UNIVERSITY of RWANDA

ADHERENCE TO ANTIEPILEPTIC TREATMENT AND ITS PREDICTORS AMONG ADOLESCENTS WITH EPILEPSY AT NDERA NEURO-PSYCHIATRIC HOSPITAL, RWANDA.

Josephine NYINAWUMUNTU, MD

College of Medicineand Health Sciences

Schoolof Medicineand Pharmacy

MasterofMedicinein Pediatrics and Child Health

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By

Josephine NYINAWUMUNTU

Registration Number: 215014647

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In the College of Medicine and Health Sciences

Supervisor: Fidèle Dr SEBERA, MMED

Co-Supervisors: 1. Janvier Dr HITAYEZU, MMED

2. Archana Patel, MD, MPH

3. Innocent HAHIRWA, PhD

February 2019

DECLARATION

I declare that this Dissertation contains my own work except where specifically acknowledged

Dr Josephine Nyinawumuntu
215014647

Signed……
Date : February 2019

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DEDICATION

I dedicate this project report to Richard SIBOMANA,my husband and beloved, who provided moral support, and encouraged me to pursue my postgraduate studies. Without his support, I would never have written this project.

I also dedicate this project to my friends and colleagues who have been with me all along the way.

May God bless you all!

ABSTRACT

Background : Epilepsy is a neurological disorder that affect people of all ages especially children. It is with particular relevance in developing countries where an estimate of 85% of the World population with epilepsy live. The control seizures and prevention ofepilepsy burden require proper adherence to the prescribed medications and doses. This needs strong and regular information, education and communication provided to the patients with epilepsy.

Objectives: The present study sought to (1)assess the level of knowledge of adolescent on epilepsy treatment, (2) determine the level of adherence to antiepileptic drugs (AEDs), (3)determine barriers to adherence tomedications among adolescents with epilepsy and (4)determine caregivers and adolescents beliefsabout medication efficacy among adolescents with epilepsy.

Methods: A cross-sectional study was conductedat NDERA Neuropyschiatric Hospital over a period of two monthsfrom December 2018 through January 2019. Participants were epileptic patients aged 12 to 18 years. Assessment of adherence to antiepileptic drugs was done by self report using the Adolescent Epilepsy Medication Questionnaire (PEMSQ). The main outcome variable was medication adherence. The data were analsysed using SPSS version 21. The Chi-square test was computed to assess the association between adherence to AEDs and its predictors.

Results: A total of 110 adolescents with epilepsy were enrolled. Adherence to antiepileptic treatment was 91%. Knowledge of adolescent on epilepsy medication beliefs about medication efficacy, andbarriers to medication adherence show a strong association with adherence to AEDs (p-value <0.001).

Conclusion and recommandation:

A good knowlege about epilepsy and anti-epileptic drugs is associated with a good adherence to treatment among adolescents with epilepsy at Ndera hospital. Continuous education of patients and caregivers about AEDs to build the capacity of epilepsy self-management in the community is therefore recommended.

KEY WORDS

Epilepsy, adherence, adolescent, Rwanda

LIST OF SYMBOLS AND ACCRONYMS

AEDs - Antiepileptic Drugs

AESMQ-Adolescent Epilepsy Self-Management Questionnaire

CHUK– Centre Hospitalier Universitaire de Kigali

CHWs- Community Health Workers

CMHS-College of Medicine and Healthy sciences

CNS-Central nervous System

ED-Emergency department

EEG - Electroencephalogram

HIE-Hypoxic Ischemic Encephalopathy

IRB- Institutional Review Board

IVH-Intraventricular Hemorrhage

MEMS- medication event monitoring system

NGOs- Non-governmental organization(s)

RLAE- Rwandan League against Epilepsy

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CHAPTER I : INTRODUCTION

1.1.BACKGROUND

Epilepsy is a common neurological disease with high morbidity, increased mortality, and significant physical, psychological and social problems affecting approximately 50 million people worldwide. Nearly 85% of people afflicted with epilepsy live in developing countries. Two million new cases occur in the world each year (1). It is characterized by a tendency for recurrent seizures and clinically defined by two or more unprovoked seizures separated by 24 hours, or one unprovoked seizure and a clinical assessment determining that there is a significant risk (60% or more) for a second unprovoked seizure(1).People with epilepsy have a higher rate of suicide, anxiety, depression, sudden unexplained and accidental deaths. Prolonged seizures may cause physical injury, neuronal death leading to cognitive impairment, and can be fatal(2). Children are particularly vulnerable, which has been demonstrated in studies in sub-saharan Africa (3).

Rwanda is one of the developing countries and health system strengthening and preventive therapy are among its priorities. After successfully addressing and controlling many of the infectious diseases, Rwanda is now putting more focus on non-communicable diseases, including epilepsy(4). However, management of epilepsy is still a challenge. A survey done in 2008 in Rwanda revealed that 59.6% of patients with epilepsy did not receive treatment for their illness, for various reasons ranging from poor knowledge epilepsy to seeking traditional remedies (5).

Rwanda has only one neuropsychiatric referral hospital. It receives patient from different ages (infant, children and adult) with neurological and psychiatric problem from entire country . In 2016 Ndera Hospital annual report showed that consultations for epilepsy represented 70% of all consultations in outpatient clinic and among those with epilepsy 64, 98% were below 20 years-of-age. Around 52 % of all patients admitted for status epilepticus were also below 20 years-of-age(6).

The aim of antiepileptic drug (AED) therapy is to achieve acceptable seizure control .Adherence is generally defined as the extent to which patients' treatment-related behaviors like taking medication, following a diet, modifying habits, or attending clinics correspond to health professionals' advice (7).

The aetiology or risk factor for epilepsy depends on the age of the patient and the type of seizure.The most common acquired causes in young infants are perinatal hypoxia and trauma, metabolic disturbances, congenital malformations of the brain, and infection. In young children and adolescents globally, idiopathic epilepsies account for the majority of cases, although trauma and infection play a role. In developing countries, parasitic disorders such as cysticercosis and malaria may be important causal agents for epilepsy, and symptomatic epilepsy has been found more prevalent (8). Recent studies in both low- and middle-income countries have shown that up to 70% of children with epilepsy can be successfully treated (i.e. their seizures well controlled) with anti-epileptic drugs (AEDs) (9). For the treatment for this chronic disease to be successful, patients must be adherent to medications in order to achieve sustained therapeutic blood levels. However, rates of adherence to medication regimens among children with chronic diseases have been reported to be only 50% (9).

Achieving full adherence in adolescent patients requires not only the child's cooperation but also a devoted, persistent, and adherent parent or caregiver. And the involvement of family members, schools, and other social supports are valuable strategies for maximizing children's ability to adhere to medication regimens (9).Adherence to antiepileptic drugs in resource limited settings is difficult to assess. These settings are prone to frequent drug shortages and because of the poverty level in these settings, patients and/or caregivers may not always afford purchasing antiepileptic drugs as prescribed and unable to attend clinic visit appointment regularly (9).

A study done at Ndera neuropsychiatric Hospital in 2016 on epilepsy demonstrated that epilepsy in Rwanda is prominent in the younger population, but with good follow-up and support for obtaining medication, good seizure control can be achieved. This study showed that in the outpatient epilepsy visits, over 70% of patients who consulted for epilepsy were below 20 years-of-age. Above 90% of patients had insurance and among patients on treatment, above 80% were on monotherapy. Seizures control was achieved on above 60% of patient after 6 months of follow-up (10). Although the hospital has achieved significant milestone in epilepsy management, there is scarcity of information on how much caregivers, children and adolescent adhere to treatments available. The present study therefore envisages to

shed light on current level of adherence to epilepsy treatment among adolescent at Ndera Hospital.

1.2.PROBLEM STATEMENT

Patients with epilepsy constitutes more than 70% of all consultations seen in out patient clinic at CARAES Ndera neuropsychiatric referral hospital. Approximately 65% of those are young patients less than 20 years-of-age(6).A study done in 2016 at same hospital using file record showed that 32.2% of patients were lost to follow-up after 6 months (10). The current body of literature has suggested poor adherence in our region similar to other lower resource regions, but has not specifically looked at the pediatric age group, which has different considerations and potential intervention targets, to the best of our knowledge(11–13). Therefore,the present study is of need to assess the rate of antiepileptic medication adherence and its predictors among adolescent with epilepsy at CARAES Ndera neuropschiatric hospital in Rwanda. Patients with epilepsy was chosen because there is a scarcity of information regarding AEDs adherence in children. In addition, the research wants to highlight barriers to AEDs adherence in young age as impaired adherence may lead to dropout or lost to follow up while epilepsy requires continuous follow up to avoid recurrent seizures.

1.3.AIM

To understand antiepileptic drug adherence and self-managemet of epilepsy in adolescent patients.

1.4.RESEARCH OBJECTIVES

- To assess the level of knowledge of adolescent on epilepsy treatment
- To determine the level of adherence to antiepilepticmedications among adolescents.
- To determine barriers to medication adherence among adolescents with epilepsy.
- To determine caregivers and adolescents beliefs about medication efficacy among adolescents with epilepsy.

1.5.RESEARCH QUESTIONS

- At which level caregivers of adolesecent or adolescents with epilepsy are knowledgeable about epilepsy treatment and what do they expect?
- What is the level of adherence to antiepileptic treatment in adolescent patients with epilepsy followed-up in the outpatient clinic ?
- Which barriers are associated with the levels of medication adherence among adolescents with epilepsy

1.6.CONCEPTUAL FRAMEWORK

The present study is based on the proposed new model of epilepsy care that best describes the process on which epilepsy care should be done(14).

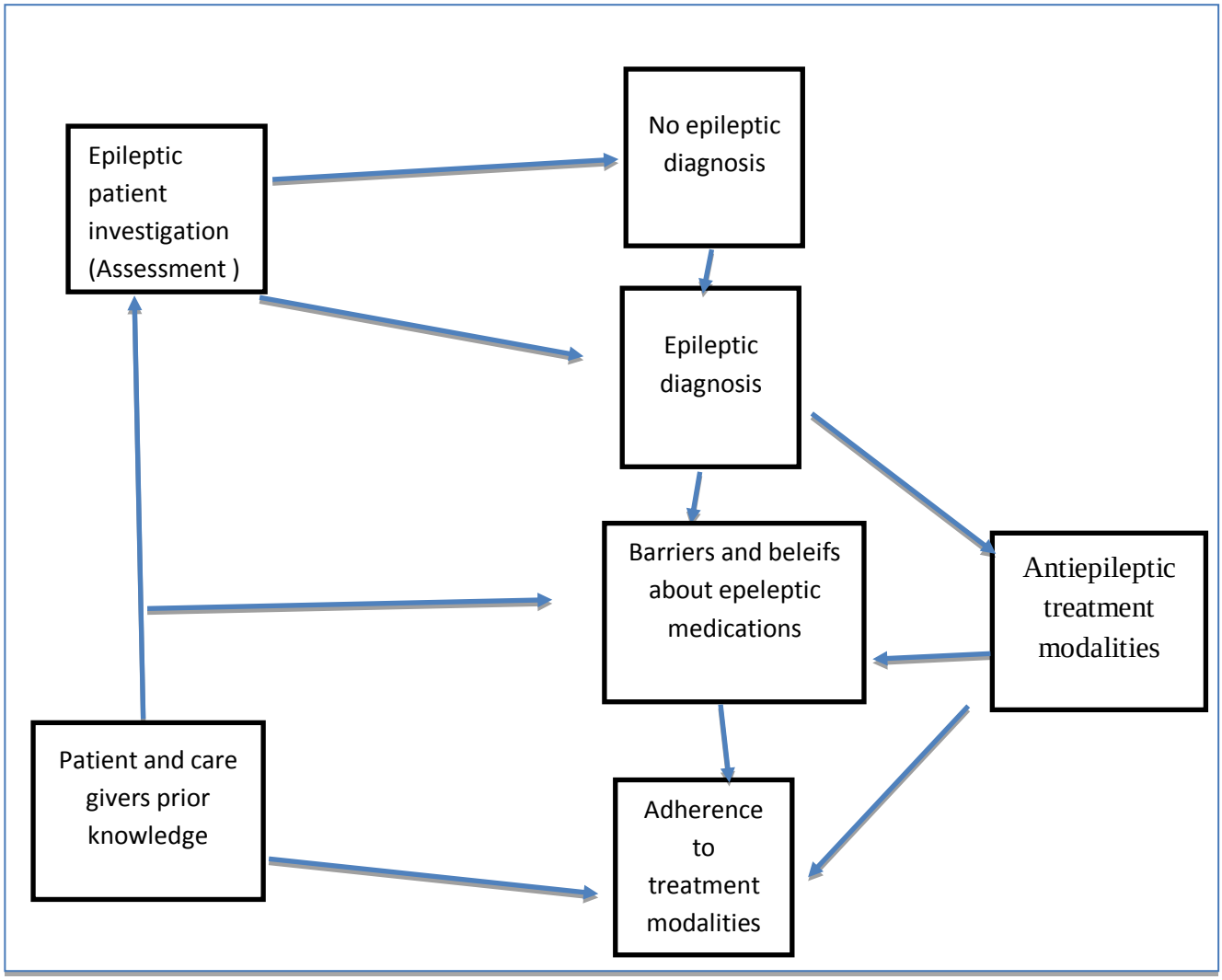

Figure 1Conceptual model for epilepsy care adapted from the Framework for Technological Therapies(14)**.**

The present conceptual framework summarizes logical sequences of epileptic patients management process or the response of their care givers on the disease to the level of seeking medical attention and finally have a comfirmed diagnosis which leds to treatment prescriptions by medical personnel. The role of epileptic patients in treatment process as well as their caregivers can lead to poor or good adherence to treatment.

CHAPTER II: LITERATURE REVIEW

2.1.Introduction

The present chapter summarises the main points reviewed in the literature. It includes general overview of drug adherence, knowledge of caregivers and children on management of epilepsy, expectation of epileptic patients and their caregivers on treatment, adherence to medication and factors associated with adherence with medication among children in different settings, and finally the medication adherence questionnaires.

2.2.Overview of drug adherence

Adherence to medication regimen or compliance is generally defined as the extent to which patients take medications as prescribed by their health care providers(15). The word adherence is preferered against compliance because the latter implies simply that the patient is not following the doctors orders. Adherence is in addition expressed in terms of prescribed doses of medication taken by a patient in a specified time frame. The rates of adherence of medication are higher among patients with acute conditions compared to patients with chronic conditions whereby it rapidly decreases in the six month of the therapy(16).Research on adherence in clinical trials show that the average rates of adherence can be high, owing to the attention study patients receive and to selection of the patients, yet even clinical trials report average adherence rates of only 43 to 78 percent among patients receiving treatment for chronic conditions (16) .

2.3.Methods to measure medication adherence

The methods to measure medication adherence were adopted from existing literature (17). The existing methods include direct and indirect methods, whereby direct method is mainly physiologic where the level of drug absorption in blood or urine is measured together with biological markers. The indirect method on the other hand use questionnaire, patients self reports,pill counts, rates of prescription refills, assessment of patient's clinical response, electronic medication monitors, measurement of physiologic markers, as well as patient diaries. It is further mentioned that among the two methos, none is considered to be the best. (17). However, the use of patients self reports is the simplest. The use of questionning the patient, patient

diaries and assessment of clinical response are all methods that are relatively easy to use, these methods are prone to overestimation of the adherence(18).

The adherence in the present study was based on the definition used in the tool whereby the adherence scale will be used to assess the rate of adherence. The scale is an-eight-items tool of 5 Likert scale from strongly disagree to strongly agree. The sum of all scores of the 8 items will result into a composite score that range from 8–40. The higher scores (>25) represent adhered while the score (<25) represent non adhered(19).

2.4.Drug adherence and barriers to adherence in pediatric and adolescent patients with epilepsy

There have been several attempts to study antiepileptic drug adherence and clinic visit compliance in different parts of the world including developing countries. Many methods have been used, including reviewing pharmacy records, direct pill counting, self-reporting, using electronic pill dispenser monitoring, following serum drug levels, etc; however, none of these have been fully sensitive in accurately assessing adherence. Self-reporting has been used as a fairly reliable method as well, particularly in developing countries. Many studies use a combination of methods (7,13,20–25).

In Uganda, a study on antiepileptic drug adherence among children between 6 months to 16 years using self-report and serum drug levels of the antiepileptic drugs showed that adherence to antiepileptic drugs by self-report was 79.5% and 22.1% by drug levels. The majority of the children (95/122), in both adherent and no-adherent groups by self-report had inadequate drug doses. Children were found to be more non-adherent if the caregiver had an occupation (21). A study conducted on determinant to noncompliance to clinic appointment and medications among pediatric patients with epilepsy with different age between 0 -18 years, compliance to clinic attendance was assessed by checking case record and regurality of clinical attendance in the preceding six months, medication compliance was assessed using pill count and pharmacy record of drugs supplied.It has showed that noncompliance to clinic appointment and medication was 23% and 15.3%, respectively. The major reasons given were lack of finance, clashing with school time, and forgetting to take the

drugs. Children whose mothers were less educated and unemployed were more likely to miss clinic appointments (22).

In Ethiopia, a study done on Cause of default from follow up in patient with epilepsy using clinic records has showed that the main reason given for default, in 44% of the patients, was difficulty in travelling to the health center. 12% claimed that they preferred traditional remedies and 9% felt that they had not been improved by medical treatment (24).

2.5.Adolescent adherence to medication

Adherence to medication among adolecsents as for the other population with epilespy, has a considerable role in control of seizures and prevention of morbidity and mortality.

A recent retrospective study conducted in Germany on adherence to medication in children and adolescents, revealed that overall 68% adhered to the drugs. The authors of the same study further confirmed that some factors including those like age, place of residence and comorbidities are strongly associated with adhrence. Smith et al. in their longitudinal study on adherence to antiepileptic drugs in adolescents with epilepsy concluded that higher socioeconomic status predicts higher adherence (24).

Another study on adherence to medication among outpatient adolescents with epilepsy concluded that 61.7% of the patients were adheringto their medications according to their self or parental reports. This study highlighted a number of factors that affect medication adherence. Those factors include age of mother, family number, number of administered drugs, family support, seizure frequency and the relationship between patients and their healthcare providers(26). The researchers ultimately concluded that adolescents need frequent support, encouragement, and positive feedback in order to improve their adherence to medications(26–28).

2.6.Drug adherence questionnaires

The literature reports diverse self-filled questionnaires which measure drug adherence in different populations. The available tools were developed to measure either patient's subjective experience of treatment with antipsychotic drugs and are mainly quantitative.

The questionnaire, AESMQ (see appendix 2) , was selected to be used in the present study to measure adherence of adolescent between 12-to-18 years who are followed at the Ndera Neuro-psychiatric hospital, due to the fact that it captures aspects of self-management that are relevant to the adolescent epilepsy population. It is also a recently available tool compared to the old versions that are intended to measure drug adherence in different populations. The tool was used and validated in Cincinnati Children's Hospital Medical Center in the United States of America and was recommended to be used in different population(19). The presented tool was used in the adolesecents to measure adherence to antiepileptic drugs in 12-to-17-years outpatient Pediatric Neurology Clinic at the University of Michigan Health System, USA(29). The adolescent version is used for the purpose of the present study to meet the objectives.

CHAPTER III. METHODOLOGY

4.1. Study design, site, period and population

This was a cross-sectional study assesing medication adherence among epileptic adolescents. The study was conducted at CARAES Ndera, a neuropsychiatric referral Hospital for patients with neurological and psychiatric disorders in Rwanda. It receives between eighty and a hundred patients/day of which around fifty to seventy patients have epilepsy. The hospital has only two neurologists who work with the General practitioners for the management of patients who attend the hospital OPD clinic.The study data collection was done over a period of two months starting from December 2018 to January 2019. This study targeted adolescent aged from 12 to 18 years of age with confirmed epilepsy and on AEDs for at least six months, who come for consultation in OPD clinic of neuropsychiatric Ndera Hospital.

4.2. Inclusion criteria

Adolescents diagnosed with epilepsy, on AEDs for at least six months, aged 12 -18 years, attending CARAES Ndera hospital OPD clinic for consultation, and consent for participation.

4.3. Exclusion criteria

Children with significant developmental disorder(s) like down syndrome, cerebral palsy, intellectual disability, or comorbid chronic illnesses that requires daily medication like diabetes were excluded.

4.4. Sample size calculation

Our primary outcome is adherence to AEDs. Sample size for determining the frequency of a factor in a population was calculated using Kelsey formula (appendix 3).

4.5. Sampling

Participants were selected conveniently to meet the inclusion criteria. Every adolescent who meet the selection criteria was included in the study.

4.5. Data collection tool and procudure

Data were collected using the Adolescent Epilepsy Medication Questionnaire, adapted from an original tool for Pediatric Epilepsy medication Self-management (PEMSQ) (19,29). This tool was developed from an original tool of Pediatric Epilepsy mediacation Self-management (PEMSQ), this was developped to be used in self-management measure validated for caregivers of children with epilepsy, with clinical and research utility, and was validated to be used in adolescent to mesure adherence. The tool has 27-item measure consisting of four scales: Epilepsy and treatment knowledge and expectations (8 items), adherence to medications and clinic appointments (8 items), barriers to Medication Adherence (8 items), and beliefs about medication efficacy (3 items). These four scales make up a total self-Management score.

The questionnaire was translated in Kinyarwanda (the language of participants) by a professional English translator, knowledgeable in both languages and the principle investigator cross-cheked the translated version before approval. A back translation was also done to ensure linguistic equivalence.

The questionnaire was piloted to 10 participants before the actual study in order to ensure comprehension of questions, and confirm time spent for completion of a questionnmaire was within anticipated time frame. Necessary review and amendments weredone based on the piloting feedback. People who participated in pilot were not allowed to participate in the main study to avoid recall bias.

Prior to the data collection the Principle Investigator (PI) trained data collectors. During the data collection period, the data collector identified the names of the patients who meet the inclusion criteria in the patient data files available at the Hospital. The data collectors then matched the patient's names from files with scheduled clinic visit to identify the participants. They worked with the health provider from a consultation room to request the adolescent with epilepsy and the accompaining care giver to meet the researcher in a separate room after consultation. The researcher/data collector received one participant after another, explained to him/her about the study details and ask for participation. Those who accepted to participate were requested to sign a written consent. The researcher read the questionnaire to the participants not able to read and then filled in their response.

Participants who were able to read were given questionnaires and completed them on their own.

After completing the questionnaire and handing in to the researcher/data collector, the participants were given time to ask about any clarifications. Completed questionnaires were checked to see whether all questions have been answered and then kept in a box in the researcher's office until the end of data collection. The data were entered by 2 data entry clerks into SPSS 21, cleaned and coded for analysis.

4.6. Measures

The dependent/outcome variable for this study was the patient adherence to AEDs. The independent variables were knowledge, beliefs about medication efficacy and barriers to treatment.

Chi-square test was used to assess the associations between the adherence to medication and its predictors.

Level of knowledge was assessed using a likert scale of 8 items which has five levels from strongly disagree to strongly agree. A composite score to assess the level of knowledge was developed. The sum of all scores of the 8 items resulted into a composite score that range from 8–40. The higher scores (>25) represent better knowledge while the lower scores (<25) represent poor knowledge.

The adherence scale was used to assess the rate of adherence. A likert scale of 8 items which has five levels from strongly disagree to strongly agree. The sum of all scores of the 8 items resulted into a composite score that range from 8–40. The higher scores (>25) represented adherence while the lower score (<25) represented non adherence.

The barriers to medication adherence scale was used to assess adolescents' perceptions of things make difficult for them to take medications as prescribed. The scale scores range from 8-40.

The Beliefs about Medication Efficacy scale was used to assess adolescents/caregivers' perceptions of how well they believe the medication will work to treat seizures. The scale scores range from 3–15 for the beliefs about

medication. The scores >9 represented good beliefs and the lower score represented poor beliefs on medication efficacy.

4.7. Data analysis

Descriptive statistics with frequency and percentages were used to summarize the sociodemographic data. Cross-tabulations with Chi-square test was used to assess the association between knowledge, barriers to treatment and beliefs about medication efficacy and adherence to AEDs . A significance level of 0.05 at 95% confidence interval was considered.

4.8. Ethical consideration

The present study was approved by theUR-CMHS Institutional Review Board (IRB) [Approval notice: No 357/CMHS IRB/2018].Permission from CARAES Ndera Hospital administration was also obtained before the actual study. Participants signed consent before the data collection and participation was voluntary. Participants were informed on their right to withdraw in the study at any time. There were no incentives to participate in this study. Neither risk to subjects nor social risks were involved in the present study.

CHAPTER IV. RESULTS

This chapter reports the results of the present study in relation to the objectives. It starts by socio-demographic characteristics of the participants, the level of knowledge of adolescents on epilepsy follows, the rate of adherence to medication, barriers to medication adherence and finally adolescent beliefs about medication efficacy.

4.1. Socio-demographic characteristics of participants

A total of 110 participants were retained for analysis after exclusion of two enrolled individuals who were not meeting the inclusion criteria.

The median age was 16 (range 12-18 years old, SD 1.68) with and 57% of participants being male and females, 43%. The majority of the adolescents with epilepsy are from Kigali City with a percentage of 45%. The province with the lowest number is North and the Western provinces with similar proportions of 5% as shown in table1.The findings from the present study show that the responsibility for medication follow up was taken by the mothers and fathers or both in the proportion of 53.6%, 16% and 11.8% respectively. The children who attained primary school were 39.2% and 35.3% reached the secondary. Few children (12.7%) have initiated the primary school but did not complete the cycle. The child reported school performance place them 41.7% into middle class. Moreover, good class represents 30%.The socioeconomic classes show that families with epileptic child show that a big proportion (57.3%) of participants was into the 3rd class. Over 26 % were into the 2nd social class. Children with epilepsy were generally the first and the second born with similar proportion of 27.8%.

Table1. Socio-demographic characteristics

Variable		N (%) or median	Mean (SD)/ Min-Max
Age		16	16 (1.68) /12-18
Sex	**Male**	60 (57)	
	Female	46 (43)	
Parents status *(N=106)*	Alive	93(87.7)	
	Died	13(12.3)	
Medication follow up *(N=110)*	Mother	59(53.6)	
	Father	18(16.4)	
	Myself	9(8.2)	
	Someone else	11(10)	
	Both Mother and father	13(11.8)	
Child education *(N=102)*	None	13(12.7)	
	Not completed Primary education	13(12.7)	
	Primary School	40(39.2)	
	Secondary School	36(35.3)	
School performance *(N=96)*	Good (Among the best 10)	29(30.2)	
	Average (Middle position)	40(41.7)	
	Poor (Among the last 10)	27(28.1)	
Parents employment *(N=107)*	Yes	32(29.9)	
	No	75(70.1)	
Parents education *(N=106)*	None	17(16)	
	Primary School Level	40(37.7)	
	Secondary School level	29(27.4)	
	University level	20(18.9)	
Social classes (Ubudehe) *(N=110)*	Level 1	15(13.6)	
	Level 2	29(26.4)	
	Level 3	63(57.3)	
	Level 4	3(2.7)	
Child rank *(N=108)*	First child	31(28.7)	
	Seconf child	31(28.7)	
	Third Child	18(16.7)	
	Fourht child	11(10.2)	
	Fifth child	13(12)	
	Above fifth	4(3.7)	
Next of kin *(N=108)*	Father	31(28)	
	Mother	52(47)	
	Both parents	11(10)	
	Grand mother	3(3)	
	Step mother	1(1)	
	Cousin	1(1)	
	Brother	1(1)	
	Aunt	2(2)	

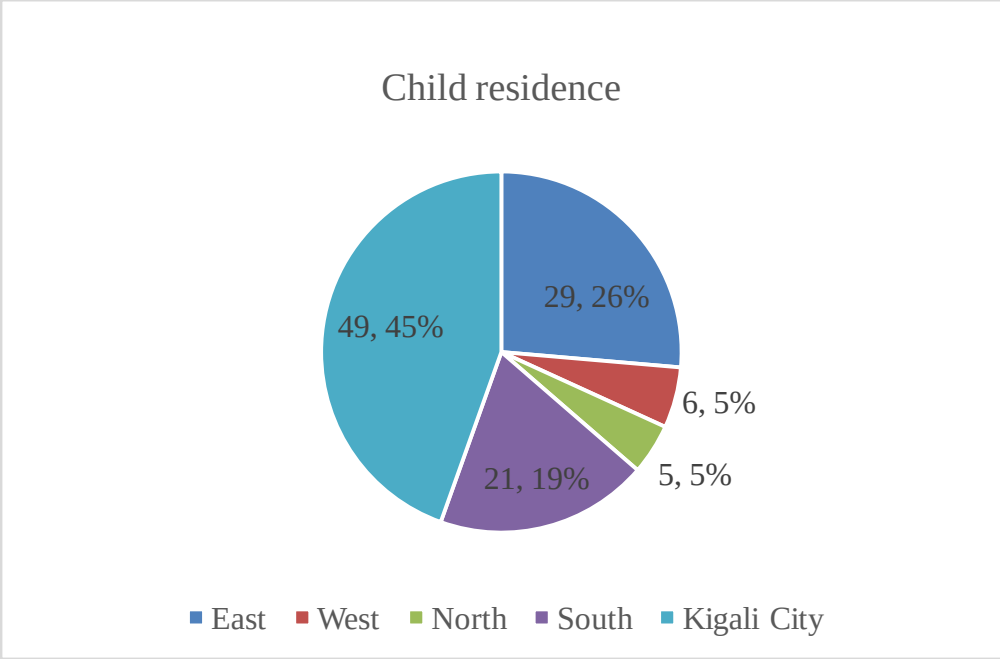

Figure 2. Distribution of participants according to the province

4.2. Epilepsy and its management

The study findings in table 3 reveal that 81(79.4%) had no previous known history of epilepsy in their families. Quite a big number 68 (64.6%) of participants experienced generalized convulsions. Over 90% of the respondents were able to access drugs. Valproic acid was the most common monotherapy used in 34.3% of all participants. In a slightly higher proportion of participants (36.2%), a combination of drugs was being used.Up to 40% of participants also tried traditional medicine.

The main side effects reported by the patients due to the antiepileptic drugs were as follow: bad smelling of the body (Kunuka igikara), dizziness, weight gain, drowsiness, adominal pain, loss of appetite, prolonged sleep, amenorrhea, constipation, gum swelling, bad behavior, skin rash, weakness, feeling dumb, to forget, headache, aggravated symptoms.

Tableau 2. Epilepsy and its management

Variables		N	%
Family history of epilepsy (N=102)	None	81	79
	One person	9	8.8
	Two persons or more	1	1
	Don't know	11	11
Type of convulsions *(N=96)*	Generalize	62	65
	Focal	21	22
	Mixed	13	14
Access to drugs *(N=88)*	Yes	80	91
	No	8	9.1
Types of antiepileptic drugs *(N=105)*	Carbamazapine/Carbatrol	13	12
	Valproic acid	36	34
	Levetiracetam(Keppra)	8	7.6
	Phenytoin	3	2.9
	Phenobarbital	1	1
	Others	6	5.7
	More than 2 drugs	38	36
Counceling (N=99)	Yes	72	72
	No	21	21
	Don't know	6	6
Use of traditional medicine *(N=110)*	Yes	44	40
	No	66	60
EEG *(N=94)*	Yes	83	88
	No	11	12
Side effects on your AEDs*(N=89)*	Yes	27	30
	No	62	70

4.3. Level of knowledge, rate of adherence, barriers and adolescent beliefs about medication efficacy

The results on the level of adolescent knowledge on epilepsy and its treatment revealed that 90(82%) of participants scored more than 25 scores on knowledge scale. There was a relative high adherence to AEDs where 100(91%) of all participants folllowed prescribed doses. The baririers to medication accesss were found to be many in 91% of the participants. Beliefs on medication efficacy was reported as poor among 69 % of the study population.

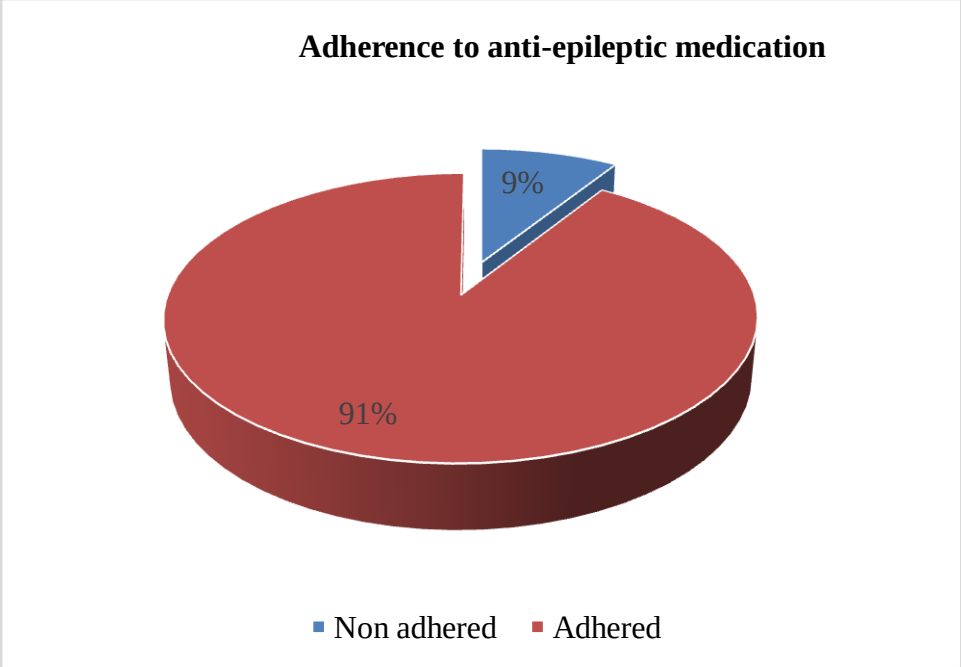

Figure 3.Reported adherence to antiepileptic drugs

Theadherence to medication is high where 100(91%) of all participants folllowed prescribed doses.

Tableau 3.Level of knowledge, barriers and adolescent beliefs about medication efficacy

Variables (N=110)		**N**	**%**
Level of knowledge	Poor Knowledge	20	18
	Better Knowledge	90	82
Barriers to treatment	Few barriers	100	9
	Many barriers	10	91
Beliefs about medication efficacy	Good beliefs	34	31
	Poor beliefs	76	69

4.3. Association of status of adherence with clinical variables

The results in table 5 indicate that adherence to treatment was associated with presence of cormorbidities with epilepsy.

Tableau 4.Association between adherence, socio-demographic and clinical variables

Variables		Adherence to treatment			
		Non adhered	Adhered	Total	P-Value
Type of convulsions	Generalize	7(70%)	55(63.9%)	62(64.6%)	
	Focal	1(10%)	20(23.3%)	21(21.9%)	
	Mixed	2(20.0%)	11(12.8%)	13(13.5%)	0.573
	Total	10(100.0%)	86(100.0%)	96(100.0%)	
Presence of cormorbidities	Yes	0(0.0%)	9(11.5%)	9(10.5%)	
	No	7(87.5%)	69(88.5%)	76(88.4%)	0.005
	Total	7(100.0%)	78(100.0%)	86(100.0%)	
Ubudehe catecory	Level 1	1(10.0%)	14(14.0%)	15(13.6%)	
	Level 2	2(20.0%)	27(27.0%)	29(26.4%)	0.829
	Level 3	7(70.0%)	56(56.0%)	63(57.3%)	
	Level 4	0(0.0%)	3(3.0%)	3(2.7%)	
	Total	10(100.0%)	100(100.0%)	110(100.0%)	
Child education	None	1(10.0%)	12(13.0%)	13(12.7%)	
	Not complited primary school	2(20.0%)	11(12.0%)	13(12.7%)	
	Primary School	4(40.0%)	36(39.1%)	40(39.2%)	0.893
	Secondary School	3(30.0%)	33(35.9%)	36(35.3%)	
	Total	10(100.0%)	92(100.0%)	102(100.0%)	
Parents of education	None	2(22.2%)	15(15.5%)	17(16.0%)	
	Primary School Level	4(44.4%)	36(37.1%)	40(37.7%)	
	Secondary School level	2(22.2%)	27(27.8%)	29(27.4%)	0.859
	University level	1(11.1%)	19(19.6%)	20(18.9%)	
	Total	9(100.0%)	97(100.0%)	106(100.0%)	
Health insurance	Yes	9(100.0%)	92(92.9%)	101(93.5%)	
	No	0(0.0%)	7(7.1%)	7(6.5%)	0.409
	Total	9(100.0%)	99(100.0%)	108(100.0%)	
History of epilepsy in family	None	8(88.9%)	73(78.5%)	81(79.4%)	
	One person	0(0.0%)	9(9.7%)	9(8.8%)	
	Two persons or more	0(0.0%)	1(1.1%)	1(1.0%)	0.782
	Don’t know	1(11.1%)	10(10.8%)	11(10.8%)	
	Total	9(100.0%)	93(100.0%)	102(100.0%)	

4.4. Association between knowledge, barriers, beleifs and adherence

The results on association between knowledge, barriers, beleifs and adherence have cleary indicated that there was a strong association between knowledge and adherence, the higher the knowledge, the higher the adherence (X^2 =12.931, P=0.000).Perceived barriers to medication access werelow and also showed a strong association with adherence (X^2=110, P<0.001).In adition, adherence was reported to be associated with beleifs of the participants on medication efficacy (X^2 =12.413, P<0.001). (Refer to Table 5)

Tableau 5. Relationship between adherence, knowledge, barriers and beleifs

		Adherence to treatment				
Variables		**Non adhered**	**Adhered**	**Total**	**Chi-square**	**P-Value**
Knowledge	Poor Knowledge	6(30%)	14(70%)	20(100%)	12.931	0.000
	Better Knowledge	4(4%)	86(96%)	90(100%)		
	Total	10(9%)	100(91%)	110(100%)		
Barriers	Few barriers	10(100%)	0(0%)	10(100%)	110	0.000
	Many barriers	0(0%)	100(100%)	100(100%)		
	Total	10(9%)	100(91%)	110(100%)		
Beleifs	Good beliefs	8(24%)	26(77%)	34(100%)	12.413	0.000
	Poor beliefs	2(3%)	74(97%)	76(100%)		
	Total	10(9%)	100(91%)	110(100%)		

4.5. Reported barriers to treatment

Multiple barriers and reasons for poor adherence were reported by participants, ranging from lack of insurance, being at boarding school, traveling and forgetting medication, being unable to access due to holidays of medical staff, lack of money, poor health, lack of food to take medication with, being away from home, and simply forgetting to take the medication.

CHAPTER V. DISCUSSION

The aim of the present study was to understand antiepileptic drug adherence and self-management of epilepsy in adolescent patients who seek care at Ndera Neuropsychiatric Referral Hospital.

The results of our study have showna high level of knowledge among the study participants, with an average of 82% on epilepsy knowledge scale. This corresponds with the above 90% adherence rates found at our center, consistent with the literature which states that better knowledge on the condition and its treatment is likely to influence a good adherence on treatment(30).

Our study confirms that adherence of epilepsy medications in this age group tends to be relatively good in the setting of good knowledge. This has been seen in previous studies in a variety of countries, including Uganda where the level of adherence to antiepileptic drugs by self report was 79.5% (21) in one study, other studies in Germany on adherence to medication in children and adolescents with epilepsyrevealed a 68% adherence rate (26–28). Moeover, another study on assessment of patients' adherence to antiepileptic medications at Dessie Referral Hospital found quite similar result and concluded that the majority of patients with epilepsywere adherent to their AED treatment. The same study further highlighted that the level of education and the side effect of drugs were the potential determinants of adherence and the association was statistically significant (31).

The findings of the present study suggest that good adherence to AEDs was high and this can be attributed to the fact that over 75% of the study particiants have at least completed primary education and more than 50% of participants' family are in moderate socioeconomic status (57.3%). Although good adherence within this age group may be suggested by the literature, it is often thought in our setting that adherence to antiepileptic medications would be poor, particularly due to lack of understanding of the condition and medications.At the study setting, 72% of participants responded to have had counselling sessions on the use of AEDs, which was likely a key contributor to good adherence rates. Counselling and community health education by our local community health workers would jointly influence good adherence to AEDs.

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In addition, we found minimal barriers to obtaining and taking medications. This is most likely due to the sociodemographis of the population studied. The majority of patients were from Kigali city, where medications were accessible. Studies looking at more rural regions of the country are required to see if geographic distribution would have an impact on adherence given the variation of antiepileptic medication availability outside of Kigali city.

Interestingly, we found a moderately high rate of poor belief in the medication efficacy despite the good adherence. Although belief and adherence correlated to a minor degree, it was minimal and less than would be expected. It also seems to suggest that despite reported good epilepsy knowledge as per our assessments, and the counseling done at our center, understanding of the medications remained minimal. This is of crucial importance to understand further as compliance in the adolescent age range is often still dependent- as seen in our study- upon parental influence. However, as these children reach adulthood, compliance may decline if there is no belief or understanding of the medications being used.

Study strengths and limitations of the study

Our study was strong in recruitment and to evaluate the question of reported adherence in our setting, which has only been done in limited studies to date. However, we did face some limitations. The main limitation is that the results of this study are based on reported adherence only. Obtaining medication serum levels would demonstrate an objective measure of adherence and would be a more conclusive study design. Although we took all measures possible to minimize bias, it remains possible that reporting by participants was inaccurate due to a desire to not be truthful about noncompliance with a clinician who was administering the survey. It remains difficult, therefore, to fully assess these high rates of compliance in conjunction with the relatively high rates of reported poor seizure control we still see in our setting. The latter is also difficult to assess, as there is no child neurologist currently in our country. Therefore, the diagnosis and management of epilepsy is by necessity, made by a nonspecialist.

CHAPTER VI. CONCLUSION AND RECOMMENDATIONS

Overall, this study is the first step to reviewing the large burden of epilepsy in our setting, particularly in the pediatric population. Understanding adherence and the variables contributing to this, is essential for good epilepsy management. Our study shows, as prior ones have done before, that counseling in this condition remains an essential component to care.

The following recommendation can serve as a guide for improvement as far as epilepsy management is concerned:

- Decentralization of epilepsy as a medical disease and reinforce patients education on efficacity of the antiepileptic drugs to improve on their beliefs about medication efficacy.
- Future research should be directed to qualitative studies and identify factors associated with poor adherence and some related negative belief(s) to medication efficacy.

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APPENDICES

APPENDIX 1. SEARCH TERMS

Table 1: Search terms (MeSH terms in italics)

	(Epilepsy OR Epilepsy seizure OR Convulsions OR Seizures* OR epileptic)*
AND	*(Anti-epileptic drugs OR antiepileptic OR anticonvulsant medications OR Anticonvulsants OR anticonvulsive OR Drug therapy OR medication OR Pharmaceutical Preparations OR therapy*)
AND	*(Drug adherence OR medication adherence OR adherence OR compliance OR medication compliance OR nonadherence OR noncompliance OR non-adherence OR non-compliance)*
AND	*(Infant OR child OR children OR adolescent OR children OR child, preschool OR pediatrics OR pediatric OR paediatric*)*
AND	
NOT	*(ketogenic OR genetic OR syndrome OR electrical)*
AND	*(Poor resources setting OR poor country OR countries OR Developing Countries OR developing country OR Poverty OR resource poor country OR low income country OR low-income country OR resource-poor country OR Africa)*
Search date:	07th September 2017 and 19th January 2018 and 14th August 2018

APPENDIX 2 SAMPLE SIZE CALICULATION FORMULA

$$\boldsymbol{n} = \mathbf{deff} \times \frac{\mathbf{N}\hat{\mathbf{p}}\hat{\mathbf{q}}}{\frac{\mathbf{d}^2}{\mathbf{1.96}^2}(\mathbf{N}-\mathbf{1}) + \hat{\mathbf{p}}\hat{\mathbf{q}}}$$

Where:

n = sample size = 112

deff = design effect = 1.0

N = population size = 200 for children with epilepsy (<18-years-of-age) seen per month in clinic

$\hat{p}$ =the estimated proportion = 79.5 based on the Ugandan self-reporting adherence (21)

$\hat{q}$ = 1- $\hat{p}$

d = desired absolute precision or absolute level of precision = 95% confidence interval

A total sample of 112 children and adolescent with epilepsy who fulfill the inclusive criteria was enough for our study.

APPENDIX 3. DATA COLLECTION FORM-ENGLISH

"Adherence to antiepileptic treatment and its predictors among adolescent with epilepsy at Ndera Neuro-Psychiatric Hospital, Rwanda"

Study No ……..... Clinic No ……../……

Date ……/……/……

I.PATIENT DEMOGRAPHICS

1. **Age**: …….Years ……..Months 2. Sex □ Male □ Female
   Weight……. Height……
2. **Address**:
   Sector……District……..Province……
   ……
3. **Next of kin**……Relationship……
4. Tel No……
5. **Are the child's parents still alive?** ☐ Yes ☐ No
   If no, who died? ☐ Father ☐ Mother ☐ Both
6. **Who is the main person responsible for making sure you take your drugs and get** you prescription refills? ☐ My mother ☐ My father ☐ Myself ☐ Someone else……
7. **What is your highest level of education?**
   - ☐ None
   - ☐ Started primary school but not completed or literacy classes only
   - ☐ Primary School
   - ☐ Secondary School
   - ☐ University level

   How is your school performance?
   - ☐ 1. Good (Among the best 10)

☐ 2. Average (Middle position)

☐ 3. Poor (Among the last 10)

8. **What is the highest level of education that your parent has completed?**

☐None

☐ Primary School Level

☐ Secondary School level

☐ University level

9. **Does your father or mother (or adult caregiver) currently have paid employment?**☐ Yes ☐No

If yes, who? ☐Father ☐Mother ☐ Both ☐None

10. **Which level of Ubudehe do you have?** ☐ Level 1 ☐ level 2 ☐ level 3 ☐ level 4

11. **How many children in your family?**.....

12. **What is your rank in the family?**☐First child ☐2nd child ☐5^{th} child ☐3rd child ☐4th child ☐above 5^{th} rank ☐don't know

13. **Do you have a health insurance?**☐ Yes ☐No

If yes, which type of insurance?.....

14. **Who else in your family members have Epilepsy?**☐ None ☐1person ☐ 2 persons or more ☐Don't know

15. **Do you have any other chronic disease/comorbidity or handicap other than epilepsy?**

If yes, specify the condition……

EPILEPSY AND DRUG-RELATED QUESTIONS

1. **When does the convulsion started?** ……Years …..Months…..Days
2. **What type of convulsions does the child have (from care givers description or from file record)?**

   ☐ Generalize

   ☐Focal

   ☐ Mixed
3. **How long has the child been on antiepileptic drugs?(in year) .....**
4. **Where do you get your drugs from?**

   ☐Ndera Hospital pharmacy ☐District hospital pharmacy ☐Private clinic ☐Other, Specify……

   Are you always able to get your drugs? ☐Yes ☐No
5. **What anti-epileptic drug(s) is the child taking?** (**Check all that apply) including the dose and how long started (**Eg : Dose: Depakine tab 200mg twice a day since May 2106)

   ☐Carbamazapine/Carbatrol:…….....

   ☐Valproic acid :……

   ☐Levetiracetam(Keppra) :……...

   ☐Phenytoin:……..

   ☐Phenobarbital:……...

   ☐Lamotrigine :……

   ☐Diazepam:……....
6. **Have you ever used traditional treatments for your child's convulsions**

   ☐ Yes ☐No
7. **Was the EEG done to this patient before starting the treatment?**

   ☐ Yes ☐No

If yes, what are the result? ☐Normal ☐Abormal

8. **Have you ever developped side effects on your AEDs**

   If yes Which one?.....

9. **Was the counselling done to you or your caretaker about the epilepsy and AEDs?**☐ Yes ☐No ☐ Don't know

10. **Who counselled you or your caregiver ?**

☐None ☐Doctor ☐Counsellor ☐Other, Specify……

11. **Have you ever missed a dose of Anti-epileptic medications?**
    ☐Yes ☐No

    If yes ,how many have you missed in the last one week? .....

    What was the reason for missing doses?.....

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

Adolescent Epilepsy Self-Management Questionnaire

DIRECTIONS:*The following survey asks questions regarding your experience with epilepsy management, including your expectations about treatment, your beliefs about medications, and what makes it difficult to take medications.* Please complete the following items on a scale of 1 (Strongly Disagree) to 5(Strongly Agree) for Questions 1-25 and on a scale of 1(to 5(Always) for Questions 19-27 by placing an X in the box that best describes you. REMEMBER: There is no right or wrong answer

	1 Strongly Disagree	**2 Disagree**	**3 Neither Agree Nor Disagree**	**4 Agree**	**5 Strongly Agree**
Disease and Treatment Knowledge and Expectations					
1. The doctors explained my diagnosis of epilepsy.					
2. I understand what side effects to look for while I am in treatment.					
3. I know who to contact with questions or problems.					
4. I am sure that I can manage any side effects with the help of my doctor.					
5. I am sure that I can attain seizure freedom.					
6. I understand the risks of stopping my medicine before I have been seizure free for 2 years.					
7. My health care team listens to my concerns.					
8. My doctors and nurses are easy to contact and quickly answer questions.					
Adherence to Medications and Clinic Appointments					
9. I take my medicine as prescribed.					
10. I have someone to take me to my appointments.					

11. I usually follow the medical advice and treatment plans prescribed to me.					
	1 Strongly Disagree	**2 Disagree**	**3 Neither Agree Nor Disagree**	**4 Agree**	**5 Strongly Agree**
12. I feel it is important for me to get my treatment as directed.					
13. It is not hard to come in for follow-up appointments.					
14. Everyone in my family agrees with my treatment plan.					
15. I take my medicine most of the time.					
16. It is important to take my medicine every day.					
Beliefs about Medication Efficacy					
17. I need medicine for my seizures.					
18. The medicine I take now will stop my seizures.					
19. The medicines are easy to fit into my daily schedule.					
	1 Never	**2 Seldom**	**3 Sometimes**	**4 Often**	**5 Always**
Other things, like sports or school, get in the way of taking my medicine.					
We have run out of the medicine.					
Barriers to Treatment					
It is hard to get the medicine from the pharmacy.					
I don't like the taste of the medicine.					
I forget to take my medicine.					
The pill is hard for me to swallow.					
I am embarrassed to take medicine in front of friends or family.					
I refuse to take my medicine.					

Thank you for your participation

APPENDIX 4 : DATA COLLECTION FORM-KINYARWANDA

"**Uko abantu bitabira ikoreshwa ry' imiti ivura igicuri n'ibimenyetso bicyerekana mu bana bakirwariye mu Bitaro Bivura Indwara zo mu mutwe bya Ndera, Rwanda**"

No y'Isuzuma ……..... Numero y'Umurwayi No ……../……

Itariki……/……/……

I.UMWIRONDORO W'UMURWAYI

1. **Imyaka** : ……. Amezi …….. **Igitsina** □ Gabo □ Gore
   Ibiro……. Uburebure……
2. **Aho abarizwa:**
   Umurenge……Akarere……..Intara……
   ……
3. **Umwitaho** ……Isano……
4. No ya Telefoni……
5. **Ababyeyi b'umwana baba bakiriho?**☐ Yego ☐ Oya
   Niba ari oya, ni inde wapfuye muri bo? ☐ Ise ☐ Nyina ☐ Bose
6. **Ni inde muntu ugenzura ko ufata imiti yawe kandi ko ujya uhabwa indi iyo yashize?**
   ☐ Mama ☐ Data ☐ Njye ubwanjye ☐ Undi muntu……
7. **Wagarukiye hehe mu myigire yawe?**
   ☐Ntaho
   ☐Yatangiye amashuri abanza ariko ntiyayarangiza cyangwa yize ibyo gusoma no kwandika gusa
   ☐Amashuri abanza
   ☐Amashuri yisumbuye
   ☐Urwego rwa kaminuza
   Utsinda gute mu ishuri ?
   ☐ 1. Neza (Mu myanya10 ba mbere)
   ☐ 2. Ndagerageza(Nza mu myanya yo hagati)
   ☐ 3. Ndatsindwa (Mu myanya 10 ya nyuma 10)

8. **Umubyeyi wawe yagarukiye he mu mashuri yize?**

   ☐Ntiyize

   ☐ Mu mashuri abanza

   ☐ Mu mashuri yisumbuye

   ☐Muri kaminuza

9. **Ese iso cyangwa nyoko (cyangwa undi mukuru ukwitaho) yaba afite akazi gahemberwa umushahara?**☐ Yego ☐Oya

   Niba ari yego, ni inde?

   ☐ Data ☐Mama ☐ Bombi ☐Nta n'umwe

10. **Uri mu kihe cyiciro cy'Ubudehe ?** ☐ icyiciro cya 1 ☐ icyiciro cya 2☐ icyiciro cya 3 ☐ icyiciro cya 4

11. **Mu muryango wawe mufite abana bangahe ?**.....

12. **Uvuka uri uwa kangahe mu muryango?**☐Imfura ☐Uwa 2

    ☐uwa 3 ☐uwa 4 ☐uwa 5 ☐hejuru y'uwa 5

    ☐simbizi

13. **Ugira ubwishingizi bw'ubuzima?**☐ Yego ☐oya

    Niba ari yego, ni ubuhe bwoko bw'ubwishingizi ufite?.....

14. **Ni inde wundi mu muryango wawe urwaye igicuri ?**☐ Ntawe

    ☐umuntu 1 ☐ abantu 2 cyangwa barenga ☐Simbizi

15. **Hari indi ndwara indakira ufite /isanzwe , ubumuga cyangwa indi itari igicuri**?

    Niba ihari, vuga uko umerewe……

IBIZABO KU NDWARA Y' IGICURI N'IMITI BIFITANYE ISANO

1. **Ese kugagara byatangiye ryari?** Imyaka……Amezi…..Iminsi…..
2. **Ni ubuhe bwoko bwo kugagara umwana afite** (amakuru atangwa n'umwitaho cyangwa akakurwa mu nyandiko y'umurwayi)?

   ☐ Agagara ibice byose by'umubiri

   ☐Agagara uruhande rimwe cg igice kimwe cy'umubiri

   ☐ biravanze

3. **Umwana amaze igihe kingana iki afata imiti?** (mu myaka) .....
4. **Imiti yawe uyikura he?**

   ☐ Farumasi y'Ibitaro bya Ndera ☐Farumasi y'Ibitaro by'Akarere

   ☐Ivuriro ryigenga ☐Ahandi, havuge ……

   Ese ujya ubasha kubona imiyi buri gihe? ☐Yego ☐Nta kugagara
5. **Ni uwuhe muti (imiti) w'igicuri umwana ari gufata?** (Reba ibisubizo byose bishoboka) harimo n'ingero afata ndetse n'igihe yatangiriye (Urug : Ingero: Ku binini bya Depakine 200mg incuro ebyiri ku munsi guhera muri Gicurasi 2016)

   ☐Carbamazapine/Carbatrol:…….....

   ☐Valproic acid :……

   ☐Levetiracetam(Keppra) : ……...

   ☐Phenytoin:……..

   ☐Phenobarbital: ……...

   ☐Lamotrigine : ……

   ☐Diazepam: ……....

   ☐Iyindi, yivuge……
6. **Ese waba warigeze gukoresha ubuvuzi bwa gihanga(bwa Kinyarwanda) uvura umwana wawe kugagara?**☐ Yego ☐Oya
7. **Ese hari Isuzuma ryabugenewe (EEG)ryaba ryarakorewe uyu murwayi mbere yo gutangira imiti?**☐ Yego ☐Oya

   Niba ari yego, ryatanze ibihe bisubizo? ☐Birasanzwe ☐Ntibisanzwe
8. **Ese hari ingaruka wigeze uterwa n'Imiti yawe yo kuvura Igicuri ?**

   Niba ari Yego, yivuge?.....
9. **Hari ubujyanawa waba warahawe cyangwa ukwitaho ku bijyanye n'indwara y'igicuri ndetse n'Imiti ikivura (AEDs)?**

   ☐ Yego ☐Oya ☐ Simbizi

Ni inde waguhaye ubwo bujyanama cyangwa wabuhaye ugufasha ?

☐Ntawe ☐Muganga ☐Umujyanama ☐Uwundi, muvuge……

10. Waba warigeze kubura gufata imiti ivura igicuri ?

☐ Yego ☐ Oya

Niba ari yego ,byabaye incuro zingahe mu cyumweru gishize ?.....

11. Ni iyihe mpamvu yaguteye kudafata cyangwa kubura imiti ?.....

……

……

……

Ibibazo birebana n'uko abana barwaye igicuri bigenzura

AMABWIRIZA:*Ubushakashatsi bukurikira burabaza ibibazo bijyanye n'ubumenyi bwawe mu kwita ku ndwara y'igicuri, harimo ibyo utekereza ku buvuzi bwacyo, ibyo wemera ku buvuzi bwacyo, ndetse n'igituma abantu badafata imiti.* Turagusaba kuzuza ingingo zikurikira ku mpuzandengo kuva kuri 1(Simbyemera na gato) kugeza kuri 5(Ndabyemera byimazeyo) ku bibazo 1-25 n'impuzandengo ya 1 (kugeza kuri 5(Buri gihe) ku bibazo bihera kuri 19-27c ushyira akamenyetso X mu kazu gasobanura wowe neza. ICYITONDERWA : Nta gisubizo kizima cyangwa gipfuye kirimo.

	1 Simbyemera na gato	**2 Simbyemera**	**3 Simbyemera kandi simbihakana**	**4 Ndabyemera**	**5 Ndabyemera byimazeyo**
Ubumenyi n'Icyizere ku ndwara n'Imiti iyivura					
1. Abaganga bansobanuriye ibyo gusuzuma igicuri					
2. Nsobanukiwe ingaruka nshobora guhura nazo igihe ndi kuvurwa.					
3. Nzi uwo nshobora kwirukankira ndamutse ngize ibibazo cyangwa ingorane.					
4. Nzi neza ko mbasha gukemura buri ngaruka mbifashijwemo n'Umuganga wanjye.					
5. Nzi neza uko nshobora kwifata igihe ngagaye					
6. Numva neza ingaruka zo guhagarika imiti mbere y'uko ngagara mu gihe cy'imyaka 2.					
7. Itsinda ryita ku buzima bwanjye ryumva ibibazo byanjye.					
8. Abaganga banjye n'abaforomo banoneka vuba iyo mbitabaje kandi bakankemurira ibibazo vuba.					
Kwitabira gufata imiti no kuza kwitaba kwa Muganga					
9. Mfata imiti yanjye uko bitegetswe.					
10. Mfite umuntu umperekeza kwitaba muganga ukurikirana ubuzima bwanjye					
11. Akenshi nkurikiza inama n'amabwiriza yo kunywa imiti mpabwa.					
	1 Sombyemera na gato	**2 Simbyemera**	**3 Simbyemera kandi sinabihakana**	**4 Ndabyemera**	**5 Ndabyemera cyane**

12. Nzi ko ari ngombwa gufata imiti yanjye uko bitegetswe.					
13. Kuza gukorerwa igenzura kwa muganga ntibijya bingora cyane					
14. Buri muntu wese mu muryango wanjye yemeranywa na gahunda yanjye yo gufata imiti					
15. Inshuro nyinshi mfata imiti yanjye.					
16. Ni ngombwa cyane ko mfata imiti yanjye buri gihe .					
Ibyo nemera ku Byiza byo gufata Imiti neza					
17. Nkenera imiti uko ngagaye.					
18. Imiti mfata ubu izahagarika kugagara kwanjye					
19. Gushyira gahunda yo gufata imiti muri gahunda yanjye ya buri munsi biranyorohera					

	1 Nta na rimwe	**2 Gake**	**3 Rimwe na rimwe**	**4 Kenshi**	**5 Buri gihe**
Inzitizi zo Gufata imiti					
Sinkunda icyanga cy'imiti.					
Njya nibagirwa gufata imiti					
Ikinini kirangora kukimira.					
Gufatira ikinini imbere y'inshuti zanjye cyangwa abo mu rugo birambangamira					
Nanga gufata imiti					
	1 Nta na rimwe	**2 Gake**	**3 Rimwe na rimwe**	**4 Kenshi**	**5 Buri gihe**
Ibindi bintu nko Gukina, kwiga nabyo bimbuza gufata					
Imiti yaranshiranye					
Birangora kubona imiti muri farumaci					

Mbashimiye ubwitabire bwanyu

APPENDIX 5. INFORMED CONSENT FORM-ENGLISH

Study Topic: "**Adherence to antiepileptic treatment and its predictors among adolescent with epilepsy at Ndera Neuro-Psychiatric Hospital, Rwanda**"

Research ID:……..

PART I: Information sheet

1. Purpose of the study:

Doctor Josephine NYINAWUMNTU is a resident in pediatrics, in final year , college of medicine and health sciences , she is conducting a study at Ndera hospital which is aiming to know how the adolescent with epilepsy is taking his/her medications according to the Doctors's prescriptions and what are factors which can prevent your him/her to take his/her medication as prescribed or to follow the Doctor's order.

This study will be a cross-sectional study conducted on all children and adolescents diagnosed with epilepsy either clinically or by EEG on AEDs at least six months, who consulted CARAES Ndera Hospital and being followed up there.

2. Description of the Process

The compliance to AEDs medications will be evaluated using self reporting questionnaire where your will be asked to answer to some questions using a designed questionnaire and other records from your medical file.

The data collection will take two month, in which period we will meet with you at the hospital during the consultation and ask you to answer some questions asked by the researcher or the representative. This study will be conducted with the approval of the Institutional Research Board of the CMHS and the CARAES Ndera Ethical committee.

There is no any experimentation planned in this study.

3. Risk or discomfort:

There is no physical, psychological or moral harm that is planned to be induced by this study, and the research team will be opened to discuss any discomfort and let the participant decide freely.

4. Benefits: The benefit expected is to participate in a study which should change or improve the interventions given by CARAES Ndera or better the management of a epilepsy in a better way of improving adherence to treatment/follow-up.

We will meet with participant at CARAES Ndera hospital when they come in outpatient for follow-up.

5. No alternative treatment or special management proposed to the participant who will report any problem with his AEDs. But he may be advised to see the usual medical Doctor.

6. Confidentiality:

We can ensure you high level of confidentiality because the information you will give will be recorded under a study number and analyzed blindly.

7. Voluntary participation, Refusal or withdrawal:

The participation in this study is totally voluntary, it requires you to know well what the purpose of the study and give an informed and signed consent. Any informed participant is free to consent or refuse and it is possible to withdraw yourself from the study if uncomfortable with the procedures used.

8. Who to contact if any question or concern, you can call the principal Investigator or the representatives of the CMHS IRB.

1. Dr Josephine Dr NYINAWUMUNTU (Principal Investigator): (+250) 0784 858 496)Email: ketchi06@gmail.com

2. Dr Fidel SEBERA (Neurologist, Supervisor):(+250788486102) Email: seberafidele@gmail.com

3. Prof Kato (Chair Person of the CMHS IRB): (+250788` 490 522)

4. Prof Jean Bosco GAHUTU (The Deputy Chairperson): (+250783 340 040)

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant_____

Signature of Participant _____

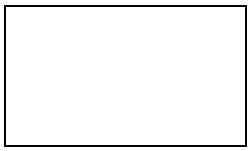
Date _____

Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness…….. AND Thumb of participant



Signature of witness……

Date ……/……/……..

Statement by the researcher/person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been persuaded into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Name of Researcher/person taking the consent……

Signature of Researcher /person taking the consent……..

Date……/……/……

APPENDIX 6. ASSENT FORM ON CHILDREN AND ADOLESCENT WITH EPILEPSY-ENGLISH

Research ID :……

RESEARCH TOPIC:

"**Adherence to antiepileptic treatment and its predictors among adolescent with epilepsy at Ndera Neuro-Psychiatric Hospital, Rwanda** "

I certify that, (Name, given names).....

Resident at.....authorizes.

Doctor Josephine Nyinawumuntu is a resident in pediatrics, in 3rd year, college of medicine and health sciences (CMHS) and her phone number is + (250)788674692, with other doctors are going to carry out a study which will help them to know the level of adherence to antiepileptic treatment in children and adolescence including me, this will help them improve the care given by CARAES Ndera or better the management of adolescents epilepsy in a better way of improving adherence to antiepileptictreatment.

The Doctor explained to me the nature of the study she is conducting which will require my presence and responding to some questions about how I take medications and symptoms of my illness, she will also use some imaging result and data concerning my illness which recorded in the file.

☐ I authorize the use of some recorded data concerning my clinical condition and use them in her research for public health purpose.

☐ I accept to participate in the study and respond to any question I will be asked to help Dr Josephine Nyinawumuntu do her study.

I have read and understood this Notice and Consent Form. I voluntarily consent for myself and I have right to request and receive a copy of this form. A photocopy of this form will be as valid as the original.

Signature of the Child (adolescent) and
name……

Signature and the name Signature of the investigator…….

Signature of the parent or Legal Guardian……
…….

Date……/……/……

APPENDIX 7 CONSENT FORM-KINYARWANDA

INYANDIKO YO KWEMERA KUGIRA URUHARE MU BUSHAKASHATSI

INYITO Y'UBUSHAKASHATSI:

"Uburyo ingimbi n'abangavu babana n'uburwayi bw'igicuri bafata imiti, bubahiriza gahunda ya muganga ndetse n'imbogamizi bahura nazo mu gukurikirana gahunda ya muganga ku bitaro bya CARAES Ndera"

Nimero iranga ubushakashatsi:……

IGICE I: Iriburiro

1. Intego y'ubushakashatsi:

Mugana Joesphine NYINAWUMUNTU , Umunyeshuri mu mwaka wa nyuma mu ishami ry'ubuvuzi rusange ry'abana arimo gukora ubushakashatsi mu Bitaro bya CARAES NDERAku buryo ki abana b'ingimbi n'abangavu babana n'uburwayi bw'igicuri bafata imiti ndetse nuburyo bitabira gahunda ya muganga, bakazarebera hamwe nababyeyi bafasha abo bana ibyerekeranye n'imbogamizi bahura nazo buri munsi mu gufata imiti bagenewe no kubahiriza gahunda ya Muganga.

Ubushakashatsi buzakorerwa ku ngimbi n'abangavu bafite indwara y'igicuri ,bafata imiti y'igicuri nibura amazi atadatu ashize kandi bakaba asanzwe bakurikirana gahunda y'ubuvuzi bwabo ku bitaro bya CARAES Ndera.

2. Uko ubushakashati buteganijwe gukorwa:

Ubu bushakashatsi bushingiye mu gufata amakuru atangwa n'ingimbi n'abangavu bafite imyaka kuva uri 12 kugeza kuri 18y'amavuko hakurikijwe urutonde rwibibazo ruteganyijwe.

Abakora ubushakashatsi bakazakusanya amakuru yerekeye nuburyo imiti ifatwa mu mibereho ya buri munsi hamwe nayerekeye imbogamizi bahura nazo mu gufata imiti ndetse nuburyo abana n'ababyeyi bitabira gahunda ya muganga.

3. Ibanga :

Ifishi yo gusubirizaho ifite nimero iyiranga. Nta zina ry'umwana rizagaragaraho. Iyo fishi kandi izabikwa ahantu hizewe. Buri murwayi azahabwa numero imuranga kuburyo ntahantu nahamwe amazina y'umurwayi azagaragara mu bushakashatsi tugiye gukora.

4. Inyungu :

Ubu bushakashatsi buzafasha mu ikurikiranwa ry'abarwayi b'igicuri ku bijyanye n'uburyo bafata imiti, tukamenya ibibazo bahura nabyo buri munsi bikazadufasha kubateganyiriza uburyo bunoze bwo kubakurikirana buri munsi, ndetse byanadufasha kunoza imivurire yacu.

5.Ntago twemerewe guhindura imiti y'umurwayi: Iyo uwinjiye mu bushakashatsi atumenyesheje ko imiti y'igicuri afata imutera ikibazo , nta yindi miti twemerewe kumuha isimbura iyo afite ahubwo tumugira inama yo kongera kureba Umuganga usanzwe amukurikirana.

6. Ingaruka:

Nta ngaruka n'imwe umwana urebwa n'ubu bushakashatsi ashobora guhura nazo.

7. Uburenganzira:

Ufite uburenganzira busesuye bwo kwemera cyangwa kwanga kujya muri ubu bushakashatsi nta guhanwa kuberako wanze. Ufite kandi uburenganzira bwo kubuvamo igihe cyose bibaye ngombwa kandi ibyo nta ngaruka bishobora kugira ku mivurirwe yawe.

8. Ukeneye ibisobanuro :

Ku bisobanuro cyangwa se ibibazo wagira kuri ubu bushakashatsi, waziyambaza :

1. Dr Josephine Dr NYINAWUMUNTU (Principal Investigator): (+250) 0784 858 496)Email: ketchi06@gmail.com

2. Dr Fidel SEBERA (Neurologist, Supervisor):(+250788486102) Email: seberafidele@gmail.com

3. Prof Kato (Chair Person of the CMHS IRB): (+250788 490 522)

4. Prof Jean Bosco GAHUTU (The Deputy Chairperson): (+250783 340 040)

IGICE II.KWEMERA

Maze gusobanurirwa neza intego yubu bushakashatsi kandi ndemeza ko nahawe umwanya uhagije wo kubaza ibibazo byose ntumvaga,nemeye kugira uruhare muri ubu bushakashatsiku bushake byanjye.

Amazina_____

Umukono/igikumwe _____

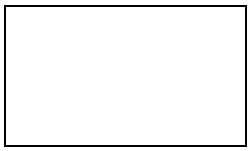
Itariki _____

Ku muntu utabasha kwandika no gusoma

Ndahamya ko iyi nyandiko yo kwemera kugira uruhari mu bushakashatsi yasomewe ugiye kugira urahare mu bushakashatsi kandi ndemeza ko yabonye umwanya wo kubaza ibibazo byose yari akeneye gusoanuza. Ndemeza ko uwasobanuriwe yawawe ibisobanuro byose kandi yemeye kugira uruhare mu bushakashatsi ku bushake bye nta gahato.

Amazina y'umuhamya…….. AND

Igikumwe cy'uwinjiye mu bushakashatsi



Umukono w'umuhamya……

Itariki ……/……/……..

Uhagarariye ubushakashatsi

Ndemezako umurwayi/uhagarariye umurwayi yahawe ubusobanuro buhagije ku bijyanye nubu bushakashatsi tugiye gukora kandi ko yahawe umwanya uhagije wo kubaza ibibazo kandi byose byasubijwe nkuko abyifuza kandi ko nta gahato kakoreshejwe kugirango akorerweho ubushakashatsi.

Izina ry'ukora ubushakashatsi/Uhagarariye ubushakashatsi:

……..…….

Umukono: ……

Itariki:……/……/……

APPENDIX 8 ASSENT FORM-KINYARWANDA

URUPAPURO RW'UBWUMVIKANE MU BUSHAKASHATSI BWIGA KU NDWARA.

Amazina y'ubushakashatsi:

"**Uburyo abana b'ingimbi babana n'uburwayi bw'igicuri bafata imiti, bubahiriza gahunda ya muganga ndetse n'imbogamizi bahura nazo mu gukurikirana gahunda ya muganga ku bitaro bya CARAES Ndera"**

Numero y'uwinjiye mu bushakashatsi:

Njyewe……

Utuye……

☐Nemereye ukora ubushakashatsi Dogiteri Josephine NYINAWUMUNTU gukoresha amakuru ku burwayi bwanjye, ibimenyetso mfite, ibisubizo by'ibizamini mu bushakashatsi buzafasha mu kureba uburyo ababana n'indwara y'igicuri bafata imiti nuburyo bubahiriza gahunda ya muganga.

Ukora ubushakashatsi yansobanuriye neza umumaro w'ubushakashatsi

☐Nemeye ko amakuru ajyanye n'ubuzima bwanjye ari mu madosiye y'ibitaro bashobora kuyakoresha Ibijyanye n'ububushakashatsi hamwe n'abandi bakorana uyu murimo mu rwego rwo kubafasha mu bushakashatsi no kuvugurura Ibijyanye n'imivurire y'uburwayi bw'igicuri.

☐Nemeye ko nabanje gusoma no gusobanukirwa ibikubiye muri uru rupapuro mbere yo kurusinya. Nemeye ku giti cyanjye nta gahato gukorerwa ibyavuzwe hejuru. Numvise kandi ko mfite uburenganzira bwo gusaba ikopi y'uru rwandiko rw'ubwumvikane.

Umukono n'izina ry'umwana……

Umukono w'uhagarariye umwana …….

Umukono w'ukora ubushakashatsi…….

Bikorewe i……..... Bikorewe i…….....

Kuwa…….

APPENDIX 9. UR-IRB CLEARENCE LETTER

UNIVERSITY OF RWANDA — COLLEGE OF MEDICINE AND HEALTH SCIENCES

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 26th /10/2018

Dr Josephine NYINAWUMUNTU
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 357/CMHS IRB/2018

Your Project Title ***"Adherence to Antiepileptic Treatment and Its Predictors among Adolescents with Epilepsy at Ndera Neuro-Psychiatric Hospital, Rwanda"*** has been evaluated by CMHS Institutional Review Board.

		Involved in the decision		
			No (Reason)	
Name of Members	**Institute**	Yes	**Absent**	**Withdrawn from the proceeding**
Prof Kato J. Njunwa	UR-CMHS	X		
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS	X		
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gishoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 16th October 2018, **Approval has been granted to your study.**

Please note that approval of the protocol and consent form is valid for **12 months**.

EMAIL: researchcenter@ur.ac.rw P.O. Box: 3286, Kigali, Rwanda WEBSITE: http://cmhs.ur.ac.rw/ www.ur.ac.rw

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 26th October 2018

Expiration date: The 26th October 2019

Professor Kato J. NJUNWA
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:

- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR