ADHERENCE TO ANTI-EPILEPTIC DRUGS AND ASSOCIATED FACTORS AMONG CHILDREN WITH EPILEPSY ATTENDING PEDIATRICS NEUROLOGY FOLLOW UP CLINIC OF JIMMA MEDICAL CENTER, SOUTH WEST ETHIOPIA

BY: HAWI MOHAMMED (MD, PEDIATRICS RESIDENT)

A THESIS TO BE SUBMITTED TO THE DEPARTMENT OF PEDIATRICS AND CHILD HEALTH, FACULTY OF MEDICAL SCIENCES, INSTITUTE OF HEALTH JIMMA UNIVERSITY FOR THE PARTIAL FULFILMENT OF THE REQUIREMENT FOR SPECIALITY CERTIFICATE IN PEDIATRICS AND CHILD HEALTH

DECEMBER, 2021

JIMMA, ETHIOPIA

JIMMA UNIVERSITY

INSTITUTE OF HEALTH

FACULTY OF MEDICAL SCIENCES

DEPARTMENT OF PEDIATRICS AND CHILD HEALTH

POST-GRADUATE PROGRAM

ADHERENCE TO ANTI-EPILEPTIC DRUGS AND ASSOCIATED FACTORS AMONG CHILDREN WITH EPILEPSY ATTENDING PEDIATRICS NEUROLOGY FOLLOW UP CLINIC OF JIMMA MEDICAL CENTER, SOUTH WEST ETHIOPIA

By: Hawi Mohammed (MD, Pediatrics Resident)

ADVISORS:

1. Dr. Teferi Mekonnen (MD, Assistant Professor of Pediatrics and Child Health)

2. Mr. Tsegaye Melaku(B.Pharm, MSc, Assistant Professor of Clinical Pharmacy)

DECEMBER, 2021

JIMMA, ETHIOPIA

DECLARATION

ASSURANCE OF PRINCIPAL INVESTIGATOR

I; the undersigned agree to accept all responsibilities for the scientific and ethical conduct of the research project with the research title: “Adherence to anti-epileptic drugs and associated factors among children with epilepsy attending Pediatrics neurology follow up clinic of Jimma Medical Center, South West Ethiopia, 2021” and for the provision of required progress reports as per terms and conditions of the guideline of post-graduate studies in Jimma University. I will provide a timely progress report to my advisors and seek the necessary advice and approval from my advisors in the course of the research.

Name of student	Signature	Date
1. Hawi Mohammed	_____	_____

APPROVAL OF THE ADVISORS

Name of Advisors	Signature	Date
1. **Dr. Teferi Mekonnen**	_____	_____
2. **Mr. Tsegaye Melaku**	_____	_____

ABSTRACT

Background: Childhood epilepsy causes a tremendous burden for the child, the family, society as well as the healthcare system. Adherence to anti-epileptic drugs(AEDs) is a key to treatment success. Poor adherence has been considered as one of the main causes of unsuccessful treatment for epilepsy and presents a potential ongoing challenge for achieving a key therapeutic goal of seizure control.

Objective: This study aimed to assess adherence to antiepileptic drugs and associated factors among children with epilepsy attending the Pediatrics neurology follow up clinic of Jimma Medical Center, Ethiopia.

Methods: A facility-based cross-sectional study design was conducted among children with epilepsy attending the Pediatrics neurology follow up clinic of Jimma Medical Center from June- 21 to September- 20, 2021. Data were collected by using a semi-structured pre-tested questionnaire. Epi data version 3.1 and SPSS version 26.0 were used for data entry and for analysis respectively. Descriptive statistics and binary logistic regresion analysis were employed. Adjusted odds ratios were used to ascertain effect sizes for any association between the dependent and associated variables while significance level at p-value of <0.05 was determined using 95% confidence intervals.

Result: A total of 170 children with epilepsy were included in this study. About 54.7% were male and 44.7% were in age range of 10-17 years. Among the study participants included, the overall adherence to anti-epileptic drugs was 54.1%. Those caregivers who were married[AOR=7.46 (95% CI= 1.46, 38.20)], those with controlled seizure status[AOR= 3.64 (95% CI= 1.51, 8.78)], those who got appropriate health care[AOR= 7.08(95% CI= 2.91, 17.24)], those caregivers who had good knowledge[AOR= 5.20(95% CI= 2.60,14.83)] and positive attitude[AOR= 2.57 (95% CI= 1.06, 6.28)] were significantly associated with adherence to AEDs.

Conclusions: More than half of the children/adolescents having epilepsy were adherent to their anti-epileptic medication(s). In addition, children's adherence to AEDs was influenced by different factors such as current marital status of the parents/caregivers,

controlled seizure status, not facing problems in the hospital during health care delivery, caregiver's knowledge and attitude towards epilepsy.

Recommedations: More efforts are required to scale up the provision of client-centred service to encourage children/adolescents with epilepsy to be adherent to their medication(s). Further, a deep and well-designed study that includes a quantitative and qualitative approach is recommended to address other hidden factors that are associated with adherence to AEDs.

Keywords: Adherence, attitude, anti epileptic drugs, children, epilepsy, knowledge, Jimma Medical Center, South West Ethiopia.

ACKNOWLEDGEMENT

First, I would like to thank Jimma University Post graduate studies coordinating office and department of Pediatrics and Child Health, Faculty of Medical Sciences, Jimma University for giving me this golden opportunity to conduct this study.

I am grateful to my advisors Dr. Teferi Mekonnen (MD, Assistant Professor of Pediatrics and Child Health) and Mr. Tsegaye Melaku (B.Pharm, MSc, Assistant Professor of Clinical Pharmacy) for their unreserved encouragement and provision of constructive comments and guidance from the beginning of the topic selection, proposal development and to complete the research thesis.

I would like to thank Jimma Medical Center Health Management and Information System(HMIS) officers, Staff working at Pediatrics neurology follow up clinic for their cooperation in giving information related to the general information about the study area and study population.

Finally, my deepest gratitude goes to study participants and data collectors for their cooperation to complete this thesis by devoting their time.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS AND ACRONYMS

ADHD	Attention Deficit Hyperactivity Disorder
AED	Anti-epileptic Drugs
AOR	Adjusted Odds Ratio
ASD	Autism Spectrum Disorder
CBHI	Community Based Health Insurance
CI	Confidence Interval
COR	Crude Odds Ratio
CP	Cerebral Palsy
DC	Data Collector
EEG	Electroencephalogram
ETB	Ethiopian Birr
GP	General Practitioner
HMIS	Health Management Information System
ILAE	International League Against Epilepsy
IRB	Institutional Review Board
JMC	Jimma Medical Center
JU	Jimma University
LMIC	Low and Middle Income Countries
NR	Nonresponse Rate
PI	Principal Investigator
RMB	Ren Min Bi(Chinese money)
SE	Status Epilepticus
SPSS	Software Program for Social Science
SSA	Sub-Saharan Africa
SUDEP	Sudden Unexplained Death in Epilepsy
T1DM	Type-1 Diabetes Mellitus
WHO	World Health Organization

1. INTRODUCTION

1.1. Background

Epilepsy is a common chronic non-communicable medical and social disorder or group of disorders with unique characteristics(1,2). It is a group of syndromes characterized by unprovoked, recurrent seizures(3). The word “epilepsy” is derived from Latin and Greek words for “seizure” or “to seize upon”(4). This implies that epilepsy is an ancient disorder; indeed, in all civilizations it can be traced as far back as medical records exist. Epilepsy is a disorder that can occur in all mammalian species, probably more frequently as brains have become more complex. Epilepsy is remarkably uniformly distributed around the world. There are no racial, geographical or social class boundaries. It occurs in both sexes, at all ages, especially in childhood, adolescence and increasingly in aging populations(1).

The definition of epilepsy requires the occurrence of at least one epileptic seizure. An epileptic seizure is a transient occurrence of signs and/or symptoms due to abnormally excessive or synchronous neuronal activity in the brain. It is characterized by an enduring predisposition to generate epileptic seizures, and by the neurobiologic, cognitive, psychological, and social consquences of this condition(5).

International League against Epilepsy (ILAE) classifies epilepsy by manifestations during seizure attack and Electroencephalogram (EEG) feature(s) between attacks as focal onset (with or without impaired awareness), generalized onset, unknown onset and unclassified seizures. This classification is important for the understanding of underlying etiology, selecting appropriate treatment, and understanding the prognosis of seizure types(6).

The primary cause of epilepsy is unknown in around two-thirds of cases (idiopathic or cryptogenic) but congenital anomalies, perinatal injuries, intracranial tumors, CNS infection, vascular and metabolic abnormalities are secondary causes of epilepsy. Most causes of secondary epilepsy are preventable and treatable(1).

Over 50 million people are affected worldwide of which 80% are in developing countries. Mortality is 2–3 times higher than that of the general population. The important epilepsy-

related deaths are sudden unexpected, unexplained death in epilepsy (SUDEP) (2–18%) of all deaths in epilepsy), death in status epilepticus (SE) (12.5%) and suicide (0–2%)(1). Approximately 1 out of 150 children is diagnosed with epilepsy during the first 10 years of life, with the highest incidence rate observed during infancy(7).

A systematic analysis of epilepsy in sub-Saharan Africa showed that, active epilepsy was estimated to affect 4.4 million people in this region, whilst lifetime epilepsy was estimated to affect 5.4 million. The prevalence of active epilepsy per age group in the same region is 5.09/1000 and 5.98/1000 among children aged 0-9 years old and 10-19 years old respectively(8).

Epilepsy symptoms can be successfully treated with one or more antiepileptic medications. Currently available anti-epileptic drugs can control seizures in 60-80% of patients with new onset epilepsy(2,3). The goal of treatment of epilepsy includes minimizing the risk of recurrent seizures and antiepileptic drug (AED) side effects, and maintaining normal psychosocial and educational/vocational adjustment(9).

Adherence to AEDs is key to treatment success, one of the main causes of unsuccessful drug treatment for epilepsy is poor adherence to prescribed medication(10,11). Medication adherence increase if the patients and families are involved in treatment choice as well as a mutual agreement between the health care providers. Adherence to anti-epileptic medications results in decrement of relapses, minimized frequency of seizures, decreased cost of health care, increased therapeutic benefits and better patient outcomes(12). Non-adherence to AEDs leads to inadequate treatment with subsequent uncontrolled seizures which lead to more emergency room visits, hospitalizations, poor quality of life, morbidity, and mortality(13).

1.2. Statement of the Problem

Epilepsy is the most common chronic neurological disorder characterized by recurrent and unprovoked seizure. Over 85% of epilepsy cases are found in LMICs specially Sub–Saharan Africa (SSA). Epilepsy severely affects the quality of life. The condition is highly stigmatised because of the commonly held misconception that epilepsy is contagious and the negative meanings attached to seizure. In many parts of SSA, epilepsy continues to be associated with witchcraft. For these reasons, people with epilepsy are often socially ostracised, have reduced life chances in terms of employment and marriage, and are prone to having poorer self–esteem, anxiety and depression(14).

It is known that about 70% of people with epilepsy could lead full, seizure- free lives if treated properly(14). Despite the fact that there are significant treatment advances in pediatrics, improvements in medical technology to assess adherence behaviors and increased focus on adherence in research and clinical practice, non-adherence rates across all pediatric chronic illness groups continue to be quite high, averaging 50–75%(12).

According to WHOs adherence to long-term therapies, adherence to antiepileptic drugs in children with epilepsy generally ranges from 25–75%(15). Specifically; the prevalence rate of adherence to AEDs in pediatric patients was 79.5% in Uganda in 2014(16), 21.3% in western China(17), 61.7% in Saudi Arabia(18), 55.2% in Nigeria(19), 55% in South Africa in 2016(20), 42% in USA in 2011(21) and 29% in Indian subcontinent(22).

The prevalence of adherence to AEDs in patients with epilepsy depends on several factors such as the populations studied, the definition used for adherence, and research methods(23–25). The study done in Jordan(25) used a self/caregiver report. The study in South Africa(20) used a modified medicine possession ratio(MPRm) while the study in the USA(21) used electronic monitors to assess adherence. The study in Uganda(16) which used both self-report and drug level monitoring found a wide disparity of adherence between the two methods (79.5% and 22.1% respectively). According to the WHO, the factors affecting adherence can be grouped into the following five dimensions: socioeconomic-related factors, health care team/health system-related factors, condition-related factors, treatment-related factors, and patient-related factors(15). Also, factors that were significantly associated with non-

adherence to AEDs include low socioeconomic status, multiple drug intake and long duration of therapy, Modi(21) also reported that family socio-economic status was the only predictor of non-adherence to AEDs in children with epilepsy in the USA in 2011. Income and social status are major determinants of the health status of the people(26). Increasing age and patients receiving their information from elsewhere(17); Adverse drug consequences and fear of medication harm(18) were predictors of non-adherence to AEDs. And also forgetfulness, the number of medications prescribed, dosing frequency, type of seizure and duration of illness influence medication adherence among epileptic patients(27,28).

Different socio-demographic, clinical and treatment, health services, parental knowledge and attitude, and psychosocial related factors may contribute to non-adherence to AEDs.

1.3. Significance of the study

The measurement of adherence to AED treatment has been a major challenge because of the chronicity of the disease and the dependency of children on their parents/caregivers. These problems are further affected by issues related to the socioeconomic status of parents/caregivers; knowledge & attitude of parents/caregivers; health system and drug related factors.

Taking into account the existing problem under study, which is a critical and major public health problem and having limited information because of lack of published study on the issue of adherence to AEDs in the study area farther strengthen the need of this study.

The factors associated with non-adherence to AEDs reported by various studies are not similar and there is a lack of information regarding the prevalence and associated factors of adherence to AEDs in the study area. In addition, previous few studies done in Ethiopia mostly focused on adult patients at the community level. Therefore, to address this problem, it is believed that this work will provide up-to-date information with regards to the magnitude of adherence to AEDs and associated factors among the study population.

Hence; this study will contribute scientific knowledge for health planners in Zonal level and health care providers to formulate evidence based intervention strategies to improve adherence to AEDs which increase school performance/productivity, decrease emergency department visits and psychosocial impact of disease, increases seizure free days, decrease morbidity and mortality.

2. LITERATURE REVIEW

Globally epilepsy affects about 70 million people of which 85% live in developing countries. Long-term antiepileptic drug (AED) administration remains the mainstay of epilepsy treatment (15,29). In up to 67% of patients with epilepsy, AEDs effectively eliminate or reduce the frequency of seizures(29). The magnitude of adherence to AEDs ranges from 25% to 75%(15).

A cross sectional study was done in the Indian subcontinent showed that 29% of epileptic children showed medication adherence to AEDs. The increasing age of children, increased duration of epilepsy, increasing mean number of family members, patients taking medications more than once per day and employed caregiver status were significantly associated with non-adherence in epileptic children(22).

Another cross sectional study done in western China among 399 children (age 0.3-17.8year) with epilepsy showed that 21.3% (85/399) patients were having good adherence, 51.4% (205/399) moderate adherence, and 27.3% (109/399) poor adherence based on MMAS-8. 57.1% (228/399) were having generalized seizures. In this study, patients whose household income was ranged from 5,000- 10,000 RBM and receiving drug information from hospital were signifificantly more adherent, while increasing age and patients receiving their information from elsewhere have poorly adhered to AEDs(17).

A study done in the Kingdom of Saudi Arabia among 94 adolescents with idiopathic epilepsy showed that thirty-six of respondents (38.3%) were non-adherent to antiepileptic treatment while 61.7% were adherent to AEDs. 83% of them were having generalized seizure and 76.6% of them were on monotherapy. Adverse drug consequences and fear of medication harm were significantly associated with non-adherent(18).

A study done in Pakistan (2018) on 120 children with epilepsy on AEDs for at least one month showed that 70(58%) of children had subobtimal AEDadherence and 50(42%) of them had satisfactory adherence according to self or parental report. AED prescription patterns, adverse effects, availability of AEDs, seizure control, treating physician’s counseling, financial

constraints, and parental/caregiver's education were more significantly associated with drug nonadherence in these communities(30).

A cross-sectional observational study was conducted among 253 patients with epilepsy in Bangladesh indicate that adherence was 38.7% and associated with well seizure control. Among AED adherent patients (n=98), 70(82.4%) had controlled seizure status(31).

A study done in Turkey in 2020 on 226 children and adolescents with epilepsy and their primary caregivers, the overall prevalence of complete drug adherence among the patients was 47.3%. The main reasons of non-adherence to AEDs were forgetting to take medication (33.6%) and the difficulties in adhering to treatment (24.3%). Age and caregivers' health literacy knowledge were found to be significantly associated with adherence in this study. Patients in the 0 to 5 years age group were more likely to have full drug adherence than were those in the 12 to 18 years age group(32).

A study done on 112 children aged 2-14year at Queen Rania AL-Abdullah Children Hospital in 2015 showed that 79.5 % of the patients display some adherence to antiepileptic medication, while 20.5% of the patients do not display adherence to their antiepileptic medication. 23 patients (20.5%) have low adherence, 56 patients (50%) have medium adherence, and 33 patients (29.4%) have high adherence. The top three reasons for non-adherence are: forget to take medication (52.2%), side effects of medications (33.8%), and being improvement and seizure free for a period (30.4%)(25).

A cross-sectional study done in Jos, Nigeria showed that Out of the 194 patients, the prevalence of non-adherence to AEDs was 44.8% and the rest (55.2%) were found adhered to AEDs. Factors significantly associated with non-adherence were low socioeconomic status, multiple drug therapy and long duration of treatment (AED therapy for >12 months). The main reasons for non- adherence were financial constraint, forgetfulness, lack of improvement and medication side effects(19).

A study done in Uganda on 122 children with epilepsy on follow up and medication showed that non-adherence to antiepileptic drugs was only 20.5%. The commonest reason given for

missing drugs was lack of drugs due to their high cost as reported by 36(48.7%) of and forgetting, reported by 22(29.7%) of study participants(16).

2.1. Conceptual frame work of the study

In the conceptualization of this study, different factors like socioeconomic related and other factors can affect the adherence of children and adolescents to AEDs. This, on the other hand, has a significant impact on the control of seizure in children and adolescents with epilepsy. Other factors like, medication side effects and parents'/caregivers' knowledge and attitude and health system related factors will have an effect on the adherence status of children/adolescents with epilepsy.

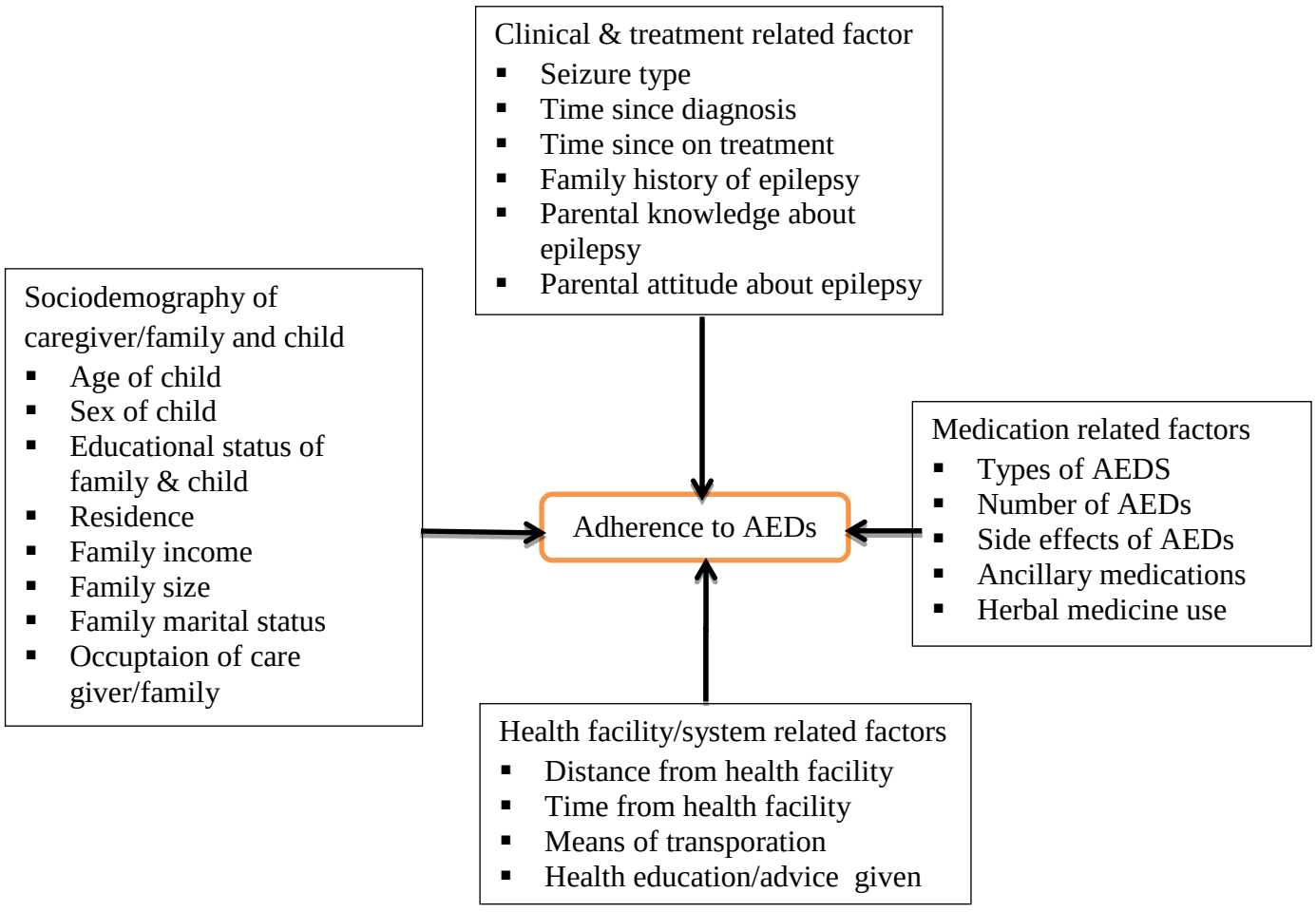

Figure 1 Conceptual frame work of the study

3. OBJECTIVES OF THE STUDY

3.1. General objective

- To assess the level of adherence to anti epileptic drugs and associated factors among children with epilepsy attending pediatrics neurology follow up clinic of Jimma Medical Center, South West Ethiopia.

3.2. Specific objectives

- To determine the level of adherence to anti epileptic drugs among children with epilepsy attending pediatrics neurology follow up clinic of Jimma Medical Center, South West Ethiopia.
- To identify factors associated with adherence to AEDs among children with epilepsy attending pediatrics neurology follow up clinic of Jimma Medical Center, South West Ethiopia.

4. METHODS AND MATERIALS

4.1. Study area and period

This study was conducted from June 21- Sep 20, 2021, in Jimma Medical Center (JMC), Jimma zone, Oromia region, South West Ethiopia. The center is one of the oldest public hospitals in the country located in Jimma town of Oromia Regional State, Ethiopia. Jimma town is located around 352 km far away from Addis Ababa.

JMC is used as a referral and specialized medical center; located in the out skirt of the Jimma town, it gives services for an estimated 20 million people from Jimma zone and the catchment population, particularly the south western Oromia and as a referral center for regions of South Western part of Ethiopia including Gambella and Southern Nations Nationalities and People (SNNP) Regional states.

With a bed size of 800, JMC provides services for approximately 15,000 inpatients, 160,000 outpatient attendants, 11,000 emergency cases and 4,500 deliveries per year coming to the hospital. It also serves as a teaching hospital for several undergraduate and post graduate programs in the field of basic sciences as well as clinical medicine for health science students of Jimma University. The hospital has many follow-up clinics for both children and adult patients (Cardiac, ART, Nephrology, Endocrinology, etc.). Pediatrics neurology clinic is one of such chronic follow-up clinics run on a once weekly basis; where patients with neurologic problems (structural, infectious, ETC) will be diagnosed clinically, followed, and treated.

4.2. Study design

A facility based cross- sectional study design was employed.

4.3. Populations

4.3.1. Source population

All children having epilepsy on follow- up attending pediatrics neurology follow up clinic of JMC.

4.3.2. Study population

Children between 6month- <18 years of age having epilepsy visiting JMC Pediatrics neurology follow up clinic and received AEDs for at least six month prior to data collection and those who fulfilled the eligibility criteria.

4.4. Inclusion and exclusion criteria

4.4.1. Inclusion criteria

Children with epilepsy aged less than 18 years of age visiting JMC Pediatrics neurology follow up clinic who were receiving AEDs for at least six months prior to data collection and those children whose parents were willing to participate in this study were included.

4.4.2. Exclusion criteria

Children with epilepsy taking AEDs for < 6 months, psychiatric illnesses (attention deficit hyperactivity disorder, autism spectrum disorder), those having repeated visits for any reason during the data collection period after they were included in their previous visit, and those parents having hearing problems who were unable to respond/speak and those who were not willing to participate in the study were excluded from the study.

4.5. Sample size determination and sampling techniques

4.5.1. Sample size determination

The required sample size for this study was determined by using single population proportion estimation formula and considering the following assumptions; Study done in Joe, Nigeria showed that the proportion of adherence to AEDs was around 55.2% with a 95% of the confidence interval and 5% of margin of error was taken. Accordingly, the calculated sample size was 380.

$$No = \frac{[(Z_{1-\alpha/2})^2 pq]}{d^2}$$ Where

- No = Initial/Desired sample size.

- d = Precision of measurement (acceptable marginal error) = 0.05
- ($Z_{1-\alpha/2}$) = the critical value at 95% level of significance (1.96)
- P = Prevalence of adherence to AEDs was 55.2%(19).
- q = 1-p =44.8%.
- NR = Non response Rate

Hence; No = $\frac{(1.96)^2\ 0.552\ (0.448)}{(0.05)^2}$ No = 380

Since the source population is < 10,000; the final sample size was determined by applying the finite population correction formula and adding 5% non-response rate. Accordingly, the calculated final sample size became 170 children/adolescents with epilepsy.

Nf = $\frac{\text{No}}{1+\{(\text{No}-1)/\text{N}\}}$ Where

- No = Initial sample size (380)
- Nf = final sample size
- N = Children with epilepsy who are registered and on follow up at pediatric neurology follow up clinic of JMC, which was estimated to be 280.
- NR = Non response rate

Hence, Nf = $\frac{380}{1+\{(380-1)/280\}} = 162$

By taking 5% NR; the final sample size became 170 Children with epilepsy.

4.5.1. Sampling technique and Procedure

According to the three consecutive months Health Management Information System (HMIS) report/activity report of JMC; the three months average visit/load at pediatrics neurology follow up clinic was around 280 children with epilepsy; hence by using this data and calculated sample size which was 170 children with epilepsy; all children with epilepsy who fulfilled the inclusion criteria and consented to participate in the study were interviewed at

interval (k^{th} value) of 1.6(~1)(280/170); then patients were interviewed consecutively until required sample size was obtained at their exit from neurology clinic.

4.6. Study variables

4.6.1. Dependent variable

- Adherence Status to AEDs

4.6.2. Independent variables

A. **Parent's Socio-demographic and economic related factors:** Age, Marital status, Educational status, Occupation status, Place of residence, Family size, Family's monthly income.
B. **Child's related factors (Socio-demographic, clinical and treatment profiles):** Age, Sex, Educational status, type of seizure, family history of epilepsy, presence of other medical illness/Comorbid illness/, Number of AEDs prescribed, duration on treatment, Reported side effects, way of getting medication (Cash/payment, CBHI, Free), Concomitantly used drugs
C. **Health facility/service related factors:** Distance from home to the hospital, Means of transportation to the hospital, time taken to reach to the hospital, getting health information and advice about epilepsy & AEDs during collection, Problems faced in the hospital during health care delivery like shortage of AEDs & poor communication that hindered them from taking the AEDs.
D. **Parental Knowledge about Epilepsy:** Knowledge about epilepsy, its causes, the sign and symptoms, consequences, prevention and treatment of epilepsy.
E. **Parental Attitude towards Epilepsy**

4.7. Data collection tools and procedures

Data were collected by two registered pharmacists and supervised by a general Practitioner (GP) who had previous experience in data collection by using pre-tested interviewer administered semi-structured questionnaire which was developed by compiling a number of questions adapted from similar study materials, review of relevant literature and articles (33–

35) that could address the objective of the study. The questionnaire was prepared in the English language and then was translated to the local languages; Amharic & Afaan Oromoo by language expert (who was fluent in English, Amharic and Afaan Oromoo languages) and then retranslated back to English by experts who had similar experiences for checking consistency.

The study participants were given an orientation on the protocol and specific details concerning participation in the study and verbal consent was obtained from each eligible study participant.The eligible participants were approached and interviewed at their exit from the neurologic follow-up clinic. The diagnosis of each child/adolescent including comorbidities, types of anti-epileptic drug(s) he/she was taking and some of the AED side effects were retrieved from charts at time of interview. The principal investigator supervised closely the overall data collection activities daily.

4.8. Operational definitions and Variable measurements

Medication Adherence: refers to the extent to which a patient's behavior corresponds with the recommendations of a health professional with respect to timing, dosage, and frequency of medication persistence as the duration of time from initiation to discontinuation of therapy(12).

Adherence to AEDs: Measured by eight-item Morisky Medication Adherence Scale (MMAS)(33) that is widely used to measure self-reported adherence adopted from the previous study. Items 1-7 are yes/no questions, in which a "no" answer receives a score of 1 and a "yes" answer receives a score of 0, except for item 5, which is reverse scored. Item 8 is measured on a five-point scale. The responses "never", "once in a while", "sometimes", "usually", and "all the time" are scored, 1, 0.75, 0.50, 0.25, and 0, respectively. The total score ranges from 0 to 8. The MMAS-8 has widespread acceptance in clinical settings and internally consistent and validated in Nigeria(19) and Ethiopia(36).

- Low adherence/non-adherence:- Patients scores < 6 of 8 items MMAS.
- Medium adherence: - Patients scores 6-7 of 8 items MMAS.
- High adherence: - Patients scores 8 of 8 items MMAS.

- Overall adherence: - Dichotomized as adherent and non-adherent. In this study individual in category of medium and high adherence taken as adherent and low adherence as non-adherent(37).

Behavioral abnormality: Includes agitation, depressed mood, aggression, psychosis, hyperactivity, and restlessness usually after initiation of AED(s).

Controlled seizures: Children/Adolescents with epilepsy on AED(s) have no seizure episode(s) in the past 3months(38).

Un-controlled seizures: Children/Adolescents with epilepsy on AED(s) have one or more seizure episode(s) in the past 3months(38).

Parental Knowledge about Epilepsy: The respondents' comprehensive knowledge of Epilepsy will be computed by summing up 12 multiple-choice items having Yes, No and I don't know/not sure answers. A correct answer for each item will be scored as "1" and incorrect/not sure answer will be scored as "0." In this study, participants who score equal to or above the mean will be classified as having good knowledge of Epilepsy and those who score below the mean will be considered as having poor knowledge.

Parental Attitude towards Epilepsy: This section had 11 items and 4- point Likert scale response options consisting of "strongly agree, agree, disagree, and strongly disagree.The response options were given (scored) a point of 4, 3, 2, and 1 respectively. The minimum score is 11, and the maximum score is 44. In this study, participants who score equal to or above the mean will be classified as having a **positive attitude towards epilepsy** and those who score below the mean will be considered as having a **negative attitude towards epilepsy**. The reliability of the pretested questionnaire was checked by using Cronbach's alpha test, and its value was 0.90 for attitude and 0.81 for the knowledge-screening tool(34).

4.9. Data management and quality control

Two registered BSC pharmacists and one general pratitioner (GP) were recruited as data collectors and supervisor respectively. To keep the uniformity of the data collection process; data collectors and supervisors were trained and oriented for two days on the objective of the

study, method of data collection, interview technique and on the context of data collection tool.

A pre-test was conducted on 5% (9) children having epilepsy was done in the pediatrics neurology follow- up clinic, JMC 1 week before collection to assess its clarity, length, completeness and consistency. After the pretest necessary adjustment was made to the tool.

Data were checked for completeness, accuracy and consistency by principal investigator on a daily basis. Double entry of data for checking errors was performed to assure quality of data before analysis.The questionnaire was prepared in the English language and was translated to the local languages; Amharic & Afaan Oromoo by a language expert and then re-translated back to English by experts who had similar experiences to check for consistency.

4.10. Data processing & analysis

The data on the questionnaire were entered into Epidata manager version 3.1 and double entry verification was made and then was exported to SPSS version 26 statistical packages for analysis. The data were edited and cleaned for inconsistencies, explored to check outliers, missing data and assumptions.

Descriptive statistics (frequencies, percentages, mean values, standard deviations and cross tabulation) was calculated for socio-demographic and economic status of the participants, child's health related factors [clinical and treatment profiles] and health facility related factors. Variables for knowledge about epilepsy, attitude towards to epilepsy and level of adherence were computed using variables recoding. Bivariate analysis was performed to select variables for multivariate analysis. Hence variables with a p-value ≤ 0.25 in the bivariate analysis were taken as candidates for multivariable analysis. Finally, multivariable logistic regression analysis was performed to identify the independent predictors of Adherence to AEDs. The final model was fitted using stepwise selection methods (backward logistic regression). Variables with a p-value of < 0.05 in multivariable logistic regressions were taken as statistically significant predictors for adherence and OR with its 95% CI was used to show the degree of association between the independent and the outcome variable. Results were reported as percentages (frequency) for categorical variables and findings were summarized

and presented in the form of tables and charts; and interpreted in the line of its objective with narration.

4.11. Ethical consideration

Ethical clearance and approval of the research was obtained from Institutional Review Board of Institite of Health, Jimma University. In addition, written permission was obtained from the Medical Director of Jimma Medical Center to conduct the study. Study participants were recruited voluntarily after providing full information about the objective of the study, the confidentiality of the data, and after a verbal consent agreement were taken.

Strict confidentiality was assured through anonymous recording and coding of questionnaires and placed in a safe place. In addition, safety precautions were implemented during training of data collectors, supervisor; and during interview of parent(s)/ caretaker(s) and children according to national COVID-19 prevention protocol.

4.12. Dissemination and Utilization of Results

The result of the study will be presented to the department of pediatrics and child health, Jimma University. The final result from the study will be submitted to the Research and Postgraduate Office, Jimma University in a form of written report. Subsequently, the study result will be published on peer reviewed journal.

5. RESULTS

5.1. Socio-demographic and economic characteristics of participants/caregivers

A total of 170 children/adolescents having epilepsy on follow- up were involved in this study. Nearly nine from ten (150, 88.2%) of caregivers of children having epilepsy were father (44.1%) and mother (44.1%). The age of most 70(41.2%) of them was between 18-35 years and more than half (98, 57.6%) of the participants were from rural area. About 132(77.5%) of parents/caregivers were married and 66(38.8%) of them can not read & write. Nearly half 84 (49.4%) of parents/caregivers were farmers, more than half 93 (54.7%) of their monthly income was 1500-3500ETB and 93 (54.7%) had family size of ≤ 5.

More than half 93 (54.7%) of the childern having epilepsy were male, most 76 (44.7%) of them were adolescents(10-17 year of age) & 32 (32/109, 29.4%) of them didn't attend school (**Table 1**).

Table 1: Socio-demographic and economic related characteristics of participants and parents/caregivers

Sr. No	Variables	Category	Frequency	Percentage (%)
Parents/caregivers background				
1	Primary caregiver (Caregiver's identity)	Father	75	44.1
		Mother	75	44.1
		Sibling	9	5.3
		Grandparents	8	4.7
		Uncle/Aunt	3	1.8
2	Age of caregiver (years)	18- 35	70	41.2
		35- 45	53	31.2
		≥ 45	47	27.6
3	Residence	Urban	72	42.4
		Rural	98	57.6
4	Current marital	Single	11	6.5
		Married	132	77.5

	status of caregiver	Separated	7	4.1
		Divorced	9	5.3
		Widowed/Widower	11	6.5
5	Educational status of the caregiver	Can not read and write	66	38.8
		Can read and write	29	17.1
		Primary school	23	13.5
		Secondary school	36	21.2
		College/University	16	9.4
6	Occupational status of the caregiver	House wife	28	16.5
		Farmer	84	49.4
		Merchant	33	19.4
		Government employee	20	11.7
		Daily laborer	4	2.4
		Others*	1	0.6
7	Family size	≤ 5	93	54.7
		>5	77	45.3
8	Average monthly income	<1,500 ETB**	37	21.8
		1,500- 3,500 ETB	93	54.7
		>3,500 ETB	40	23.5
Child's background				
9	Age of the child (years)	<1	2	1.2
		1- 5	39	22.9
		6- 10	53	31.2
		10- 17	76	44.7
10	Sex of the child	Male	93	54.7
		Female	77	45.3
11	Educational status of the child	Pre-school	61	35.9
		Primary school	73	42.9
		High school	4	2.4
		Not attend school	32	18.8

* Student ** Ethiopian Birr

5.2. Child's health related factors (clinical and treatment profiles)

Among 170 of the study participants; 104(61.2%) of them were diagnosed with generalized seizure, 10(5.9%) of them had family history of seizure/epilepsy. Around 106(62.4%) of study participants were on treatment for more than 2 years and 106(63.5%) of them were on monotherapy. Mostly prescribed AED was phenytoin only, 82(48.2%). 44(25.9%) of the children were ever stopped/missed their AED doses since starting of therapy, among main reasons of stopped/missed AEDs were forgetfulness, 31(70.5%). More than one-fourth, 46(27.1%) of the study participants reported some adverse effects with AEDs, more than half (24, 52%) of them were reporting drowsiness. With regard to co-morbidity, 9(5.3%) of the study participants have had additional diagnosis, from which two-third accounted for cerebral palsy. Among 170 study participants, the seizure was controlled in 92(54.1%) of cases (**Table 2**).

Table 2: Health related factors [clinical and treatment profiles] among study participants

Sr. No	Variables	Category	Frequency	Percentage (%)
1	Main seizure type	Focal seizure	30	17.6
		Generalized seizure	104	61.2
		Unclassified seizures	36	21.2
2	Duration since diagnosis(in years)	≤ 2	58	34.2
		>2	112	65.8
3	Duration on treatment(in months)	6- 12	34	20.0
		13- 24	30	17.6
		>24	106	62.4
4	Family history of seizure/epilepsy	Yes	10	5.9
		No	155	91.2
		I am not sure	5	2.9
5	Mode of therapy used	Mono-therapy	108	63.5
		Dual therapy	61	35.9
		Triple therapy	1	0.6
6	AEDs prescribed	Phenobarbitone only	24	14.1
		Phenytoin only	82	48.2
		Valproate only	2	1.2
		Phenytoin & Phenobarbitone	52	30.6
		Phenytoin & Valproate	4	2.4
		Phenobarbitone & carbamazepine	5	2.9

		Phenobarbitone, phenytoin and Valproate	1	0.6
7	Stopped/ missed AEDs doses	**Yes**	**44**	**25.9**
		No	126	74.1
8	Main reasons for stopping or for not taking the tablets regularly (**n= 44**)	Forgetfulness	31	70.5
		Fear of side effects	13	29.5
		Feeling better	7	15.9
		Run out of drug/Did not get adequate tablets from the hospital	16	36.4
		Child refuses to take drugs	9	20.5
		Financial constraints	9	20.5
		Others *	6	13.6
9	Adverse effects to AEDs	**Yes**	**46**	**27.1**
		No	118	69.4
		I do not know	6	3.5
10	Types of AEDs adverse effects (**n= 46**)	Behavioral abnormality	9	19.6
		Gum hyperplasia/swelling	10	21.7
		Skin rash	2	4.3
		Drowsiness	24	52.2
		Fatigue	11	23.9
		Decreased concentration	6	13.0
		Constipation	2	4.3
		Others**	2	4.3
11	Does the child have other additional diagnosis?	**Yes**	**9**	**5.3**
		No	161	94.7
12	Other comorbid conditions (**n= 9**)	Cerebral palsy	6	66.7
		Developmental delay	1	11.1
		Microcephaly	1	11.1
		T1DM***	1	11.1
13	Use of other ancillary medication(s)	Yes	1	0.6
		No	169	99.4
14	Use of herbal/traditional medicine as additional treatment	Yes	9	5.3
		No	161	94.7
15	Seizure frequencies in the last 3 months	No seizure (Controlled seizure)	92	54.1

	(Seizure control status)	≥ 1 episode (Un-controlled seizure)	78	45.9

* COVID-19 (4 cases), Mourn (2 cases) ** Dyspepsia (Epigastric discomfort) *** Type-one diabetes mellitus

5.3. Health facility/ service related factors

Among the study participants, 73(42.9%) of them travel more than 20kms to arrive JMC and 119(70%) of them were using public transport only. More than half (100, 58.8%) of study participants received counseling about epilepsy &/or AEDs sometime during follow up visit; 84(84%) of them were counselled about 'importance of AEDs' and 79(46.5%) of them get AEDs free of charge. Less than half (75, 44.1%) of the study participants faced one or more problems in hospital during follow up visit; 68(90.7%) of the reported problems were 'shortage of AEDs.' (**Table 3**)

Table 3: Health facility/ service related factors among study participants

Sr.No	Variables	Category	Frequency	Percentage (%)
1	Distance from home to hospital	≤ 10 km	68	40.0
		10- 20 km	29	17.1
		> 20 km	73	42.9
2	Means of transport to the hospital	On foot	13	7.6
		Public transport	119	70.0
		On foot then public transport	38	22.4
3	Time taken from home to hospital	< 30 minutes	41	24.1
		30- 60 minutes	55	32.4
		> 60 minutes	74	43.5
4	Health education &/or advice about epilepsy and AEDs	**Yes**	**100**	**58.8**
		No	70	41.2
5	Type of counselling/advice given about AEDs? (**n= 100**)	Importance of AEDs* tablets	84	84.0
		Method of use	50	50.0
		Side effects of the drug(s)	42	42.0
		Not to miss dose and appointment	43	43.0
6	AED(s) refill (Way of getting the medication(s))	By cash/payment	12	7.0
		By CBHI**	7	4.1
		Free of charge	79	46.5
		Free sometimes cash	72	42.4

7	Problems faced in the hospital during health care delivery (inappropriate health care)	Yes	75	44.1
		No	95	55.9
8	Type(s) of problem(s) faced in the hospital during health care delivery(n= 75)	Shortage of AEDs	68	90.7
		Long waiting time	18	24
		Poor communication from the staffs	13	17.3

*Anti-epileptic drugs **Community based health insurance

5.4. Parents/caregivers overall/mean knowledge and Attitude about and towards epilepsy respectively

Among the study participants; more than half (97, 57.1%) of them were found to have overall good knowledge about epilepsy and 95(55.9%) of them were having overall positive attitude towards epilepsy (**Table 4**).

Table 4: Overall knowledge and attitude of parents/caregivers about and towards epilepsy

Variables	**Category**	**Frequency**	**Percentage (%)**
Parental knowledge about epilepsy	Poor knowledge	73	42.9
	Good knowledge	97	57.1
Parental attitude towards epilepsy	Negative Attitude	75	44.1
	Positive Attitude	95	55.9

5.5. Adherence status to AEDs of the study participants

Among 170 study participants, more than half (54.1%) of them were found to be adherent to their AED(s).

Table 5: Overall adherence status to AEDs among study participants

Variables	**Category**	**Frequency**	**Percentage (%)**
Adherence status to AED(s)	High adherence to AED(s)	18	10.6
	Moderate adherence to AED(s)	74	43.5

	Overall adherent to AED(s)	**92**	**54.1**
	Non-adherent to AED(s)	78	45.9

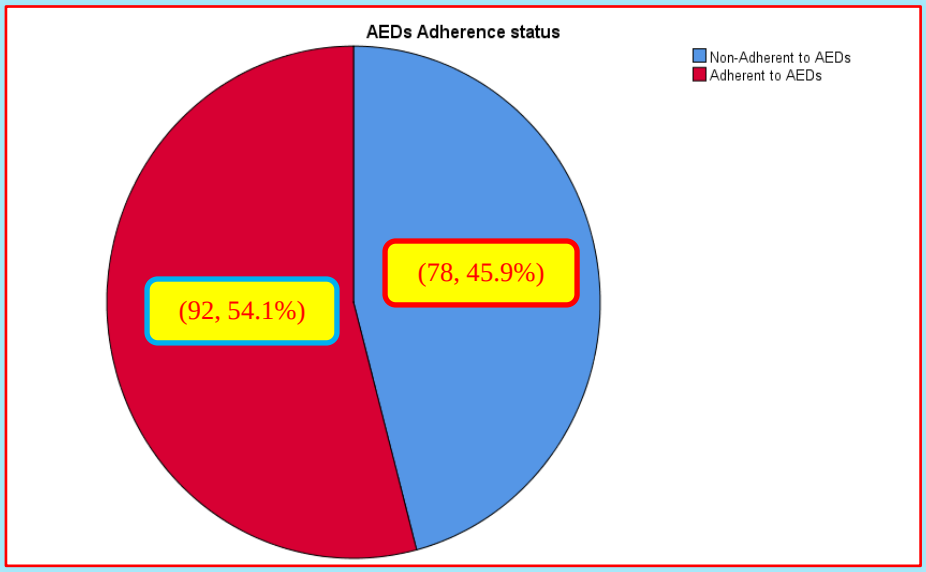

Figure 2: Overall adherence status to AEDs, Jimma Medical Center, 2021

5.6. Candidate and predictor variables to Adherence to AEDs

5.6.1. Candidate variables Associated with Adherence to AEDs

Bivariate logistic regresion analysis was made to identify candidate variables for multivariate analysis and factors including caregivers' marital status, Educational status of the child, Seizure control status, Way of getting the medication (AEDs refill), those who did not face problems in the hospital during service delivery and those caregivers who had good knowledge and positive attitude were candidate variables for the outcome variable (**Table 6**).

Table 6: Bivariate analyses for factors associated with Adherence to AEDs among study participants

Variables	Category	Adherence status		COR (95%CI)	P-value
		Non-Adherent to AEDs	Adherent to AEDs		
Current marital status of caregiver	Single	7	4	0.66 (0.11,4 .01)	0.648
	Married	47	85	2.69 (0.75, 9.66)	0.129*
	Separated	6	1	0.70 (0.90, 5.43)	0.733
	Divorced	8	1	.88 (0.14, 5.58)	0.888
	Widowed/Widower	10	1	1	
Educational status of the child	Pre-school	26	35	1.97 (0.83, 4.69)	0.127*
	Primary school	30	43	2.10 (0.90, 4.88)	0.087*
	High school	3	1	0.49 (0.05, 5.22)	0.552
	Not attend school	19	13	1	
Seizure control status	No seizure (Controlled)	30	65	3.67 (1.94, 6.93)	0.000*
	≥1 episode (Uncontrolled)	48	27	1	
AEDs refill(Way of getting the medication(s))	Cash/payment	5	7	1.75 (0.51, 6.04)	0.376
	CBHI**	5	2	0.50 (0.09, 2.75)	0.425
	Free of charge	28	51	2.28 (1.18, 4.38)	0.014*
	Free sometimes cash	40	32	1	
Problems faced in the hospital (Inappropriate healthcare)	No	20	75	0.15 (0.08, 0.29)	0.000*
	Yes	58	17	1	
Parental knowledge about epilepsy	Good knowledge	19	73	0.13 (0.10, 0.26)	0.000*
	Poor knowledge	53	25	1	
Parental attitude towards epilepsy	Positive Attitude	44	34	0.93 (0.21, 0.73)	0.003*
	Negative Attitude	31	61	1	

* P-value < 0.25 ** Community Based Health Insurance

5.6.2. Predictor variables of Adherence to AEDs

Multivariable logistic regresion analysis was used to calculate odds ratios and corresponding 95% confidence intervals for the predictors of Adherence to AEDs. Seven variables were selected by bivariate analysis and then analyzed with multivariate logistic regression. Those caregivers who were married [AOR=7.46 (95% CI= 1.46, 38.20)], those with controlled seizure status (No seizure episode in the last three months) [AOR= 3.64 (95% CI =1.51, 8.78)], those who got appropriate health care [AOR= 7.08 (95% CI= 2.91, 17.24)], children of those caregivers who had good knowledge [AOR= 6.20 (95% CI= 2.60, 14.83)] and positive attitude [AOR= 2.57 (95% CI= 1.06, 6.28)] were significantly associated with adherence to AEDs. (**Table 7**)

Table 7: Multiple logistic regression model predicting factors associated with Adherence to antiepileptic drugs (AEDs) among study participants

Variables	**Category**	**AEDs Adherence status**		**AOR (95%CI)**	**P-value***
		Non Adherent	Adherent		
Current marital status of caregiver	Single	7	4	1.73 (0.16, 18.85)	0.655
	Married	47	85	7.46 (1.46, 38.20)	0.016*
	Separated	6	1	0.50 (0.05, 5.32)	0.561
	Divorced	8	1	1.67 (0.17, 16.83)	0.665
	Widowed/Widower	10	1	1	
Educational status of the child	Pre-school	26	35	1.85 (0.53, 6.48)	0.333
	Primary school	30	43	2.92 (0.89, 9.57)	0.077
	High school	3	1	0.61 (0.01, 79.49)	0.844
	Not attend school	19	13	1	
Seizure control status	No seizure (Controlled)	29	63	3.64 (1.51, 8.78)	0.004*
	≥ 1 episode (Uncontrolled)	49	29	1	
AEDs refill (Way of getting the medication(s))	Cash/payment	5	7	2.02 (0.37, 11.12)	0.420
	CBHI**	5	2	0.32 (0.03, 3.80)	0.370
	Free of charge	28	51	1.33 (0.52, 3.31)	0.544
	Free sometimes cash	40	32	1	
Problems faced	No	20	75	7.08 (2.91, 17.24)	0.000*

in the hospital (Inappropriate healthcare)	Yes	58	17	1	
Parental knowledge about epilepsy	Good knowledge	21	76	6.20 (2.60, 14.83)	0.000*
	Poor knowledge	57	16	1	
Parental attitude towards epilepsy	Positive Attitude	56	36	2.57 (1.06, 6.28)	0.038*
	Negative Attitude	22	56	1	

* P-value < 0.05 ** Community Based Health Insurance

6. DISCUSSIONS

6.1. Discussion

Adherence to antiepileptic drugs is a key to treatment success, one of the main causes of unsuccessful drug treatment is poor adherence to prescribed medications (10,11). Adherence to antiepileptic medications results in decrement of relapses, minimized frequency of seizures, decreased cost of healthcare, increased therapeutic benefits and better patient outcomes(12). This study was conducted to assess the prevalence of AED adherence and associated factors among children/adolescents having epilepsy on follow- up in JMC.

The adherence status to AEDs in this study was 54.1% and the rest (45.9%) of the study participants were non-adherent to AEDs which was quite high. The prevalence of adherence to AEDs in children having epilepsy is nearly similar to the study done in South Africa (55%) in 2016 (20) and Joe, Nigeria (55.2%) in 2019(19), this might be because of similar socio-demographic status of the study population participated and use of similar scales(MMAS-8)(in Nigerian study) to assess adherence in these studies.

However, the prevalence of adherence to AEDs in our study was significantly lower than the study done in 94 children in the Kingdom of Saudi Arabia (61.7%) (18). The possible justification for the disparities between these studies might be different demographic status, lower study population (N=94) and use of earlier scale (MMAS-4) to assess adherence in this study; and also lower than the study done in Uganda (79.5%) in 2014 (16), this difference might be because of use of different scales to assess adherence to AEDs (self report- focus group discussion).

The prevalence of adherence to AEDs in this study was higher than that of study done in Turkey (47.3%) (32), Pakistan (42%)(30), USA (42%)(21), Bangladesh (38.8%) (31), Indian subcontinent (29%)(22) and Western China (27.3%)(17); these differences might be due to use of different adherence measuring scale (e.g. Electronic method to measure adherence in study done in USA) and different definitions of adherence to AEDs (e.g. moderate and low adherence were considered as ‘poor adherence’ in study done in Western China and Indian Subcontinent).

There were different factors contributing to the adherence to prescribed anti-epileptic regimen. The current study identified marital status of the caregivers; i,e being married caregiver(s)/parent(s) was associated with the adherence. This might be due to stable and full family support(similar with the study done in KSA, Gabr & Shams, 2015). Others associated with adherence to AEDs include children/adolescents whose seizure was controlled might be due to treatment satisfaction and frequency of seizure will increase in those who were non-adherent to thier medications(Gabr & Shams, 2015). Parents/caregivers who recieved appropriate health care in the hospital during follow- up visit were more than 6 times adherent to their AEDs; this was due to smooth and friendly communication with hospital staff(which was similar with the study done in KSA, Gabr & Shams, 2015) and also might be due to recieving of appropriate health/drug information from medical staff(similar with the study done in W. China, Yang et al, 2020); those parents/caregivers whose knowledge about epilepsy was good(about 6 times) and positive(about 4 times) attitude towards epilepsy were more adherent to AEDs (increased awareness about epilepsy & AEDs might contribute, supported by study done in Turkey, Furkan- Korkmaz et al., 2020).

In a study done in South Africa(20), long duration of therapy and medications(Oxcarbamazepine, Valproic acid and Phenytoin) were significantly associated with adherence to AEDs; the age of the patient, type of epilepsy, total household income and source of drug information in Western China(17); monotherapy, good family support & lower frequency of seizures(similar to our study) in KSA(18) were associated significantly with adherence to AEDs.

Higher family socioeconomic status was significantly associated with AED adherence in a study done in USA(21); low socioeconomic status, multiple drug intake & long duration of therapy were significantly associated with AED non-adherence in Joe, Nigeria(19).

Seizure control status is a key to adherence to AEDs which helps patients stick to their medications. In this study 92 (54.1%) of the children/adolescents had controlled seizure status (no seizure episodes in the past 3 months) which was significantly associated with adherence. Our finding was similar to the study done (seizure control=51.78%) in Indian Subcontinent in which one or more seizure episodes in the past 3 months(un-controlled seizure) adversely

affected AED adherence(22) and higher than the study done in Bangladesh (33.6% seizure control status) which was significanly associated with adherence to AEDs(31). In contrast to out study, age of the child (0- 5 years, because drugs are given by the patients/caregivers, while adolescents usually manage their own treatment) and literacy of the caregivers was significantly associated with AED adherence in the study done in Turkey(32).

Being on multiple drugs can lead to non-adherence in many ways. These include increased medication cost, pill burden and more adverse drug reactions (ADRs). Pill burden is particularly a problem in children and adolescents and refusal to take drugs is worse with increasing number of medications. Monotherapy for epilepsy is the standard management; polytherapy is more likely to be associated with drug toxicity (19). Nearly two third (108, 63.5%) of our study participants were on monotherapy (similar to study done in Nigeria, 59.3%)(19), from this 'Phenytoin only' accounted for nearly half (82, 48.2%) of cases; from those (those on monotherapy) more than half of them (61, 56.5%) were adherent to their medication but mode of therapy was not associated with adherence status to AEDs in this study.

About 97(57.1%) of parents/caregivers participated in this study had good knowledge about epilepsy which was similar to the study done in Ethiopia (North Shoa, 2018) (56.4%)(34); similar cultural, economic, and sociodemographic features might contriibute. Our finding was significantly associated with adherence to AEDs similar with the study done in Turkey(caregivers' health literacy knowledge was significantly associated with AEDs adherence,)(31); and our finding was significantly higher in comparison to the study done in India (10/60, 16.7%) (39), this difference might be due to small sample size (N=60).

Around 92 (54.1%) of the study participants were having a positive attitude towards epilepsy and was significantly associated with adherence status to AEDs which was comparable with the study done in India (55%)(39) and it was comparable with the study done in Ethiopia (N. Shoa, 2018)(58.7%)(34).

6.2. Strength

The strength of this study is inclusion of special population who need special attention as adherence status evaluation which may affect quality of life and learning ability of the child. Using professional data collectors (Registered BSC pharmacists) and supervisor (Medical Doctor) were also an advantage for effective collection of child's health related information. Using self-report measures (MMAS-8) are also strength of this study which are simple to implement in all age groups, economically sounding, capable of providing real-time feedback regarding adherence behaviors and validated for clients with most chronic illnesses including epilepsy in both developed and developing nations.

6.3. Limitations

Hence the actual prevalence of adherence to AED(s) may be even lower because we used parent/caregiver-report to assess adherence status which may be subjected to recall bias as some may feel pressured to give acceptance responses to gain positive reaction from data collectors/health care workers.

Relatively smaller sample size and the research was done in single institution which may not show the actual prevalence of the problems hence, may not help to generalize the findings of this study for regional or country level. Relatively short study period due to time and financial constraint further affect the outcome of this study.

Social desirability bias could have affected the quality of data collections because study subjects might get difficulty to answer questions related to problems faced in the facility in the presence of an interviewer. Moreover, Selection of questions and indicators could also have lead to a skewed interpretation.

Farther more, diagnosis of seizure type was based clinical presentation, there was no routine EEG for diagnosis.

7. CONCLUSION AND RECOMMENDATION

7.1. Conclusions

More than half of the children/adolescents having epilepsy were adherent to their anti-epileptic medication(s). In addition, children's adherence to AEDs was influenced by different factors such as marital status of parents/caregivers, controlled seizure status, appropriate health care delivery, caregiver's knowledge; and attitude towards epilepsy.

7.2. Recommendations

Based on the finding of this study, the following recommendations were forwarded:

- **For Jimma Zone Health Department**
  - Jimma Zone health department should give attention to increase adherence rate in Jimma Zone by developing strategies with the aim of maximum adherence to AEDs.
  - It is recommended to give community based health education and counselling about epilepsy at all levels especially teaching parents/caregivers which plays a significant role in changing their attitude and awareness about epilepsy which can help enhance their adherence to AED(s).
- **For Jimma Medical Center**
  - It is recommended to Jimma Medical Center to avail medications, expand service rooms with adequate staff to minimize waiting time and give compassionate, respectful and caring training to staff working at paediatrics (neurology) follow up clinic to increase adherence rate to AED(s).
  - It is recommended to JMC staff working at paediatrics (neurology) follow up clinic to focus on counseling of parents/caregivers and/or children about adherence to AEDs, epilepsy and medications.

REFERENCES

1. Global Campaign against Epilepsy, International Bureau of Epilepsy, International League against Epilepsy, editors. Atlas: epilepsy care in the world. Geneva: Programme for Neurological Diseases and Neuroscience, Department of Mental Health and Substance Abuse, World Health Organization; 2005. 91 p.

2. Epilepsy [Internet]. [cited 2021 Feb 22]. Available from: https://www.who.int/news-room/fact-sheets/detail/epilepsy

3. Linda L. Altizer, Roberta H. Baron. Brunner and Suddarth's Textbook of Medical-Surgical Nursing. Lippincott Co. 2010;1:2364.

4. Faheem Hyder Pottoo, Fatimah Al-Khalifa, Fatimah Al-Hassar, Sarah Al-Muhanna, Mastour Al-Ghamdi, Danah Aljaafari, et al. ANTIEPILEPTIC DRUGS: PRESCRIPTION PATTERN, HEMATOBIOCHEMICAL CHANGES AND ADVERSE EFFECTS: A RETROSPECTIVE STUDY IN EASTERN PROVINCE OF SAUDI-ARABIA. Int J Pharm Sci Res. 10(11).

5. Fisher RS, Acevedo C, Arzimanoglou A, Bogacz A, Cross JH, Elger CE, et al. ILAE Official Report: A practical clinical definition of epilepsy. Epilepsia. 2014 Apr;55(4):475–82.

6. Fisher RS. An overview of the 2017 ILAE operational classification of seizure types. Epilepsy Behav. 2017 May;70:271–3.

7. Aaberg KM, Gunnes N, Bakken IJ, Lund Søraas C, Berntsen A, Magnus P, et al. Incidence and Prevalence of Childhood Epilepsy: A Nationwide Cohort Study. Pediatrics. 2017 May;139(5):e20163908.

8. Paul A, Adeloye D, George-Carey R, Kolčić I, Grant L, Chan KY. An estimate of the prevalence of epilepsy in Sub–Saharan Africa: A systematic analysis. J Glob Health [Internet]. 2012 Dec [cited 2021 May 16];2(2). Available from: http://www.jogh.org/documents/issue201202/13-Article%20Paul.pdf

9. Goldenberg MM. Overview of Drugs Used for Epilepsy and Seizures- Etiology, diagnosis, and treatment. Pharm Ther. 2010 Jul;35(7):24.

10. Mitchell WG, Scheier LM, Baker SA. Adherence to Treatment in Children With Epilepsy: Who Follows "Doctor's Orders"? 2000;41(12):10.

11. Snodgrass SR, Parks BR. Anticonvulsant Blood Levels: Historical Review With a Pediatric Focus. J Child Neurol. 2000 Nov;15(11):734–46.

12. Aylward BS, Rausch JR, Modi AC. An Examination of 1-Year Adherence and Persistence Rates to Antiepileptic Medication in Children With Newly Diagnosed Epilepsy. J Pediatr Psychol. 2015 Jan 1;40(1):66–74.

13. Faught RE, Weiner JR, Guérin A, Cunnington MC, Duh MS. Impact of nonadherence to antiepileptic drugs on health care utilization and costs: Findings from the RANSOM study. Epilepsia. 2009 Mar;50(3):501–9.

14. Paul A, Adeloye D, George-Carey R, Kolčić I, Grant L, Chan KY. An estimate of the prevalence of epilepsy in Sub–Saharan Africa: A systematic analysis. J Glob Health [Internet]. 2012 Dec [cited 2021 Feb 1];2(2). Available from: http://www.jogh.org/documents/issue201202/13-Article%20Paul.pdf

15. Sabaté E, World Health Organization, editors. Adherence to long-term therapies: evidence for action. Geneva: World Health Organization; 2003. 198 p.

16. Nazziwa R, Mwesige AK, Obua C, Ssenkusu JM, Mworozi E. Adherence to antiepileptic drugs among children attending a tertiary health unit in a low resource setting. Pan Afr Med J [Internet]. 2014 [cited 2021 Feb 1];17. Available from: http://www.panafrican-med-journal.com/content/article/17/44/full/

17. Yang C, Yu D, Li J, Zhang L. Prevalence of medication adherence and factors influencing adherence to antiepileptic drugs in children with epilepsy from western China: A cross-sectional survey. Epilepsy Behav. 2020 Mar;104:106662.

18. Gabr WM, Shams MEE. Adherence to medication among outpatient adolescents with epilepsy. Saudi Pharm J. 2015 Jan;23(1):33–40.

19. Ejeliogu EU, Courage A. Prevalence and factors associated with non-adherence to antiepileptic drugs among children with epilepsy in Jos, Nigeria. Niger J Paediatr. 2020 Aug 6;47(3):240–5.

20. Burger J, Jacobs K, Julyan M, Lubbe M, Cockeran M. Medicine possession ratio as proxy for adherence to antiepileptic drugs: prevalence, associations, and cost implications. Patient Prefer Adherence. 2016 Apr;539.

21. Modi AC, Rausch JR, Glauser TA. Patterns of Nonadherence to Antiepileptic Drug Therapy in Children With Newly Diagnosed Epilepsy. :8.

22. Chauhan S, Prasad PL, Khurana B, Gahalaut P. Self-reported medication adherence to antiepileptic drugs and treatment satisfaction among paediatric patients having epilepsy: A cross sectional study from the Indian subcontinent. Sri Lanka J Child Health. 2018 Jun 5;47(2):129.

23. Gomes MDM, Maia Filho HDS, Noé RAM. Anti-epileptic drug intake adherence: the value of the blood drug level measurement and the clinical approach. Arq Neuropsiquiatr. 1998 Dec;56(4):708–13.

24. Sweileh WM, Ihbesheh MS, Jarar IS, Taha ASA, Sawalha AF, Zyoud SH, et al. Self-reported medication adherence and treatment satisfaction in patients with epilepsy. Epilepsy Behav. 2011 Jul;21(3):301–5.

25. Qoul KZ, Qasem DA, Samawi OH, Matter LN, Abo-tineh SI, Abo-olem M. Antiepileptic medication adherence in children with epilepsy at Queen Rania Al-Abdullah Children Hospital. Ind J Med Res Pharm Sci 2015 2 91. 2015;98.

26. Nowacki J, Viliani F, Martuzzi M, Fehr R. Health in Impact Assessments – Opportunities not to be missed. Eur J Public Health [Internet]. 2014 Oct 1 [cited 2021 Feb 10];24(suppl_2). Available from: https://academic.oup.com/eurpub/article-lookup/doi/10.1093/eurpub/cku166.136

27. Chinnaiyan S, Narayana S, Nanjappa VP. Adherence to Antiepileptic Therapy in Adults. J Neurosci Rural Pract. 2017 Jul;08(03):417–20.

28. Fiest KM, Sauro KM, Wiebe S, Patten SB. Prevalence and incidence of epilepsy. 2016;8.

29. Gurumurthy R, Chanda K, Sarma G. An evaluation of factors affecting adherence to antiepileptic drugs in patients with epilepsy: a cross-sectional study. Singapore Med J. 2017 Feb;58(2):98–102.

30. Malik M, Shabbir N, Saeed M, Malik H, Mirza A. Medication Nonadherence in Children with Epilepsy Attending Outpatient Clinics in Under-Resourced Community. J Pediatr Epilepsy. 2015 Jul 31;04(02):072–9.

31. Chowdhury S, Phani AK, Das P, Ahammed Z, Kayasthagir PK, Md Hassanuzzaman -. Adherence to Antiepileptic Drugs and Seizure Control Among Patients with Epilepsy. Chattagram Maa-O-Shishu Hosp Med Coll J. 2020 Aug 28;19(1):68–73.

32. Furkan-Korkmaz M, Erdem-Uzun M, Korkmaz M, Ekici A. Adherence to Antiepileptic Drugs and the Health Literacy of Caregivers in Childhood Epilepsy. :6.

33. Morisky DE, Ang A, Krousel-Wood M, Ward HJ. Predictive Validity of a Medication Adherence Measure in an Outpatient Setting. J Clin Hypertens. 2008 May;10(5):348–54.

34. Dargie A, Alemnew N, Admasu E. Public knowledge and attitude towards epilepsy and its associated factors in Debre Berhan, North Shoa, Amhara Region, Ethiopia, 2018/19. Community-based cross-sectional study [Internet]. Epidemiology; 2019 Jul [cited 2021 Feb 15]. Available from: http://medrxiv.org/lookup/doi/10.1101/19001578

35. Rani A, Thomas PT. Parental Knoweldge, Attitude, and Perception about Epilepsy and Sociocultural Barriers to Treatment. J Epilepsy Res. 2019 Jun 20;9(1):65–75.

36. Maregu Shegaw R kassa Yigrem al, Negatu Addissu. Prevalence and Associated Factors of Antiepileptic Drugnonadherence Among Epileptic Patients Attending at Out Patient Departement of Dilla University Referral Hospital, Dilla,gedeo,snnpr, Southern Ethiopia. Int J Biosci Med. 2017;1–11.

37. Niriayo YL, Mamo A, Kassa TD, Asgedom SW, Atey TM, Gidey K, et al. Treatment outcome and associated factors among patients with epilepsy. Sci Rep. 2018 Dec;8(1):17354.

38. Swaiman's pediatric neurology: principles and practice. Sixth edition. Edinburgh ; New York: Elsevier; 2018. 1403 p.

39. Manju VM, Joshi P, Gulati S. A STUDY TO ASSESS THE KNOWLEDGE AND ATTITUDE OF PARENTS OF CHILDREN WITH EPILEPSY. Indian J Child Health. 2015 Jun 25;02(02):76–9.

8. LIST OF ANNEXES

Annex I : Information sheet and informed consent form (English version)

Dear Sir, madam

Good morning / afternoon. My name is _____. I am here today to collect data for a study entitled "Adherence to Anti-epileptic drugs and associated factors among children with epilepsy attending pediatrics neurology follow up clinic of JMC, 2021" which is being conducted by Hawi Mohammed (MD, Pediatrics Resident) from department of Pediatrics and Child health, Jimma Medical Center. The main purpose of this study is to assess level of adherence to Anti-epileptic drugs and associated factors among children with epilepsy attending pediatrics follow up clinic of JMC.

I am asking you, your child(for age ≥10 years) and others to voluntarily participate in this study. What is expected from you and your child (for age ≥10 years) is to respond questions which take about 25 minutes. The data you and your child(for age ≥10 years) provided will be kept in a highly confidential manner by using only code number which is filled by the principal investigator and locking the data and none of your personal and child's identifiers will be on the questionnaire. If you and your child (for age ≥10 years) do not like to participate in this study, it will never affect your child's treatment. If you and your child (for age ≥10 years) feel discomfort with the study, it is your right to drop it any time you want. Thank you.

Are you willing to participate (both caregiver and adolescent)?

☐ Yes ☐ No

Signature of the interviewer certifying that informed consent has been given verbally by respondent(s)!

Questionnaire Code: _____

Date: _____

Sign of DC: _____

Sign of PI: _____

Annex II : Questionnaire (English version)

- A questionnaire prepared for collecting data for the study aiming to assess level of adherence to AEDs and associated factors among children with epilepsy attending Pediatrics neurology follow up clinic of JMC, Jimma, South West Ethiopia, 2021.
- Dear Participant,
    - I would like to thank you for your cooperation for answering this questionnaire.
    - You are kindly requested to answer the questions correctly and honestly so that your accurate responses are highly significant and influential for valuing the results of the study
    - It's not needed to write your name and rather we use a code so that your response will be kept confidential.
- Dear Data collector
    - There are multiple choice questions to be answered by making "incircle'' where indicated fill in the blank space.

Thank you all for taking time to complete the questionnaire!

Study code: _____ Card/chart Number: _____

Section I: Parent's/caregiver's Socio-demographic and economic Characteristics.

1. Primary caregiver (Caregiver's identity)

1. Father 2. Mother 3. Siblings 4. Grandparents 5. Uncle/Aunt 6. Others (specify)

2. Age (Parent's /Caregiver's) _____ years

3. Place of Residence? 1. Urban 2. Rural

4. Current Marital status of the caregiver

1. Single 2. Married 3. Separated 4. Divorced 5. Widowed

5. Educational status of the caregiver

1. Cannot read & write 2. Can read & write 3. Primary school 4. Secondary school 5. College/university

6. Occupational status of the Caregiver

1. House wife 2. Farmer 3. Marchant 4. Gov't employee
5. Daily laborer 6. Other (Specify) _____

7. What is the total family size? _____

8. What is the average **monthly** income of the family? _____ (ETB)

Section II: Child related factors [Socio-demographic, clinical and treatment profiles].

9. Age _____ Years

10. Sex 1. Male 2. Female

11. Educational status of the child

1. Pre-school 2.Elementary (1-4) 3. Juniour school (5-8) 4. High school (9-12)

12. Main seizure type (Ask or review chart)

1. Focal seizure 2. Generalized seizure 3. Unclassified seizures

13. Duration since Diagnosis? _____in Months

14. Duration on treatment? _____in Months

15. Is there any family member who have seizure/epilepsy?

1. Yes 2. No 3. I am not sure

16. Mode of therapy used (Review chart)

1. Mono-therapy 2. Dual therapy 3. Triple therapy

17. Type of anti-epileptic drugs prescribed (Review chart)

1. Phenobarbitone 2. Phenytoin 3. Valproic acid 4. Carbamazepine

5. Phenobarbitone & Phenytoin 6. Phenytoin & Valproic acid

7. Phenobarbitone & Carbamazepine 8. Phenytoin, Phenobarbitone & Valproic acid

18. Have the child ever stopped or missed AEDs dose? (If No, skip to 20)

1. Yes 2. No

19. If Yes to Q 18; what were your main reasons for stopping or for not taking the tablets regularly? (Multiple answers are possible)

1. Forgetfulness 2. Fear of side effects 3. Feeling better

4. Run out of drug/Did not get adequate tablets from the hospital

20. Does your child develop adverse effects to antiepileptic drugs?

1. Yes 2. No 3. I do not know

21. If the answer to Q 20 is 'Yes', which adverse effects does your child develop?

(**Multiple answers are possible**)

1. Behavioral abnormality 2. Gum hyperplasia/swelling 3. Skin rash

4. Drowsiness 5. Fatigue 6. Decreased concentration

7. Constipation 8. If others (Specify) _____

22. Does the child have other diagnosis? (see chart)If yes write the diagnosis.

1. Yes (_____) 2. No

23. Does the child take other drug(s) concomitantly with AEDs? [Medication other than AEDs]

1. Yes 2. No

24. Use of herbal/traditional medicine as additional treatment for epilepsy?

1. Yes 2. No

25. How many seizure episodes do your child have in the last 3months?_____

Section III: Health facility/service related factors.

26. Distance from home to the hospital: _____Km(s)

27. Means of transportation to the hospital:

1. On foot 2. Public transport 3. On foot then public transport

28. How much time it takes from your home to the hospital? (in hours) _____hr

29. During any of your neurology clinic visit did you get health education &/or advice about epilepsy and AEDs during collection of tablets? (If No, skip to Q31)

1. Yes 2. No

30. If Yes to Q 29, what type of advice did you get about AEDs?

1. Importance of AEDs tablets 2. Method of use 3. Side effects

4. Not to miss doses & appointments 5. If other specify: _____

31. How do you get the medication(s)?

1. Cash/payment 2. CBHI 3. Free of charge 4. Free sometimes Cash

32. Have you ever faced problems in the hospital during health care delivery? (If No, skip to Section IV) 1. Yes 2. No

33. If Yes to Q 32, what are these problems? (Multiple answers are possible)

1. Shortage of AEDs 2. Long waiting time

3. Poor communication & good governance issue (that hindered you from taking AEDs) 4. If other specify: _____

Section IV: Parental Knowledge about Epilepsy(35)

34. Do you believe that **'evil-eye'** predispose to seizure/epilepsy? (**If 'No', score will be=1**)

1. Yes 2. No 3. I do not know

35. Do you believe that **head injury** predisposes to seizure/epilepsy?

1. Yes 2. No 3. I do not know

36. Do you believe that epilepsy is **contagious** disease? (**If 'No', score will be=1**)

1. Yes 2. No 3. I do not know

37. Do children with epilepsy need help (like ease them to the floor, clear the area around them, loosening ties or anything around the neck) during seizure episodes?

1. Yes 2. No 3. I do not know

38. Do seizures are treatable? 1. Yes 2. No 3. I do not know

39. Do you know how to perform first aid for seizures? 1. Yes 2. No

40. Do you believe placing '**matches**' around nose stop seizure? (**If 'No', score will be=1)**

1. Yes 2. No 3. I do not know

41. Does restraining during seizures episodes **harm** the child?

1. Yes 2. No 3. I do not know

42. Do seizures are being fatal or life threatening? 1. Yes 2. No 3. I do not know

43. Do you worried about side-effects of medications? 1. Yes 2. No

44. Do you worry about future risks and potential consequences of seizures? 1. Yes 2. No

45. Do you believe that Medicines have to be kept out of reach of children?

1. Yes 2. No 3. I do not know

Section V: Parental Attitude towards Epilepsy(34).

46. Do you agree to work with epileptics?

1. Strongly disagree 2. Disagree 3. Agree 4. Strongly agree

47. Do you agree to have close relation with epileptics?

1. Strongly disagree 2. Disagree 3. Agree 4. Strongly agree

48. Is epilepsy treatable disease?

1. Strongly disagree 2. Disagree 3. Agree 4. Strongly agree

49. Do you think that epileptics shouldn't be isolated from the community?

1. Strongly disagree 2. Disagree 3. Agree 4. Strongly agree

50. Do you think epileptics can manage their family?

1. Strongly disagree 2. Disagree 3. Agree 4. Strongly agree

51. Do you shake hands of epileptics?

1. Strongly disagree 2. Disagree 3. Agree 4. Strongly agree

52. Do you let your child(have epilepsy) to contact with others?

1. Strongly disagree 2. Disagree 3. Agree 4. Strongly agree

53. Do you agree to recruit epileptics as a servant?

1. Strongly disagree 2. Disagree 3. Agree 4. Strongly agree

54. Do you agree with your family member marry epileptics?

1. Strongly disagree 2. Disagree 3. Agree 4. Strongly agree

55. Epileptics should learn in schools?

1. Strongly disagree 2. Disagree 3. Agree 4. Strongly agree

56. Do you think epileptics can lead a healthy lifestyle?

1. Strongly disagree 2. Disagree 3. Agree 4. Strongly agree

Section VI: Medication adherence status: Drug adherence status was assessed by using 8 item version of self reporting questionnaire of Morisky medication adherence scale (MMAS-8)(33).

57. Do you sometimes forget to take your medication? Yes= 0 No= 1

58. People sometimes miss taking their medications for reasons other than forgeting. Over the past 2 weeks, were there any days when you did not take your medications? Yes= 0 No= 1

59. Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it? Yes= 0 No= 1

60. When you travel or leave home, do you sometmes forget to bring your medication?

Yes= 0 No= 1

61. Did you take all your medications yesterday? **Yes= 1** **No= 0**

62. When you feel like your symtoms are under control, do you sometimes stop taking your medication? Yes= 0 No= 1

63. Taking medication every day is a real inconveinence for some people. Do you ever feel hassled about sticking to your treatment plan? Yes= 0 No= 1

64. How often do you have difficulty remembering to take all your medication? (

Never/Rarely ☐ Once in a while ☐ Sometimes ☐

Usually ☐ All the time ☐

Q61*, if the answer is **'YES'** it will score=**1** & if the answer is **'NO'** it will score=**0**

Q64* scores:- Never/Rarely(=**1.0**), Once in a while(=**0.75**), Sometimes(=**0.5**), Usually(=**0.25**) and All the time(=**0.0**)

® This is the end of our questionnaire. Thank you very much for taking time to answer my questions. We appreciate your help. Please re-check that you have filled all the questions.

Name of data Collector _____

Signature _____

Date _____

Annex III : Information sheet and informed consent form (Oromiffaa version)

GUCA RAGAAFI EYYAMUMMAA GAAFACHUU

GUCA RAGAA

Akkam jirtu, akkaam bultaan/oltaan. Ani maqaan koo _____jedhama. Har'aa kanaa asitti argamee qurannoo dr. Hawii Mohammedin (kan Yuunivasiiti jimma giddu-gala, kutaa dhukkuba ijjoolee kan deddebi'anii yaalu, qorichoota dhibee gaggabdoo waliin wantoota wal-qabataam) irratti raga sassabuufi kaayyoon qorannoo kanaan inniguddaan ijjoolleen dhukuba gaggabdoo faban, haala qorichoota dhukkuba gaggabdoo itti fudhataniffi qorachuu to'u dha.

Ani, isinis ta'ee, namooni biroo qurannoo kanaa irratti fedha(fedhi) keesaniin akka hirmaatamidha. Kan isinirra eggamuu wantoota isin gaafannuuf deebii akkaa nuf kennitanidha. Kunis yeroo daqiiqaa 25 ol kan hincaalle kan fudhatuudha. Ragaa isinirraa fudhannuu kana sassabuu koodii fayyadama. Enyuummaa keessanis ta'ee kan mucaa keessan, akkasumass iddoon jireenya keesan guca kana irratti hin gutaamu. Eyyamamaa yoo ta'uu battannis tajajiila mica keessaniif kennamuu irratti hooma rakkoo hin uumu. Hirmaanna keessanif isin galateefanna.

GUCA EYYAMUMMAA

Qorannoo irratti hirmanchuuf eyyamamadhaa?

☐ Eeyyeen eyyamamadha ☐ Lakkii hin barbaaduu

Nama ragaa sassabuun kan mallallegamu, guca armaan oli kanaa dubbisee, hirmaata hubachiisu koo mallattoo kootin nan mirkanessa.

Koodii gaaffichaa: _____

Guyyaa: _____

Maqaafi mallattoo sassabaa: _____

Maqaafi mallattoo too'ataa: _____

Annex IV : Information sheet and informed consent form (Amharic version)

የመረጃ እና የፈቃደኝነት መጠየቅያ ቅጽ

የመረጃ ቅጽ

ሰላም! ደህና አደሩ/ዋሉ! እኔ ስሜ _____ይባላል። ዛሬ እዚህ የተገኘሁት በዶ/ር ሀዊ መሀመድ ለሚሰራ ጥናት (በጅማ ሜዲካል ሴንተር የህፃናት ተመላላሽ ህክምና ክሊኒክ፤ የሚጥል በሽታ መድሃኒት ጥብቅ ቁርኝትና ተያያዥ ነገሮች) መረጃ ለመሰብሰብ ነው። የዚህ ጥናት ዋና አላማው የሚጥል በሽታ ያለባቸው ህፃናት ለመድሃኒቱ ያላቸው ቁርኝት(ክትትል) ለማጥናት ነው።

እኔ እርሶንም ሆነ ልሎችን የምጠይቀው በሙሉ ፈቃደኝነታችሁ በዚህ ጥናት እንድትሳተፉ ነው። ከርሶ የሚጠበቀው ለምንጠይቆት ጥያቅ ምላሽ መስጠት ነው። ይህም ከ25 ደቂቃ የማይበልጥ ግዜ ነው የሚወስድብን። ከርሶ የምንወስደውን መረጃ ምስጥራዊነቱን ለመጠበቅ በመረጃ ሰብሳቢው የሚሞላ ኮድ እንጠቀማለን። የርሶም ሆነ የልጅዎ ማንነት ወይም አድራሻ በመጠይቁ ላይ አይሞላም። ፍቃደኛ አለመሆንዎ ልጅዎ በሚያገኘው ማነኛውም የጤና እርዳታ ላይ ምንም አይነት ተጽእኖ አይኖረውም። ስለተሳትፎዎ እናመሰግናለን።

የፈቃደኝነት ቅጽ

በጥናቱ ለመሳተፍ ተስማምተዋል?

☐ ኣዎ ተስማምቻለሁ ☐ ኣይ አልተስማማሁም

በመርጃ ሰብሳቢው የሚፈረም፡ ከላይ በመረጃ ቅጽ ላይ ያለውን ለጥናቱ ተሳታፊ በተገቢው ሁኔታ በንባብ ማስረዳቴን በፊርማዬ አረጋግጣለሁ።

የመጠይቅ ኮድ፡ _____

ቀን፡ _____

የጠያቂው ስምና ፊርማ፡ _____

የተቆጣጣሪው ስምና ፊርማ፡ _____