

**DETERMINANTS OF ADHERENCE TO ANTICONVULSANT THERAPY AMONG  
OUTPATIENT EPILEPTIC CHILDREN AGED TWO TO TWELVE YEARS AT  
KENYATTA NATIONAL HOSPITAL**

**BY**

**DEOGRATIAS M KATABALO, Bpharm.**

**(U59/80217/2012)**

Department of Pharmaceutics and Pharmacy Practice,  
School of Pharmacy  
University of Nairobi

**A dissertation submitted in partial fulfilment of the requirements for the award of the degree of master of pharmacy in clinical pharmacy, university of Nairobi.**

**NOVEMBER, 2014**

## **DECLARATION**

I hereby declare that this dissertation is my original work and has not been presented to any other institution for evaluation for research and/or examination.

DEOGRATIAS MWOMBEEKI KATABALO, B. Pharm

U59/80217/2012

Signature\_\_\_\_\_ Date\_\_\_\_\_

### **Supervisors' Approval**

This dissertation has been submitted for evaluation for research and examination with our approval as university supervisors

1. DR. DAVID NYAMU, M. Pharm (Clin.Pharm)

Department of Pharmaceutics and Pharmacy Practice, University of Nairobi

Signature\_\_\_\_\_ Date\_\_\_\_\_

2. DR. AMUGUNE K. BEATRICE, PhD

Department of Pharmaceutical Chemistry, University of Nairobi

Signature\_\_\_\_\_ Date\_\_\_\_\_

3. PROF. MURIUKI GICHURU, PhD, OGW, EBS

Department of Pharmacology and pharmacognosy, University of Nairobi

Signature\_\_\_\_\_ Date\_\_\_\_\_

## **DECLARATION OF ORIGINALITY**

Name: Deogratias Mwombeki Katabalo

Registration Number: U59/80217/2012

Department of pharmaceuticals and pharmacy practice.

Master of pharmacy in clinical pharmacy

Topic: Determinants of adherence to anticonvulsant therapy among outpatient epileptic children aged two to twelve years attending neurology clinic at KNH.

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## **DEDICATION**

I dedicate this work to the glory of almighty God who has entrusted me with his love, strength and wisdom so that I can serve others for his glory.

I also dedicate this dissertation to my family for the inspiration and support you are giving me every time I think of you.

I also dedicate the work to all children who needs our love, support and care.

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## **ABBREVIATIONS**

AEDs: Anti-Epileptic Drugs

AIDS: Acquired Immunodeficiency Syndromes

ERC: Ethical Research Committee

GI: Gastrointestinal

HIV: Human Immunodeficiency Virus

ILAE: International League Against Epilepsy

IQ: Intelligence Quotient

KNH: Kenyatta National Hospital

MD: Medical doctor.

MMAS: Morisky Medication Adherence Scale

OR: Odds ratio

TB: Tuberculosis

WHO: World Health Organization

PWE: People With Epilepsy

QOL: Quality Of Life

UON: University of Nairobi

USA: United States of America.

## DEFINITION OF TERMS

**Adherence:** The extent to which the patient's history of therapeutic drug taking coincides with the prescribed treatment.

**Anticonvulsants:** (also commonly known as *antiepileptic* drugs) are a diverse group of pharmaceuticals used in the treatment of epileptic seizures.

**Determinant:** Is a factor which decisively affects the nature or outcome of something

**Epilepsy:** is a brain disorder in which a person has repeated seizures (convulsions) over time.

**Non adherence:** Is the number of doses not taken or taken incorrectly that jeopardizes the patient's therapeutic outcome.

**Prescriber:** A medical personnel who designate or order the use of a medicine, remedy or treatment.

**Seizures:** are episodes of disturbed brain activity that cause changes in attention or behaviour

## ABSTRACT

**Background:** Epilepsy is a chronic disease requiring prolonged treatment with anticonvulsants to control seizures. Adherence to anticonvulsants by epileptic children is crucial but studies from developed countries have shown that adherence of patients to anticonvulsants is averaging at 50 %. Parents/guardians and prescribers of anticonvulsants have a big role in the enhancement of adherence to anticonvulsants among children.

**Study objective:** To evaluate the determinants of adherence to anticonvulsants in outpatient epileptic children aged two to twelve years at neurology clinic in Kenyatta National Hospital.

**Methods:** This study involved 176 epileptic children aged two to twelve years attending neurology clinic, their parents/guardians and 10 attending prescribers. A cross-sectional study design was used. Systematic random and convenience sampling was used to enrol parents/guardians and prescribers respectively. Predesigned questionnaires were used to identify determinants among the participants whereas Morisky tool was used for assessing medication adherence.

**Results:** Among the study patients, there was male predominance at 62.5 %. Rates of adherence to anticonvulsant by epileptic children were found to be 36.9 % for high adherence, 39.8 % medium adherence and 23.3 % low adherence. Adherence was shown to be statistically significantly associated with parents/guardian marital status ( $p= 0.01$ , OR= 5.72, CI= 1.5, 21.78), education level ( $p= 0.001$ , OR= 5.16, CI= 1.88, 14.02). Lack of time by prescribers due to patient load, assumptions that the patient will adhere and lack of knowledge on the importance of adherence were the major prescriber's related factors impacting on adherence. Unavailability and inaccessibility of anticonvulsants impacted on adherence because majority of patients could not obtain their medications from Kenyatta National Hospital pharmacy facility at affordable cost.

**Conclusion:** Adherence to anticonvulsants therapy among children was poor due to parents/guardians and prescriber related factors. We recommend these factors to be minimized. Identifying appropriate means so that adherence may be improved.

# CHAPTER ONE

## INTRODUCTION

### 1.1: Descriptions of epilepsy

Epilepsy is a brain disorder characterized predominantly by recurrent and unpredictable seizures and the individual experiences increased neuronal discharges from the cortical cells of the brain<sup>1, 2</sup>. It is chronic neurological disease which is not contagious and an individual is diagnosed to have epilepsy if he/she experiences two or more unprovoked seizure in a year<sup>3</sup>. The disease presents in two general forms; partial epilepsy and generalised epilepsy<sup>2</sup>. Although the disease onset can be at any age, majority of patients start suffering from childhood thus making the paediatrics the largest group of patients<sup>4</sup>.

### 1.2: The Global Burden of Epilepsy

It is estimated that over 50 million people have epilepsy worldwide with 80 % of them found in developing countries<sup>5</sup>. The incidence is three times higher in the childhood than in mid adulthood age groups and it is further estimated that of the new epileptic cases in a year, 40 % of them are children below 15 years of age<sup>3</sup>. In Africa the mean prevalence is 15 per 1000 with 90 % of patients receiving inappropriate treatment or no treatment at all<sup>3, 6</sup>.

### 1.3: Kenyan Burden of Epilepsy

In Kenya, epilepsy is ranked 37<sup>th</sup> as a cause of death and contributes 0.42 % of all deaths from diseases. Nevertheless, the socioeconomic impact of epilepsy is far beyond other chronic diseases. It contributes significantly to increased total production and school days wasted, reduced quality of life and cost of failed therapy and side effects. In addition social cohesion is impaired due to differences in belief of its source<sup>7, 8</sup>.

### 1.4: Treatment of Epilepsy

Anticonvulsants have been the mainstay of the drugs used in the management of epilepsy for many years. Anticonvulsants are pharmacologically grouped into various classes which are sodium voltage-gated channel modulators, calcium voltage-gated channel modulators, potassium gated ion channel stabilizers, inhibitory transmitters (GABA) agonists and glutamate excitation inhibitors<sup>9</sup>.

Anticonvulsants have wide range of side effects, interactions, individual response differences and resistance which in part contribute to non-adherence<sup>10</sup>.

Among the anticonvulsants drug which are highly prescribed to epileptic children are phenobarbitone and phenytoin at the rate of 65 % and 85 %, respectively. This is attributed to their low cost compared to other anticonvulsants. Other drugs prescribed and their rate includes carbamazepine (5-20 %), sodium valproate (5 %), while the rest are prescribed to less than 5 % of patients<sup>11</sup>. Studies have also shown that significant number of patients do not take conventional drugs and seek treatment with traditional herbs and alternative therapy due to misconception of the cause of disease or affordability of conventional treatment<sup>12</sup>. However most epileptics get inappropriate treatment which causes preventable death and high treatment cost<sup>5, 13</sup>.



## **CHAPTER TWO**

### **LITERATURE REVIEW**

#### **2.1. Adherence to Anticonvulsants**

The desired outcome in the treatment of epilepsy is the achievement of freedom of seizure while suffering little or no tolerable side effects<sup>14</sup>. With anticonvulsants being the only pharmacological therapy for epilepsy non adherence to treatment poses great challenge to both parents and prescribers<sup>15</sup>. Prescribers must decide and choose a regimen which best suits an individual patient at the same time ensuring that the patient follows the treatment recommendations. A patient on the other hand must agree with the prescriber and follow the recommended treatment protocol<sup>16</sup>.

When strictly adhered to, anticonvulsants have shown to be effective in the control of seizure both in short term and in long term use. In fact seizures remain controlled for long time after anticonvulsants have been discontinued<sup>11</sup>. The rates of adherence to anticonvulsants by epileptic children differ slightly from countries to countries. The differences are explained by difference in duration of treatment, health systems, development of the country and patient related factors<sup>17</sup>.

In a study carried out in USA, data obtained from 124 epileptic children aged two to twelve years showed persistent non adherence of 58 % during the first 6 month of therapy. The study identified 5 different adherence patterns and classified as either severe early non adherence (13 %), severe delayed non adherence (7 %), medium non adherence (13 %), mild non adherence (26 %) or near-perfect adherence (42 %). The adherence pattern of most patients was established by the first month of therapy. According to this study, socioeconomic status was the sole predictor of adherence and it was concluded that the pattern of non adherence was significantly associated with socioeconomic status<sup>18</sup>.

In another study done in USA, the rate of adherence among children with chronic diseases was found to average at 50 % and tended to decrease with time. The study went further to report that, adherence in children is indeed more difficult than in adults due to lack of cooperation from children and involvement of a third party, the care giver, instead of two (prescribers and patient), as is the case in adults<sup>19</sup>.

In a study done in Iran on drug adherence amongst children and adolescents with epilepsy it was shown that out of 181 study participants, adherence was a problem in 27.7 %. According to patient care giver report, the reason for non adherence was given as side effects (drowsiness and GI upset) in 7.5 % and in the rest the reason was cognitive or simply judgemental about the benefit of treatment and disease denial. In this study adherence rate was good in nearly three quarter of research subject as compared to other studies and the authors concluded that it was probably because of inclusion of a children group whose parents played an active role in the treatment programme<sup>20</sup>.

Mativo et al, in their study done at KNH on the factors associated with poor control of epilepsy at adult neurology clinic, pointed out that 40% of the patient had poor control of seizures. Non-adherence accounted for 40% of all causes of poor seizure control. This study used direct method of measuring adherence by assessing serum drug levels of antiepileptic drugs in blood randomly sampled from participants. The studies revealed that 61% of all random serum drug levels were sub-therapeutic. The study went further to give the reasons of non adherence to be financial difficulties 30%, Just forgetting 23%, Unavailability of drugs 14%, inaccessibility to health care services 10%, side effects of the drugs 0.4% and others 14%. The study also revealed that some patients with poorly controlled seizure used herbs 73% and prayers 27%<sup>21</sup>.

Adherence to medication is usually good initially and decreases over time. However, a study done in USA by Avan *et al* on one month adherence in children with new onset epilepsy showed the rate of adherence of 79.4 %. This is still a poor rate of adherence considering it is presented during the first one month and treatment outcome is very much affected if the adherence rate is below 85 %. For disease condition where there is concern of drug resistance such as in HIV/AIDs and epilepsy adherence should be at most 95 % and above<sup>22</sup>.

## **2.2: Causes of Non-adherence**

Non adherence to anticonvulsants as stipulated by many studies cites two major reasons; behavioural such as simply forgetting and cognitive such as having concerns about side effects<sup>23</sup>.

In another study done in USA, it was shown that 30 % of research subjects had non adherence attributed to forgetfulness, 9 % due to lack of information about the diseases and treatment, 34 % due to cognitive factors and 275 (42 %) did not provide reason for non adherence<sup>18</sup>. In another study done in different part of USA on medication adherence and persistent lack of supporting and trusting relationship between patient and care giver, inability to obtain or pay for medication and language barrier when the patient's first language is different from that of the health provider were reasons for non adherence<sup>11</sup>. Factors influencing adherence as suggested by many other studies are grouped in five categories; social economic, health care team/ health system, disease related factors, treatment and patient related factors<sup>23, 24, 25</sup>.

In a study done in Zambia on epilepsy associated stigma in sub-Saharan Africa it was revealed that stigma is one of the causes of epilepsy treatment gap with many patients being denied participation in social activities and tending to hide information of their condition to people making them lack access to beneficial hospital treatment. In this case adherence to treatment was influenced by the patient and society belief on the conditions. This study showed that many of the people with epilepsy (PWE) seek treatment from traditional healers before they are seen at the hospital clinic<sup>26,38</sup>.

In another study in Zambia comparison of epileptics and normal people on factors such as employment and education, showed that the epileptics were facing great challenges on employment and accessing education<sup>27</sup>. The productive time of parents/guardian were wasted due to frequent hospital visits and provision of care during seasons of frequent attacks which put their employment at risk and also loss of school days by epileptic children and at the same time these children suffered low intelligent quotients (IQ) from some of drugs taken<sup>28</sup>.

A study in Kilifi, Kenya, on the risk factors associated with the epilepsy treatment gap showed that out of 502 people with epilepsy reported taking antiepileptic drugs (AEDs), only 189 (38 %) had the AEDs detected in their blood samples suggesting that adherence to

medication was poor. In this study many patients were not on treatment. Unavailability of drugs was reported as one of the causes of epilepsy treatment gap and inability to attend health facility due to distance; cultural beliefs of the cause of the disease and use of traditional herbs instead of prescribed conventional drugs were other causes which influenced adherence<sup>4</sup>.

A study done in KNH on the quality of life among patients with epilepsy attending the neurology clinic at KNH showed that the mean quality of life among people living with epilepsy was 49.9% while that of their accompanying normal control was 77.6%. This showed that epileptic patients have low esteem which may hinder them to seek for proper treatment or seek for non-conventional treatment for the fear of other people. The study discovered this inability of access to proper health care and recommended improvement of patient's empowerment in management from the time of diagnosis to management and addressing their social needs. The study also recommended improving accessibility, affordability and availability of AEDs to reduce the treatment gap and hence improving the QOL of PWE<sup>29</sup>.

Some studies have shown that adherence also is influenced by lack of enough and clear information on the treatment from physician to primary care giver of a child and use of complex therapeutic regimens<sup>30</sup>.

### **2.3: Methods of Measuring and Improving Adherence**

Various methods of measuring adherence have been developed, but none of them is entirely satisfactory<sup>22</sup>. In a study done in USA on review of the measurement of the adherence to epilepsy treatment the researchers showed that adherence can be measured through two major ways namely; direct and indirect measurements. Direct measurements involve detection of drug, its metabolite or marker in body fluids, hair or observing a patient taking medication. Indirect measurements of adherence involve review of patient's response, pill count, appointment attendance and treatment response. The study noted that each direct or indirect method has advantages and disadvantages in terms of accuracy, practicality and sustainability<sup>31</sup>.

Strategies of improving adherence to anticonvulsants by epileptic children have been studied. The main strategies involve dealing with the causes of non adherence. This includes education to patients and primary care givers on the importance of adherence, drug regimen simplification, refill follow up reminders and comprehensive management, in which case all strategies are used together<sup>21, 32, 33, 34</sup>.

#### **2.4: Impact of Anticonvulsant Adherence to Clinical Response**

Many studies have shown that more children (70 %) than adults (60 %) can be completely liberated from epileptic seizure attack for many years after they completely adhere to treatment protocol for a period of 2-5 years<sup>15, 16</sup>. However complete adherence may be difficult to achieve as adherence is influenced by many factors including socioeconomic, patient disease, physician-patient relationship and in children, care giver related factors<sup>11</sup>.

In epileptic patients non-adherence behaviour has been associated with increased morbidity and mortality along with increased time of hospitalization and the overall cost of treatment. The worst consequences of non adherence to anticonvulsants are increased frequencies of status epilepticus and sudden unexplained death from epilepsy<sup>35</sup>. Adherence has been regarded as a good determinant for intended clinical response<sup>12</sup>. Patients are expected to change their pre-treatment behaviour in favour of adherence<sup>36</sup>. This depends on motivation on treatment, value of illness, age and desire to come out of the condition<sup>37</sup>.

Lack of seizure control and treatment failure is attributed in part by non-adherence to anticonvulsant therapy. A study done in children attending KNH neurological clinic to assess seizure control in children revealed that anticonvulsant therapy had failure rate of treatment at 14.7 %<sup>10</sup>. This study followed the care of a group of epileptic children receiving treatment at the neurological clinic and assessed the treatment response as an outcome variable.

The financial implication of non adherence in developing countries is lacking but in countries like United States, it is estimated that over 12.5 US billion dollars is lost annually as direct costs of non adherence according to Epilepsy foundation of America<sup>17</sup>. However indirect cost due non adherence to anticonvulsants in children is huge, in children it involves loss of school days, waste of parents working days and increased frequencies of attending hospital clinics<sup>7, 8</sup>.

## **2.5: The Need for Emphasis on Adherence to Anticonvulsants**

Studies have revealed that more emphasis on adherence to treatment protocols is put on treatment of other chronic diseases like HIV/AIDS, diabetes, hypertension, cancer, asthma than in epilepsy<sup>38, 39</sup>.

This has made the rate of treatment failure among epileptic patients to be significantly higher than in other chronic diseases<sup>40</sup>. In addition to lack of emphasis on adherence, epileptic patients are kind of a neglected group of patients in terms of comprehension of therapy. For example, a study done at KNH on knowledge, attitude and practice of parents/ guardians of epileptic children showed that knowledge gap in parents/guardians concerning epilepsy treatment was the single independent factor causing non adherence and treatment failure<sup>49</sup>. Prescribers and other care givers play a big role in the enhancement of adherence to anticonvulsants as they are the source of reliable information to patients and their primary care givers<sup>41</sup>. A study done in United Kingdom showed that epilepsy is surrounded by misconception of its cause and this lead to a significant number of patient not taking conventional treatment and preferring other less beneficial type of therapies<sup>42</sup>. Studies in other developed countries have also shown that clear comprehensive information from prescriber or dispenser to patient improves treatment satisfaction, adherence to treatment and treatment outcome<sup>18, 29</sup>. Therefore it is important that prescribers treating epileptic children understand the role of adherence to treatment protocols and how to emphasise on it.

## **2.6. Morisky tool for assessing medication adherence**

Many studies on adherence to medication have used morisky tool to assess adherence<sup>43</sup>. This tool is specially designed and validated questionnaire which can be modified to capture information from the study participants on the rate of adherence<sup>43, 44</sup>. The tool were first used in 1980's and continued to be used in the same version until 2008 when it was revised<sup>45</sup>. The scale of adherence is measured depending on the scores resulting after calculation, in which scores greater than 2 is regarded as low adherence, 1-2 is medium adherence and 0 is high adherence<sup>46</sup>.

## **2.7: Problem Statement**

“Drugs don't work in patients who don't take them appropriately!” is a famous remark by Dr C. Everett Koop, MD which has gained attention dragging many researchers into various

studies on how to improve adherence to treatment in chronic diseases such as epilepsy<sup>47</sup>. Moreover, good seizure control is as a result of adherence to anticonvulsants because non adherence increases the risk of seizure attacks and sudden epileptic death syndrome<sup>48</sup>. In addition, studies have shown that patients get resistant to some anticonvulsants when they are used inappropriately for some time<sup>49</sup>. For instance, if epileptic patients adhere to anticonvulsant treatment for 2 to 5 years, it has been demonstrated that 60%-70 % of them can live for many years without recurrence of seizures after stopping anticonvulsants<sup>8, 15</sup>.

Nevertheless, anticonvulsants use in children is indeed a challenge as primary care givers are responsible for comprehension of therapy<sup>50</sup>. Furthermore, studies have revealed that a significant number of parents had insufficient knowledge on the management of epilepsy thereby compromising adherence to treatment<sup>51</sup>. Other studies have pointed out that one of the causes of high rate of treatment failure was attributed to non adherence<sup>52,53</sup>. Whereas, determinants of adherence to anticonvulsants should have been considered so as to give better outcome and minimise treatment cost<sup>3,12</sup>, many studies on adherence have focussed on adherence to management of HIV/AIDS and TB because of the concern of resistance to drugs<sup>54,55</sup>.

## **2.8: Justification of the Study**

Better response and outcome from use of anticonvulsants depend on good adherence to prescribed drug. However, a number of factors have been associated with non adherence to anticonvulsants<sup>27, 48</sup>. For example, studies done in the developed countries have revealed that paediatric patients face challenges in adhering to drugs, because of issues of side effects, unavailability of drugs, irresponsibility of care givers and non availability of appropriate dosage forms of some anticonvulsants<sup>15,56</sup>. These factors may also be rampant in the developing countries.

Therefore, in order to address the issue of adherence in low resource setting, the rate and determinants of adherence should be established. Understanding these factors can enable a prescriber to promote adherence when working with susceptible patients and can also encourage the development of interventions to improve adherence. Moreover, understanding of the factors may facilitate the formulation of policy to enhance adherence to anticonvulsant therapy and also enhance evidence based epilepsy management.

## **2.9: Research Questions**

- i. What is the rate of adherence to anticonvulsants among epileptic paediatric patients aged two to twelve years attending KNH neurology clinic?
- ii. What are the factors associated with non-adherence to anticonvulsants by epileptic children attending KNH neurology clinic?

## **2.10: Objectives**

### **2.10.1: Broad objective**

To evaluate the determinants of adherence to anticonvulsants in outpatient epileptic children aged two to twelve years at neurology clinic in KNH.

### **2.10.2: Specific objectives**

1. To determine the rate of adherence to anticonvulsants medication in epileptic children aged two to twelve years attending neurological clinic in KNH.
2. To determine the patient/caregiver related factors associated with non-adherence to anticonvulsants among epileptic children aged two to twelve years attending neurological clinic at KNH.
3. To determine the prescriber related factors associated with non-adherence to anticonvulsants among outpatient epileptic children attending KNH neurology clinic.



## **CHAPTER THREE**

### **METHODOLOGY**

#### **3.1: Study Design**

A cross sectional design was employed. This involved primary data collection through interviews of the consenting participants after approval from the KNH/UON ERC. Secondary data were retrospectively collected from patient files and Pharmacy 20 records. These were used to confirm diagnosis, treatment progress and information on availability of drugs. From pharmacy records information on availability of drugs and their formulations were sought.

#### **3.2: Study Area and Site Description**

The study site was the neurology clinic at KNH which operates every Tuesday afternoon. KNH is the largest referral hospital in Kenya that serves all epileptic cases including those referred from other hospitals. All outpatients' epileptic patients are seen at the neurology clinic and this was the most feasible study site to access the targeted study population of children. Pharmacy 20 located near the neurology clinic serves all epileptic patients attending the clinic and it was where the prescription and refill information could be found and thus it was a suitable site for retrieving anticonvulsants dispensing and use information.

#### **3.3: Study Population**

Outpatient epileptic children attending the neurology clinic at KNH, their parents/guardians and the attending prescribers constituted the study population. The group of children aged two to twelve years was chosen for the study because; at two years is when the actual diagnosis of epilepsy is mostly certain. Children over 12 years are treated with anticonvulsants at adult dose level and are starting to be independent of caregivers influence in taking their drugs<sup>57</sup>.

##### **3.3.1: Inclusion criteria**

The study included parents of outpatient epileptic children aged 2- 12 years who attended neurology clinic at KNH, who consented and/or assented to participate in a study and prescribers who were treating epileptic children at the neurology clinic who consented to participate in the study.

### 3.3.2: Exclusion criteria

The study excluded parents/guardians of outpatient epileptic patient aged less than 2 or over 12 years, Prescribers who were not involved in treating epileptic children at the outpatient neurology clinic and participants who did not consent and/or assent to participate to study.

### 3.4: Sample Size Determination

The estimated prevalence rate of non-adherence to anticonvulsants among epileptic children in KNH was 14.7 % according to a study carried out in 2011<sup>10</sup>. In this study, non adherence was considered a single independent cause of uncontrolled seizure. Therefore, the prevalence of 14.7 % was used in the estimation of the sample size using Fischer's formula<sup>58</sup>:

$$n = Z^2 \times P(1-P)/d^2$$

Where n= sample size

P = estimated prevalence rate of adherence to anticonvulsant treatment

Z= 1.96 which is Z-value corresponding to a significance level of 0.05

d= 0.05 which is the desired degree of accuracy for the study

$$n = \frac{1.96^2 \times 0.147(1-0.147)}{0.05^2}$$

$$0.05^2$$

**=192 Participants (children/Parents/guardians)**

However, we collected data from 176 patients and their caregivers. There were no significant statistical differences in the results obtained from 176 and 192, a calculated sample size. Sixteen patients were not included to avoid repetition of the same patients as it was the start of first round at the end of data collection.

For the prescribers: At the neurology clinic there were 12 prescribers during study duration, 10 of them consented and were interviewed.

### 3.5: Sampling Method and Recruitment of Participants

The participant was first recruited using eligibility assessment form (Appendix 2). The patients were selected through systematic random sampling method. Parent/guardian of every

2<sup>nd</sup> patient leaving the consultation room at neurology clinic, who met the inclusion criteria and sign an informed consent, was enrolled into the study. If the parent/guardian declines to sign the informed consent the next patient who met the criteria was selected and recruited for the study.

Prescribers were recruited through convenience sampling method. This means it included any consenting prescriber who was at the clinic during data collection time. The study involved all prescribers working at the clinic.

### **3.5.1: Consenting and recruitment processes**

The eligibility assessment form (appendix 2) will be given to research assistants who performed the recruitment process. The patients who met the inclusion criteria were recruited by research assistants after consultation; then they were referred to the principle investigator for the consenting and administration of the questionnaire.

### **3.6: Data Collection Tools**

Pre-constructed semi-structured questionnaire (Appendix 3) was used to collect information from parents/guardians on the issues of adherence and factors influencing adherence. Information, which was collected, included demographic information of patients, social economic information of parents, types of drugs in use, how drugs are used, information on knowledge of adherence and importance of adherence to anticonvulsant therapy.

Morisky (MMAS) scale was used to scale the patient on adherence to medication<sup>2</sup>. This is a special tool with 6 items which complemented the above questionnaire and gave the scale of adherence to medication into >2 low adherence, 1-2 medium adherence and 0 high adherence<sup>40</sup>. This is one of the most widely used validated tools for assessing medication adherence and has been used in various studies including WHO published studies of adherence<sup>6,7</sup>.

Patient files were used to confirm diagnosis on the type of seizures and to obtain information on the treatment progress and trend of clinic attendances.

A semi-structured questionnaire was used to for the Prescriber to collect information on their level of understanding of adherence, what they do to enhance adherence, what they have

observed concerning adherence, what they think of their patient behaviour towards adherence and what should be done to promote adherence.

### **3.6.1: Determination of adherence**

Using morisky tool for measuring adherence, the response of the participants were rated according to the scale of adherence to medication into >2 low adherence, 1-2 medium adherence and 0 high adherence. Then calculation was then computed into percentages. Other determinants of adherence were determined by response of the participant and information from the patient's file.

### **3.6.2: Questionnaire for parents/guardians**

The researcher designed questionnaire was used to capture information on the demography of patient, occupation of parent/guardian, report on the use of drug and attendances at the clinic, knowledge of the disease, therapy and adherence to therapy. (Appendix 3)

### **3.6.3: Semi-structured questionnaire for prescribers**

This was used to capture information from clinician treating epileptic children on the knowledge about adherence, its importance and how do they promote it. (Appendix 4)

## **3.7: Ethical Consideration**

### **3.7.1 Approval to carry out the study**

The study started upon approval from the UON/KNH Ethics and Research Committee (Appendix 11) and permission from KNH Neurology clinic. Written informed consent was sought from all participants first before administering the study tools. All participants including parents/guardian of patients were required to fully understand the study, know their rights and voluntarily sign the informed consent before participation. Participants were free to ask any questions regarding the study, their rights and seek any clarification.

### **3.7.2 Informed consent and assent**

Consent from the participants or/and assent from older children (7-12 years) who met the inclusion criteria and were willing to be enrolled to participate in the study were sought and a consent form (Appendix 7) and assent form (Appendix 10) presented for signing after the

participant have been taken through a detailed consent explanation process (Appendix 6 and 8, respectively) by the researcher.

### **3.7.3: Confidentiality**

Names of participant were not recorded anywhere on any study tool but instead codes which bare no link to the identification of the participant were used for statistical purposes. Interviews were conducted in a private room and all other forms including consent forms were being kept privately by the investigator. Patients were assured that their identity will not appear anywhere in the study documents or publications.

### **3.7.4: Risk involved**

There was no known risk which would occur following participation in the study, as the study involved asking questions, and participants were allowed to respond in their own way and were assured of continued benefit from the treatment at the clinic whether they agree to participate or not.

### **3.7.5: Benefit from the study**

There was no direct benefit to the participants but the study was beneficial in creating awareness on the role and benefit of adherence to treatment protocols for epileptic children. It also gave the rate and determinants of adherence which can be used to improve treatment outcome in epileptic children treated at KNH

### **3.7.6: Compensation plan for participants**

There were no monetary or other compensation to participants for agreeing voluntarily to use their time for the study. They benefited from free drug and treatment information, which were being offered during the study. Patient who was found to be non adherent received help accordingly through appropriate drug information counselling.

## **3.8. Data Management**

### **3.8.1 Data processing and analysis**

Raw data were collected using study tools and entered into a password protected Microsoft Access (version 2007) Database and then exported to Stata version 10 for analysis. Before and after analysis, the filled questionnaires were stored in a lockable cabinet in a principal

investigator's office. They were moved to a lockable cabinet in the statistician's office during data entry and analysis. Upon completion of Data entry, hard copy forms were compared with the entered data to identify errors and corrections made appropriately.

Descriptive statistics were carried out, where discrete variables were summarized with frequencies and percentages while continuous variables were summarized using measures of central tendency and dispersion such as mean, median, mode, standard deviation and inter-quartile ranges.

The rate of adherence was estimated using frequencies and percentages. Using Morisky tool for adherence each individual patient was categorized according to the scores as follows; >2 low adherence, 1-2 medium adherence and 0 high adherence.

Patient/care giver and prescribers related factors associated with non-adherence identified were estimated in frequencies and percentages. Association between these factors and other variables was done using Multivariate analysis in which Chi-squared tests was used. Some of these factors included age, marital status, education level, occupation and family income.

During multivariate analysis, we adjusted for confounders and effect modifiers in the model to determine independence in the relationship between independent and dependent variables. This was achieved using binary stepwise backward multinomial logistic regression.

### **3.8.2 Data quality control**

Before commencement of the study, two research assistants were recruited and trained on how to collect data. A pilot test on a sample of 10 participants was done to assess the suitability of the questionnaires in which the recruited research assistants also gained experience. The data were kept safely by the principle investigator and analysis was done with assistance of statistician. The data stored was coded, entered into the computer and data cleaning was employed to ensure complete data quality assurance.

### **3.8.3: Management of health records during the study Period**

During the study, patient's files were concurrently used by the prescribers and the researcher. To avoid confusion and loss of the records prescribers research assistants wrote down somewhere the eligible participant's file number. These were used to trace all the files sent to

the researcher. On encounter with the participant, the investigator also noted down the patient's file. On returning the files to health record department after use, the records personnel confirmed by counterchecking the numbers from the investigator with the ones from the research assistant.

#### **3.8.4: Qualifications of research assistants**

The two research assistants were holders of diploma in nursing sciences. They were trained on facilitating consenting processes, filling research tools, organising and handling research tools and health records. The training also involved demonstration of the all process during pilot experiment of the study so that they can familiarize themselves before the actual study.

#### **3.8.5: Dissemination of the Results**

The results from this research will be shared through the following ways; the final documents will be sent to the neurology department at KNH, CHS library, department of pharmaceutics and pharmacy practice and at the school of pharmacy library. The power point presentation will be done to health workers at the neurology clinic and other symposia. Finally, this work will be published in health related journal, preferably east African medical journal

#### **3.8.6: Limitations of the study**

Our study is a cross-sectional study which determines the association of dependent and independent variables once in a study period which could not be the case other times. It also relied on participant's responses which are subjected to recall bias.

Some of the groups of participants were small to carry out statistical significant test and also decreased strength of association.

Another limitation is the relatively small sample size which is not all epileptic children in the country. However, our sample size correlates well with the number of patients seen at the clinic and this did not significantly affect the power of the study.

## CHAPTER FOUR

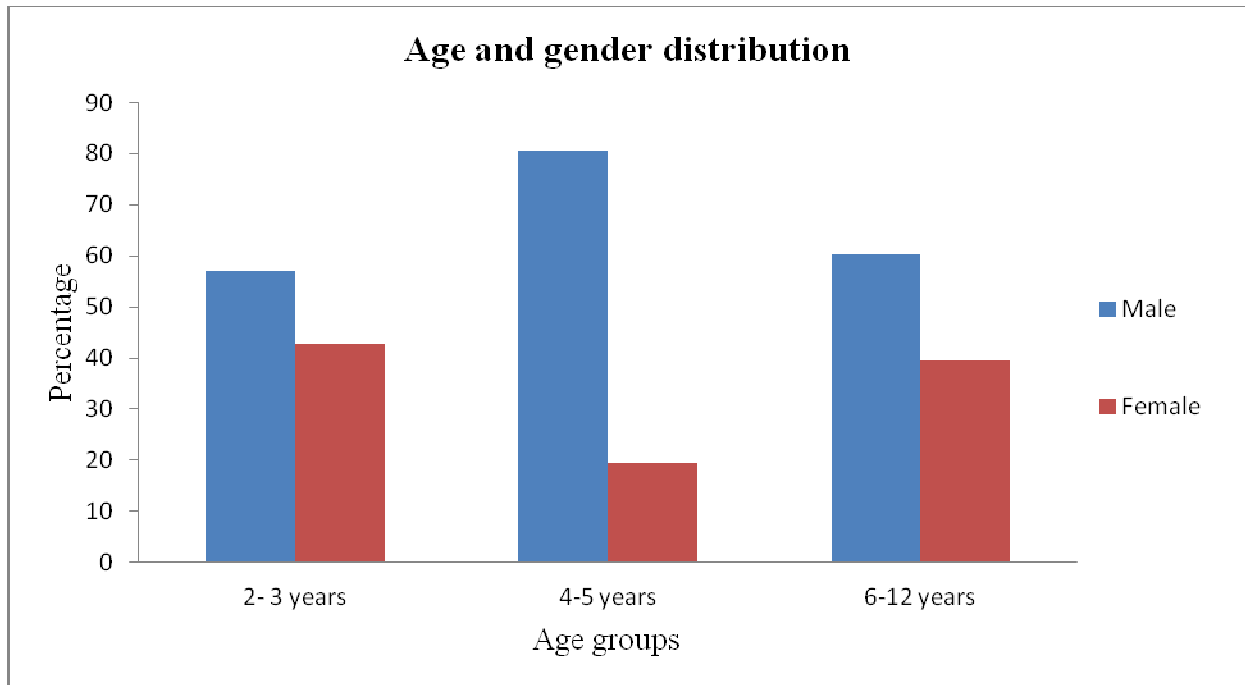
### RESULTS

The Morisky scale tool was used to determine the rate of adherence to medication during a period of drug therapy. Factors influencing adherence to medication throughout the course of treatment was determined through caregiver self report using a standardized questionnaire (Appendix 2), Information of patient's files, information from the files and prescriber's response using pre-designed questionnaire.

#### 4.1: Demographics of the Study Groups

##### 4.1.1: Baseline characteristics of the patients

We analysed data from 176 patients who participated. Female patients accounted for 66 (37.5 %) of the study patients, although there were more females aged 4-5 years (Figure 1). The median age of the study patient was 6 years (Range 4 to 9 years). Majority of the patients, 102 (57.4 %) were aged 6-12 years.



**Figure 1: Age and gender distribution of the patients**



#### **4.1.2: Baseline characteristics of parents/guardians**

Majority of patient's primary care givers were females 128 (72.8 %) as compared to 48 (27.3 %) who were males (Table 1). The mean age was 34.4 (SD=  $\pm 7.04$ ) and median age was 33, while inter-quartile range was 29 and 39 years. Most of the parents/guardians who participated in this study were married 138 (78.4 %). Forty eight (27.3 %) of the care givers had received primary education, 67 (38.1 %) had received secondary education, 57 (32.4 %) had received college education and 4 (2.3 %) had received none of the formal education. The employment status and average family monthly income were assessed, and it was observed that, majority of participants 71 (39.8 %) were unemployed while 51 (29.0 %) and 29 (16.5 %) of the total participants were employed and casual labourer respectively. Nevertheless, 25 (14.2 %) were doing other jobs. Majority of Parents/guardians 134 (76.1 %) were earning an average of less than 20 thousands Kenya shillings per month, and few were earning above 20 thousands. However few of them 13 (7.4 %) declined to give detail of their earning as shown in table 1 (Next page).

**Table 1: Baseline characteristics of Parents/guardians.**

<b>Variable</b>	<b>n</b>	<b>Percentage</b>
<b>Parent/Guardian age and gender</b>		
<b>Ages</b>		
< 33 years	88	50.6
> 33 years	87	49.4
<b>Gender</b>		
Male	48	27.3
<b>Female</b>	<b>128</b>	<b>72.7</b>
<b>Marital status</b>		
Single	29	16.4
<b>Married</b>	<b>138</b>	<b>78.4</b>
Divorced	1	0.6
Widowed	4	2.3
Separated	4	2.3
<b>Employment status</b>		
Employed	51	29.0
<b>Unemployed</b>	<b>71</b>	<b>39.8</b>
Casual labourer	29	16.5
Others	25	14.2
<b>Family average monthly income</b>		
0-5 thousands Ksh	37	21.0
<b>6-10 Thousands Ksh</b>	<b>52</b>	<b>29.5</b>
11-20 Thousands Ksh	45	25.6
21-30 Thousands Ksh	14	7.9
31-40 Thousands Ksh	9	5.1
41-50 Thousands Ksh	5	2.8
>50 Thousands	1	0.6
Declined to answer	13	7.4

**4.1.3: Baseline characteristics of the prescribers**

Among the prescribers of anticonvulsants who participated in the study 10% were male, 90% were females (Table 2). Sixty percent were holders of masters of medicine and 40% were holders of bachelor of medicine. Twenty percent had over 10 years experience in treating epilepsy in children. 10%, 50%, 20% had 0-1 year, 2-5 years and 5-10 years experience in treating epilepsy respectively.

**Table 2: Baseline characteristics of the prescribers.**

<b>Parameter</b>	<b>n</b>	<b>Percentage</b>
<b>Gender</b>		
Male	1	10
Female	9	90
<b>Academic qualification</b>		
MBCHB	4	40
MMED	6	60
<b>Experience in treating epilepsy</b>		
1 year	1	10
2-5 years	5	50
5-10 years	2	20
Over 10 years	2	20

#### **4.2: General Knowledge on Epilepsy by Parents/Guardians**

On the assessment of the knowledge on epilepsy, 115 (65.3 %) of the participants admitted that they know the disease (Table 3).

Majority of the participants gave the description according to the signs of the disease shown by their children. On the other hand 61 (34.7 %) participants admitted that they don't know the disease and they couldn't state what it is.

On assessing the knowledge on acquiring epilepsy, 11 (6.23 %) participants indicated that it can be transmitted from one person to another. 117 (66.5 %) participants indicated that it cannot be transmitted from one person to another, and 48 (27.3 %) said they don't know if it can be transmitted.

The assessment went further to determine the parent/guardians knowledge on curability of epilepsy. One hundred and four (59.1 %) participants indicated that epilepsy has a cure, 11

(6.3 %) participants indicated that it does not have a cure while 61 (34.7 %) participants acknowledged that they don't know if epilepsy has a cure or not. For those who said that epilepsy is curable, they were required to give the duration of treatment. Forty two (23.9 %) of them said it is treatable in six months, 37 (21.0 %) of participants said treatment is life time, 9 (8.65 %) said treatment takes a year. Also 2 (1.1 %) and another 2 (1.1 %) said that, treatment of epilepsy takes three months and less than 1 month respectively. Nevertheless 13 (7.4 %) participants said they don't know the duration of treatment of epilepsy.

It was observed that 66 (37.5 %) participants knew the side effects and could mention at least one of them. The side effects of anticonvulsants which were mentioned by participants were; confusion, oversleeping, loss of attention, slow in studies, overplaying, allergy, headache, persistent tiredness, dizziness, loss of memory, persistent weakness, nausea, retarded growth, dental damage, sweating, vomiting, restlessness, aggressiveness, body rashes, overeating, discolouring of teeth, weight gain, recurrent sickness, over salivation, loss of appetite and infertility.

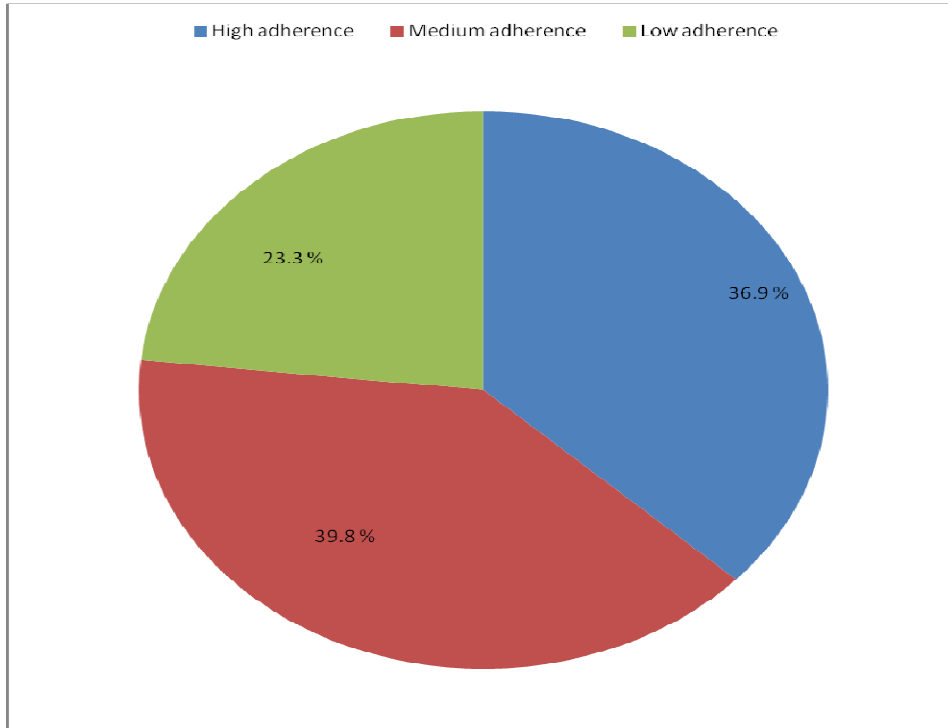
On the other hand 110 (62.5 %) of participants did not know the side effects of the anticonvulsants.

**Table 3: Response on general knowledge of parents/guardians**

<b>Variable</b>	<b>n</b>	<b>Percentage</b>
<b>Knowledge on what epilepsy is</b>		
Yes	<b>115</b>	<b>65.3</b>
No	61	34.7
<b>Can epilepsy be transmitted from one person to another?</b>		
Yes	11	6.3
<b>No</b>	<b>117</b>	<b>66.5</b>
Don't know	48	27.3
<b>Does it have a cure?</b>		
<b>Yes</b>	<b>104</b>	<b>59.1</b>
No	11	6.3
Don't know	61	34.7
<b>How long is the treatment?</b>		
1 month	2	1.1
3 months	2	1.1
<b>6 months</b>	<b>42</b>	<b>23.9</b>
1 year	9	5.1
Lifetime	37	21.0
I don't know	13	7.4
<b>Do you know the side effects of the drugs being taken?</b>		
Yes	66	37.5
<b>No</b>	<b>110</b>	<b>62.5</b>

### 4.3: Rate of Adherence to Anticonvulsants Therapy

The rate of adherence was determined using Morisky scale tool of measuring medication adherence. After analysis of parents/guardians response it was observed that, 65 (36.9 %) of participants showed high adherence level, 70 (39.77 %) showed Medium adherence level and 41(23.3 %) of participants showed Low adherence level (figure 2).



**Figure 2: Levels of adherence to anticonvulsants by epileptic children attending neurology clinic at KNH**

### 4.4: Prevalence of use of anticonvulsants and types of Formulation

Majority of patients 98 (55.7 %) were on single anticonvulsants and 47 (26.7 %) were on two anticonvulsants drugs while 25 (14.2 %) and 6(3.4 %) were on three and four anticonvulsants respectively (Table 4).

Majority of patients 134 (76.1 %) were taking anticonvulsants in form of tablet. Few patients 38 (21.6 %) were on syrup and very few patients 1 (0.6 %), 1 (0.6 %) were on capsules and injection respectively. When parents/guardians were asked if the formulation is suitable for their children, 155 (88.1 %) of participants said it was suitable and 21 (11.9 %) said the formulation was not suitable.

**Table 4: Number of anticonvulsants, formulation being taken and duration on which they have been taken.**

<b>Variable</b>	<b>n</b>	<b>percentage</b>
<b>Number of anticonvulsants in use</b>		
<b>1 anticonvulsant</b>	<b>98</b>	<b>55.7</b>
2 anticonvulsants	47	26.7
3 anticonvulsants	25	14.2
4 anticonvulsants	6	3.4
<b>Duration of treatment</b>		
Less than on month	2	1.1
1-5 months	25	14.4
5-12 months	18	10.2
<b>over one year</b>	<b>131</b>	<b>74.4</b>
<b>Drug formulation which the child is using</b>		
Syrup	38	21.6
<b>Tablets</b>	<b>134</b>	<b>76.1</b>
Injection	1	0.6
Capsules	1	0.6
<b>Is the formulation suitable for a child?</b>		
<b>Yes</b>	<b>155</b>	<b>88.1</b>
No	21	11.9

#### **4.5: Parents/ Guardian Satisfaction with the Service**

Satisfaction of the services provided at the clinic was also assessed. Parents/guardians were interviewed on their feeling on their interaction with health care giver. Majority of the participants admitted that they had good interaction with the health care provider. At the clinic, they had enough time with the health care provider, were assisted if there were problem with treatment (Table 5).

Drug availability was also assessed and it was observed that 81 (46.0%) admitted getting drugs at KNH pharmacy facility and 95 (54.0%) obtain anticonvulsants from other pharmacy facility outside KNH. However majority of the parents/guardians 128 (72.7%), said that, drugs were accessible and only few participants 48 (27.3%) acknowledged facing difficult with drug availability.

Majority 95 (54.0%) of patients admitted the cost of treatment of epilepsy was high. Very few participants 16 (9.1 %), admitted that the cost of treatment was cheap and the rest 65 (37.0%) said the cost of treatment was fair.

Knowledge on the awareness of other perceived treatment options was assessed. It was observed that few of the parents/ guardians, 19 (10.1%) were aware of the presence of other forms of treatment which included; Prayers, Herbs, surgery, cell implant, magnetic alignment, keeping a child well, showing love to a child, keeping a child warm and supplements like Omega-3. Nevertheless majority of parents/guardians 157 (89.2 %) were not aware of any other form of treatment for epilepsy apart from anticonvulsants therapy.

Majority of epileptic children 146 (83.0%), were willing to take their medications as compared to 30 (17.0%) children who sometimes refused to take medication and their parents/guardian had to force them or promise to give present for them to take their medications. It was observed that 119 (67.6%) children took their drugs after meals, 40 (22.7 %) children took their drugs at bed time and 17 (9.7%) children took their anticonvulsant drugs before meals. Furthermore our study observed Majority 163 (92.6%), of the parents/guardians revealed that presence of friends or relatives during administration of the

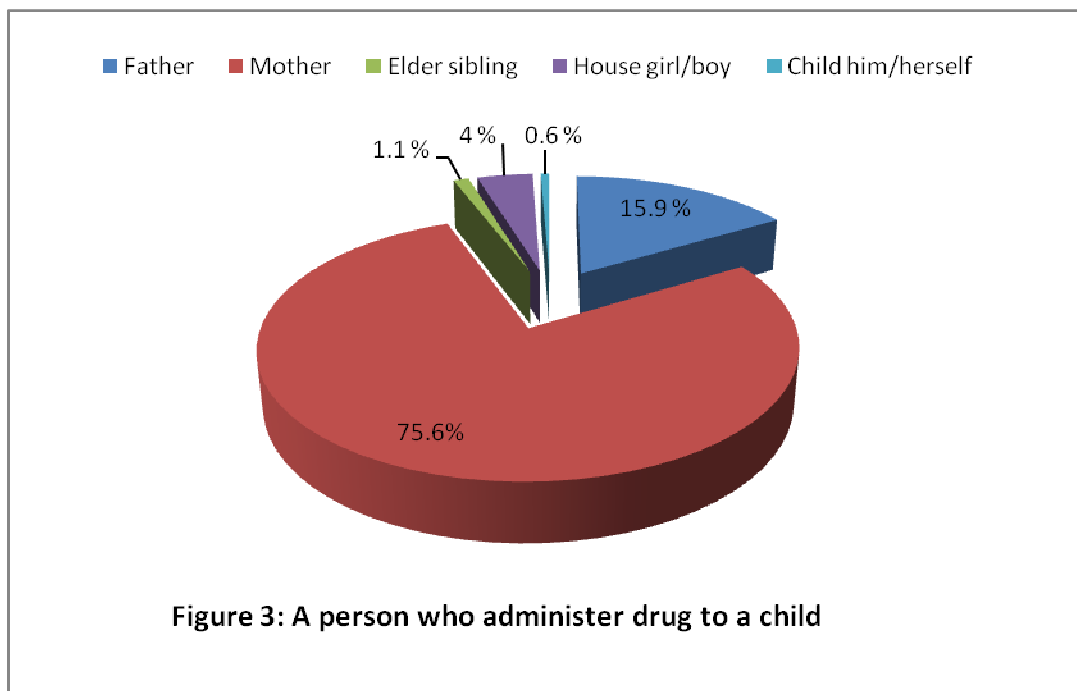


drugs did not interfere with the process of administration. However a few, 13 (7.4%) parents/guardians acknowledged there was interference.

**Table 5: Responses of parents/guardians on management of epilepsy.**

<b>Parameter</b>	<b>n</b>	<b>percentage</b>
<b>Cost of treatment</b>		
Easily affordable	16	9.1
Fair	65	36.9
<b>Expensive</b>	<b>95</b>	<b>54.0</b>
<b>Is the time spent with health care provider enough?</b>		
<b>Yes</b>	<b>151</b>	<b>85.8</b>
No	25	14.2
<b>Does health care provider assist in sorting a problem with treatment?</b>		
<b>Yes</b>	<b>133</b>	<b>75.6</b>
No	43	24.6
<b>Does health care provider gives all information on disease and drugs?</b>		
<b>Yes</b>	<b>121</b>	<b>68.8</b>
No	56	31.2
<b>Awareness of other forms of treatment of epilepsy apart from anticonvulsants.</b>		
Yes	19	10.8
<b>No</b>	<b>157</b>	<b>89.2</b>
<b>Do you get drug from KNH?</b>		
Yes	81	46.0
<b>No</b>	<b>95</b>	<b>54.0</b>
<b>Are drugs always available?</b>		
<b>Yes</b>	<b>128</b>	<b>72.7</b>
No	48	27.3
<b>Does presence of friends or relative interfere with the way you give medication?</b>		
Yes	13	7.4
<b>No</b>	<b>163</b>	<b>92.6</b>
<b>Does the child refuse to take medication?</b>		
<b>Yes</b>	<b>30</b>	<b>17.0</b>
<b>No</b>	<b>146</b>	<b>93.0</b>

Environment and process through which the child receives anticonvulsants was assessed. Starting with drug administration process, it was observed that majority of children 133(77.8%) got medication at home from their mother followed by 28 (16.4 %) children who receive from their father and the rest very few, received drug administration by their house boy/girl, elder sibling and by themselves respectively (shown in figure 3).



#### **4.6: Parents/Guardians Factors Influencing Adherence to Anticonvulsant Therapy**

The study determined rate of adherence and factors influencing adherence to anticonvulsant therapy by children using a predesigned semi-structured questionnaires. Upon analyzing responses by parents/guardians the adherence rates were put into three levels; high adherence level, medium adherence level and low adherence level. Because epilepsy is a chronic disease requiring persistence high adherence, the rates were eventually put into two groups adhering children with high adherence and non adhering children with low and medium adherence for the purpose of determining factors that influence adherence to anticonvulsants.

##### **4.6.1: Relationship between adherence to anticonvulsants therapy and baseline characteristics of the patient**

On observing adherence by age distribution, majority of highly adhering children 39.5 % were aged between two and three years followed by those with age four to five years 38.7 % and last were the school children 35.3 %, aged six to twelve years. However there was no statistical significant association ( $p > 0.05$ ) between age groups of the patients and adherence level. The likelihood of adhering to anticonvulsant when the child in preschool years (4-5 years) is 0.97 times (95 % CI 0.42, 2.49) and when he/she is in school years (6-12 years) is 0.83 times (95 % CI 0.40, 1.74). Also our study showed that adherence to anticonvulsants by

children has no predilection to sex as there was no statistical significant association between adherence and sex of an epileptic child ( $p > 0.05$ ). Nevertheless this study showed that female child were 1.53 times adhering to anticonvulsants than male epileptic children (95 % CI 0.81, 2.89)

**Table 6: Relationship between adherence to anticonvulsants therapy and baseline characteristics of the patient.**

Variable	Medium and low adherence	High adherence	Bivariate		
	n (%)	n (%)	OR	95% CI of OR	p- value
<b>Age in years</b>					
2-3	26 (60.5)	17 (39.5)	1	-	-
4-5	19 (61.3)	12 (38.7)	0.97	0.47,2.49	0.94
6-12	66 (64.7)	36 (35.3)	0.83	0.40,1.74	0.63
<b>Gender</b>					
Male	73 (66.4)	37 (33.6)	1	-	-
Female	36 (56.3)	28 (43.8)	1.53	0.81,2.89	0.19

**4.6.2: Relationship between adherence to anticonvulsant therapy and demographic characteristics of primary caregiver.**

Marital status, education level, employment status and average family monthly income were analyzed for their association with adherence to anticonvulsant therapy of children (Appendix 1).

There was a statistically significant association between level of education of parent/guardian of an epileptic child and adherence to anticonvulsant therapy ( $p < 0.05$ ). Taking primary education as a reference group children receiving primary care from a parent/guardian who had secondary education were 5.16 times more adherent to anticonvulsant therapy (95% CI

1.88, 14.02). Also epileptic children receiving primary care from parent/guardian who had college education were 3.72 times adherent to anticonvulsant therapy (95% CI 1-86, 10.92). However there was no statistical significant association between being cared by parent/guardian with no formal education and adhering to anticonvulsant therapy ( $p > 0.05$ ). Epileptic children receiving primary care from a parent/guardian with no formal education were 1.67 times likely to adhere to anticonvulsants therapy when compared to epileptic children being cared by a parent/guardian with primary education (95% CI 0.09, 36.45).

There was a statistical significant association between marital status of the parent/guardian and adherence to anticonvulsants. Taking parent/guardian who were single as a reference group; an epileptic child receiving primary care from a married parent/guardian was 5.72 times likely to adhere to anticonvulsant therapy (95% CI 1.5, 21.78). Epileptic children receiving care from separated parent/guardian were 14.89 times more likely to adhere to anticonvulsant therapy (95 % CI 1.12, 197.74). However association of an epileptic child receiving care from parent/guardian who is widowed and adherence is not statistically significant ( $p > 0.05$ ) but this study showed that, this child is 4.76 times more likely to adhere to anticonvulsant therapy. Epileptic children receiving care from divorced parent/guardian were all adhering but the number was very small to carry out statistical significance test.

There was no statistically significant association between adherence of an epileptic child and employment status of a parent/guardian giving primary care ( $p > 0.05$ ). Using unemployed as a reference group, it was observed that an epileptic child receiving care from employed parents/guardian was 1.22 times more likely to adhere to anticonvulsants therapy (95 % CI 0.57, 2.60). Also an epileptic child was 1.46 and 1.25 times more likely to adhere to anticonvulsant therapy if he/she was receiving primary care from parents/ guardians doing casual labour and other jobs respectively (95 % CI 0.56, 3.76 and 0.45, 3.47).

The relationship between the family's average monthly income and adherence to anticonvulsants was not statistically significant ( $p > 0.05$ ). When comparing the group whose monthly income was 0-5 thousands Ksh as reference group. The family whose earning was 6-10 thousands, their children were 1.20 times more likely to adhere to medication 95% CI 0.45, 3.48). Those who earned 11-20Tousands Ksh were 2.19 times adherent ( 95% CI 0.72, 6.71), children from family earning 21-30 thousands were 0.69 times more likely to adhere

(95% CI 0.09, 4.71) and those from family earning between 31-40 and over 50 thousands were 1.38 and 0.60 times respectively to adhere to anticonvulsants therapy as compared to those earning 0-5 thousands Ksh. As shown in table (Appendix 1)

#### **4.5: Prescriber's Factors Influencing Adherence.**

Prescribers, who participated in our study, were actively prescribing anticonvulsants to epileptic children at the clinic during the study. They were assessed on the knowledge on the anticonvulsants, their side effects, adherence, emphasis on adherence and methods of measuring adherence to their patients (Table 7).

All prescribers were able to give common side effects of anticonvulsants. They categorized them into very common, common and rare. The very common side effects were drowsiness, ataxia, weight gain, nausea and hypersensitivity. The common side effects were gum hyperplasia and dental carries. The rare side effects were lack of appetite, hyperactive and anaemia.

All prescribers acknowledged that a financial constraint is the most important reason for non-adherence of their patients. Other reasons were lack of proper knowledge among the patient's primary care givers on disease and side effects of anticonvulsants, stigma of the family towards a patient, absconding from a clinic visit, long duration of treatment and fear of unpleasant side effects.

All prescribers acknowledged that they assess adherence of their patients to anticonvulsants by asking the patients and assess progress of treatments and 50% of them do this both before and after prescribing.

All prescribers acknowledged giving information on adherence to their patients, but the frequency of giving information among prescribers differed. 60% of them said they gave information on every patient visit.

**Table 7. Response of prescribers on factors influencing adherence**

<b>Response</b>	<b>n</b>	<b>percentage</b>
Knowledge on side effects of anticonvulsants	<b>10</b>	<b>100</b>
<b>Why are your patients not adhering to medication?</b>		
Financial constraints	4	40
<b>Lack of knowledge among the care givers</b>	<b>5</b>	<b>50</b>
Stigma	1	10
Long duration of treatment	3	30
Absconding from treatment	1	10
Fear of unpleasant side effects	3	30
<b>When do you assess adherence?</b>		
<b>Before and after prescribing</b>	<b>5</b>	<b>50</b>
Before prescribing only	<b>3</b>	<b>30</b>
After prescribing only	<b>2</b>	<b>20</b>
<b>How often do you assess on adherence?</b>		
<b>Every patient visit</b>	<b>6</b>	<b>60</b>
During the first visit only	2	20
On intervals between the patient visit	1	10
Only after suspecting non-adherence	1	10

#### **4.5.1: Factors that hinder prescribers from promoting adherence to treatment protocols by their patients.**

Majority of the prescribers (70%) said lack of knowledge on the importance of adherence among prescribers and belief that because patients have come to hospital are likely adhere to treatment protocol as the major hindrance of the prescribers from giving adherence information to their patients (Table 8).

**Table 8: Factors that hinder prescribers from promoting adherence.**

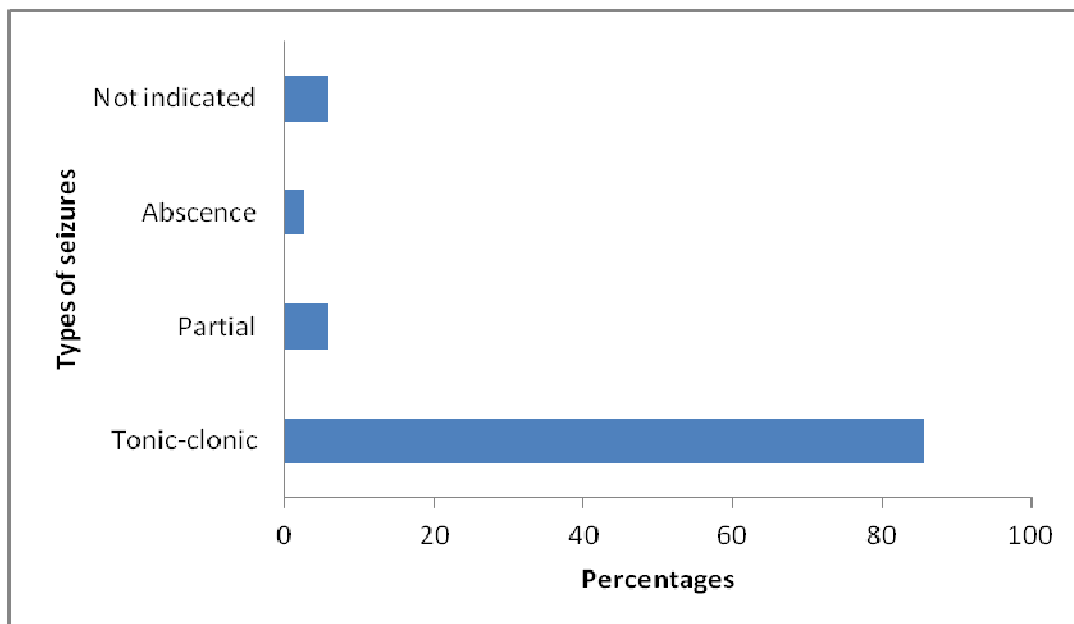
Factor	Number of Prescribers rating the occurrence of these factors		
	High	Medium	Low
Lack of time due to heavy patient load	4	3	2
Lack of knowledge on importance of adherence	7	1	2
Belief that the patient or care giver understand	4	4	2
Belief that because patient have come to hospital they will likely adhere to treatment	7	2	1

Also lack of time due to heavy patient load and assumption that the patient understands the importance of adherence were rated high by 40% of prescribers as the cause of hindrance to prescribers from giving adherence information to patients.

#### **4.6: Assessment of Treatment Progress**

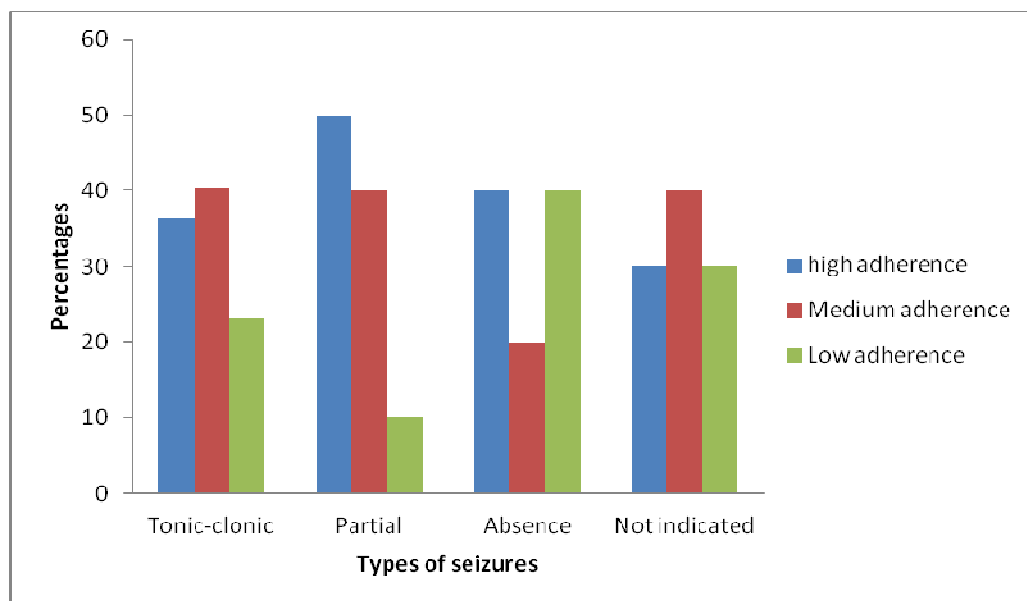
Treatment progress of the epileptic children was assessed by analyzing treatment information from their files. Types of seizures and number of seizure attack were assessed along with types and number of anticonvulsants they were using. It was observed that majority of patients, 151 (85.7 %) had tonic-clonic seizure, 10 (5.8 %) had partial seizure and 5 (%) had absence seizure. For a small group of 10 (5.8 %), their seizure type could not be traced because EEG results were unavailable despite being on anticonvulsants (Figure 4).





**Figure 4: Prevalence of types of seizures**

On assessment of types of seizure and adherence, it was observed that for patients who had tonic-clonic seizure, majority of them 61 (40.4 %) were rated medium in adhering to anticonvulsants as compared to 55 (36.4 %) who were highly adhering and 35 (23.2 %) had low adherence level. For patient with partial seizure, 5 (50%) of them were highly adhering, 4 (40%) rated medium in adhering and 1 (10%) lowly adhering. For those with absence seizure, it was observed that 2 (40%), 1 (20 %), 2 (40 %) of them were highly, medium and lowly adherent to anticonvulsants respectively and for epileptic children whose seizure was not indicated; 3 (30 %), 4 (40 %), 3 (30 %) had high, medium and low adherence level respectively. However this distribution of seizure types and level of adherence to anticonvulsants was not statistically significant ( $p > 0.05$ ) (figure 5)



**Figure 5: Distribution between Types of seizure and adherence to anticonvulsants.**

A large group of patients 119 (67.5 %) had four and above seizure attack after they have been started on anticonvulsants as compared to 32 (18.18%) patients who had no seizure attack after they have been put on anticonvulsants. The rest 15 (8.4 %), 8 (4.6 %) and 2(1.3%) had seizure attack once, thrice and twice respectively (Table 9)

**Table 9: Information about the progress and treatment of patients**

Variable	n	Percentage
<b>Number of seizure attack after first visit</b>		
≥ 4 times	119	67.5
3 times	8	4.6
2 times	2	1.3
1 time	15	8.4
No seizure attack	32	18.2
Total	176	100

All epileptic children who participated in this study were on anticonvulsants. The types of anticonvulsants used were phenytoin, Phenobarbital, Sodium valproate, Clonazepam, Carbamazepine, topiramate. These drugs were prescribed in different regimens and the distribution of them and their regimen is as shown in table 10 (next page).

**Table 10: Prevalence of anticonvulsants regimens used at the paediatric neurology clinic**

<b>Therapy</b>	<b>n</b>	<b>Percentage</b>
<b>One drug</b>		
<b>Phenobarbital</b>	<b>49</b>	<b>28.0</b>
Carbamazepine	21	12.0
Sodium Valproate	24	13.7
Phenytoin	2	1.1
Total	96	54.9
<b>Two drugs</b>		
<b>Phenobarbital / Sodium valproate</b>	<b>23</b>	<b>13.1</b>
Carbamazepine / Sodium Valproate	7	4.0
Clonazepam / Sodium Valproate	12	6.9
Carbamazepine / Phenobarbital	7	4.0
Clonazepam / Phenobarbital	3	1.2
Clonazepam / carbamazepine	3	1.2
<b>Total</b>	<b>54</b>	<b>31.4</b>
<b>Three drugs</b>		
<b>Carbamazepine / Sodium valproate / Phenobarbital</b>	<b>9</b>	<b>5.1</b>
Carbamazepine / Clonazepam / phenytoin	1	0.6
Carbamazepine / Sodium valproate / lamotrigine	1	0.6
Carbamazepine / Sodium valproate / Clonazepam	3	1.7
Sodium valproate / Clonazepam / Phenobarbital	3	1.7
Sodium valproate / clonazepam / Topiramate	1	0.6
Phenobarbital / Clonazepam / Carbamazepine	1	0.6
<b>Total</b>	<b>19</b>	<b>10.9</b>
<b>Four drugs</b>		
Carbamazepine / sodium valproate / clonazepine / topiramate	1	0.6
Carbamazepine / Sodium valproate / Phenobarbital / phenytoin	1	0.6
<b>Carbamazepine / Sodium valproate / Phenobarbital / Clonazepam</b>	<b>3</b>	<b>1.7</b>

#### 4.7: Availability of Anticonvulsants at the Pharmacy

The Pharmacy that serves the neurology clinic caters for fill and refill services of anticonvulsants. During the study period, assessment for availability of anticonvulsant at this pharmacy was done regularly during clinic days. Types of anticonvulsants, their formulations and the consistence of their availability were as shown in the table 11.

**Table 11: Types of anticonvulsant available at the pharmacy**

<b>Type of anticonvulsant</b>	<b>Class</b>	<b>Extent of availability</b>	<b>Formulations available</b>
<b>Phernobarbitone</b>	Barbiturate	<b>Always</b>	Tablets
Phenytoin	Hydantoin	Sometimes	Injection, capsules
<b>Carbamazepine</b>	Carboxamide	<b>Always</b>	Tablet, syrup
<b>Clonazepam</b>	Benzodiazepines	<b>Always</b>	Tablets
Sodium valproate	Fatty acid derivative	Most of the time but not always	Tablets
Topiramate	Fructose derivatives	Not available	
Diazepam	Benzodiazepines	Not available	
Gabapentin	GABA analogs	Not available	
Lamotrigine	Phenyltriazine	Not available	
Lorazepam	Benzodiazepines	Not available	

## **CHAPTER FIVE**

### **DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS**

#### **5.1: Discussion**

Our study revealed that out of the 176 study patients there was male preponderance at 62.5%. This tally with a similar study done by Amolo et al, in the same setting, which showed that there were more males than females at 54.9 %<sup>11</sup>. However, median ages of our study population of 6 years, deviate from the latter's study; it was 5 years because whereas our study population comprised of ages 2-12 years, Amolo et al study comprised from ages 0-12 years

A similar trend in demographics of parents/guardians like ours was observed by Muasya et al in the study on Knowledge altitude and practice of parents and guardians of children with epilepsy at KNH in which the revealed trend was that, there were more female guardians than males taking children to the hospital<sup>53</sup>. Probably as males go out to look for money, females are left to look after the children as a norm in African setting.

Like the similar study done at the same clinic, the social-economical structural factors of the parents/guardians were similar in trend; majority of them were married 78.4 %, had achieved secondary education 38.1 % and were unemployed at 39.8 %. In this other study by Amolo et al they were shown to be at 88 % married, 74.5 % had secondary education and 30.4 % were unemployed<sup>11</sup>. This is probably because most of the participants were female who were house wives.

The rate of adherence to anticonvulsant therapy by children attending neurology clinic at KNH is 36.9% high adherence, 39.8 % medium adherence and 23.3 % low adherence. However according to WHO and other studies, the successful outcome of treatment of epilepsy with anticonvulsants, depend on high adherence level<sup>13, 36, 38, 39, 47, 49, 51, 54</sup>. Therefore the rate of adherence in children attending neurology clinic at KNH is 36.9%. The study done in 2010 at the same clinic to determine levels of seizure control in children, suggested the cause of poor control of seizure was due to non-adherence. In this study the rate of partial and poor seizure control was 38.8%. Another study done in adult epileptic clinic at KNH showed the rate of non-adherence to be at 40 %. This study showed that many non-adhering patients had poor seizure control<sup>11, 52</sup>. Other studies done in developed countries particularly USA

showed that the rate of adherence is averaging at 50% in children with chronic diseases after taking consideration of time of treatment as a factor. One study in USA showed the rate of 58 % non-adherence in children who have been on treatment for six months and another study showed adherence rate by epileptic children to be 79.4% in one month of treatment<sup>18, 19</sup>. In our study majority of patients who participated had been on treatment for more than a year, showing that time of treatment may influence adherence as suggested by other studies that adherence rate tend to decrease with time.

Our study has shown that non-adherence rate increase with the age of patients. Majority of non-adhering children were in higher age group. Rate of adherence in toddlers was 39.5%, in preschool children was 38.7% and 35.3% in school children. However the association between rate of adherence and age of the patients was not statistically significant in bivariate analysis ( $p > 0.05$ ). The difference could be due to decreased social cohesion between a parent/guardian as a child grows older and become independent in some activities giving a care giver time to tend to his/her occupation. In a study done in Uganda on adherence to antiepileptic drug among children attending a tertiary health unit in a low resource setting found occupation of a care giver influences adherence. Children receiving care from a primary care giver with very involving occupation were not likely to adhere to anticonvulsant therapy<sup>61</sup>.

Gender of a patient had no statistical significant association with adherence to anticonvulsant therapy. Another study which was done in adult patients in United Kingdom but used the similar method of determining adherence rate did not show an association between adherence rate and gender of a patient. Other two studies on seizure control which were done in KNH at adult and paediatric clinics did not show the association between adherence to anticonvulsants or poor seizure control and gender<sup>11, 21, 52</sup>.

As with many other studies done at KNH and in developed countries, our study showed that majority of epileptic children had generalized seizures followed by partial seizures, absence seizure and unclassified respectively. When the distribution between types of seizure and level of adherence was done, it was observed that, majority of patients with tonic-clonic seizure had medium adherence rate, suggesting high rate of non-adherence in this group of patients. Fifty percent of patients with partial seizure had high adherence while for the rest of

two groups, the rate of having high adherence, medium adherence or low adherence were comparable. However several studies on poor control of epilepsy identified the high rate of poor control in patients with partial seizures as compared to patient with generalized seizures<sup>11,21</sup>.

Education level and marital status of parent/guardians was shown to be statistically significantly associated with adherence to anticonvulsants of their children. Children from parents who had attained secondary education were 5.31 times and 5.16 times likely to adhere to anticonvulsants as shown by bivariate and multivariate analysis respectively. Likewise children from a family whose primary care giver had college education were 3.14 times and 3.72 times to adhere to anticonvulsants. This was probably because these parents had more and appropriate information on the disease and importance of adherence. Furthermore because of their education level, they can interact well with health care givers and ask relevant questions. The study done previously at KNH on knowledge, attitude and practice of parents and guardians of children with epilepsy revealed the influence of knowledge on the outcome of epileptic children and the more the parent/guardian is informed the better the outcome<sup>52</sup>. Another study done in USA concluded that lack of clear information on the disease contributed to non-adherence in children and this is supported by another study which was also done in USA<sup>30</sup>. Because lack of clear information can be caused by lack of education to understand the information given, then parent/ guardian education level influences adherence level of his/her child with epilepsy. Marital status of parents/guardian influences adherence of the child to anticonvulsants therapy. It was found that a child receiving primary care from a family of married couple was 5.72 times more likely to adhere to anticonvulsants as compared to child being raised by a single parent. Majority of participants were married. Another study which was done at KNH determining determinants of adherence to anti TB medication showed the same association<sup>62</sup>. This is probably due to the fact that married couples support each other in the care of a child and it was evident during study collection that some patients were brought at the clinic by both parents.

As it is indicated in many studies, knowledge of the disease and its treatment is very crucial for primary care givers to influence adherence to treatment protocols<sup>12, 14, 53</sup>. Our study found that many parents/guardian had an idea about epilepsy, its acquisition, curability, duration of



treatment and side effects of anticonvulsants. However they had different responses on these matters. According to International League Against Epilepsy (ILAE) and other studies; epilepsy is defined as having two or more unprovoked seizures in a year<sup>1, 2</sup>. Almost all participants who had an idea of the meaning of epilepsy described it according to the signs and symptoms their children present with but gave the right description of the signs and symptoms. Some of the description given were; brain problem causing convulsion, brain disease, convulsion, loss of consciousness and passing urine, convulsion due to high temperature, loss of memory, being unconscious, falling down, overactive brain, neurological disorder, loosing focus, difficulty in breathing, dizziness, a brain condition affecting a person during or after birth, Mental disorder, strange behavior, lack of oxygen in the brain, Weakness caused to a child born after prolonged labor, insufficient of blood supply in the brain, lack of coordination in the brain, convulsion and forming in the mouth and loss of senses. Many parents described convulsion due to fever as epilepsy. This condition which normally occurs in children can mark the start of epilepsy but it is not epilepsy. Other studies on emphasis of adherence suggest proper information and knowledge of a disease to be given to a patient or primary care giver (Parent/guardian) for higher adherence to treatment protocols. The study found that majority of parents/guardians 42 (39.4 %) believed that epilepsy is curable within six months This could be due to the facts that many patients experience seizure free period after being on treatment for six months to one year as shown in some studies. This period of seizure free can cause the parent/ guardian to stop medication causing non-adherence and this could be the reason of low rate of adherence of 36.9% found by our study.

Few parents/guardians 66 (37.5 %) had knowledge on the side effects. The side effect which was commonly mentioned was drowsiness. However many parents/guardians were concerned with gradual reduction of their children school performance after they have been started on anticonvulsants. This side effect is common to anticonvulsants and caused anxiety to parents/guardians on the future of their children and probably it may interfere with adherence in the long run. Many of children were receiving medication after meals and at bed time, probably because of nausea and drowsiness associated with anticonvulsants. Many parents/guardian in our study acknowledged that, they would give medication to their children at home despite presence of friends or relatives. This was to determine the influence

of the factor of stigma which was found by a study done in Zambia among epileptic patients<sup>41</sup>. In our study the fear of stigma was found among 13 (7.39 %) parent/ guardians. This had influence on adherence as parents/guardian may forget to give medication after friends or relatives have left.

WHO suggest treatment of epilepsy with single anticonvulsant agent, and the second, third or fourth drug added gradually if symptoms are not under control, it also suggest the first line drug to be Phenobarbital in developing countries because of its low cost. Our study found many patients were on single anticonvulsant agent most of whom were on Phenobarbital followed by sodium valproate then carbamazepine and lastly phenytoin .The most commonly used combinations was Phenobarbital and sodium valproate . The study done by Mativo et al in adult neurology clinic at KNH, found most patient on monotherapy were on carbamazepine followed by phenytoin then phenobarbitone and lastly sodium valproate This study also pointed out the most common combination regimen used was Carbamazepine and phenytoin by 33% of epileptic patients<sup>11, 21, 52</sup>. Family average monthly income had no statistical significant association to adherence in our study. However majority of parents/guardians rated the cost of treatment to be expensive while others said it is fair and a few said it is easily affordable. Their response to higher cost of anticonvulsants could be due to the fact that drugs sold in pharmacies outside KNH tend to be expensive because they are not subsidized. Our study found that majority of parents/guardians do obtain anticonvulsant drugs from pharmacies outside KNH. This is supported by information from the pharmacy which was collected during entire period of the study, which showed that phenobarbitone, carbamazepine and clonazepam, were only anticonvulsants which were always available at the pharmacy. Others like phenytoin and sodium valproate were available in certain periods while other anticonvulsants were not available during the whole period of this study. Other studies on adherence singled one of the causes of non-adherence to be lack of access to anticonvulsants because of cost and availability<sup>11, 21, 38, 52</sup>.

Satisfaction of parents with health care delivery is a determinant of the treatment outcome. Studies have shown that, the more patients are satisfied with the health care delivery the more they adhere. Our study showed high rate of satisfaction of parent/guardian to the health services offered at the clinic. Many care givers acknowledged to have more enough time with

health care giver receive necessary information from the health care giver. For adherence to be enhanced health care professionals must accept that patient's or primary care giver's belief, preference and prior knowledge influence adherence to medication. Therefore other factors rather than health professional and patients relationship seems to influence adherence as observed in other studies<sup>23, 24, 25, 60</sup>.

Some studies have found that adherence interventions by prescribers are frequently made after the prescription is written and patient or primary care giver might not have had much influence on the choice of drug<sup>14,16,20,60</sup>. However our study found majority of prescribers emphasize on adherence both before and after prescription, while other emphasize only before prescription and after prescription. Before and after prescription is the best way to increase adherence as it incorporate patient/s preference to the type of drug. Our study found that all prescribers had enough knowledge on the side effects of anticonvulsants and importance of adherence to anticonvulsants. However almost all prescribers relied on patient's response and progress of patient's condition during treatment as the only methods of monitoring adherence. These two methods are not optimal as some studies show<sup>11,60</sup> most patients tend to exaggerate their adherence rate and using progress of patient's condition only work if the right medicines were prescribed to patients. The study found, prescribers lack of knowledge on the importance of adherence, lack of time due to patients heavy load and assumption that the patient will adhere, are the main factors that hinder prescriber from promoting adherence to anticonvulsants by their patients. Other studies have shown the big impact of prescribers on adherence of prescribed medication by their patients<sup>24, 26, 29, 61</sup>.

## **5.2: Conclusion**

Adherence to anticonvulsant therapy by children is 36.9 %, this is very low compared to the required of over 95%. This is also low compared to studies done in western countries which show it to be around sixty percent. Availability of drugs, general cost of treatment and parents/guardians social and structural factors are the major determinants along with prescriber's lack of time in assessing and promoting adherence. These should be addressed together with the health care delivery system to promote, enhance and maintain adherence to anticonvulsants in epileptic children.

## **5.3: Recommendation**

### **5.3.1 Recommendations for policy and practice**

Children need special consideration as their decision towards their health care is determined by another person, the primary care giver. It is important that these primary care givers routinely receive enough information on the disease, its treatment and importance of adherence from a well-trained prescriber at clinic on every visit, so that to prevent the observed trend of patient not adhering due fear or misconception about medicines and their side effects. Also prescribers and pharmaceutical manufacturers should endeavour to formulate simple regimen and appropriate dosage forms for children which are supposedly easier to take. Health care delivery system must also ensure availability of anticonvulsants and at affordable cost.

### **5.3.2 Recommendations for further research**

Adherence determination has no gold standard technique; rather the combination of direct methods and indirect methods gives a clear picture. Our study used indirect methods of determining adherence. We recommend direct methods to be employed in future studies using the same group of patients to complement the results of our study.

Epilepsy is a chronic disease which causes anxiety and depression to primary care giver both of which can impair their health care delivery. We recommend a complete study on the association between psychosocial status of the primary care providers and adherence of their children to treatment protocols.

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## APPENDICES

### Appendix 1: Relationship between adherence to anticonvulsants and structural and economic factors of the primary care givers.

Variable	Medium and Low adherence n (%)	High adherence n (%)	Bivariate				Multivariate			
			OR	95% CI of OR		P value	AOR	95% CI of AOR		P-Value
				Lower	Upper		AOR	Lower	Upper	
<b>Level of education</b>										
Primary	40 (83.3)	8 (16.7)	1.00	-	-	-	1.00	-	-	-
Secondary	32 (48.5)	34 (51.5)	5.31	2.16	13.06	0.00	5.16	1.88	14.02	0.001
College	35 (61.4)	22 (38.6)	3.14	1.24	7.95	0.02	3.72	1.86	10.92	0.024
None	3 (75.0)	1 (25.0)	1.67	0.15	18.14	0.68	1.67	0.09	36.45	0.689
<b>Marital status</b>										
Single	24 (85.7)	4 (14.3)	1.00	-	-	-	1.00	-	-	-
Married	80 (58.8)	56 (41.2)	4.20	1.38	12.77	0.01	5.72	1.50	21.78	0.01
Divorced	0 (0.0)	1 (100.0)	-	-	-	-	-	-	-	-
Widowed	3 (75.0)	1 (25.0)	2.00	0.16	24.33	0.59	4.76	0.26	88.43	0.30
Separated	2 (50.0)	2 (50.00)	6.00	0.65	55.66	0.12	14.89	1.12	197.74	0.04
<b>Employment status</b>										
Employed	33 (66.0)	17 (34.0)	1.00	-	-	-				
Unemployed	43 (61.4)	27 (38.6)	1.22	0.57	2.60	0.61				
Casual labourer	16 (57.7)	12 (42.9)	1.46	0.56	3.76	0.44				
Others	14 (60.9)	9 (39.1)	1.25	0.45	3.47	0.67				

**Family's  
average  
monthly  
income  
(Thousands  
in Kshs)**

0-5	25(71.43)	10(28.57)	1.00	-	-	-	1.00	-	-	-
6-10	32(65.31)	17(34.69)	2.39	0.52	3.40	0.55	1.20	0.41	3.48	0.74
11-20	22(51.16)	21(48.84)	2.92	0.93	6.15	0.07	2.19	0.72	6.71	0.17
21-30	6 (46.15)	7 (53.85)	2.92	0.78	10.85	0.11	2.49	0.57	10.77	0.22
31-40	6 (75.00)	2 (25.00)	0.83	0.14	4.85	0.84	0.69	0.09	4.71	0.70
41-50	2 (50.00)	2 (50.00)	2.50	0.31	20.27	0.39	1.38	0.16	12.09	0.77
>50	9 (75.00)	3 (25.00)	0.83	0.19	3.73	0.82	0.60	3.74	3.74	0.58

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**Appendix 2: Study eligibility checklist**

**TITLE: DETERMINANTS OF ADHERENCE TO ANTICONVULSANTS AMONG  
OUTPATIENT EPILEPTIC CHILDREN AGED TWO TO TWELVE YEARS AT  
KENYATTA NATIONAL HOSPITAL.**

Date.....

Data collector's initials.....

Participant code no.....

Part A: Inclusion criteria (if any of the criteria is marked NO the participant is not eligible for enrolment)

Yes      No

    1. Parents/Guardian of outpatient epileptic children aged 2- 12 years

    2. parents/guardians will consent to participate in study

Part B: Exclusion criteria (If any of the exclusion criteria is marked YES the participant is not eligible for enrolment)

Yes      No

    1. Parents/guardians of outpatient epileptic patient aged less than 2 or over 12 years

    3. Participant who did not consent and/or assent to participate in the study

Is the participant eligible for the study?

Yes       No

**Appendix 3: Questionnaire for parents/guardians.**

**TITLE: DETERMINANTS OF ADHERENCE TO ANTICONVULSANTS AMONG  
OUTPATIENT EPILEPTIC CHILDREN AGED TWO TO TWELVE YEARS AT  
KENYATTA NATIONAL HOSPITAL.**

**Code**.....

**Date**.....

**Part A: Patient bio-data.**

1. Patient age (years).....
2. Patient gender: 1.Male [ ] 2.Female [ ]

**Part B: Parent/Guardian bio-data and other demographic information**

3. Parent/guardian age (years).....
4. Parent gender: 1.Male [ ] 2.Female [ ]
5. Parent's marital status: 1.singe [ ] 2.Married [ ] 3.Divorced [ ] 4. Widowed [ ]  
5. Separated [ ]
6. What is your level of education: 1Primary education [ ] 2. Secondary education [ ]  
3. College [ ] 4. None [ ]
7. Employment status: 1 Employed [ ] 2.Unemployed [ ] 3.Casual labourer [ ]  
4.others [ ] (specify). .....
8. Family average monthly income: 1. 0-5 thousands Ksh 2. Ksh 5-10 thousands [ ] 2.  
Ksh 10-20 thousands [ ] 3. Ksh 20-30 thousands [ ] 4. Ksh 30-40 thousands [ ] 5  
Ksh 40-50 thousands [ ] 6. Ksh over 50 thousands [ ] 7. Declined to answer [ ]

**Part C: General knowledge.**

9. Do you know what epilepsy is? 1. Yes [ ] 2.No [ ]

If yes briefly state what it is.....

10. Can epilepsy be transmitted to another person? 1. Yes [ ] 2.No [ ] 3.I don't know[ ]

If yes, explain.....

If No, why/explain.....

11. Does it have a cure? 1. Yes [ ] 2.No [ ] 3.I don't know [ ]

If yes, how long is the treatment? 1. One month [ ] 2. Three months [ ] 3. Six months [ ] 4. A year [ ] 5. Lifetime [ ] 6. I don't know [ ]

12. Do you know the side effects of drugs being taken? Yes [ ] No [ ] I don't know [ ]

If yes mention:

- a).....
- b).....
- c).....
- d).....
- e).....



**Part D: Adherence to medication (Modified Morisky question tool) (Answer yes= 1 or No = 0) (Adapted from Morisky et al<sup>43</sup>)**

13. Are there situations or factors that will make you fail to give medication to your child.

Yes [ ] No [ ]

14. In the past two weeks are there days the child failed to take medication. Yes [ ] No

[ ]

15. When you travel or leave home with your child, do you forget to bring along his/her medicine? Yes [ ] No [ ]

16. When you feel like his/her symptoms are under control, do you sometimes stop him/her from taking his/her medicine? Yes [ ] No [ ]

17. Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to the treatment plan? Yes [ ] No [ ]

18. How often do you have difficulty remembering giving your child his/her medicine?

(A=0. B-E= 1)

A. Never/rarely [ ]

B. Once in a while [ ]

C. Sometimes [ ]

D. Usually [ ]

E. All the time [ ]

**Part E: Other information relevant to adherence to anticonvulsants**

19. When was the child started on epileptic treatment? 1. less than 1 month [ ] 2. 1-5 months [ ] 3. 5-12 months [ ] 4. over 1 year [ ]

20. Which drug(s) is he/she currently on? (Tick)

<b>Drug name</b>	<b>(Tick)</b>
Phernobarbitone	
Phenytoin	
Carbamazepine	
Clonazepam	
Valproate	
Topiramate	
Diazepam	
Gabapentin	
Lamotrigine	
Lorazepam	
Others, Names	

21. Which drug formulation is your child on? 1. Syrup [ ] 2. Tablets [ ] 3. Injection [ ]  
4. Capsules [ ] 5. Others [ ]

22. Is the drug formulation suitable for your child? 1. Yes [ ] 2. No [ ]
23. Do you get the drugs from Kenyatta National Hospital? 1. Yes [ ] 2. No [ ]
24. Are the drugs always available for you: 1.Yes [ ] 2.No [ ]
25. Who administers the drug to the child: 1.Father [ ] 2.Mother [ ] 3.Elder sibling [ ] 4.House girl [ ] 5.Child him/herself [ ] 6. Others [ ]
26. When does a child take the drugs? 1.Before meals [ ] 2.After meals [ ] 3.With meals [ ] 4.At bed time [ ]
27. Does the child sometimes refuse to take medication? 1. Yes [ ] 2.No [ ]

If yes, how do you ensure that the child takes medicines?

1. Promise to give present [ ]
2. Force the child [ ]
3. Mix the drug with food [ ]
4. Give with plenty of juice or milk [ ]
5. Others: [ ]

Specify.....

28. How do you describe the cost of all the services provided for epilepsy treatment?  
1.Easily affordable [ ] 2.Fair [ ] 3.Expensive [ ]
29. Does the presence of friends or relatives visiting you at home interfere with the way you give the drug to the child? 1.Yes [ ] 2.No [ ]
30. Did you have enough time with the healthcare giver? 1. Yes [ ] 2.No [ ]  
If no Why?.....
31. When you have a problem with treatment, does the health care provider assist you in sorting it out? 1.Yes [ ] 2.No [ ]

32. Does your health care provider give all the necessary information on the disease and drugs that the child is taking including side effects: 1.Yes [ ] 2.No [ ]

33. Are you aware of any other treatment of epilepsy apart from drugs:1.Yes[ ] 2.No[ ]

If yes mention any

.....  
.....  
.....

THANKS FOR PARTICIPATION

**Appendix 4: Questionnaire for prescribers**

**TITLE: DETERMINANTS OF ADHERENCE TO ANTICONVULSANTS AMONG  
OUTPATIENT EPILEPTIC CHILDREN AGED TWO TO TWELVE YEARS AT  
KENYATTA NATIONAL HOSPITAL.**

**Code.....**

**Date:.....**

Gender 1 female [ ] 2 male [ ]

Age (years). .....

Highest academic achievement: 1.PhD/MD [ ] 2.MMED/MSC [ ] 3.MBCHB [ ] 4.RCO [ ] 5.BSCN [ ]

Experience in the management of epilepsy. 0-1 year [ ] 2-5 years [ ] 5-10 years [ ] > 10 years [ ]

What are the common side effects of anticonvulsants you experience with your patients:  
list them

Side effect	Rate ( 1= rare, 5= very common)
1)	
2)	
3)	
4)	

6. What are factors affecting adherence to anticonvulsants in children that you treat?

1).....

2).....

3).....

7. How do you assess adherence?

a) Assess progress of condition 1. Yes [ ] 2. No [ ]

b) Ask patients 1. Yes [ ] 2. No [ ]

c) Count pills 1. Yes [ ] 2. No [ ]

d) Other (explain) .....

8. With your busy schedule how often do you emphasize to the patients on adhering to treatment protocols?: 1. Rarely [ ] 2. Sometimes [ ] 3. Always [ ]

At what point do you emphasize on adherence to patients

Before prescribing [ ]

After prescribing [ ]

Both before and after prescribing [ ]

9. How would you rate your emphasis of adherence to the following by your patients

Care	Rate ( the higher the number the higher the rate)			
	1	2	3	4
Medicine taking				
Outpatient appointment attending				
Non pharmacological therapy				
Other, (Explain)				

10. How would you rate the following strategies on adherence monitoring

Strategy	Rate			
	1	2	3	4
Using monitoring dose systems which are special 'dosette boxes' for patient who might have difficulty understanding or following instructions because of language, learning or memory problems				
Asking patients or primary care giver to set alarms				
Checking on refill/follow-up information of the patients				
Simplify regimen				
Give written and oral information to patient or primary care giver.				
Letting the patient or care giver decide on his/her own				

11. Please recommend methods of enhancing adherence to anticonvulsant therapy in children.

.....  
 .....  
 .....

12. How often do you give information on adherence to your patients

During the first patient visit only [ ]

On every patient visit [ ]

At intervals between visits [ ]

After suspecting of non-adherence [   ]

I don't give information at all [   ]

Pharmacists do this work [   ]

13. Rate factors that hinder health care providers from promoting adherence to treatment protocols by their patients (tick respective number) (1= 0%, 2= 25%, 3= 75%, 4= 100%)

S/No	Factor	1	2	3	4
1	Lack of time due to heavy patient load				
2	Lack of knowledge on importance of adherence				
3	Belief that the patient or care giver understand				
4	Belief that because patient have come to hospital they will likely adhere to treatment				
5	Others (Explain)				

Thank you very much for participation



**Appendix 5: Tool for obtaining data from patient files and pharmacy records**

**TITLE: DETERMINANTS OF ADHERENCE TO ANTICONVULSANTS AMONG  
OUTPATIENT EPILEPTIC CHILDREN AGED TWO TO TWELVE YEARS AT  
KENYATTA NATIONAL HOSPITAL.**

Code.....

Date:.....

**PART 1: Information from patient files.**

1. Patient code.....
2. Diagnosis.....
3. Type of seizures.....
4. Treatment progress after first visit (Tick relevant)
  - a)  $\geq 4$  times of seizure attacks [    ]
  - b) 3 times of seizure attacks [    ]
  - c) 2 times of seizure attacks [    ]
  - d) 1 time of seizure attacks [    ]
  - e) No seizure attacks [    ]
5. Type of anticonvulsants the patient is on

Class	Specific type	formulation	Dose	Frequence
1)				
2)				
3)				

4)				
----	--	--	--	--

**PART 2: Information from pharmacy records**

6. Types of anticonvulsants available

class	Specific type	Formulation
1)		
2)		
3)		
4)		

## **Appendix 6a: Consent explanation form for parents/ guardians**

### **TITLE: DETERMINANTS OF ADHERENCE TO ANTICONVULSANTS AMONG OUTPATIENT EPILEPTIC CHILDREN AGED TWO TO TWELVE YEARS AT KENYATTA NATIONAL HOSPITAL**

To be read in the language the respondent understands best.

#### **Introduction**

My name is **Dr. Deogratias Mwombeki Katabalo**; I am a postgraduate student currently pursuing a Master of Pharmacy in Clinical Pharmacy at the University of Nairobi. I am conducting a study which will be assessing the determinants of adherence to anticonvulsants by outpatient epileptic children aged two to twelve years at KNH. I would, therefore, like to request your permission to enrol you into this research study. Please feel free to ask me any questions during this session as I take you through the explanations of what the study intends to do.

#### **Study Title**

Assessment of determinants of adherence to anticonvulsants among outpatient epileptic children aged two to twelve years at KNH.

#### **Objectives**

The objective of this study is to evaluate the determinants of adherence to anticonvulsants in outpatient epileptic children aged two to twelve years at neurology clinic in KNH.

#### **Procedure to be followed**

The study will involve face to face interviews in which I will ask you some questions about anticonvulsants use by your child. I will also use your child's file to obtain some information on his/her disease progress. All information will be handled with confidentiality and will only be used for the purpose of this study.

## **Participation**

Your agreement to participate in this study is voluntary. You are free to withdraw from the study at any point without necessarily giving any reason and this will not in any way jeopardize the care that you are receiving at Kenyatta National Hospital.

## **Benefits**

During the interview, I will, to my level best, address any concerns you may have with regard to the use of antiepileptic by your child. You are free to ask any questions with regards to epilepsy and its management.

## **Compensation.**

There will be no monetary or other compensation to participants for agreeing voluntarily to use their time for the study. They will benefit from free drug and treatment information, which will be offered during the study. Patient who will be found to be non adherent will be helped accordingly through appropriate drug information counselling.

## **Risks**

There are no foreseen risks involved in this study as the study will only involve face to face interviews and retrieving of information from your file. This research will not in any way jeopardize the current care you are receiving at Kenyatta National Hospital.

## **Confidentiality**

All the information you provide will be treated with confidentiality. Serial study numbers will be used instead of your name to safeguard your identity and the data collecting material will be kept under lock and key by me (the principal investigator) during the entire period of the study.

## **Questions**

In case of any questions or clarifications about the study, you are free to contact any of the persons in the contacts provided below. If you have any ethical concerns or questions about your rights as a patient you may contact the Secretary of Kenyatta National Hospital

/University of Nairobi /Ethical and Research Committee (KNH/UoN-ERC). Full contacts are provided below.

## **Contacts**

Principal investigator;

Dr. Deogratias Mwombeki Katabalo, Post-graduate student (Clinical Pharmacy),

Department of Pharmaceutics and Pharmacy Practice, P.O. Box 30197–00400, School of Pharmacy, University of Nairobi, Mobile Number: +254 705 144 687.

The first Supervisor;

Dr. David Nyamu

Lecturer, Department of Pharmaceutics and Pharmacy Practice, P.O. Box 30197–00400, School of Pharmacy, University of Nairobi, Department’s telecom No: 2726300 Ext. 43673

The second supervisor;

Dr. Beatrice Amugune

Lecturer, Department of Pharmaceutical Chemistry P.O. Box 30197–00400, School of Pharmacy, University of Nairobi, Department’s telecom’s No: 2716962

The third supervisor,

Prof Muriuki Gichuru

Professor, Department of Pharmacology and Pharmacognosy, P.O. Box 30197–00400, School of Pharmacy, University of Nairobi, Department’s telecom No: + 254 20 272509

The Secretary, KNH/UoN-ERC

Kenyatta National Hospital,

P.O Box 20723-00202, Nairobi

Tel No. 2726300-9 / 2716450 ext. 44102, Fax: 725272

## **Ethical Approval**

Ethical approval will be granted by Kenyatta National Hospital /University of Nairobi /Ethical and Research Committee (KNH/UoN-ERC) to conduct this study at the KNH, medical outpatient clinic.

I, therefore, kindly request you to sign the attached consent form. Thank you for your consideration.

## **Kiambatisho 6b: Maelezo ya kukubali kwa mzazi/mlezi**

**KICHWA: VIGEZO VYA MATUMIZI SAHIHI YAKINIFU YA DAWA ZA KIFAFU KWA WATOTO WENYE UMRI WA KUTOKA MIAKA MIWILI MPAKA KUMI NA MIWILI WANAHUDHURIA MATIBABU KATIKA HOSPITALI YA TAIFA YA KENYATTA.**

Isomwe kwa lugha anayoilewa mshiriki.

### **Utangulizi**

Jina langu ni Dr. Deogratias Mwombeki Katabalo; Mwanafunzi wa shahada ya uzamili ya utabibu wa dawa katika shule ya famasia, chuo kikuu cha Nairobi. Ninafanya utafiti kuangalia vigezo vinavyoathiri matumizi sahihi yakinifu ya dawa za kifafa. Hivyo basi, nakuomba kwa ruhusa yako ukubali kushiriki katika utafiti huu. Tafadhari jisikie huru kuuliza maswali yoyote wakati ninapokupatia maelezo ya nini kitafanyika.

### **Utafiti**

Tathimini ya vigezo vya matumizi sahihi yakinifu ya dawa za kifafa kwa watoto wenye umri wa miaka miwili mpaka kumi na miwili wanaohudhuria matibabu KNH.

### **Malengo**

Lengo la utafiti huu ni kutathimini vigezo vinavyoathiri matumizi sahihi yakinifu ya dawa za kifafa kwa watoto wenye miaka miwili mpaka kumi na miwili wanaohudhuria kliniki ya magonjwa ya mishipa ya fahamu katika KNH.

### **Utaratibu utakaofuatwa**

Utafiti huu utahusisha mahojiano ya hana kwa hana, nitakuuliza maswali kuhusu matumizi ya dawa kwa mtoto wako, nitatumia pia faili lenye taharifa za matibabu yake kujua maendeleo ya ugonjwa wake. Taharifa zote zitachukuliwa na kuhifadhiwa kwa usiri mkubwa na zitatumika tu kwa ajili ya utafiti huu.

## **Ushiriki**

Kukubali kwako kushiriki katika utafiti huu ni hiari. Uko huru kujitoa katika utafiti huu katika hatua yoyote bila lazima ya kutoa taharifa na hii haitaathiri kwa aina yoyote huduma anazopata mtoto wako katika hospitali ya taifa ya Kenyatta.

## **Faida**

Katia mahojiano nitakuuliza maswali yanayohusiana na matumizi ya dawa kwa mtoto wako, Taharifa zitakazopatikana zitawasilishwa kwa watoa huduma za afya ili kuboresha huduma kwa ujumla, utapewa nafasi ya kuuliza swali lolote kuhusiana na matibabu ya mtoto wako.

## **Malipo**

Hakuna malipo yoyote kwa kukubali kushiriki katika utafiti huu kwa hiari. Mshiriki atafaidika kwa kupata ufafanuzi sahihi juu ya maumizi sahihi ya dawa ana atakayekutwa hafati maelekezo ya matumizi sahihi yakinifu vizuri, atapata maelezo ya kumsaidia.

## **Hatari.**

Hakuna athari zozote atakazopata mshiriki wa utafiti huu kwani utafiti huu utahusisha mahojiano ya hana kwa hana, taharifa zingine zitachukuliwa kwenye faili la matibabu ya mtoto wako, taharifa zote zitatumika kwa usiri mkubwa na zitatumika kwa ajili ya utafiti huu pekee. Aidha kushiriki katika utafiti huu hakutahatarisha kwa vyovyote huduma anazopata mtoto wako katika hospitali ya Taifa ya Kenyatta.

## **Usiri**

Taharifa zote utakazotoa zitatumika kwa usiri mkubwa, namba zitatumika badala ya jina lako kwa ajili ya kuhifadhi utambulisho wako, taharifa zitakazokusanywa zitahifadhiwa na mtafiti mkuu pekee kipindi chote cha utafiti.

## **Maswali**

Kwa maswali zaidi au ufafanuzi juu ya utafiti huu unaweza kuwasiliana na yeyote kati ya anwani zilizoandikwa hapo chini. Kama una wasiwasi wowote wa kimaadili au maswali kuhusu haki zako kama mgonjwa unaweza kuwasiliana na katibu wa hospitali ya taifa ya



Kenyatta/chuo kikuu cha Nairobi/Kamati ya maadili ya utafiti (KNH/UON-ERC).  
Mawasiliano kamili hapo chini.

**Mawasiliano.**

**Mtafiti mkuu;**

Dkt. Deogratias Mwombeki Katabalo, mwanafunzi uzamili (utabibu dawa),

Idara ya Pharmaceutics na Pharmacy Practice, S.L.P 30197–00400, Shule ya Pharmacy, Chuo kikuu cha Nairobi, Simu Namba: +254 705 144 687.

**Msimamizi wa kwanza;**

Dkt. David Nyamu

Mhadhiri, Idara ya Pharmaceutics na Pharmacy Practice, P.O. Box 30197–00400, Shule ya Pharmacy, chuo kikuu cha Nairobi, simu ya idara No: 2726300 Ext. 43673

**Msimamizi wa pili;**

Dkt. Beatrice Amugune

Mhadhiri, Idara ya Pharmaceutical Chemistry S.L.P 30197–00400, Shule ya Pharmacy, Chuo kikuu cha Nairobi, Simu ya idara No: 2716962

**Msimamizi wa tatu,**

Profesa Muriuki Gichuru

Profesa, Idara ya Pharmacology na Pharmacognosy, S.L.P 30197–00400, Shule ya Pharmacy, Chuo kikuu cha Nairobi, Simu ya idara No: + 254 20 272509

Katibu mkuu, KNH/UoN-ERC

Hospitali ya taifa ya Kenyatta,

S.L.P 20723-00202, Nairobi

Tel No. 2726300-9 / 2716450 ext. 44102, Fax: 725272

Uthibitisho wa kimaadili

Utafiti huu utathibitishwa kimaadili na Hospitali ya taifa ya Kenyatta/chuo kikuu cha Nairobi/  
Kamati ya maadili ya utafiti (KNH/UoN-ERC) ili ufanyike KNH kliniki ya wagonjwa wan  
nje.

**Appendix 7a: Consent Declaration form for parents/ guardians**

**TITLE: DETERMINANTS OF ADHERENCE TO ANTICONVULSANTS AMONG  
OUTPATIENT EPILEPTIC CHILDREN AGED TWO TO TWELVE YEARS AT  
KENYATTA NATIONAL HOSPITAL**

I \_\_\_\_\_(name of participant), being 18 years and more and having full capacity to consent for my child have been informed about the study, hereby do consent to voluntarily participate in this study. The nature of the study has been explained to me by the principal investigator and I have been given opportunity to ask questions concerning the study which have been answered to my satisfaction. The benefits and risks of this study have been clearly explained to me and I am aware that I am free to withdraw from this study at any point and this will not jeopardize the care I receive at the hospital.

I therefore give consent to be interviewed and that information from my file can also be used having understood the purpose of the study.

Signature: ..... Date: .....

Researcher's statement:

I \_\_\_\_\_ confirm that I have explained to the patient the purpose and nature of the study.

Signature: ..... Date: .....

**Kiambatisho 7b: Hati ya makubaliano kwa mzazi/ mlezi**

**KICHWA: VIGezo VYA MATUMIZI SAHII YAKINIFU YA DAWA ZA KIFAFa KWA WATOTO WENYE UMRI KATI YA MIAKA MIWILI MPAKA KUMI NA MIWILI WANAOHUDHURIA MATIBABU KATIKA HOSPITALI YA TAIFA YA KENYATTA.**

Mimi..... (jina la mshiriki), nikiwa na umri wa miaka 18 au zaidi na nikiwa na akili timamu ya kushiriki kwenye utafiti huu. Ninakubali kushiriki kwenye utafiti huu. Aina ya utafiti na yatakayofanyika nimeelezwa kwa ufasaha na mtafiti mkuu, nimepewa fursa ya kuuliza maswali na kupata ufafanuzi zaidi, nimeridhika. Faida ya matokeo ya utafiti huu nimeelezwa na nimeelewa kwamba naweza kujitoa katika utafiti huu wakati wowote bila kuhathiri huduma ninazopata hospitalini hapa.

Kwahiyo ninaruhusu kuulizwa maswali na kuchukuliwa kwa taharifa za matibabu ya mtoto wangu katika faili lake kwa madhumuni ya utafiti huu.

Sahihi: ..... Tarehe: .....

Taharifa ya mtafiti:

Mimi \_\_\_\_\_ Nathibitisha kuwa nimeeleza kwa kina aina na madhumuni ya utafiti huu.

Sahihi: ..... Tarehe: .....

## **Appendix 8: Consent explanation form for prescribers**

### **TITLE: DETERMINANTS OF ADHERENCE TO ANTICONVULSANTS AMONG OUTPATIENT EPILEPTIC CHILDREN AGED TWO TO TWELVE YEARS AT KENYATTA NATIONAL HOSPITAL**

To be read in the language the respondent understands best.

#### **Introduction**

My name is **Dr. Deogratias Mwombeki Katabalo**; I am a postgraduate student currently pursuing a Master of Pharmacy in Clinical Pharmacy at the University of Nairobi. I am conducting a study which will be assessing the determinants of adherence to anticonvulsants by outpatient epileptic children aged two to twelve years at KNH. I would, therefore, like to request your permission to enrol you into this research study. Please feel free to ask me any questions during this session as I take you through the explanations of what the study intends to do.

#### **Study Title**

Assessment of determinants of adherence to anticonvulsants among outpatient epileptic children aged two to twelve years at KNH.

#### **Objectives**

The objective of this study is to evaluate the determinants of adherence to anticonvulsants in outpatient epileptic children aged two to twelve years at neurology clinic in KNH.

#### **Procedure to be followed**

The study will involve face to face interviews in which I will ask you some questions about anticonvulsants prescribing practice, anticonvulsants use and their side effects encountered by your patients. All information will be handled with confidentiality and will only be used for the purpose of this study.

## **Participation**

Your agreement to participate in this study is voluntary. You are free to withdraw from the study at any point without necessarily giving any reason and this will not in any way jeopardize the care that you are giving at Kenyatta National Hospital

## **Benefits**

During the interview, I will, to my level best, address any concerns you may have with regard to the prescribing practices and use of anticonvulsants by your patients. You are free to ask any questions with regards to epilepsy and its management.

## **Risks**

There are no foreseen risks involved in this study as the study will only involve face to face interviews. This research will not in any way jeopardize your carrier at Kenyatta National Hospital.

## **Confidentiality**

All the information you provide will be treated with confidentiality. Serial study numbers will be used instead of your name to safeguard your identity and the data collecting material will be kept under lock and key by me (the principal investigator) during the entire period of the study.

## **Questions**

In case of any questions or clarifications about the study, you are free to contact any of the persons in the contacts provided below. If you have any ethical concerns or questions about your rights as a patient you may contact the Secretary of Kenyatta National Hospital /University of Nairobi /Ethical and Research Committee (KNH/UoN-ERC). Full contacts are provided below.

## **Contacts**

1. Principal investigator;  
Dr. Deogratias Mwombeki Katabalo, Post-graduate student (Clinical Pharmacy),  
Department of Pharmaceutics and Pharmacy Practice, P.O. Box 30197–00400,  
School of Pharmacy, University of Nairobi, Mobile Number: +254 705 144 687.
  
2. The first Supervisor;  
Dr. David Nyamu  
Lecturer, Department of Pharmaceutics and Pharmacy Practice, P.O. Box 30197–  
00400, School of Pharmacy, University of Nairobi, Department’s telecom No:  
2726300 Ext. 43673
  
3. The second supervisor;  
Dr. Beatrice Amugune  
Senior lecture, Department of Pharmaceutical Chemistry P.O. Box 30197–00400,  
School of Pharmacy, University of Nairobi, Department’s telecom’s No: 2716962
  
4. The third supervisor,  
Prof Muriuki Gichuru  
Associate professor, Department of Pharmacology and Pharmacognosy, P.O. Box  
30197– 00400, School of Pharmacy, University of Nairobi, Department’s  
telecom No: + 254 20 272509
  
5. Thee Secretary, KNH/UoN-ERC  
Kenyatta National Hospital,  
P.O Box 20723-00202, Nairobi  
Tel No. 2726300-9 / 2716450 ext. 44102, Fax: 725272

## **Ethical Approval**

Ethical approval will be granted by Kenyatta National Hospital /University of Nairobi /Ethical and Research Committee (KNH/UoN-ERC) to conduct this study at the KNH, medical outpatient clinic.

I, therefore, kindly request you to sign the attached consent form. Thank you for your consideration.



**Appendix 9: Consent Declaration form for prescribers**

**DETERMINANTS OF ADHERENCE TO ANTICONVULSANTS AMONG  
OUTPATIENT EPILEPTIC CHILDREN AGED TWO TO TWELVE YEARS AT  
KENYATTA NATIONAL HOSPITAL**

I \_\_\_\_\_(name of prescriber), being 18 years and more and having full capacity to consent for the study, have been informed about the study, hereby do consent to voluntarily participate in this study. The nature of the study has been explained to me by the principal investigator and I have been given opportunity to ask questions concerning the study which have been answered to my satisfaction. The benefits and risks of this study have been clearly explained to me and I am aware that I am free to withdraw from this study at any point and this will not jeopardize my carrier at the hospital.

I therefore give consent to be interviewed and that information from my file can also be used having understood the purpose of the study.

Signature: ..... Date: .....

Researcher's statement:

I \_\_\_\_\_ confirm that I have explained to the patient the purpose and nature of the study.

Signature: ..... Date: .....

**Appendix 10: Assent declaration form (For children aged 7 -12 years)**

**TITLE: DETERMINANTS OF ADHERENCE TO ANTICONVULSANTS AMONG OUTPATIENT EPILEPTIC CHILDREN AGED TWO TO TWELVE YEARS AT KENYATTA NATIONAL HOSPITAL.**

**Investigator:** Dr. Deogratias Mwombeki Katabalo, phone no 0705144687, M.Pharm student School of Pharmacy; University of Nairobi

I am doing a research study about the determinants of adherence to anticonvulsants in outpatient epileptic children aged two to twelve years at neurology clinic in KNH. This research study is a way about learning more on how you use your medicines for treating your condition. If you decide that you want to be part of this study, you will be asked to give information about your treatment, how you take drugs, how you manage the disease at home and how you interact with your parents/guardians and prescribers. You will be asked only once.

There are some things about this study you should know. These are; you will be asked about your personal details and disease related details, we will look into your files and talk to your parents and clinicians about your condition.

Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. However I will ensure that you will be aware of things that you don't know, especially management of your condition. Also results from this study will enable proper management of you and other children with condition like yours in the future.

If you do not want to be in this research study, we will agree with your decision without influencing your treatment at all.

When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.

You do not have to be in this study if you do not want to be. If you decide to stop after we begin, that's okay too. Your parents know about the study too.

If you decide you want to be in this study, please sign your name.

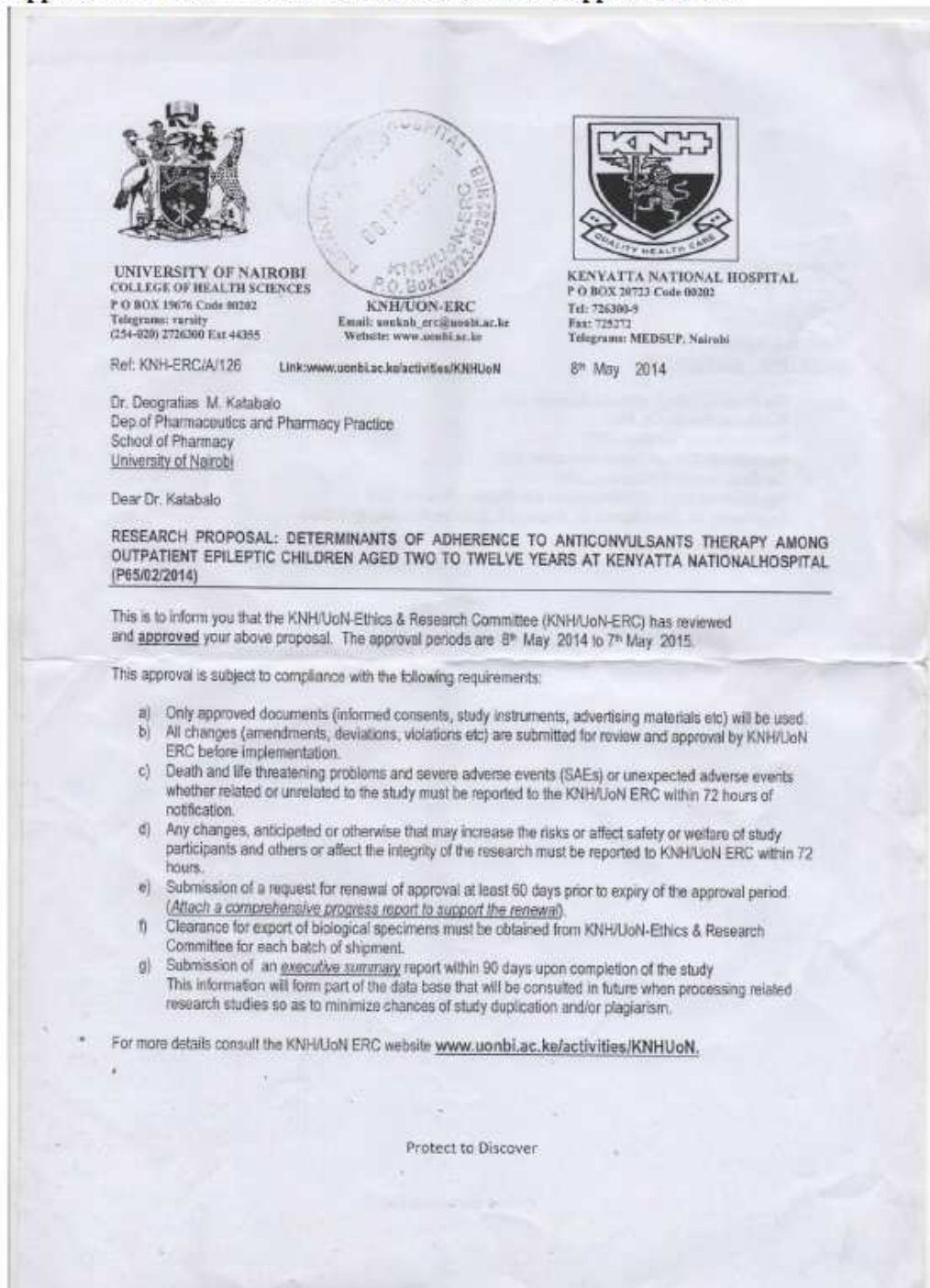
I, \_\_\_\_\_, want to be in this research study.

\_\_\_\_\_

(Sign your name here)

(Date)

Appendix 11: KNH/UON-Ethics research committee approval letter.



UNIVERSITY OF NAIROBI  
COLLEGE OF HEALTH SCIENCES  
P O BOX 19676 Code 00202  
Telegrams: varsity  
(254-020) 2720300 Ext 40355

KNH/UON-ERC  
Email: [sonkh\\_erc@uonbi.ac.ke](mailto:sonkh_erc@uonbi.ac.ke)  
Website: [www.uonbi.ac.ke](http://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/126      Link: [www.uonbi.ac.ke/activities/KNH/UON](http://www.uonbi.ac.ke/activities/KNH/UON)

8<sup>th</sup> May 2014

Dr. Deogratias M. Katabalo  
Dep. of Pharmaceutics and Pharmacy Practice  
School of Pharmacy  
University of Nairobi

Dear Dr. Katabalo

**RESEARCH PROPOSAL: DETERMINANTS OF ADHERENCE TO ANTICONVULSANTS THERAPY AMONG OUTPATIENT EPILEPTIC CHILDREN AGED TWO TO TWELVE YEARS AT KENYATTA NATIONAL HOSPITAL (P65/02/2014)**

This is to inform you that the KNH/UON-Ethics & Research Committee (KNH/UON-ERC) has reviewed and **approved** your above proposal. The approval periods are 8<sup>th</sup> May 2014 to 7<sup>th</sup> May 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/KNH/UON](http://www.uonbi.ac.ke/activities/KNH/UON).

Protect to Discover.

Yours sincerely



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

- c.c.    The Chair, KNH/UoN-ERC  
         The Deputy Director CS, KNH  
         The Principal, College of Health Sciences, UoN  
         The Dean, School of Pharmacy, UoN  
         The Chairman, Dept. of Pharmaceutics & Pharmacy Practice, UoN  
         The Assistant Director, Health Information, KNH  
         Supervisors: Dr. Peter N. Karimi, Dr. Nasser Nyamweya

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