanical ventilators and oxygen source. Alternatives to infusion pumps can be mechanical drop regulators.

Looking at essential drug support it was noted that inotropic agents that are first line i.e dopamine, dobutamine lacked in all provincial hospitals. Implementing surviving sepsis campaign guidelines in these facilities can pose a challenge. Baelini I et al in his study 2011, noted that drugs, equipment and disposable materials required to implement the surviving sepsis campaign bundles were less frequent in African than high income counties. Antiarrythmic agents amiodarone was absent in all provincial hospitals yet it is included in the advanced cardiac life support algorithm in managing shockable rhythms.

Most of the ICUs in republic had access to laboratory services to perform biochemistry investigation (Kidney Function Test, Liver Function Test, Blood Electrolytes) and microbiology investigations. Blood gas analysis was not available in all provincial hospitals, 1 mission hospital and 2 private hospitals. Blood gas analysis plays key role in managing respiratory failure in ventilated patients and also following up correction of acid base disbalance. This poses a
challenge to hospitals managing these patients in terms of achieving goal targets and weaning patients from ventilators. Portable US equipment lacked in all provincial hospitals, 1 mission hospital and 1 private hospital. Baker T and et al noted that inadequate laboratory facilities affected quality of ICU hospital care in low income countries. There was limitation in biochemistry analysis as i did not survey lactate levels, c reactive proteins. As noted by Baker even the most simple basic lab investigation like serum electrolytes were not measured in some facilities in low income countries.
CHAPTER 9

9 CONCLUSION AND RECOMMENDATIONS

9.1 CONCLUSIONS
1) There is a deficit of ICUs in the Republic Of Kenya.
2) The bed capacity of ICUs is low.
3) Deficit of equipment, essential drugs, laboratory support used in patient care.
4) Shortage of workforce in areas of ICU nursing and Specialized ICU Physicians.
5) Post operative surgical cases are the leading causes of ICU admissions in Kenya.

9.2 RECOMMENDATIONS
1) Improve funding in health care budget with a strategic plan to facelift Critical Care Service.
2) Provincial Hospital ICUs to be expanded and have auxillary high dependency units.
3) Investment in training opportunities for nurses and doctors in critical care specialty.
4) Mission Hospitals to invest in critical care with associated church support organizations.

9.3 Study limitations
During the survey there were 3 hospitals that had started new intensive care units with an age of 3-5 months old hence data on staff and case admission would have not given me expected conclusive results.
REFERENCES


9. Surgical Care At the District Hospital, 2003 edition, *WHO publication.*


16. European Society Of Anaesthesiology Journal Vol 25 January 2013 page 1
## APPENDIX 1

### BUDGET

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost (ksh)</th>
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<td>Photocopy and Binding</td>
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<td>Ethics Review Committee Fee</td>
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<tr>
<td>Travelling</td>
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</tr>
<tr>
<td>Accommodation</td>
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<td>10% contingency</td>
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<td><strong>Total</strong></td>
<td><strong>81,400</strong></td>
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## APPENDIX 2

### WORK PLAN

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<th>Activity</th>
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<td>Proposal presentation</td>
<td>July 2013</td>
</tr>
<tr>
<td>Submission To Ethics</td>
<td>Aug-Dec 2013</td>
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<tr>
<td>Data Collection</td>
<td>Jan-Feb 2013</td>
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<td>Data Analysis</td>
<td>March 2014</td>
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<td>Dissertation Writing</td>
<td>April 2014</td>
</tr>
<tr>
<td>Dissertation Presentation</td>
<td>April 2014</td>
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APPENDIX 3

CONSENT EXPLANATION

**TITLE:** A Survey Of ICU Setups In The Republic Of Kenya

**Institution:** Department Of Surgery, University of Nairobi.

**Investigator:** Dr Kevin Umani Okech.

**Supervisor:** Dr T.M Chokwe.

**Explanation:**

Permission is requested from you for enrolment in a medical research study. You should understand the following general principles, which apply to all participants in medical research:

1) Your Decision to enroll in the study is entirely voluntary.

2) You may withdraw from the study at any time.

3) Refusal to participate will invoke no penalties or loss of benefits to which you are otherwise entitled.

4) Feel free to ask any questions regarding the study or your participation.

Purpose of this study is to assess the current state of ICUs in our Kenyan Republic. The findings of study after evaluation can address any deficits or challenges that are faced by hospitals. This creates room for future improvement of critical care services in our country hence improve quality health care.

Absolute confidentiality regarding participation is ensured. No names will be used in any documents. All information obtained will be treated with utmost confidentiality.
MADA: Utafiti Wa Vitengo Vya Wagonjwa Mahututi Nchini Kenya

Taasisi: Idara Ya Upasuaji, Chuo Kikuu cha Nairobi.

Mpelelezi: Dr Kevin Umani Okech.

Msimamizi: Dr TM Chokwe

Maelezo:

Ruhusa ni ombi kutoka kwenu kwa ajili ya uandikishaji yako katika utafiti utafiti wa matibabu. Unapaswa kuelewa kanuni za jumla zifuatazo, ambayo yanahusu washiriki wote katika utafiti wa matibabu:

1. Uamuzi Wako kujiandikisha katika utafiti ni hiari kabisa.
2. Unaweza kuondoa kutoka utafiti wakati wowote.

Madhumuni ya utafiti huu ni kutathmini hali ya sasa ya vitengo vya wagonjwa mahututi katika jamhuri yetu ya Kenya. Matokeo ya utafiti baada ya tathmini inaweza kushughulikia Mapungufu yoyote au changamoto ambazo zinakabiliwa na hospitali.

Usiri kabisa kuhusu ushiriki ni kuhakikisha. Hakuna majina zitatumika katika nyaraka yoyote. Habari zote zilizopatikana itakuwa kutibiwa na usiri mkubwa.
APPENDIX 4

INFORMED CONSENT FORM

INVESTIGATOR

I,………………….. (Initials), do hereby give consent to participate in the study titled ‘A Survey Of ICU Setups In The Republic Of Kenya’ whose relevance has been explained to me. I have neither been coerced nor enticed to participate. I fully understand the right of withdrawal from the study at any time.

Signature……………………

ICU PARTICIPANT

I,……………………….. (initials), do hereby give consent to participate in the study titled ‘A Survey Of ICU Setups In The Republic Of Kenya’ whose nature and relevance have been explained to me. I have neither been coerced nor enticed to participate. I fully understand the right of withdrawal from study at any time.

Signature……………………
FOMU YA IDHINI

SEHEMU YA MPELELEZI


Sahihi………………

SEHEMU YA MSHIRIKI


Sahihi………………
SURVEY TOOL FOR ICU SETUPS

TYPE OF HOSPITAL

☐ Referral Hospital. ☐ Mission Hospital.

☐ Provincial hospital. ☐ District Hospital.

BED CAPACITY

a) Total Number of Hospital beds ……………
b) Number of ICU beds ……………

A) STAFFING AND TRAINING

PART 1
a) Total number of nurses working in ICU …………
b) Total number of nurses per shift …………

PART 2

Training experience of nurses in ICU:

i) Number of ICU trained…………
ii) Number of basic nursing trained………
iii) Specialty trained nurses
   a) Renal Number ………
   b) Paediatric Number ………
PART 3

Primary care clinician in ICU:

□ Medical Officer.        □ Clinical Officer Anaesthetist.
□ Senior House Officer Anaesthesia. □ Nurse Anaesthetist.
□ Consultant Anaesthesiologist.

Consultant support in other field’s i.e. surgical, obstetrics, paediatrics

□ YES  □ NO

B) CASE ADMISSION TO ICU

a) Trauma  Number of cases in past 1 year ............
b) Post Operative surgical cases  Number of cases in past 1 year ............
c) Paediatric illness  Number of cases in past 1 year ............
d) Obstetric complication  Number of cases in past 1 year ............
c) Cerebral Vascular Accident  Number of cases in past 1 year ............
d) Cardiac illness  Number of cases in past 1 year ............
e) Neuromuscular disorder  Number of cases in past 1 year ............
f) Poisoning  Number of cases in past 1 year ............

C) EQUIPMENT/SUPPORT

PART 1: EQUIPMENT

1.1 Ventilators  □ Available □ None  a) Total number ............

b) Number working.......  c) Number not working.......
1.2 Monitors □Available □None a) Total number............

b) Number working....... c) Number not working........

1.3 Suction Machine □Available □None a) Total number.............

b)Number working......... c) Number not working........

1.4 Infusion pump □Available □None a) Total number.................

b) Number working........ c) Number not working........

1.5 Defibrillator □Available □None a) Total number............

c) Number working......... d) Number not working........

1.6 Oxygen supply
A) Piped Oxygen □Available □None

B) Oxygen Concentrator □Available □None a) Total Number.....

b) Number working.........

c) Number not working.....

1.7 Dialysis Equipment □Available □None a) Total Number.............

b) Number working....... c)Number not working......

1.8 Invasive Monitoring

a) BP (blood pressure) □Available □None
PART 2: ESSENTIAL DRUG SUPPORT

2.1 Resuscitation drugs

a) Atropine □ Yes □ No
b) Adrenaline □ Yes □ No

2.2 Sedatives (Benzodiazepine) □ Yes □ No

2.3 Anticonvulsants (Phenytoin, Phenobarbitone) □ Yes □ No

2.4 Antibiotics

a) Penicillins □ Yes □ No
b) Cephalosporins □ Yes □ No
c) Carbapenems □ Yes □ No
d) Aminoglycosides □ Yes □ No
e) Tetracyclines □ Yes □ No
f) Flouroquinolones □ Yes □ No

2.5 Inotropes

a) Dopamine □ Yes □ No
b) Dobutamine □ Yes □ No
c) Adrenaline □ Yes □ No

2.6 Analgesics

a) Opiods □ Yes □ No
b) NSAID □ Yes □ No
2.7 Antiarrythmic (Amiodarone) □ Yes □ No

PART 3: LABORATORY SUPPORT

3.1 Blood Gas Analysis □ Yes □ No

3.2 Biochemistry Investigation

a) Kidney Function Test □ Yes □ No

b) Blood Electrolytes □ Yes □ No

c) Liver Function Test □ Yes □ No

3.3 Microbiology Investigation

a) Blood cultures □ Yes □ No

b) Urine cultures □ Yes □ No

3.4 Hematology investigation

a) Full Haemogram □ Yes □ No

b) Coagulation Profile □ Yes □ No

3.5 Radiology

a) Portable Ultrasound □ Yes □ No

b) Portable X-ray □ Yes □ No
APPENDIX 5
COPY OF THE ETHICS AND RESEARCH COMMITTEE APPROVAL LETTER

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P.O. BOX 30093 Code 00202
Telephone: 2772300 Fax: 44355

KENYATTA NATIONAL HOSPITAL
P.O. BOX 30093 Code 00202
Telephone: 2772300 Fax: 44355

Ref: KNH-ERC/A/2

Dr. Umni Kevin Okoch
Dept. of Surgery
School of Medicine
University of Nairobi

Dear Dr. Okech,

RESEARCH PROPOSAL: A SURVEY OF I.C.U SETUP IN THE REPUBLIC OF KENYA (P403/07/2013)

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 6th January 2014 to 5th January 2015.

This approval is subject to compliance with the following requirements:

a) Only approved documents (inform consent, 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]

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