A SEVEN-DAY MORTALITY PROFILE OF MEDICAL INPATIENTS AT KENYATTA NATIONAL HOSPITAL

BY;

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THIS DISSERTATION IS SUBMITTED TO THE SCHOOL OF MEDICINE, COLLEGE OF HEALTH SCIENCES IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTERS OF MEDICINE IN INTERNAL MEDICINE

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DECLARATION

This dissertation has been prepared as part fulfillment of the requirements for the award of Masters in Internal Medicine by the University of Nairobi, Faculty of Health Sciences. It is my original work and all efforts have been made to ensure accuracy of information presented in it. References to other works are made and this has been clearly indicated.

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ABSTRACT

Morbidity and mortality statistics are an important resource for research and informing policy in any country as it reflects on the public health status. Majority of the mortality in the medical wards occur within the first few days following admission. Factors such as age, sex, diagnosis, co-morbidities, social-economic factors and duration of hospital stay have been show to affect mortality. There is a paucity of such studies in Kenya.

Objective: This study sought to describe the causes and circumstances around early mortality among inpatients in the KNH Medical Wards.

Design: An observational cohort study comprising of a retrospective and prospective arm.

Methodology: The study was conducted from 7th April to 18th June 2014. The retrospective arm reviewed the files of patients who had died within seven days of admission to the medical wards six months prior to the study onset. The purpose of this arm was to determine the overall mortality and case specific mortality rate. The prospective arm followed up patients for seven days to ascertain the seven-day mortality rate and associated factors. Post mortems were conducted in a proportion of these patients.

Results: 695 files were reviewed in the retrospective arm while 193 patients were recruited into the prospective arm. The mean age of the participants in the retrospective and prospective arms were 46.7 years (Range 15-107 years) and 44.5 years (Range 15-100 years) respectively. The overall mortality rate was 29.6%. The seven-day mortality rate was 17.6%. Malignant neoplasms at 12.5% were the leading cause of death followed by congestive heart failure at 10.5%. The leading co-morbidity was HIV at 42%, followed by hypertension at 18.8% and diabetes at 8.7%. The median Karnofsky's Score at admission and the mean duration of stay in hospital in days were the two variables strongly associated with risk of dying.

Conclusion: The 7 day mortality rate was high. Malignancies were the commonest cause of death. Most of the early deaths were preventable.

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LIST OF ABBREVIATIONS

CRF   Case Report Form

ED   Emergency Department

HIV   Human Immunodeficiency Virus

ICD-10   International Statistical Classification of Diseases 10

ICU   Intensive Care Unit

KNH   Kenyatta National Hospital

KNH/UON-ERC   Ethics and Research Committee

UNAIDS   The Joint United Nations Programme on HIV/AIDS

UON   University of Nairobi

WHO   World Health Organization

CHAPTER 1: INTRODUCTION

1.0 BACKGROUND

Morbidity and mortality statistics are an important resource for research and informing policy in any country as it reflects on the public health status[1]. In the recent years, children have been the principal focus of public health research and policy formulation in developing countries in an attempt to achieve the millennium development goals. With improved interventions, nearly 90% of children born in developing countries are living to be fifteen years old and above owing to substantial reductions in child mortality[2]. However, many of the health problems affecting adults are still largely neglected whereas the majority of morbidity and mortality in this age group defined as fifteen years to sixty years are preventable[3]. In any society adults are the economically productive age group, biologically reproductive and responsible for the support of children and elderly dependants. The health of adults in sub Saharan Africa is therefore, increasingly becoming an important priority in global health policy. The survival of children is closely linked to that of adults and to maintain the gains made in reducing child mortality, the causes of early adult mortality need to be identified[4].

Recent studies show that adult mortality rates are four to forty times higher in sub Saharan Africa than they are in developed countries [2, 5, 6]. In Kenya the estimated adult mortality rate is 7.26 deaths /1,000 of the population. Awareness of common causes of death is part of the basic steps to extend life and promote healthy communities. However in many developing countries including Kenya, there is paucity of this vital data at the national level to reliably inform policy. Unavailability of population-based statistics makes hospital based studies a suitable alternative to

provide correlates. This research dissertation therefore, sought to examine the inpatient mortality among adults admitted at the medical wards in Kenyatta National Hospital (KNH). The study hoped to determine the pattern of mortality, determinants of early mortality; defined as mortality occurring within the first seven days following admission and the primary cause of death.

CHAPTER 2: LITERATURE REVIEW

2.0 ADMISSION TO THE MEDICAL WARDS

There are several factors that determine if a patient would be admitted to the medical wards. This is determined by the age, severity of the illness, co existing illness (co-morbidity), physical and laboratory findings, the ability of the patient to comply reliably with an oral medication, and the resources available to the patient outside the hospital[7]. In earlier studies done in developed countries, medical admissions accounted for 22% in the United States[8], 33% in Australia[9] and 13% in Hong Kong[10]. Cardiovascular causes were mainly responsible for these admissions contributing to 29% in the cited Australian study and 30.3% of all medical cases in the Hong Kong study referred to above. Similar findings were observed in several earlier studies done in South Africa. Admissions to Hillbrow Hospital were most frequently associated with the circulatory system (27.9%) followed by respiratory (15.9%) and infectious diseases (11.9%)[11]. More recently in a study done in a rural hospital in Limpopo province of South Africa found that hypertension (19%) and pulmonary tuberculosis (10%) accounted for most of the admissions[12].

However, studies from other parts of sub Sahara Africa showed different results from those seen in South Africa and the developed countries. Recent studies from Nigeria showed that infectious diseases still were the most common cause of admission to the medical wards[13, 14]. Similar findings were reported in a study done in Ethiopia where infectious diseases contributed to 16.4 % and cardiovascular diseases 12.8% of all admissions to the medical wards[15]. Irrespective of the reasons for admission, several factors play an important role in determining mortality, including age of the patient[16], gender, diagnosis, access block effect[17] [18] which refers to the

situation where patients requiring emergency admission spend more than eight hours in an emergency department (ED) because they are unable to gain access to appropriate hospital inpatient beds, day and time of admission[19-21]. The types and complexities of co-morbidities, the health seeking behavior of the patient, and the duration of hospital stay are other factors that affect mortality [22].

2.1 DETERMINANTS OF MORTALITY

Published data on determinants of patient outcomes admitted in medical wards reveal that several factors play a role in the eventual mortality, over which hospitals and physicians have no control. In theory however, mortality rates can be standardized to remove some of these factors in order to assess the actual quality of care in a given hospital[23]. These factors are multifaceted but can be generally categorized into patient factors and administrative factors.

2.1.1. Patient Factors

Patient factors can be further divided into fixed patient factors; which include age and gender and non-fixed patient factors[24]. Non-fixed patient factors include health seeking behaviors, functional status (physical and cognitive) and the primary diagnosis and co-morbidities[22, 24].

2.1.2 Fixed Patient Factors
The age and gender of the patient play an important role in mortality. Chronologic age is a well-documented risk factor for death from acute illness that is independent of severity of disease. In a study conducted at the medical wards in Nigeria at Ahmadu Bello Teaching University Hospital, it was observed that while admission was fairly distributed among the age groups, persons above seventy years constituted 26.3% of all admissions with males constituting most of the medical admissions

(65.9%)[22]. Different results were reported in a study done in Ethiopia where the highest number of medical admissions was in the twenty one-thirty years age group (36.0%) followed by thirty one-forty years age group (20.0%) while males constituted 53.1% of the total admissions in the medical wards[15]. Whereas these two studies showed a variation in age group commonly admitted which could be explained by the differences in population structure of the two countries [22], males were still more likely to be admitted compared to females. These findings were similar to what's in the World Bank Report that revealed that globally, the male all cause mortality was 11% higher than that for females[24]. There were no local studies available for review to compare the age characteristics of patients admitted to the medical wards in local hospitals and whether males were more likely to be admitted compared to women.

2.1.3 Health Seeking Behaviors

Recent reviews of literature reveal that treatment seeking and cost burden vary by the type of disease[25, 26]. In a study in Nigeria, it was noted that health-seeking behavior was generally poor with most of the patients presenting in advanced stages of disease conditions thereby increasing their chances of dying[22].A study done in Cameroon reported that the average time of symptom onset to admission was 18.5 days for children and 68.5 days for adults (p<0.001) and 43.7% of these adults died on or before the day following admission[27]. Similar trends were noted in a community survey looking at health seeking behaviors in coastal Kenya[28]. It was reported that households in the urban areas were more likely to report illness than their rural counterparts (19.5% versus 16.9%) and more likely to visit a health provider (81.5 % versus 75.9% respectively). These findings were strongly linked to the socio-economic status of the households interviewed and the costs of seeking

treatment which resulted in coping strategies employed that had negative implications for the future survival of these households [25, 29]. These findings echo those of Ahmadu Bello University Teaching Hospital in Nigeria where it was noted that most patients who die in the hospital's medical wards presented late and did not have adequate financial support or were often referred late from other hospitals[22].

2.1.4 Severity of Illness at Admission

Previous studies have indicated that functional status measures are important predictors in hospital outcomes in elderly medical patients [30-32]. Moreover, functional measures are stronger predictors of hospital outcomes including-functional decline, length of stay in hospital and death- than admitting diagnoses, co-morbidities, and standard indices of disease burden[32]. For example a study demonstrated that a measure of physical functioning was the best single predictor of hospital mortality, surpassing acute physiologic measures[33]. In one study in the United States it was reported that inpatient mortality increased from 0.9% in the patients' dependent in no ADL (Activity of Daily Living) on admission, to 17.4% in patients dependent on all 6 ADLs[34]. Other more complex tools for measuring disease severity include the APACHE II score, which has predicted consistently that patients with higher scores are at an increased risk of dying[35].However, this tool has had limited application in routine care. For this study we used the Karnofsky's Scale to assess the performance status of the patients.

2.1.5 Structural or Administrative Factors

These refer to local hospital factors, which singly or collectively contribute directly or indirectly to eventual patient mortality.

2.1.6 Access Block Effect and Ward Overcrowding

Access block refers to the situation where patients requiring emergency admission spend more than eight hours in an emergency department (ED) because they are unable to gain access to appropriate hospital inpatient beds[36]. Access block is linked to increased ED waiting time for medical care leading to overcrowding in the ED. This overcrowding is generally accepted to lead to decreased efficiency and possibly quality of care due to delay in initiating time critical care such as administration of antibiotics in sepsis, prolonged pain and suffering of patients, long waits and dissatisfaction of patients and decreased clinical productivity and effectiveness and mortalities occurring in the emergency department[37-39]. In a study conducted in Western Australia to determine the effect of access block and overcrowding on mortality, it was reported that there was a positive relationship between level of hospital occupancy and death by day two, seven and thirty after the index ED attendance[18]. In this study, patients who died and experienced overcrowded conditions were likely to be male (risk ratio, 1.3; $p<0.007$), had longer durations of stay in the ED (risk ratio per hour of stay in the ED stay, 1.1; $p<0.001$). This phenomenon contributed to the poor health seeking behaviors of patients as was reported in a survey in coastal Kenya, which showed that people used formal health care facilities less often. In general, people used private clinics (10.3% in rural areas versus 24.4% in urban) more than government facilities (8.6% rural versus10.6% urban)[28]. Private clinics were preferred over government dispensary in both settings because of speedy services. Government hospitals though were the main sources of inpatient care in both settings (61.4 % of all hospitalizations in rural and 55.4 % in urban) with cost of care being the major determinant in making this choice.

2.1.7 Day and Time of Admission

Some studies have shown that patients admitted to hospitals during the weekend have higher mortality rate than those admitted on a weekday, whether surgical or medical patients [40-43]. One reason attributed to this observation is that staffing levels tend to be lower on weekends than on weekdays, whereas the incidence of medical emergencies is similar from day to day [44].In a Study in Spain, it was observed that patients admitted during the weekends had a 57% risk of dying when compared to patients admitted during weekdays[45]. This study also showed that patients who died on weekends were older (79.3 years SD=11, p<0.01), more frequently male (53.3%), more severely ill, admitted for longer period and had more co-morbidities. These observations were attributed to the number of physicians working on the internal medicine wards on weekends and holidays to be below the mean number working on weekdays[46-48].Another factor that could be important is that the performance of diagnostic and therapeutic studies, as well as consultations with specialists is limited during the weekends [48]. In addition, weekend staff may have less experience and knowledge about the patients than the regular physicians who know their patients best.

Some studies have also shown that patients who suffer acute illness and are admitted during the "after hours" (nights) may be at higher risk for adverse outcomes as compared to patients admitted during normal working hours. A study done reported a relative risk for death associated with admission in the afterhours of 10.59[49]. More recently, another study found an increased risk for hospital mortality associated with admissions during evenings/nights of 17% versus 14% (p<0.001)[50]. The reasons for this were given as for the factors responsible for increased weekend mortality.

2.1.8 Length of Hospital Stay

Studies have demonstrated a strong association between the length of stay in hospital and mortality. In a study in Ahmadu Bello Teaching University Hospital in Nigeria, it was reported that 30% of all deaths occurred on the first day of admission, 55% of all deaths by the second day and by the fifth day 65% of all deaths had occurred. Only 15% of the deaths occurred after the tenth day[22]. A study in Ethiopia also found that 53% of all admissions in the medical ward died before the fifth day and 75% of all admissions had died by the tenth day of admission[15].Different results were however reported in a study in Spain where it was reported only 2.5% of the patients died within the first forty eight hours of admission.

In Nigeria, it was postulated that late referrals to the tertiary institution was possibly responsible for the high mortality rates a few days after admission[22].

2.2 PROBLEM STATEMENT

The global burden of disease due to medical conditions is enormous with widespread geographical variations. The WHO predicts that by 2020, the causes of morbidity and mortality will have undergone a significant shift towards endemic non-communicable diseases away from the infectious diseases[51]. This shift will necessitate changes in the deployment of resources to deal with priority health challenges. However, health policy change will need to be informed based on local findings from local research due to variations in morbidity and mortality patterns even within the same country. For instance, studies done in medical wards of two different South African hospitals in an urban setting, showed a shift in morbidity and mortality from communicable to non-communicable causes which was attributed to, increased urbanization and westernization[11, 52]. Another study conducted at the medical wards of GF Jooste Hospital medical wards, South Africa showed that circulatory disorders (22%) and infections (19%) were the major causes of admission[53]. These findings were however, different from those conducted at a hospital in Ethiopia, which showed that infectious diseases (16.4%) were the most common causes of admissions in the medical wards followed by circulatory disorders (12.8%)[15]. Intra-institutional variations in morbidity and mortality patterns were observed in studies conducted in Aminu Kano Teaching Hospital, Kano, and Northern Nigeria over different periods. One of the studies done between 2001 and 2003, showed a mixed spectrum with circulatory disorders accounting for 17% of the mortality and infectious diseases other than HIV accounting for 17.9%[13]. A similar study done in the same wards between 2005 and 2008 showed the leading causes of mortality to be infectious disease (9.2%) and circulatory disorders (6.3%)[54]. These findings demonstrate a need for conducting regular mortality audits within the department to identify

management errors and prevent recurrence of avoidable deaths. Currently at KNH, mortality audits in the medical wards are only conducted on a regular basis in one of the seven wards (Ward 7D). This therefore, results in a missed opportunity to characterize objectively the pattern of morbidity in the department, which may be instrumental in reviewing local and informing national health policy and processes.

Studies in mortality patterns have indicated that most of the mortalities occur in patients with shorter duration of hospital stay. One study in Ethiopia showed that 53% of patients who died in the medical wards died within five days of admission and 75% of all mortalities died within ten days of admission[15, 27].A study done in northern Cameroon reported that 43.7 % of all adult deaths admitted with medical conditions occurred within forty eight hours of admission in one hospital. There are no local studies that explain the causes or factors that may contribute to this trend. This study sought to bridge the knowledge gap in the morbidity and mortality trends observed.

2.3 JUSTIFICATION

More than one quarter of all deaths occurring in developing countries occurs in the adult age group, and about three quarters of these ten million deaths are preventable[55]. Adult's account for about 21% of all the avoidable years of life lost in developing countries and for more than that if the years are weighted for their productivity and discounted[56]. The pattern of illnesses responsible for the high mortality rates in sub Saharan Africa has not been well characterized due to deficient data to make this evaluation[3, 5]. Locally, there are no studies that have been recently done to facilitate this characterization. Knowledge of morbidity and mortality patterns are essential not only for planning interventions and setting health priorities but also for assessing the quality of health delivery systems. At the moment, few countries in the developing world rely on research evidence for guiding policy interventions[4]. Community based studies provide an accurate picture of the profile of the illnesses of adults because they minimize the bias inherent on hospital based studies occasioned by variable access to health care[57, 58]. However, these surveys are expensive undertakings and useful information could be obtained from an analysis of well-conducted clinical surveillance activities[59]. Although in-hospital mortality may not give a true reflection of deaths from all causes in the general population, it may give insight into the burden of disease in the community and may be valuable in evaluating the quality of care and health delivery systems at the KNH. This study aimed to provide information on the current trends of mortality at the medical wards at KNH. This in turn, would provide all the stakeholders with an opportunity to critically reflect upon the processes and outcomes of their interventions with the aim of maintaining or improving health delivery through informed policy change.

The study sought to describe in details the morbidity and mortality patterns in our health institution and the factors that contribute therein and explore ways in which these could be mitigated. This study also sought to help in planning interventions, changing health care policy and improving the quality of health delivery systems.

Though this study aimed to make specific recommendations based on the findings, it was hoped that by doing this study would help push for resources to be availed in the hospital such as an ICU/HDU room in every Medical Ward. It was hoped that the study findings would help sensitize clinicians to request for post mortems as a learning exercise to help improve in their diagnoses and management of patients.

2.4 RESEARCH QUESTION

What is the magnitude and causes of early mortality amongst medical inpatients in

KNH?

2.5 STUDY OBJECTIVES

2.5.1 General Objective

To describe the causes and circumstances around early mortality among

inpatients in the KNH Medical Wards.

2.5.2 Specific Objectives

1. To determine the in-patient mortality rates within the first seven days in

    the KNH Medical Wards.

2. To determine the case-specific mortality rate within the first seven days.

3. To determine the patient and structural factors contributing to mortality

    within the first seven days.

CHAPTER 3: STUDY METHODS

3.0 STUDY DESIGN

This was an observational cohort study comprising of two arms, retrospective and prospective as described below.

Retrospective arm: In this arm the files of patients who died within the first seven days of admission to the medical wards were reviewed. This arm covered a period of six months prior to the onset of the study. The arm was used to ascertain the overall mortality rate and determine the case specific mortality rates in the medical wards.

Prospective arm: This was a time based prospective cohort study on deaths involving medical patients managed at the medical wards of KNH that was conducted over a period of two months. This arm helped to establish the patient and structural factors contributing to mortality within the first seven days.

3.1 STUDY SETTING

The study was conducted at the medical wards of KNH. The Hospital was established in 1901 to fulfill the role of being a National Referral and Teaching Hospital, as well as to provide medical research environment. In 1987, KNH became a State Corporation with a Board of Management and is at the apex of the referral system in the Health Sector in Kenya. (KNH website). KNH has fifty wards, twenty-two outpatient clinics, twenty-four theatres (sixteen specialized) and an Accident & Emergency Department. The total bed capacity of the hospital is one thousand eight hundred beds of which two hundred and nine beds are for the Private Wing. The hospital has nine divisions including the Medical Services division. The Medical Services division comprises of the following departments; Pediatrics, Specialized Medical units, Critical Care and Medicine. The department of Medicine has seven admitting wards: ward 7A, ward 7 B, ward 7D, ward 8D, ward 8C, ward 8A, and

ward 8B.Only patients admitted through specialty clinics go straight to their specialty wards. Each ward has one admitting day per week through which patients diagnosed with medical conditions at the emergency department will be admitted. On average, each ward admits fifteen to thirty medical patients on their admission days through the emergency department.

3.2 STUDY PERIOD
The study was conducted from 7th April to 18th June 2014.

3.3 RETROSPECTIVE ARM

3.3.1 Study Population

All the files of the patients who died in the medical wards in the preceding six months prior to the onset of the study were reviewed.

The Eligibility criteria for these files were

1. All Medical files of patients aged fifteen years and above who died during the study period.

2. The files of patients who had died during this six month period within seven days of admission.

The exclusion criteria were

1. Incomplete files

2. Files with missing records

3. Mutilated files

3.3.2 Sample Size

All files within the study period of six months were reviewed.

3.3.3 Sampling Method

Consecutive sampling of all the files during this six month study period was done.

3.3.4 Data Collection

Data was collected by use of a structured Case Report Form (CRF) specifically designed for this study (Appendix 1). During data collection the patient's case notes were reviewed and study specific information was identified and entered in the corresponding CRF. Information collected included socio-demographic details of the patient, time patient was seen at emergency department/ specialty clinic, date and time of admission to the medical ward, primary diagnosis at admission, co-morbidities, duration of hospital stay, time of death and primary cause of death. Data on post-mortem results was collected from the copies of the original post-mortem result if a post mortem had been conducted. Diagnoses was standardized by using the WHO international statistical classification of diseases-ICD 10[60].

3.4 PROSPECTIVE ARM

3.4.1 Study Participants

All adult medical patients admitted to the Medical wards through the ED and specialty clinics at KNH during the study period were eligible to participate in the study. In this study all patients above fifteen years of age were classified as adults in accordance with WHO convections[61]. The following eligibility criteria was used to include participants into the study:

1. The patient should have been aged fifteen years and above.

2. The patient should have been willing to participate in the study and document this by means of a written informed consent form.If the patient had not achieved the legal age of majority in Kenya which is 18 years, or was incapacitated then a parent or legally acceptable representative would sign the informed consent form on their behalf.

3.4.2 Sample Size

The minimal sample size was calculated as follows

$$n = \frac{z^2(p(1-p))}{e^2}$$

Where

n = the sample size

z = the statistic associated with the level of significance we wished to test our result at

p = an estimate of the proportion of seven day mortality in participants (11.2% in Nigerian population)

e = the proportion of error we were prepared to accept

$$n = \frac{3.8416 \times [0.112 \times (1-0.112)]}{0.05 \times 0.05} = 152$$

If the target population is less than 10,000 then the final estimate is calculated using the formula

$$n_f = \frac{n}{1 + n/N}$$

where n_f = desired sample size where population < 10,000

N = total study population estimated to be 800 admissions during the one month of the study.

$$n_f = \frac{152}{1 + 152/800}$$

$$= 128 \text{ Participants}$$

3.4.3 Sampling Method

Simple random sampling was used to select the participants. We generated 200 numbers representing our patient sample and these numbers were then randomly distributed to the number of days within the study period using a computer program. The recruitment days were computer generated to ensure all the days of the week were evenly covered during the study period.

On each day of the study the research assistants had a specific number of patients to recruit into the study.

On each assigned day the research assistants did go to the record book in the accident and emergency department with the numbers assigned for that day and using the record book picked the study participants. When the patient refused to consent the next consecutive patient was picked.

3.4.4 Recruitment and Consenting Procedure

Patients were recruited from their point of admission in the accident and emergency department.

The purpose of the study was explained to the patients and their relatives with the objective of the study being to determine the outcome of patients admitted to the medical wards (Appendix III).

Informed consent was obtained in form of signing an informed consent form (Appendix IV). This was from the patient or if the patient had not achieved the legal age of majority or incapacitated from a legally acceptable representative.

Patients were followed up daily through the course of a week for the primary end point of death. Follow up of each patient ceased at the point of death of the patient and establishing a post-mortem diagnosis or upon surviving past seven days of

admission. Each patient received the normal standard of care accorded to patients admitted to the medical wards at KNH.

3.4.5 Data Collection

Data was collected by use of structured Case Report Forms specifically designed for this study (Appendix II). During data collection the patients' case notes were reviewed and study specific information was identified and entered in the corresponding CRF. Information collected included socio-demographic details of the patient, time patient was seen at emergency department/ specialty clinic, date and time of admission to the medical ward, primary diagnosis at admission, co-morbidities, duration of hospital stay, time of death and primary and underlying cause of death.

The primary and underlying cause of death were based on the consultant clinician review in the wards, which established the primary reason for admission and comorbidities affecting the patient. For those patients who did not have a consultant diagnosis,had multiple diagnosis or refused consent for a PM the cause of death was determined by consensus through a panel of three consultants.

The cause of death in selected cases was ascertained through post-mortems conducted by a hospital pathologist. The results of the post mortem were relayed to the pts relatives.

Data on post-mortem results was collected from the copies of the original post-mortem result. Diagnoses was standardized using the ICD 10[60] for all cases.

Research Assistants: The principal investigator recruited five research assistants whose role was to assist in the data collection and filling of questionnaires. The research assistants were clinical officers who had qualified with a diploma in clinical medicine from the Kenya Medical Training College. The Principal Investigator

trained them to observe all the principles of research ethics as stipulated by the declaration of Helsinki and Good clinical practice involving the handling of an individual patient's private information and maintenance of confidentiality. The research assistants were also trained on assessing the patient's performance status using the karnofsky scale.

3.5 STUDY VARIABLES

3.5.1 Dependent variables

The dependent variable was death of a patient in the medical ward within the first seven days of admission.

3.5.2 Independent variables

Explanatory variables were collected to determine if there was an association between these variables and mortality. To explore patient factors that impact on mortality the following data was collected; age, sex and socio-economic status, duration of symptoms before seeking treatment, primary diagnosis and co-morbidities at admission and the patients performance scale using the karnofsky's scale and the primary cause of death. To explore administration factors the following variables were explored; Date (Day) and time of admission, duration of time spent between emergency department and time of admission in the medical wards and length of stay in the ward before death.

3.6 DATA ANALYSIS

Data analysis was done using SPSS version 20. The seven-day mortality rate, which was the primary variable, was calculated as the number of deaths that occurred within seven days of admission divided by the total number of patients recruited into the prospective arm of the study. The proportion of deaths was stratified by specific

disease conditions according to ICD-10 classification and the differences in proportions (mortality) was compared using the chi-square test ($\chi 2$) for a contingency table for significance. Frequency distribution of secondary categorical variables was computed where appropriate. Means and Standard deviations were computed for normally distributed continuous variables. Multiple logistic regressions were used to assess for the differences in mortality rates (early= < forty eight hours following admission and overall mortality= seven days after admission) between these two groups after adjusting for age and sex. The results of logistic regression were reported as Odds Ratio. Length of stay in hospital (LOS) was calculated as the number of midnights that the patient observed in the ward between admission and primary outcome. Comparisons between night admissions and day admissions, and between weekend and weekday admission, for the continuous variable LOS, was assessed using two-tailed t- test. All reported p-values were two-tailed. In assessing the effect of emergency department overcrowding and ward overcrowding on inpatient mortality, the hospital and ED occupancy was calculated. Ward occupancy was calculated from the admitted patient census at 2359 hours on the day of attendance, divided by the 99th percentile 2359 hours patient census for the ward during the first six months of the calendar year. Access block phenomenon was calculated as the number of patients who spent greater than eight hours from the time of being attended to at the ED and time of admission to the ward over the total admissions. The relationship between these two variables and mortality was assessed using Cox regression.

3.7 ETHICAL CONSIDERATIONS

All the principles of research ethics as stipulated by the declaration of Helsinki and Good Clinical Practice involving the handling of an individual patient's private information and maintenance of confidentiality were observed. Ethical approval for the study was sought from the KNH/UON Ethics Research Committee before execution of the study. Written informed consent was also obtained from individual participants to document their willingness to participate. All patients participating in the study received normal standard of care for their conditions according to the wards patient management guidelines. No coercion or methods that may unduly influence the patients to participate were employed.

CHAPTER 4: STUDY RESULTS

4.1 PATIENT RECRUITMENT

4.1.1 Retrospective Arm patient recruitment

Four thousand seven hundred and thirty four patients were admitted into the medical wards within the six months prior to the onset of the study. Out of these one thousand four hundred and two patients died. We were able to retrieve nine hundred and eighty five files, which represented 70.2 % of the total number of patients who had died. Two hundred and fifty six files were excluded because the patients died more than seven days after admission. Thirty-four files were either mutilated or had missing data. We were therefore left with six hundred and ninety five files of patients for data analysis.
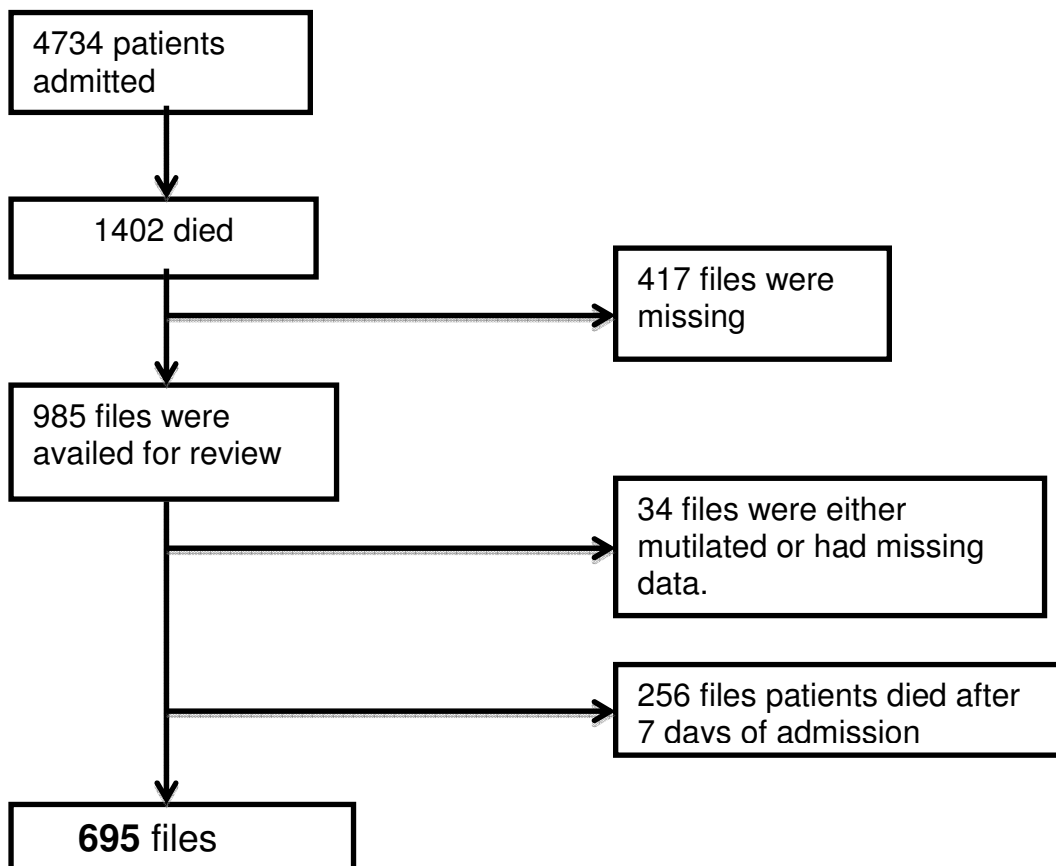
Figure 1:Retrospective arm file review flow chart

4.1.2 Prospective arm: Patient recruitment flow

In the prospective arm we were able to obtain two hundred patients using computer-generated numbers and informed consent was given to them at various points in the study period. However seven patients refused to sign the consent forms and were excluded from the study. We were therefore left with a hundred and ninety three patients. Thirty-four patients representing 17.6% of our sample died within seven days and were analysed.
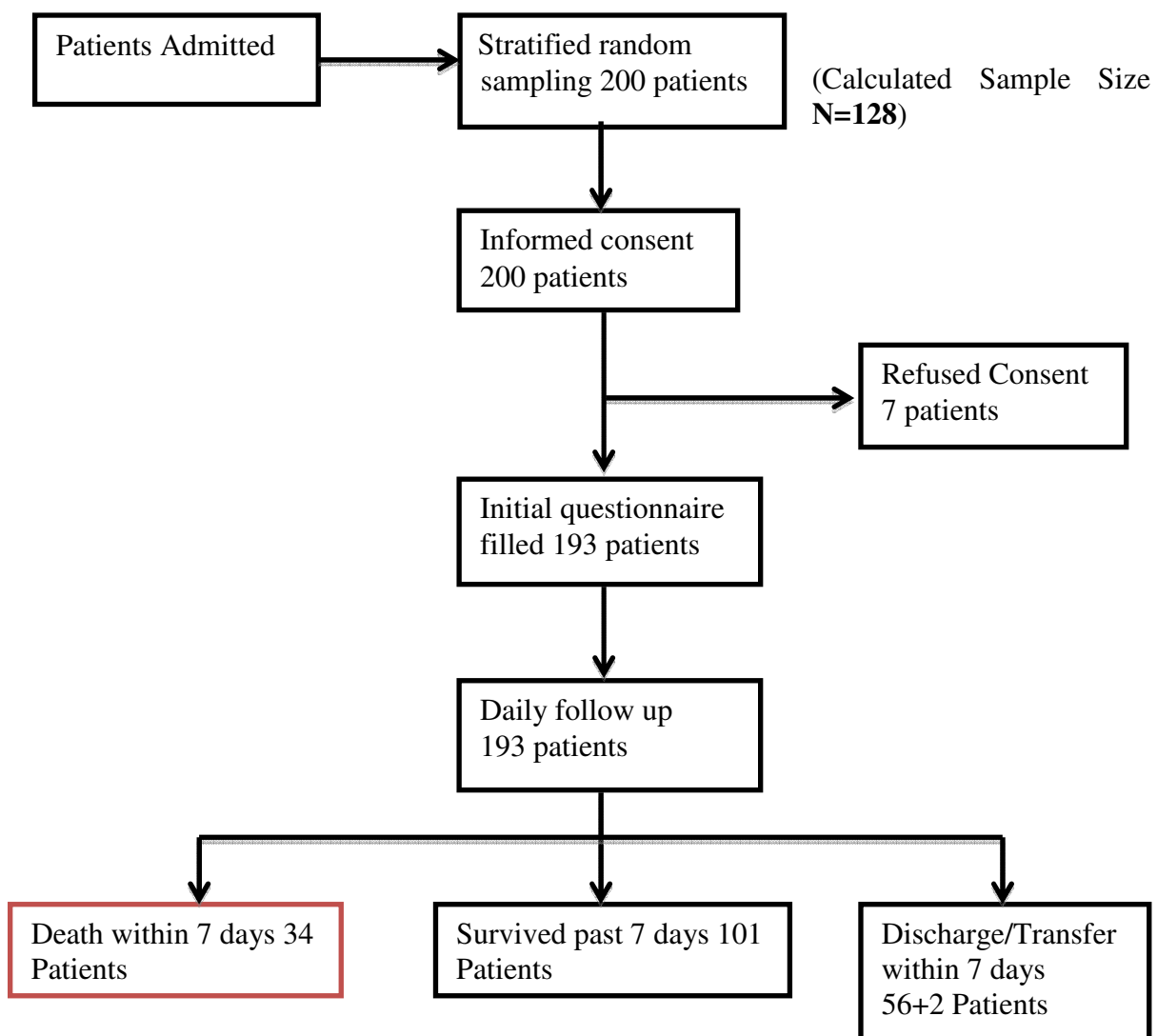
Figure 2: Prospective arm patient recruitment flow chart

4.2 DEMOGRAPHIC CHARACTERISTICS

4.2.1 Retrospective arm demographic characteristics

The mean age was found to be 46.7 with an age range of 15-107 years. There were more males 53.7% than females. Majority of the patients 66.8 % were referred from other facilities. The median length of stay in days was three days.

Table 1:Demographic and admission characteristics of patients in the retrospective arm (N=695)

Variable	Frequency (%)
Age in years, mean (SD) Min-Max	46.7 (20.0) 15-107
Sex Female Male Missing	 311 (44.7) 373 (53.7) 11 (1.6)
Referral Pattern Hospital Self Missing	 464 (66.8) 221 (31.8) 10 (1.4)
Length of Stay in days, median (IQR)	3.0 (2.0-6.0)

4.2.2 Prospective Arm demographic characteristics

One hundred and ninety three patients were included in this study. Of those interviewed one hundred and three (53.4%) were female. The average age was 44.5 years with an age range from 15-100 years.

Most of the patients were referrals 54.9%. Majority, 67.9% of the patients spent more than eight hours in ED.The median duration of symptoms before admission in days was seven days with a range of one day to six months. The Karnofsky's score at admission ranged from twenty to ninety percent. The average ward occupancy at admission was 95.7%. This was calculated by adding the daily ward occupancy for the recruitment days divided by the total number of all the recruitment days.

The baseline characteristics at admission are presented on Table 2 below.

Table 2:Demographic and admission characteristics of study patients in the prospective arm (N=193)

Variable	Frequency (%)
Age in years Mean (SD) Min-Max	 44.5 (18.9) 15-100
Sex Female Male	 103 (53.4) 90 (46.6)
Referral Pattern Hospital Self Not specified	 106 (54.9) 86 (44.6) 1 (0.5)
Casualty Overcrowding Yes No	 131 (67.9) 62 (32.1)
Median duration of symptoms before admission in days (IQR) Min-Max	7.0 (3.0-14.0) 1 day – 6 months
Karnofsky's Score at Admission Min-Max	 20-90
Average Ward Occupancy at admission (%) Min-Max	95.7 (17.4) 68-129

4.3 MORTALITY RATE

The overall mortality rate was 29.6 % using data from the retrospective arm. It was not possible to calculate the seven-day mortality using the retrospective arm due to the large number of missing files. We therefore used data from the prospective arm and found our seven-day mortality rate to be 17.6%.

This information is depicted in the following table.

Table 3:Table showing the overall and seven-day mortality

	N=4734 N (%)	95% Confidence Interval
Overall Mortality	1402 (29.6 %)	28.3-30.9
	N=193	**95% CI**
7-day Mortality	34(17.6%)	(12.4 – 23.3)

4.4 CASE SPECIFIC MORTALITY RATE

4.4.1 Primary diagnosis at admission and immediate cause of death

The primary diagnosis at admission was used to determine the immediate cause of death. Malignant neoplasms at 12.5% were the leading cause of death followed by congestive heart failure at 10.5%. Chronic kidney disease was third at 9.6%. Stroke and pulmonary tuberculosis were fourth and fifth respectively while acute renal failure was sixth at 5.11%.

However if both chronic kidney disease and acute renal failure were combined then kidney disease as a whole was the leading cause of death.

Other causes were meningitis, pneumonia, anemia and gastroenteritis in that order.

The figure below shows this.
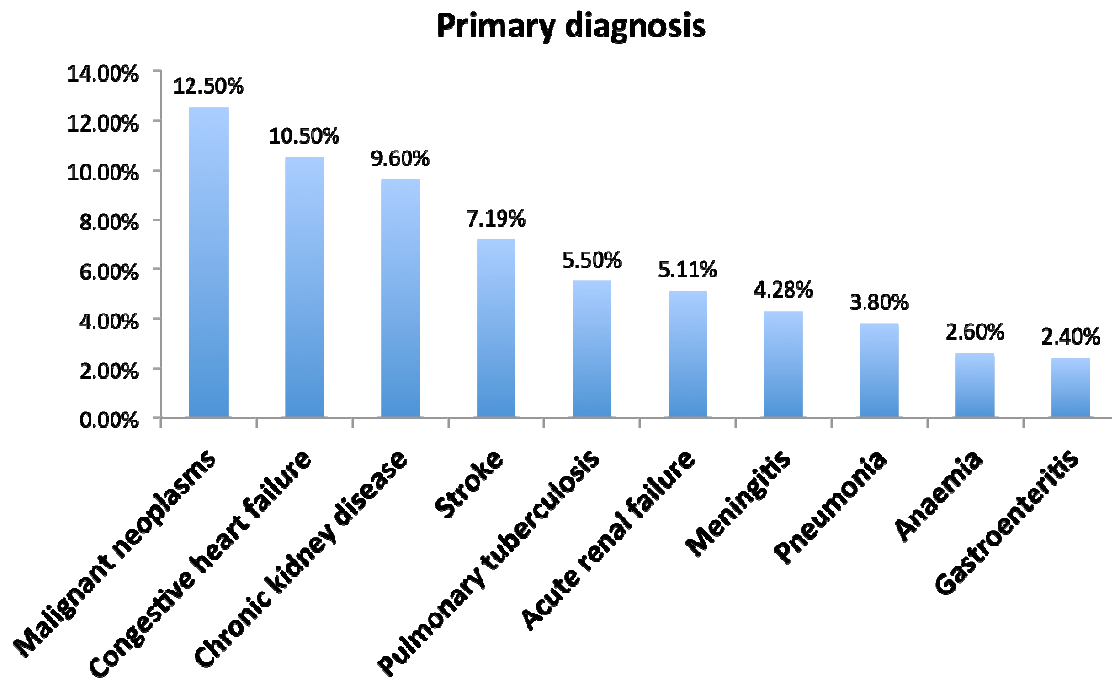
Figure 3:Case specific mortality rate according to primary diagnosis

4.4.2 Co-Morbidities at admission and underlying causes of death

The co-morbidities at admission were determined to be the underlying causes of death. HIV at 42% was the leading comorbidity followed by hypertension at 18.8% and diabetes at 8.7%. Other diseases that were not the immediate cause of death were chronic kidney disease, acute renal failure, pulmonary tuberculosis, anemia, sepsis and rheumatic heart disease. The following graph shows this.

ICD coding	N	%
Infectious and parasitic diseases	391	53.6%
Disease of circulatory system	309	42.4%
Disease of genitourinary system	185	25.4%
Malignant neoplasms	115	15.8%
Endocrine, nutritional, and metabolic diseases	92	12.6%
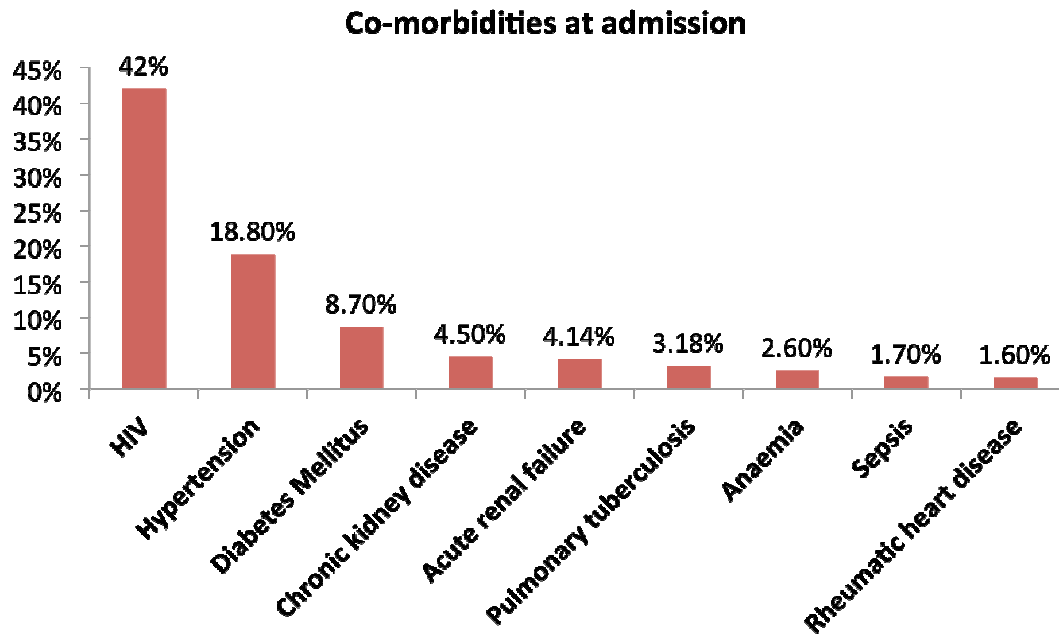
Figure 4:Co-morbidities by disease categories associated with primary diagnosis

4.4.3 Disease categorisation according to ICD 10

We further subcategorized the top causes of death according to the ICD 10 coding and infectious and parasitic diseases were the most common at 53.6% followed by diseases of the circulatory system and genitourinary in that order.Below is a table depicting the information.

Table 4:Disease categorization according to ICD 10 (Cumulative) N=729

4.5 SEVEN DAY OUTCOMES IN THE PROSPECTIVE ARM

There were thirty-four (17.6%) deaths recorded during the period of the study. The mean duration of stay in the wards was four days (standard deviation 1.9, CI 3.7-4.4). One hundred and fifty nine 85.4% of the patients recruited into the study survived past seven days of admission.

Table 5:Outcomes at 7 days of admission among patients in the prospective arm

Variable	Frequency (%)	95%Confidence Interval
Outcome Dead Alive	 34 (17.6) 159 (85.4)	 13.0-22.8 68.4-95.3
Length of stay in the wards in days Mean (SD) Min-Max	 4.0 (1.9) 1-7	 3.7-4.4

Ten (29.1%) of deaths occurred within 24 hours of admission, 12(35.2%) of the deaths occurred after 24 hours and within 3 days of admission and another 12 patients representing 35.2% of the total seven day mortality occurred between 3 and 7 days. The figure below shows a Kaplan Meier curve demonstrating the survival of patients in the medical wards during the study period.
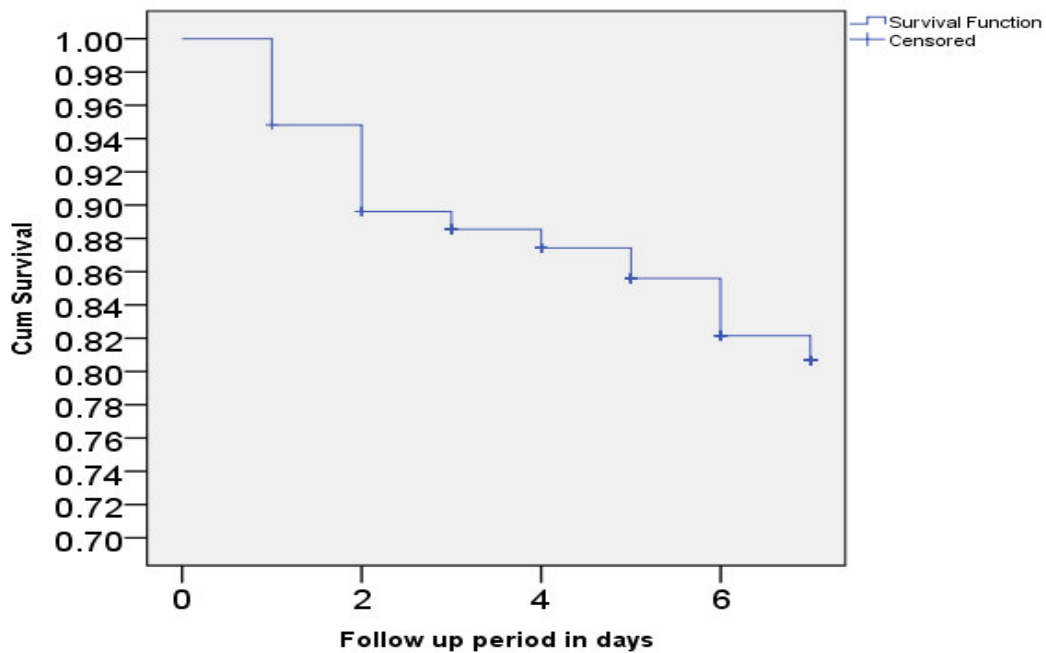
Figure 5: Kaplan Meier curve showing survival of study patients admitted in the medical wards during the study period

4.6 DETERMINANTS OF MORTALITY

The only patient factor that demonstrated a strong association with mortality was the median Karnofsky's Score at admission (score (IQR), dead 40(14.6) versus 60(14.4), $p < 0.001$). No strong association was observed with the other patient factors. Among the administrative factors it was observed that the mean duration of stay in days in the hospital was significant. Majority (58%) of the deaths occurred within Forty-eight hours following admission.

Table 6: Factors associated with mortality in the wards

Variable	Dead (n=34)	Alive (n=159)	OR (95% CI)	P value
Age, mean (SD)	44.3 (19.1)	44.6 (19.0)	-	0.930
Sex Female Male	18 (17.5%) 16 (17.8%)	85 (82.5%) 74 (82.2%)	1.0 (0.5-2.1) 1.0	0.956
Admission day Mon Tue Wed Thur Fri Sat Sun	6 (12.2%) 7 (17.5%) 4 (19.0%) 4 (23.5%) 7 (19.4%) 2 (16.7%) 4 (22.2%)	43 (87.8%) 33 (82.5%) 17 (81.0%) 13 (76.5%) 29 (80.6%) 10 (83.3%) 14 (77.8%)	0.6 (0.2-1.5) 1.0 (0.4-2.5) 1.1 (0.3-3.5) 1.5 (0.5-4.9) 1.2 (0.5-2.9) 0.9 (0.2-4.5) 1.4 (0.4-4.5)	0.905
Casualty Overcrowding (>8hrs) Yes No	 26 (19.8%) 8 (13.5%)	 105 (80.2%) 51 (86.4%)	 1.3 (0.5-3.4) 1.0	 0.334
Median duration of symptoms before admission In days (IQR)	7.0 (2.0-14.0)	7.0 (3.0-14.0)	-	0.448
Median Kanofskys Score at admission (IQR) Range	40 (30-50) 20-70	60 (50-70) 30-90	-	<0.001
Ward Occupancy at admission (%)	97.4 (17.3)	95.3 (17.4)		0.529
Duration of stay in casualty (Mean SD) Range 2 hr. – 28 hrs.	12.2(4.7)	12.1(5.4)		0.853
Referral pattern Hospital Self	 20 (18.9%) 14 (16.3%)	 86 (81.1%) 72 (83.7%)	 1.2 (0.6-2.5) 1.0	 0.640
Mean hospital stay in days (SD) Categories	3.0 (2.1)	6.1 (1.4)	-	<0.001
≤1 day 2 Days 3 Days 4 Days 5 Days 6 Days 7 Days	10 (90.9%) 10 (76.9%) 2 (16.6%) 2 (15.3%) 3 (15%) 5 (35.7%) 2 (1.8%)	1 (9.1%) 3 (23.07%) 10 (83.3%) 11 (84.6%) 17 (85%) 9 (64.2%) 108 (98.1%)	1.0 0.1 (0.0-0.8) 0.0 (0.0-0.2) 0.0 (0.0-0.1	<0.001

4.7 POST-MORTEM RESULTS

Postmortems were done for the patient's who had died and their relatives had consented to the procedure. The main objective for performing the postmortems was to explore if misdiagnosis of patients as an administrative factor was responsible for mortalities. 10 (29.45%) of the relatives consented to having a post mortem done, while 24(70.6%) declined. Most of the relatives declined consent because they did not view it as important. Majority of the ward diagnosis were found to be keeping with the post mortem diagnosis. The results of postmortem diagnosis are shown in the table below.

Table 7: Post- mortem diagnosis as compared to ward diagnosis

Ward Diagnosis	Immediate cause of death	Underlying cause of death	Misdiagnosed
Diabetic ketoacidosis	Acute respiratory distress syndrome	Diabetes Mellitus	No
Gastroenteritis	Aortic Dissection	Hypertension	Yes
Congestive heart failure	Pulmonary Embolism	Fracture femur	Yes
Community acquired pneumonia	Lobar pneumonia	HIV	No
Stroke	Massive ICH	Hypertension	No
AML		AML	No
GE	Disseminated TB	HIV	Yes
Encephalopathy	Hypertensive heart disease	Hypertension	No
CKD	ESRD (HIVAN)	HIV	No
CKD	ESRD (HIVAN)	HIV	No

Our post-mortem acceptance rate was found to be modest at 29.4 %. We only performed 10 of the 34 patients who died.

Majority of the patients relatives declined to give consent for post-mortems with reasons for decline being: The relatives did not find it important to do a post-mortem, some relatives transferred the bodies out of the hospital morgue immediately and others declined due to religious and cultural beliefs concerning death.

Below is a figure showing the reasons for postmortem consent decline.
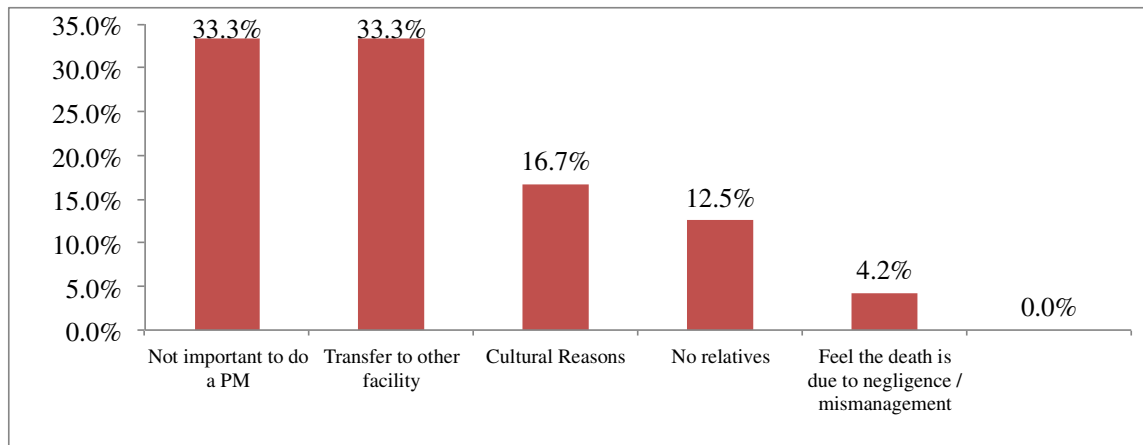
Figure 6: Reasons among deceased patient's relatives for declining to consent to a postmortem

CHAPTER 5: DISCUSSION

5.1 OVERALL AND SEVEN DAY MORTALITY

The overall mortality for the medical wards in KNH was higher than that of other hospitals compared. While the overall mortality rate at KNH medical wards was 29.6%, the overall mortality rate at Jimma University Specialized Hospital in Ethiopia was 12.6% [15] while at Ahmadu Bello University Teaching Hospital; Kaduna, Nigeria was 11.2% [22]. This difference in overall mortality could be explained by the difference in patient characteristics at admission. Majority of the patients at KNH at admission were diagnosed with chronic non-communicable diseases such as malignant neoplasms, congestive heart failure and chronic kidney disease. These diseases are associated with a poor prognosis. On the other hand most of the patients in Ethiopia and Nigeria were diagnosed with community-acquired pneumonia and other infectious related conditions, which were mostly treatable [15, 22]. However, the seven-day inpatient mortality was similar for KNH (17.6%) compared to that of the studies done in Ethiopia, Nigeria and Cameroon [11, 22, 27]. Elias and Mirkuzie [15] in a study done in Jimma Specialized Hospital in Ethiopia reported that 53% of the mortalities occurred within 5 days of admission in the medical wards. This could be attributed to the fact that the hospital specialized in the treatment of tuberculosis and other infectious respiratory illnesses, which acutely are associated with high risk of death if not managed properly. Garko et al [22] in a study done at Ahmadu Bello University Teaching Hospital, Kaduna, Nigeria also reported a mortality rate of 65% within 5 days of admission, which were mainly attributed to infectious diseases at primary diagnosis. In a different study in Cameroon, Einterz and Bates [27] reported a mortality rate of 43.7% within 48 hours of admission. This sharp mortality rate was attributed to late presentation to hospital and low socio-

economic status, which delayed institution of correct treatment since patients were required to buy the medical supplies before care could be given. Being a rural set up, the district hospital possibly was ill equipped to handle some of the cases, which resulted in high mortality.

5.2 CASE MORTALITY RATE

At KNH the most common causes of mortality among the admitted patients were malignant neoplasm, congestive cardiac failure, chronic kidney disease, stroke and pulmonary tuberculosis. Similar findings were reported by studies done in medical wards of two different South African hospitals in an urban setting, which showed a shift in morbidity and mortality from communicable to non-communicable diseases [11, 52]. Another study conducted at the medical wards of GF Jooste Hospital medical wards, South Africa showed that circulatory disorders (22%) and infections (19%) were the major causes of admission[53]. These findings were however, different from those conducted at a hospital in Ethiopia, which showed that infectious diseases (16.4%) were the most common causes of admissions in the medical wards followed by circulatory disorders (12.8%)[15]. This hospital was situated in a rural area of Ethiopia and suggests that infections could still be an important cause of morbidity and mortality especially in the rural areas. Intra-institutional variations in morbidity and mortality patterns were observed in studies conducted in Aminu Kano Teaching Hospital, Kano, and Northern Nigeria over different periods. One of the studies done between 2001 and 2003, showed a mixed spectrum with circulatory disorders accounting for 17% of the mortality and infectious diseases other than HIV accounting for 17.9%[13]. A similar study done in the same wards between 2005 and 2008 showed the leading causes of mortality to be infectious disease (9.2%) and circulatory disorders (6.3%) [54]. This shows that even within the same institution

varying results of disease patterns may be observed at different times of the year and therefore, creating the need for constant disease surveillance within healthcare institutions. Moreover, more studies will need to be done in other urban set ups across the country to determine if similar disease patterns to that observed at KNH medical wards will be demonstrated.

5.3 DETERMINANTS OF MORTALITY

The determinants of mortality for this study were divided into two major categories namely; patient factors and structural factors.

5.3.1 Patient Factors

While chronological age and gender has been identified as the most important risk factor for death in acute illness independent of severity of disease [22]. In this study age and gender were found to have no effect on the risk of dying among admitted patients in the medical wards. The distribution of the gender at admission and among the mortalities in this study was even and the difference in proportions observed showed a slight preponderance towards the female gender though not statistically significant. These results were however, different from those reported by Garko et al [32] in a study in Nigeria that observed elderly males above 70 years to constitute a larger proportion (65%) of the admitted patients. This could be attributed to the fact that this hospital was located in a rural setting, which in Africa is affected by urban migration of the young population. The patients admitted at KNH however, came from a cosmopolitan geographical area.

The patient's health seeking behavior was studied as a factor to determine if it played any role in the overall mortality. Delays in seeking medical attention by patients and late hospital referrals of patients from lower hospitals to tertiary hospitals have been attributed to contribute to increased inpatient mortality [22]. In this study the mean

duration of symptoms in patients before seeking medical attention was seven days while the proportion of patients who self referred versus hospital referred was almost even. This is in contrast to findings reported by Einterz and Bates in a study done in rural Cameroon, which reported the mean duration of symptom days before presenting to hospital to be 68.5 days. These findings were strongly linked to the socio economic status of the patients interviewed and the costs of seeking treatment which resulted in coping strategies employed that had negative implications for the future survival of these patients [25, 28]. Conversely in KNH, it could be argued that due to the relatively higher socio-economic status of the urban patient population, access to medical care was faster improving their survival once admitted in hospital. Furthermore, the findings of this study echo those of a survey done in coastal Kenya [28] which reported that households in the urban areas were more likely to report illness than their rural counterparts (19.5% versus 16.9%) and more likely to visit a health provider (81.5 % versus 75.9% respectively).

Severity of illness at admission has also been reported as an important determinant of mortality among admitted patients [33]. Karnofsky Performance Scale at admission was found to be the strongest determinant of mortality of death among patients admitted in KNH medical wards. Patients who died had a median score of 40 compared to a median score of 60 among those who survived. While no studies could be identified that directly used Karnofsky's Performance Scale as a determinant of inpatient mortality, Convisky et al [34] in a study in the US reported that inpatient mortality increased from 0.9% in the patients' dependent in no ADL (Activity of Daily Living) on admission, to 17.4% in patients dependent on all 6 ADLs. This finding is important as it underscores the importance of assessing the functional status of the patients during admission as predictor of the outcomes [32]. The patient's

performance status should be used to stratify patients within the first 48 hours following admission when the risk of death is highest. Patients with poor scores should be prioritized and receive more focused care in order to improve patient outcomes.

5.3.2 Structural /Administrative Factors

Local hospital factors may singly or collectively contribute directly or indirectly to eventual patient demise. Among the most studied phenomena is access block phenomenon. Access block refers to the situation where patients requiring emergency admission spend more than eight hours in an emergency department (ED) because they are unable to gain access to appropriate hospital inpatient beds[36]. Access block generally leads to overcrowding in the ED and delays in instituting appropriate medical care to acutely ill patients. The patients usually receive basic care while waiting to be moved from the ED to the medical wards. While only 19.8% of the patients who died within seven days of admission reported overcrowding at casualty, the mean duration of their stay at casualty was 12.2 hours, which means all of them, experienced access block phenomenon. While this study could not replicate the results of the study done in Western Australia which reported that there was a positive relationship between level of hospital occupancy and death by day two after the index ED attendance[18], more studies may need to be conducted to fully understand how this phenomenon impacts on the quality of care at KNH since even among the survivors at day seven of admission, access block was observed.

Some studies have observed that patients admitted to hospital over the weekend and at night are at a greater risk of dying compared to those admitted during weekdays or normal working hours [40-43]. The results of this study did not demonstrate this "weekend effect" [45] as the number of mortalities was evenly distributed throughout

the days of the week and time of day. Marco et al [45] in a study in Spain reported that patients admitted on weekends had a 57% greater risk of dying than those admitted on weekdays (OR = 1.57; 95% CI = 1.48-1.67). This was attributed to the number of physicians working on internal medicine wards on weekends and holidays being below the mean number working on weekdays which could result in less intense medical care during the weekend. Another attributed factor was that performance of diagnostic and therapeutic studies, as well as consultations with other specialists, was limited during weekends. In addition, weekend staffs were mainly on call physicians, who had less experience and knowledge about patients than the regular ward physicians, who know their patients best. While the same factors apply in our set up, the failure to demonstrate this phenomenon could be attributed to the small sample of our study and limited period of follow up, since the study done in Spain examined 400,000 consecutive admissions over a period of one year.

A strong association has been demonstrated between the length of stay in hospital and mortality in previous studies [15, 22]. The findings of this study demonstrated a strong association between the length of hospital stay and mortality. Majority of the deaths occurred within the first 48 hours of admission. Garko et al [22] in a study done in Nigeria reported that 55% of all mortalities occurred within 48 hours of admission. The similarity of these findings could be as a result of similar structural factors since both studies were conducted in University Teaching hospitals. However, the higher day 2 mortality rates for the Nigerian study were attributed mainly to late referrals from other hospitals and to infectious diseases as the major reason for mortality compared to KNH where non-communicable diseases were the main reason for admission. However, different results were reported in Spain where day two-inpatient mortality was reported to be 2.5% [49]. This low inpatient mortality was

attributed to the stratification of patients based on their performance status and patients with poor scores were admitted to the intensive care units or high dependency units. These findings are significant since it indicates that the most important time to change patient outcomes that the physician has are within the first 48 hours of care.

5.4 EXTERNAL VALIDITY

Whereas there are several important findings that this study has revealed, these findings should be interpreted against the background of the following limitations. This study was conducted on a sample drawn from a national referral hospital whose patients may not reflect the general patient population in our public hospital and therefore, the results of this study may not apply in other non-tertiary teaching hospitals. Second, intra-hospital variability of disease patterns have been reported in literature and therefore a snap shot of the morbidity and mortality patterns observed during the limited study period may not always be the case. A longer and better-powered study in terms of sample size may need to be performed to conclusively study all the variables that impact on mortality. Thirdly, missing files and missing data from some of the patient files limited the amount of information that could be extracted and used in the overall analyses.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.0 CONCLUSION

The overall mortality rate for patients in the medical wards is 29.6% with a seven-day mortality rate of 17.6%. Most of these deaths were preventable deaths if early measures were put in place. Malignant neoplasm was the commonest cause of death followed by congestive cardiac failure and chronic kidney disease. HIV infection was the commonest co-morbidity associated with primary diagnosis. Majority of the admitted patients died within the first 48 hours of admission. The important predictors of early mortality in this study were Karnosfsky's Performance Scale and length of stay in the ward. An association between early mortality and access block phenomenon, "weekend effect", poor health seeking behavior and late patient referrals and were not demonstrated. However, continued disease surveillance and well powered studies may need to be done to conclusively exclude these factors as impacting early mortality at KNH.

6.1 RECOMMENDATIONS

In view of the foregoing, the following recommendations are made: First- to the government- there is an urgent need to allocate resources to tackle non-communicable diseases and specifically malignant neoplasms and kidney disease which are the commonest cause of mortality in the medical wards at KNH.

Secondly-to KNH management- there is need to institute long term disease surveillance activities and regular mortality audits to characterize the disease patterns and any intra-institutional variations that may exist and to continually evaluate the quality of care that the patients are receiving. Long-term studies are recommended to enable the detailed study of the effect of access block and "weekend effect" phenomenon on patient mortality at KNH.

Thirdly-to medical ward management-there is need to assess the patient's performance status at admission in order to enable proper stratification of care either to the general wards, acute room, high dependency unit or intensive care unit in order to optimize patient management within the first 48 hours. Protocols that define close follow up of patients within the first 48 hours of admission should be written in order to standardize the care of patients in the acute phase following their admission to the ward. There should be proper standardization of disease diagnosis using internationally accredited systems like the ICD-10 to facilitate classification of disease and utilization of data retrospectively for future studies in the department. Finally, follow up studies should be done to ascertain why mortality from HIV and TB is still high. An operational research should also be done to assess the treatment modalities and adherence to protocols viz a viz the causes of mortality in order to optimize patient management within the department.

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APPENDICES

Appendix I

RETROSPECTIVE ARM CRF
MEDICAL WARD MORTALITY STUDY CASE REPORT FORM

Patient Study ID Number ☐☐☐   **Patient initials** ☐☐☐   **Age (Yrs.)** ☐☐

Date of Admission (dd, mm, yyyy) …../…./……   **Sex M** ☐   **F** ☐

Day of week (Circle one) Mon / Tue / Wed/ Thur / Fri/ Sat/ Sun

		Time (HH:MM)
Time patient seen at	**Casualty**	
	Medical Ward	
	Total hours before admission	

Referral Pattern. Self ☐   **Hospital** ☐

Duration of symptoms before admission in days ☐☐

Primary Diagnosis at Admission...ICD code ☐☐☐

Co-morbidities at Admission (1) ....ICD code ☐☐☐

(2) ....ICD code ☐☐☐

(3) ....ICD code ☐☐☐

Date of Death (ddmmyyyy)   ___ /___ /___ ___   Time of Death (HH:MM) ___ : ___

Length of Stay in ward in days ☐☐

PM Diagnosis .... ICD Code ☐☐☐

Appendix II

MEDICAL WARD MORTALITY STUDY CASE REPORT FORM

Patient Study ID Number ☐☐☐ **Patient initials** ☐☐☐ **Age (Yrs.)** ☐☐

Date of Admission (dd/mm/yyyy) —/— —/— —— **Sex M** ☐ **F** ☐

Day of week (Circle one) Mon / Tue / Wed/ Thur / Fri/ Sat/ Sun

		Time (HH:MM)
	Casualty	
Time patient seen at	**Medical Ward**	
	Total hours before admission	

Casualty Overcrowding (>8 hrs.)   Yes ☐   ☐

Referral Pattern. Self ☐   **Hospital** ☐

Duration of symptoms before admission in days ☐☐

Primary Diagnosis at Admission...ICD code ☐☐☐

Co-morbidities at Admission   (1) ....ICD code ☐☐☐

(2) ....**ICD code** ☐☐☐

(3) ....**ICD code** ☐☐☐

Karnofsky Score at admission

Ward Occupancy at admission (%) ☐☐

Date of Death (ddmmyyyy) ___ /___ /___ ___ **Time of Death (HH:MM)** ___ ___

Length of Stay in ward in days ☐☐

Consent obtained for PM   Yes ☐ **No** ☐

Reason for Decline......................................

PM Diagnosis .... ICD Code ☐☐☐

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Appendix III

INFORMED CONSENT EXPLANATION FOR ADULTS

Title of the study:
A Seven-Day Mortality profile of Medical Inpatients at Kenyatta National Referral Hospital.

Principal Investigator: Dr.Macharia Matu

Introduction:
We are interested in finding out the outcomes of patients admitted to the medical wards in Kenyatta National Hospital. This study seeks to find out how patients are managed and the outcomes of their management. The study shall help to improving service delivery and quality of care in the Medical Wards of the Hospital.

Procedure to be followed:
Upon accepting to participate in this study you will be requested to sign a consent form after which you will answer questions relating to your socio-demographics, present and past illnesses and current treatments.
We shall follow you up in the wards for a period of seven days.
Participation of this study is voluntary and you can choose to decline or withdraw from the study without any penalty.
Risk:
There are no risks associated with participation in this study.
Benefits:
The study will help in the development of policy and treatment guidelines that will improve the quality of care for future generations.
Confidentiality:
Strict confidentiality will be maintained and all data obtained will be securely stored and used for purposes of this study only.
Who can participate in this study?
A person above 15 years and is admitted to the medical wards or to the Emergency ward, ICU or Renal Unit with a medical condition at initial diagnosis.
Participation: Your participation in this study is voluntary. Refusal to participate will not be penalized. You may discontinue participation at any time without any penalty.
Subject:
If during the course of this you have any questions concerning the nature of the research you should contact:

Dr. Macharia Matu, P.O. Box 2064-00202 Nairobi, Kenya. Mobile +254722674916

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke
Link: www.uonbi.ac.ke/activities/KNHUoN
KNH-Tel No: 726300-9
UON-Tel No: (254-020) 2726300 Ext 44355

PARTICIPANT'S STATEMENT:

I………………………………………………………………………………………
do hereby give consent/permission to Dr. Macharia Matu to include me in this study
entitled 'A Seven-Day Mortality Profile of Medical Inpatients at Kenyatta National
Referral Hospital'. I have read and understood the contents of this form, and have been
accorded the opportunity to ask questions. I am also aware I can withdraw from this study
without any penalties.

VOLUNTEER

NAME……………………………………………….SIGNED………………………

WITNESS……………………………………………………………………………

DATE…………………………………………………………………………………

Appendix IV

INFORMED CONSENT EXPLANATION FOR MINORS

Title of the study:
A Seven-Day Mortality profile of Medical Inpatients at Kenyatta National Referral
Hospital.

Principal Investigator: Dr.Macharia Matu

Introduction:
We are interested in finding out the outcomes of patients admitted to the medical wards in
Kenyatta National Hospital. This study seeks to find out how patients are managed and
the outcomes of their management. The study shall help to improve service delivery and
quality of care in the Medical Wards of the Hospital.

Procedure to be followed:
Upon accepting to participate in this study your parents or guardians will be requested to
sign a consent form. Once in the study you will be required to answer questions relating
to your socio-demographics, present and past illnesses and current treatments.
We shall follow you up in the wards for a period of seven days.

Risk:
There are no risks associated with participation in this study.

Benefits:
The study will help in the development of policy and treatment guidelines that will
improve the quality of care for future generations.

Confidentiality:
Strict confidentiality will be maintained and all data obtained will be securely stored and
used for purposes of this study only.

Who can participate in this study?
Any person aged 15 years and above admitted to the medical wards or to the Emergency
ward, ICU or Renal Unit with a medical condition at initial diagnosis.

Participation: Your participation in this study is voluntary. Refusal to participate will
not be penalized. You may discontinue participation at any time without any penalty.

Participant (Minor)
I have read this information and had it explained to me .I have had my questions
answered and I know that I can ask questions later if I have them.
I agree to take part in the research.

Name of Minor   --

Signature/Mark of Minor   ---

Date   ---=-

I have accurately read out the information sheet to the potential participant who is a minor and to the best of my ability made sure the minor understood. I answered all the questions asked by the minor. I confirm the minor has given assent freely and understands that the parents/guardians still have to sign a consent form. I confirm that the individual has not been coerced into giving consent.

Name of researcher   ---
Signature of researcher   ---
Date   ---

Parent/Guardian has signed an informed consent
Yes   -----------------------
No   -----------------------

Subject:
If during the course of this you have any questions concerning the nature of the research you should contact:

Dr. Macharia Matu, P.O. Box 2064-00202 Nairobi, Kenya. Mobile +254722674916
KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke
Link: www.uonbi.ac.ke/activities/KNHUoN
KNH-Tel No: 726300-9
UON-Tel No: (254-020) 2726300 Ext 44355

PARTICIPANT'S STATEMENT *(to be signed by parent/guardian):*
I……………………………………………………………………………………
do hereby give consent/permission to Dr. Macharia Matu to include the above minor in this study entitled 'A Seven-Day Mortality Profile of Medical Inpatients at Kenyatta National Referral Hospital'. I have read and understood the contents of this form, and have been accorded the opportunity to ask questions. I am also aware that the minor can withdraw from this study without any penalties.

VOLUNTEER

NAME…………………………………………………..SIGNED………………………

WITNESS…………………………………………………………………………………

DATE………………………………………………………………………………………

Appendix V

Post Mortem Consent Form

KENYATTA NATIONAL
HOSPITAL
P.O.BOX 20723
NAIROBI

Date……………………20…

POST-MORTEM EXAMINATION

I here give permission for a post-mortem examination to be performed on

…….………………………………………………………………………

Signed………………………
(Relationship)

Witness……………………………………………………………………………….

Date………………20…

GPK 378-60m-2/84

Appendix VI

Karnofsky performance status

- 100% – normal, no complaints, no signs of disease

- 90% – capable of normal activity, few symptoms or signs of disease

- 80% – normal activity with some difficulty, some symptoms or signs

- 70% – caring for self, not capable of normal activity or work

- 60% – requiring some help, can take care of most personal requirements

- 50% – requires help often, requires frequent medical care

- 40% – disabled, requires special care and help

- 30% – severely disabled, hospital admission indicated but no risk of death

- 20% – very ill, urgently requiring admission, requires supportive measures or treatment

- 10% – moribund, rapidly progressive fatal disease processes

- 0% – death.

Appendix VII
KNH/UON-ERC LETTER OF APPROVAL
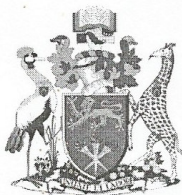
UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/92   Link:www.uonbi.ac.ke/activities/KNHUoN   8th April   2014

Dr. Macharia Matu
Dept.of Clinical Medicine & Therapeutics
School of Medicine
University of Nairobi

Dear Dr. Matu

Research proposal: A SEVEN-DAY MORTALITY PROFILE OF MEDICAL INPATIENTS
AT KENYATTA NATIONAL HOSPITAL   (P559/11/2013)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed
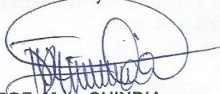and **approved** your above proposal. The approval periods are 8th April 2014 to 7th April 2015.

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

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

c.c.   The Chairperson, KNH/UoN-ERC
        The Deputy Director CS, KNH
        The Principal, College of Health Sciences, UoN
        The Dean, School of Medicine, UoN
        The Chairman, Dept. of Clinical Medicine & Therapeutics,UoN
        The Assistant Director, Health Information, KNH
        Supervisors: Prof. Amayo Erastus Olonde, Dr. Maritim Marybeth Cherono, Dr. Rogena Emily Adhiambo,
                Dr. Sigilai William Kiprono

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