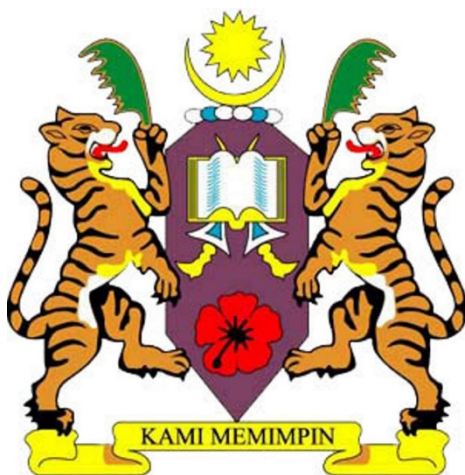


**COST EFFECTIVENESS OF TELEPHONE FOLLOW UP FOR PAEDIATRIC  
PATIENTS WITH EPILEPSY IN HOSPITAL UNIVERSITI SAINS MALAYSIA  
KELANTAN**

**BY**

**DR. JOVITRA GIRUBAHARAN**

**DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE  
REQUIREMENT FOR THE DEGREE OF MASTER OF MEDICINE (PAEDIATRIC)**



**UNIVERSITI SAINS MALAYSIA**

**UNIVERSITI SAINS MALAYSIA**

**MAY 2014**

## **ACKNOWLEDGEMENT**

I would like to extend my deepest appreciation to Prof Zabidi Azhar Mohd Hussin and Dr Rosminah Mohamed for their continuous support and expert guidance that made this dissertation possible.

A special thanks to Dr.Rosminah for her patience and guidance of cost effectiveness analysis, a topic that is new to me and would have not been possible for me to understand without her guidance.

Special thanks also goes to En. Muhammad Faris Irfan Che Yusoff our science officer at the Paediaatric Department and Cik Siti Nur Farliza of the Biostatistics and Research Methodology Unit who shared their valuable time to impart their knowledge regarding statistical analysis with me.

Last but not least I would like to thank my beloved parents, sister and husband for their continuous support and encouragement and dearly to my son, who reminds me that there is no limit in acquiring knowledge.

<b>TABLE OF CONTENT</b>	<b>PAGE</b>
<b>ACKNOWLEDGEMENT</b>	<b>ii</b>
<b>TABLE OF CONTENT</b>	<b>iii</b>
<b>LIST OF TABLES</b>	<b>vi</b>
<b>ABSTRAK</b>	<b>vii</b>
<b>ABSTRACT</b>	<b>viii</b>

## **CHAPTER 1 : INTRODUCTION**

1.1	Epilepsy in children and the long term management	1
1.2	Telemedicine	3
1.3	Economics evaluation	4
1.4	Cost effectiveness analysis	6
1.5	Problems associated with clinic follow up for families of children with epilepsy	7
1.6	Study objectives and hypothesis	8

## **CHAPTER 2 : LITERATURE REVIEW**

2.1	Introduction	10
2.2	Burden of high patient load in clinics in Malaysia	10
2.3	Use of telecommunication services for patients with chronic diseases	10

### **CHAPTER 3 : RESEARCH METHODOLOGY**

3.1	Study design and location	13
3.2	Study population	13
3.3	Sampling size	13
3.4	Sampling frame	13
3.5	Inclusion criteria	14
3.6	Exclusion criteria	14
3.7	Data collection	15
3.8	Research flow chart	16
3.9	Statistical analysis	17
3.10	Costing method	18
3.11	Cost Effectiveness Analysis (CEA) Procedure	19

### **CHAPTER 4: RESULTS**

4.1	Geographical representation of Paediatric Epilepsy patients in Hospital USM	21
4.2	Demographic of epilepsy patients	23
4.3	Clinical evaluation of paediatric epilepsy patients	24
4.4	Conditions associated with childhood epilepsy	25
4.5	Time involved in clinic and telephone follow up	26
4.6	Socio economic data of families of paediatric epilepsy patients.	27
4.7	Cost incurred to patients from clinic and telephone follow up	27
4.8	Cost incurred to Hospital USM from clinic and telephone follow up	29
4.9	Health outcome analysis	33

**CHAPTER 5: DISCUSSION**

5.1	Outcome of our study	34
5.2	Conclusion	39

**CHAPTER 6: RESEARCH LIMITATIONS AND 40**

**RECOMMENDATION FOR FUTURE WORKS**

**REFERENCES 41**

**APPENDIX 43**

I.	Case recording form for children with epilepsy	43
II.	Consent form	47
III.	Ethical approval letter	58

## LIST OF TABLES

- Table 1: Decision rule of cost-effectiveness analysis
- Table 2: Distribution of respondents by district
- Table 3: Socio demographic of paediatric epilepsy patients
- Table 4: Conditions associated with childhood epilepsy
- Table 5: Average time spent for appointment between the telephone and clinic follow up.
- Table 6: Average household income of families with children who have epilepsy
- Table 7: Comparison of cost of follow up between clinic and telephone follow up
- Table 8: Frequency of hospital admissions for breakthrough seizures between clinic and telephone follow up
- Table 9: Frequency of break through seizures between clinic and telephone follow up
- Table 10: Operational cost per patient for clinic follow up
- Table 11: Operational cost per patient on telephone follow up
- Table 12: Comparison of operational cost to HUSM for patients on clinic and telephone follow up for epilepsy
- Table 13: Cost effectiveness analysis with logic table

## **ABSTRAK**

### **Pengenalan**

Penyakit sawan di kalangan kanak-kanak merupakan penyakit yang kronik dan memerlukan rawatan susulan yang berpanjangan. Rawatan susulan adalah amat penting untuk memastikan bahawa kanak-kanak ini dapat menjalankan kehidupan yang normal dan bebas daripada stigma sawan. Walau bagaimanapun, kekerapan temujanji klinik untuk rawatan susulan membebaskan pesakit dari segi kos dan masa dan ini merupakan antara sebab pesakit tidak menghadiri temujanji klinik. Rawatan susulan yang kerap juga membebaskan pihak hospital dari segi anggota tenaga kerja yang diperlukan. Tujuan kajian ini adalah untuk menunjukkan bahawa telekomunikasi melalui telefon boleh digunakan untuk mengganti rawatan susulan klinik yang kerap.

### **Kaedah**

Kajian ini merupakan kajian asas yang dijalankan di Klinik Pakar Kanak-Kanak Neurologi di Hospital USM daripada June 2013 sehingga February 2014. Kajian ini melibatkan 68 orang kanak-kanak yang mempunyai penyakit sawan dari umur 2 hingga 21 tahun yang memenuhi kriteria kajian tersebut. Pesakit tersebut di bahagikan kepada dua kumpulan, kumpulan pertama menerima rawatan susulan melalui telefon dalam tiga bulan seterusnya sementara kumpulan kedua menerima rawatan susulan di klinik dalam jangka masa sama.

### **Keputusan**

Hasil keputusan kajian menunjukkan bahawa rawatan susulan melalui telefon sememangnya mengurangkan kos rawatan bagi pihak keluarga pesakit serta pihak hospital jika dibandingkan dengan rawatan susulan klinik tanpa menyebabkan apa-apa masalah dari segi kawalan penyakit. Purata kos rawatan susulan klinik kepada Hospital USM RM 25.57 manakala purata kos rawatan susulan melalui telefon di anggarkan RM 4.86 bagi seseorang pesakit. Purata kos yang terpaksa ditanggung oleh pesakit bagi rawatan susulan klinik adalah RM 44.85 sementara purata kos konsultasi melalui telefon adalah RM 1.84, memandangkan panggilan telefon dibuat oleh pihak hospital.

### **Kesimpulan**

Ini membuktikan bahawa rawatan telefon adalah satu cara rawatan susulan yang boleh membawa manfaat kepada pesakit serta pihak hospital

## **ABSTRACT**

### **Background**

Childhood epilepsy is a condition that has a wide possibility of causes. Most of the children with epilepsy also suffer from other complications either from the underlying condition or epilepsy itself. It is of utmost importance that these children are followed up to ensure that their illness is controlled and to help them achieve a good quality of life. However frequent clinic visits for follow up appointments have placed a high financial burden on most families and is also a cause of defaults for appointments. The high patient load in clinics from these frequent appointments have also placed a burden on the hospitals in terms of cost and labour force needed. The purpose of this study is to use the telephone as a tool for follow up of patient's well-being and control of seizures at home. This does not require them to come to the hospital and would reduce the financial burden to both, the family of the child and the hospital.

### **Method**

The study was a pilot study and was conducted in the Paediatric Neurology clinic of HUSM from June 2013 till February 2014. It involved a total of 68 children with epilepsy aged 2 years till 21 years who fulfilled the study inclusion criteria. They were divided into two arms, one arm had a telephone follow up in the following three months and the other arm had a clinic appointment.

### **Results**

The results showed significant reduction in cost in the telephone follow up group as compared to the conventional clinic follow up with no significant increase in morbidity or mortality. The average cost to Hospital USM for clinic follow up was RM 25.57 per patient whereas the cost for telephone follow up averaged RM 4.86 per patient. The cost to patients for clinic follow up averaged RM 44.85 and a consultation via telephone averaged RM 1.84, as the phone calls were made by the hospital.

### **Conclusion**

The cost effectiveness analysis has quantitatively showed in this pilot study that it is more cost effective to the hospital if patients with chronic disease who needed regular follow up could be followed up with telephone consultation.



## CHAPTER 1

### Introduction:

Epilepsy is a disorder of the brain characterised by the generation of seizures and by the neurobiological, cognitive, psychological and social consequences of this condition. Approximately 4-10% of children experience at least 1 seizure in the first 16 years of life. The cumulative lifetime incidence of epilepsy is 3% and more than half of the cases present in childhood. The annual prevalence is 0.5-1%.

An epileptic syndrome is a disorder that manifest one or more specific seizure types and has a specific prognosis. The epilepsies are a heterogeneous group of disorders with many causes. Studies have found that a genetic aetiology may be present in up to 40% of patients. Cerebral palsy is another common cause of symptomatic epilepsy due to insult to the developing brain. It may cause cerebral atrophy in severe cases. There are certain type of epilepsies whose underlying cause is unknown, resulting in abnormal neurological function. These are termed as cryptogenic epilepsies.

A study by Sarisjulis et al. in France concluded that in over three quarters of infants with cryptogenic/idiopathic epilepsy, it was possible to reach a syndromic diagnosis within the first months of the disease, based on clinical and EEG characteristic(Sarisjulis *et al.*, 2000)

Studies have found that cognitive and learning disabilities are highly associated with most epilepsy syndromes. “Behavior problems” and “language difficulties” associated with epileptic syndromes have also been reported and are also used as measured tools to ascertain quality of life of these children.(Soria, 2012)

For these reasons, it is of utmost importance that these children are followed up over a long term to ascertain that they have good seizure control and are able to achieve a good quality of life given their pre-existing condition.

The follow up may need to be more frequent during the early stages of the establishment of diagnosis as many investigations will need to be conducted. The investigations done are essentially to help classify the aetiology of epilepsy and the types of epilepsies so that appropriate treatment may be instituted.

Investigations commonly done include EEG, to look for abnormal epileptic wave form discharges which may also point to a diagnosis as some changes are specific for certain conditions. A brain imaging, MRI is particularly important in patients who develop epilepsy before the age of 2 years, who have any suggestion of any focal onset on history, examination or electroencephalography and in whom seizures continue despite first-line medication as they may be candidates for epileptic surgery.(Appleton *et al.*, 2012)

Detailed assessment of an epileptic child includes achievement of developmental milestones, special senses and functional capabilities. Subsequently problems with behaviour, sleep disorders and learning disabilities ought to be identified. Once identified appropriate referral to specific specialities are then needed to improve their quality of life.

This comprehensive care plan is usually agreed between the family the paediatrician and would involve many clinic visits to many different specialities during the initial phase such as Ophthalmology, Radiology, Audiology, Occupational and Physiotherapy for functional rehabilitation and sometimes child psychologist for IQ assessment and identification of behavioural disorders in these children.

However upon establishment of diagnosis and once the preliminary problems have been dealt with, the clinic visit are more focused on the general wellbeing of the child and their control of seizures. This comprises of their compliance to treatment, how the child is functionally developing and their achievements in school or coping strategies. The way the family is coping and their concerns are also addressed during these clinic visits.

Anti-epileptics are chosen based on the presenting epilepsy syndrome and are optimised to achieve seizure control that is acceptable to the child and family and allows the child to have normal development with good acceptance in society.(Appleton *et al.*, 2012)

Children with epilepsy whose seizures have not responded to appropriate anti epileptics should be given consideration on the use of a ketogenic diet, a modified diet scheme that uses fat as the main dietary energy source. The state of ketosis that is produced is somehow protective for brain with refractory seizures and has been used in the treatment of seizures since it was first reported in 1921.(Cross *et al.*, 2010)

## 1.2 Telemedicine

The Telemedicine Blueprint 1997 was an initiative by the Malaysian government to employ the use of telehealth in the country healthcare system. There are 4 main components in the blueprint which later restructured into 7 components in 2000. Malaysia's Telemedicine Blueprint provides the framework to change from an era of industrial age medicine to information age healthcare.

The plan is for future healthcare system to be supported and strengthened by telemedicine – the provision of healthcare services using telecommunications, information and multimedia technologies. The purpose is so that information and other services will become more virtual, more distributed and more integrated, resulting in better, more timely and more efficient healthcare services.

Telemedicine links people and delivers services by utilising multimedia applications, tools, technologies and networks. It provides services where individuals and providers need not be present in the same location.

By 2020, Malaysia's healthcare system is expected to be fully transformed into information age healthcare. This would require implementation of pilot projects and the expansion of initial pilots before that with all telemedicine projects selected, implemented and functional nationally by 2020.

Four high-impact projects have been selected as the initial telemedicine pilot projects. The pilot projects are: Mass Customised/Personalised Health Information and Education; Continuing Medical Education; Teleconsultation; and Lifetime Health Plan. The first two are essentially informational and educational services respectively targeted at the general public and the healthcare community. Teleconsultation covers multimedia connectivity between healthcare service providers. The lifetime health plan system will be a person-centred implementation and also a lifelong continuity between episodic contacts with healthcare service provider. A systematic, consistent and summary of an individual's Lifetime Health Record is obtained and used to formulate prospective Personalised Lifetime Health Plans (PLHP) that caters for wellness preservation together with illness treatment for each individual.(Abidi *et al.*, 1998)

### 1.3 Economic Evaluation

Health economics analyses how choices are made to obtain maximum value for money within the resources that are available. Decisions are made based on analysis of cost and benefits of competing interventions. Therefore the health outcome of competing healthcare provisions should be carefully studied and compared to achieve the maximum benefit with the allocated resources.

When resources are scarce it is important to evaluate how effectively they are being used to achieve the desired outcome. There are three key concepts of efficiency which are:

- i. Technical efficiency
  - Is the effectiveness at which a given set of inputs (resources) is used to achieve a desired output( health out come)
  - Is achieved when maximal possible improvement is achieved with less resource input
- ii. Productive efficiency
  - Is assessing the relative value for money of different interventions, which have outcomes that are directly comparable.
  - The concept is therefore to minimise the cost of resources for a given healthcare outcome or maximise the outcome for a given cost
- iii. Allocative efficiency
  - Involves measuring the extent to which the available resources area allocated to individuals who will benefit the most
  - Allocative efficiency takes into account the productive efficiency of the resources available and the efficiency of distributions of the outcome in society.
  - Allocative efficiency has implications for the definition of opportunity cost.
  - Opportunity cost is what is lost when an alternative service is not provided because resources are directed elsewhere.

A full economic evaluation of health care involves systematically comparing the cost (input) and benefits (outcome ) of at least two alternative interventions and considering both the cost and benefits of all alternative interventions being compared. Economical cost itself implies both direct and indirect cost and may include

1. Cost to service providers
  - a) Overhead cost
    - i. Managerial cost
    - ii. Administrative cost
    - iii. Staff cost
    - iv. Drug cost
    - v. Equipment cost
    - vi. Building cost
2. Cost to patients
  - a) Out of pocket expenses
    - i. Travel cost
    - ii. Prescription cost
  - b) Intangible cost
    - i. Stress
    - ii. Pain
    - iii. Side effects
3. Productivity cost
  - a) Production losses
  - b) Other uses of time

The cost measured from a study will depend on whether the evaluation is from the health service perspective, the patient perspective or may even be from a wider perspective.

In the case of this pilot study the evaluation is from the patient perspective and the healthcare perspective, as in the cost to the hospital per patient follow up. The overhead cost for Hospital USM were obtained from the case mix analysis that has already been

conducted in an extensive manner by Dr. Rosminah Mohammed in the implementation of USM Case Mix System. (Mohamad, 2012)

#### **1.4 Cost Effectiveness Analysis (CEA)**

Cost-effectiveness analysis (CEA) is a form of economic analysis that compares the relative costs and outcomes (effects) of two or more courses of action.

Cost effective analysis forms the majority o the economic evaluations in health economics. It compares the cost and health effects of competing interventions and are compared in terms of cost per unit effectiveness (Rojas and Gagnon, 2008).Cost-effectiveness analysis has been defined by the National Institute for Health and Clinical Excellence (NICE) as an economic study design in which consequences of different interventions are measured using a single outcome, usually in 'natural' units (for example, life-years gained, deaths avoided, heart attacks avoided or cases detected). Alternative interventions are then compared in terms of cost per unit of effectiveness.

The aim of cost- effectiveness analysis is to maximise the level of benefits, health effects relative to the level of resources available.

## **1.5 Problems associated with clinic follow up for families of children with epilepsy**

The heterogenous presentation and types of epilepsy makes the management of childhood epilepsy challenging. Continuation of care is of utmost importance for these children to ensure that they are managed in a holistic manner and are able to lead near normal lives.

Any follow up plans should take into consideration, whether the child is mobile or wheel chair/bed bound. Coexistence of epilepsy with other brain malformations would pose additional difficulties in attending follow up.

Other factors that need to be given consideration are the overall family income and occupation of the parents and as shown, the distance the families have to travel from for clinic appointments at tertiary hospitals. These factors are important as each clinic visit will cost the family time and will incur further expenses.

Hence the option of telemedicine which has been upcoming in the past few years would be an attractive option for these families. It would ease the financial burden of the parents as they would not need to leave work to come for appointments and could address their concerns of the child's control of seizure progress in terms of development and school performance via telephone. This option of follow up offers them the convenience of getting medical care or consultation without the additional burden of coming to the hospital.

## 1.6 STUDY OBJECTIVES AND HYPOTHESIS

### 1.6.1 General Objectives

To observe the cost effectiveness of follow-up using telephone as compared to clinical follow up for patients with well controlled epilepsy.

### 1.6.2 Specific objectives

- i. To determine the average consultation time spent between clinic and telephone follow up for a patient with well controlled epilepsy at Hospital USM
- ii. To estimate the cost for telephone and clinic follow-up for children with well controlled epilepsy in Hospital USM.
- iii. To observe the cost effectiveness between telephone and clinic follow up for children with well controlled epilepsy at Hospital USM.
- iv. To demonstrate no adverse effects from telephone follow up as compared to clinic follow up for children with well controlled epilepsy.

### 1.6.3 Study hypothesis

- i.  $H_{01}$  : There is no significant difference in the mean time spent for telephone and clinic follow up  
 $H_{A1}$  : There is a significant difference in the mean time spent for telephone and clinic follow up
- ii.  $H_{02}$  : There is no significant difference in the mean cost for parents in the telephone follow up group as compared to clinic follow up group.  
 $H_{A2}$  : There is a significant difference in the mean cost spent by parents for telephone follow up as compared to regular clinic follow up



- iii.  $H_{03}$  : The telephone follow up is less cost effective as compared to clinic follow up  
 $H_{A3}$  : The telephone follow-up is more cost effective as compared to clinic follow up
  
- iv.  $H_{04}$  : There is no worsening seizure control for children with epilepsy under the telephone follow up  
 $H_{A4}$  : There is a worsening of seizure control for children with epilepsy under the telephone follow up

## **CHAPTER 2:**

### **Literature review**

#### **2.1 Introduction**

The paediatric clinic in HUSM sees an average of 8200 patients per annum, of which 1250 (15%) are seen at the paediatric neurology clinic. Childhood epilepsy is among the most prevalent and therefore important neurological conditions in the developing years. Population-based studies report prevalence rates of 3.6 to 4.2 per 1000 for children in developed countries, and approximately double these rates in developing countries.

The importance of long term care and follow up for these patients have been emphasized in the earlier section and is aimed at achieving a holistic approach in managing these children and allowing them to be accepted in society. However the frequent appointments for multidisciplinary teams in their management may pose a burden to the families of these children.

#### **2.2 Burden of high patient load in Clinics in Hospital USM.**

A study by *Jamil. et al* in 2011, found that failure to attend appointments in paediatric clinics was estimated to be 31.8% in HUSM, Kelantan which is comparable to studies from other countries including the USA but higher than in European countries. During this 2-month study, he found that there were more than 201 patients who were on medications not attending their follow-up appointments in the paediatric clinic. The main reason for non-attendance was forgetfulness. He had also demonstrated that a telephone call by the doctor was moderately helpful in getting the patient back into the system. (*Jamil et al., 2011*)

This study shows the effectiveness of telecommunication in bridging the gap of healthcare needs and compliance of patients for their continuation of care.

#### **2.3 Use of telecommunication services for patients with chronic diseases**

The use of telemedicine brings about change in health-care organizations and opens up new possibilities for service delivery. The Malaysian government has planned to use telemedicine

to reform the country's public healthcare delivery and management service, which is under pressure from rising costs, lack of resources and overworked staff.

In June 2000, four pilot programs were launched by the Ministry of Health, Malaysia with a focus on telemedicine applications: Lifetime Health Plan, Mass Customized/Personalized, Health Information and Education, Continuing Medical Education and Teleconsultation. This was implemented in the 8th Malaysian Plan with some success and was reinforced in the 9th Malaysia Plan from 2006 to 2010.

A RCT done by *Liew. et al* in 2009 involving seven primary health care clinics in Malaysia had also shown that the use of text messaging leads to higher attendance rate for primary care was significantly higher compared with that of the control group. The study showed that both text messaging and telephone reminders were effective in reducing non-attendance in people who required long- term follow-up for chronic diseases. It was also hypothesised that text messaging was as effective as telephone reminder, however analysis showed that there was no significant difference in non-attendance rates between the two reminder groups.

Another study by *Pinnock et al* published in the *British Journal of General Paediatrics* in Sept 2000 entitled "Accessibility, clinical effectiveness, and practice costs of providing a telephone option for routine asthma reviews" showed that routinely offering telephone reviews cost-effectively improved asthma care by increased asthma review rates, enhanced patient enablement and confidence with management and had no detriment to asthma morbidity

*Ahmed et al* in 2006 had conducted a similar study which focused on patients with epilepsy as part of a dissertation and has yet to be published .This was a pilot study and was meant to demonstrate the feasibility of epilepsy follow-up care through telemedicine. The study was a pilot study which focused on the patient's perspective and had shown that telemedicine does reduce patient cost and improve patient satisfaction in terms of follow up.

The purpose of our study is to combine the relevant findings from the studies that had been done with the use of telecommunication devices to explore if this method of follow up may benefit our patients in terms of reducing cost and saving time as compared to consultation via frequent clinic visits. We will be measuring the outcome of clinical cost in terms of cost effective analysis which has not been done in previous studies.

Cost-effectiveness analysis (CEA) is a form of economic analysis that compares the relative costs and outcomes (effects) of two or more courses of action (Crowe, 1998) and has been used in the field of health services, where it may be inappropriate to measure health effects in terms of money. (Davis *et al.*, 2011)

Optimal allocation of available resources to maximize health will be the key challenge to health-care systems and this has caused an increasing awareness that resource allocation must be addressed in a systematic rather than intuitive manner. (Eichler *et al.*, 2004)

The continuation of medical research is expected to produce an increasing number of alternatives for the detection, prevention, and treatment of various diseases. However, budgetary constraints will not allow health-care systems to make all of these available for everybody. The decisions are therefore made based on cost-effectiveness (CE) analysis to determine the most treatment option that is most beneficial and economically effective. (Eichler *et al.*, 2004)

A study by *Franzini et al* in 2011 which was on Tele ICU implementation had shown that Tele ICU did not reduce the length of stay or complications but had a main positive clinical outcome of reduction in ICU and hospital mortality in the sickest patients. In this subgroup of the sickest patients, Tele ICU was cost effective because it decreased hospital mortality without increase in cost significantly. (Franzini *et al.*, 2011). Cost effectiveness analysis was also used in another recent study by *Gordon et al.* in 2014 on telephone linked care for patients with Type 2 diabetes in Australia and concluded that telephone linked care as part of diabetes intervention was a low-cost investment for individuals with established diabetes and may result in medication cost-savings to the health system.

## **CHAPTER 3**

### **RESEARCH METHODOLOGY**

#### **3.1 Study design and location**

This was a pilot study conducted in the paediatric neurology clinic, Hospital University Sains Malaysia( Hospital USM) in Kubang Kerian, Kelantan. Hospital USM is one of the main tertiary centres for paediatric Neurology referrals in Kelantan.

#### **3.2 Study population**

The reference population were the paediatric patients with epilepsy under the paediatric neurology clinic follow up.

#### **3.3 Sample size calculation**

A previous study by Pinnock et al had demonstrated a SD of 8.8 minutes for telephone consultations. Therefore based on sample size calculation software (Dupont and Plummer 1998) to calculate a sample size for a power of 80%,  $\alpha = 0.05$ ,  $\Delta = 5$ , 50 patients would be needed for this study.

However as this was a pilot study, each arm comprised of 40 patients which brought the total number of patients to 80 participants. In the previous study the response within each subject group was normally distributed with standard deviation 8.8. Given that the true difference in the experimental and control mean is 5, with a type I error probability of 0.05 to reject the null hypothesis, a sample size of 40 experimental subjects and 40 control subjects would achieve a power of 71% .

#### **3.4 Sampling frame**

The sampling frame was from June 2013 till February 2014. The parents of the patients who consented to be part of the study were given a randomised envelope by the clinic staff nurse. The randomisation was done with a computer software and random numbers were allocated for each arm. These random numbers categorised them into either the telephone or clinic arm for the next follow up which would have been in the next 3 months from their initial clinic appointment date.

The method and purpose of the study would then again be explained to the parents of the patient. If agreeable, they would sign the consent form and be participants of the study.

Parents who consented were further asked a series of questions prepared for the purpose of this study. (As attached in Appendix 1)

### **3.4 Inclusion criteria**

- i. All patients who come for follow up of controlled epilepsy at the Paediatric clinic in HUSM between the age of 2-21 years old, who live within a 80km radius from HUSM.
- ii. Parents of patients who are willing to participate and give informed consent to be part of the study
- iii. Parents of patients who have mobile phones and do not have problems with phone/telecommunication coverage at their living areas.

### **3.5 Exclusion criteria**

- i. Parents of children with uncontrolled epilepsy who need regular follow up for management of epilepsy
- ii. Parents of children who are less than 2 years old and live further than a 80km radius from Hospital USM.
- iii. Parents who do not consent for their children to be part of the study
- iv. Parents who have problems with telephone coverage at their living areas.

### **3.6 Ethical approval**

Approval for the study was obtained from the HUSM Research Ethical

Committee. (reference : USM KK/PPP/JEPeM [266.3(5)])

### **3.7 Data collection and research tool**

All paediatric patients who registered at the counter were clocked in and the time taken for waiting and consultation time were recorded. Upon consultation with the doctor, they were assessed and if fulfilled the inclusion criteria they were offered to be part of the study. Those, whose parents consented, would be allocated randomly into the two arms of the study. The randomisation was done as mentioned in the sampling method.

After being allocated to either arm of the study parents would again be briefed on the purpose and nature of the study and any concerns would be addressed. If agreeable to the follow up method randomised to them they would then sign the consent form.

They would be interviewed by the doctor for a series of questions in the questionnaire prepared for the study. The questionnaire was prepared from an extrapolation of a questionnaire used in a previous asthma control study and had undergone a pretest before the start of the project.(Juniper *et al.*) The pretest was done with 10parents of patients with epilepsy and there were no major corrections for the questionnaire prepared.

The questionnaire encompasses a number of questions pertaining to the social demographic data, the clinical condition and control of seizures of the child and the social economic status of their families. (Attached in Appendix I)

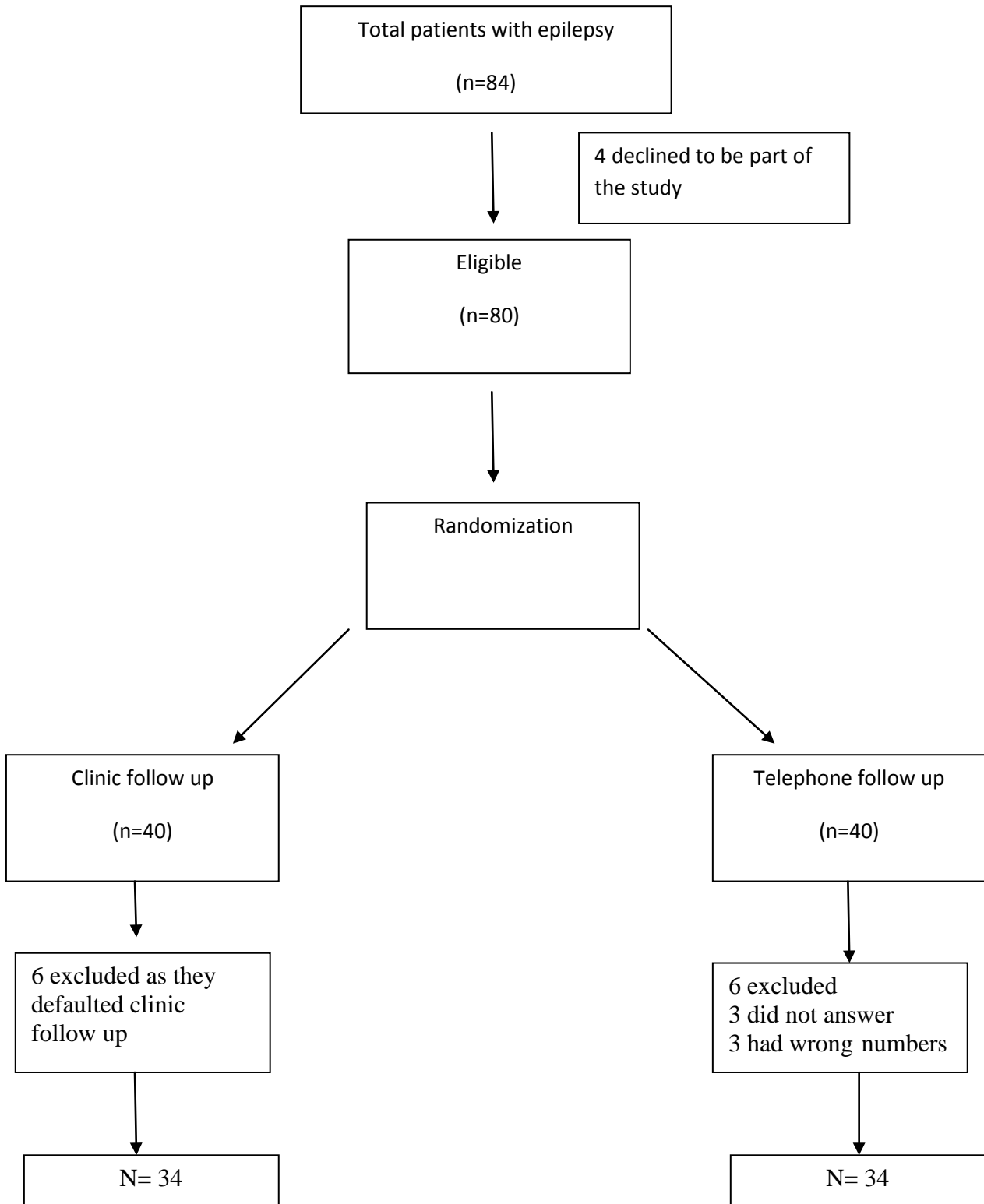
In the following three months from their first visit, the parents would receive a telephone call or come to the clinic for an appointment.

Six patients were excluded from the telephone follow up arm as they were not contactable by telephone. Of these six patients, three were excluded due to wrong phone numbers that were given and the other 3 participants did not answer their phones when contacted, despite being contacted on three separate occasions within the same month. As for the patients who were in the clinic follow up arm, six patients had also defaulted their follow up. The reason for not attending follow up could not be ascertained as they were not contactable by telephone either.

During the follow up in each respective arm, their control of seizures, compliance to medications and functional capabilities were assessed again and any further concerns were also addressed. They were given another questionnaire on their perception of future telephone follow up to assess their views on this option of follow up.

The total time taken for registration, waiting for consultation and consultation with the doctor were recorded. The time recorded for telephone consultation was also recorded for those in the telephone arm.

### 3.8 Research flow chart





### **3.9 Statistical analysis**

The data was processed and analysed using IBM SPSS statistics version 20. The demographic and numerical data would be presented as mean, standard deviation (SD) and median (interquartile range, IQR) according to data distribution. The categorical data would be expressed as proportion and analysed using Chi square or Fisher exact test

Comparisons between time spent for telephone and clinical follow-up will be made with an Independent T Test. Cost for healthcare will be calculated as means and compared with independent sample *t* test. P value of  $< 0.05$  is used to define statistical significance

Cost effectiveness analysis will be used to assess the gains (effectiveness) and resource input requirements (cost) of both the alternative ways of conducting follow up. The results will be expressed in terms of cost per unit of effectiveness for each alternative. The alternative with the lowest cost per unit effectiveness is the most cost effective economically efficient, as described in the previous section.

### **3.10 Costing method**

As there are two arms to the study cost from each arm will be calculated individually. For the clinic follow up arm, the cost that will be calculated are considering both the direct and indirect cost from the patients and companions involved, transportation cost, the cost for parking during the total duration of clinic visit and the cost of meals for the patients and those who accompanied the patient for follow up as these are the most common cost that would have to be incurred by the family for a clinic follow up. The time spent for the duration of clinic appointment would also be converted to monetary value as the loss of income of the working parent who has accompanied the child for follow up on that day. This is described as productivity cost.

In terms of the hospital perspective, the cost involved for the set up of a clinic setting is taken into consideration. The built up area of the clinic, registration counter and waiting area and the common equipment used in clinic are all taken into consideration as the capital cost. The overhead cost in this setting would be the administrative and the staff cost.

A nearly similar setting is used for the patients on the telephone follow up arm, where by the cost from the patient perspective would be significantly lesser as the phone call is made by the doctor and can be answered by the parents at any time that is convenient to him. The time spent for the telephone conversation would be converted to monetary value as described by productivity cost if the parent who was contacted was working at the time of the call.

And from the hospital perspective the capital cost would comprise of the built up area of the clinic and the overhead cost would be lesser as lesser staff assisting and doctors would be required for the telephone follow up.

Cost effectiveness analysis is use to compare the significance of the cost between follow-ups option of both arms. The cost saving analysis can be used as a tool to show the effectiveness of one method over the other.

### **3.11 Cost Effectiveness Analysis (CEA) Procedure**

The cost is generally computed from the societal perspective that involves all societal resources used in the treatments. The costing will be based on individual (patient) basis. This step will involve another four steps as follow:

- a. Compute gross follow-up costs

Cost for clinical and cost for telephone follow-up.

- b. Compute monetary savings

This is also known as direct benefit that attribute to the given follow-up options. This savings are the cost of avoided screening that otherwise would have been obtained.

- c. Compute net cost (gross costs less savings)

Subtracting saving costs from gross costs and the resulted net costs could be positive, negative or zero.

Apply a decision rule

The rule will be based on the net costs and the net effects of the above treatments as tabulated below.

Table 1: Decision rule of cost-effectiveness analysis

Net effects	Net costs positive	Net costs negative
Positive	Case 1	Case 2
	<p>Cost-effectiveness = net costs / net time of consultation</p> <p>Select most efficient treatment for improving health (highest ratios)</p>	<p>Follow-up economically valuable. Should generally be implemented.</p>
Zero or Negative	Case 3	Case 4
	<p>Treatment benefit offset by morbidity or inconvenience. Screening should not be implemented.</p>	<p>Cost-effectiveness = net costs / net time of consultation</p> <p>Select most efficient follow-up for containing costs (lowest ratios)</p>

## CHAPTER FOUR

### RESULTS

Eighty patients between ages of one and a half years to twenty one years were enrolled for the purpose of the study, of which there were 6 defaulters for each arm. Of these six patients in the telephone arm, 3 of the defaulters were due to wrong phone numbers given and the other 3 participants did not answer their phones when contacted on three separate occasions within the same month. As for the patients in the clinic arm, 6 patients had defaulted their clinic appointment which was given in 3 months from the date of first encounter. The reason for defaulting follow up could not be ascertained as they were not contactable by phone either.

#### 4.1 Geographical representation of Paediatric Epilepsy patients in Hospital USM

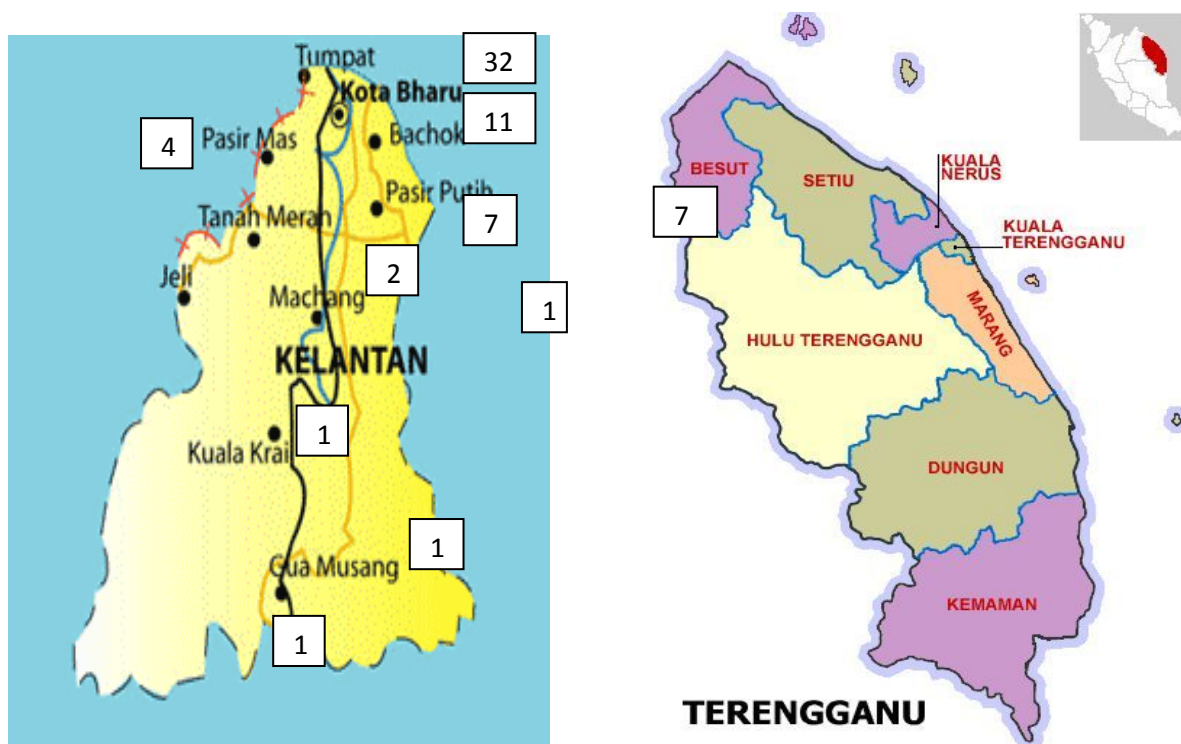


Table 2 : Distribution of patients by district in Kelantan and Terengganu

	Clinic Follow up	Telephone follow up
Kota Bahru, Kelantan	17	15
Bachok, Kelantan	8	3
Pasir Mas, Kelantan	2	2
Pasir Puteh, Kelantan	4	3
Gua Musang, Kelantan	0	1
Machang, Kelantan	0	2
Kuala Krai, Kelantan	0	1(70km)
Besut, Terengganu	3	4

The majority of paediatric epilepsy patients attending the Hospital USM neurology clinic in our study are from Kota bahru with 32 patients followed by Bachok with 11 patients. 7 of the patient enrolled in our study were from Besut which is a district in the neighbouring state of Terengganu.

## 4.2 Socio demographic characteristics of paediatric epilepsy patients.

Table 3 : Demographics of paediatric epilepsy patients

Characteristics	Clinic follow up n=34 (%)	Telephone follow up n= 34(%)	p-value
Age in years <sup>a</sup>	8.8 (4.72)	11.7 (5.05)	0.017
Gender			0.624
• Male	20 (58.8)	22 (64.71)	
• Female	14 (41.2)	12 (35.29)	
Race			0.695
• Malay	31 (91.18)	30 (88.24)	
• Chinese	3 ( 8.82)	4 (11.76)	
Classification of epilepsy			0.478
• Idiopathic Epilepsy	17(50.00)	19(55.88)	
• Symptomatic Epilepsy	16(47.06)	14(41.18)	
• Cryptogenic Epilepsy	1(2.941)	1(2.941)	
Number of epileptics			0.634
• Single anti epileptic	24	26	
• Combination of two	6	5	
• Combination of three	3	2	
• Combination of four	1	1	
Distance from home to hospital(km)	24.82( 17.75 )	16( 12.37)	0.052

### **4.3 Clinical evaluation of paediatric epilepsy patients**

The different types of epileptic disorders are classified below in Table 5. This classification is according to the cause of the seizures whether from a known cause, a suspected cause or a genetic predisposition.

Majority of patients in our study were in the 2 major groups, idiopathic epilepsy with 50% in the clinic follow up group and 55.88% in the telephone follow up group followed by symptomatic epilepsy with 47.06% and 41.18% respectively in the clinic and telephone follow up group.

All the patients who consented to be part of the study were assessed clinically during the first encounter in the clinic. The demographic, social economic details and disease progress was documented in the prepared questionnaires. Complications such as contractures, poor weight gain and learning difficulties were dealt with in the with appropriate referrals to physiotherapist, dieticians and child psychologist for further interventional programmes.

Upon further review via telephone and clinic follow up, we had asked the parents a series of questions to ascertain the control of epilepsy at home and compliance to treatment, the general well-being of the child, school performances and if the parents had any other concerns that they wished to express. The added benefit from the clinic follow up was that these children received a repeated clinical assessment in 3 months as compared to the telephone follow up. However there were no additional complications that were picked up by a repeat clinical assessment in the 3 month review.