CHAPTER III

Strengthening of The Public Health Care System to Improve Epilepsy Treatment in Nakhonratchasima Province: An Integrative Approach

Introduction and Rationale

Introduction

Epilepsy is a major neurologic disease which is distributed throughout the world, and which has considerable personal familial and societal impacts. This symptom complex constitutes the commonest noninfectious diseases of the nervous system. Around the world, there are more than 50 million people with epilepsy and approximately 5 million patients (10%) have seizures more than once a month. The prevalence of epilepsy in developing countries ranges from 4 – 49/1000 in adults, higher than that reported in the developed countries (4 – 7.5/1000). This disparity may partly be explained by differences in diagnostic criteria and partly by study design, but there are other factors unique to developing countries; these include inadequate health care services, particularly obstetic care and vaccination programs, exposure to infectious agents such as Taenia Solium and head injury. The incidence rate of patients with epilepsy in developing countries is around 11-134 /100,000 per year. The incidence rate of patients with recurrent seizures is between 30 and 50

/100,000 per year. The prevalence of active epilepsy is approximately 22/1000. The standard mortality ratio for patients is 3.0.

In Thailand, epilepsy is the third most common neurologic disease following cerebrovascular disease and headache. Most patients are in the young age groups who are essential for the development of the country. This disease needs to be treated for at least 2-4 years and good patient compliance on medication is necessary, otherwise it might be harmful for those non-compliant patients.

The Natural History of Epilepsy

Epilepsy is defined as the presence of two or more afebrile seizures unrelated to acute metabolic disorder or to the consumption and/or the withdrawal of alcohol or drugs.

Active epilepsy refers to seizures that occur at least once in the previous 2 years despite treatment.

Chronic epilepsy means seizures that occur within 5 years after the onset of epilepsy.

Studies have shown that approximately 70-80 % of treated patients achieve long-term (5 years) remission. The remission rate improves with an increasing duration of follow up and maximizes in the first 2 years. Of those patients with long-term remission, 70-80 % could be withdrawn from medication (burst pattern) and 20-30 % have relapses (intermittent pattern). The remaining treated patients (20-30 %) continue to have recurrent seizures (continuous pattern), called chronic epilepsy, but may have occasional short-term remission.

For untreated patients, spontaneous remission can occur, more frequently in patients with a longer history and less severe seizures. A failure to provide early treatment may lead to an intractable condition.

Prognosis of Epilepsy

Factors which influence prognosis include: presence of epilepsy in family history; a pre-existing neurological, psychological, behavioral or social handicap; early age at onset; partial or mixed type of seizures; high frequency of seizure; prior to treatment; the cause of seizure; long duration of seizure.

Factors Influencing Effectiveness

There are three main factors which influence the effectiveness of seizure control. First, health caregivers need to have sufficient knowledge and an ability to diagnose, classify and manage patients with epilepsy. Second, patients should comply with their medications, adhere to their appointments and avoid factors that might aggravate their seizure attacks; thus, they should be provided with the knowledge about the adverse-effects of AED and drug interaction that might be the cause of non-compliance. Finally, the severity of disease is an inevitable cause of uncontrolled epilepsy.

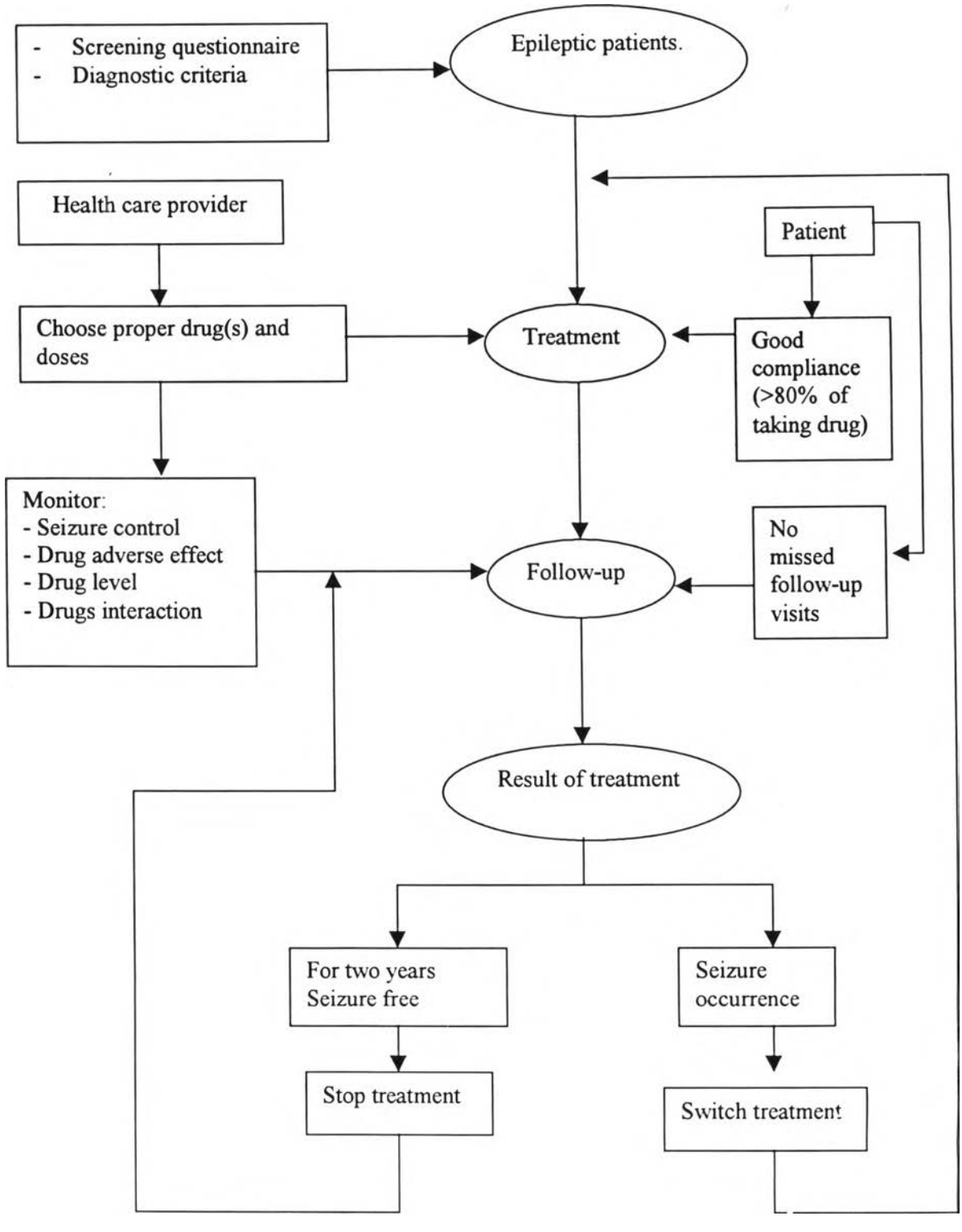
Consequences of Active and Chronic Epilepsy

From the natural history of epilepsy, at least 20-30 % of patients will inevitably become active or have chronic epilepsy (severity of disease). To achieve

a long-term remission of 70-80%, health caregivers must have sufficient knowledge and good clinical practice, and patients need to adhere to medications, attend the follow-up appointments and avoid precipitating factors. If the long-term remission target can not be attained, patients will have to shoulder the long-term costs of their medical and non-medical care and suffer from impaired quality of life. Patients may have an increase in the number and severity of seizures which may lead to any of the following: greater number of ambulance rides; emergency department visits and hospitalization; direct accident and physical injury; dementia; mental retardation; psychiatric disorders; disability; poor quality of life; unemployment; restriction of work and activities; unexpected death. For the family and caretakers, it will be a big burden. For society, patient accidents might injure others and damage property.

The steps involved in caring for epileptic patients are diagnosis and treatment, as shown in Figure 1.

Figure 1: The Care Taking Steps



In current conventional care, sub-district health officers just survey suspected epileptic patients by using the screening questionnaire of the Mental Health Department. This questionnaire can detect only generalized tonic clonic epilepsy, and a home visit is required to ask for general health. While a few sub-district health officers dispense drug(s), most refer patients to General Practitioners (GPs) in a community hospital for treatment with antiepileptic drugs (AEDs).

In the community hospital, GPs just follow known-cases of epilepsy and prescribe antiepileptic drugs for these patients. Some GPs adjust doses or change AEDs following the standard treatment of epilepsy but others do not. They seldom make the diagnosis of epilepsy for patients, referring them to a specialist for diagnosis. They also refer patients to a specialist, if they cannot handle patients on the basis of their individual knowledge.

Based upon the conventional care, following are some of the defects in the provision of health care services:

1. According to the screening and diagnostic criteria for epileptic patients of the Mental Health Authority of Thailand, 1361 patients were registered as epileptic at Nakhonratchasima Provincial Public Health Office in 1997, giving a prevalence rate of 0.7/1,000. That is likely lower than the true rate (from the literature review, the prevalence of epilepsy for developing countries is 4-49/1000). This indicates that the current screening and diagnostic criteria are not good tools.

Some missing patients have never been treated and some treated patients have not been registered.

2. Therapeutics depends on two factors. The first factor is the patient-factor which includes patient-compliance and patient-knowledge about their disease (epilepsy). Previous studies (on pages 9-10) reveal that 50% of patients did not take medication following doctor prescription because of their insufficient knowledge.

The other is the health care provider factor. Based upon the previous survey (on pages 9-10) up to 50% of health care providers treated the patients improperly; 23% and 29%, respectively prescribed inadequate doses and unreasonable polypharmacies to patients. The time given to patients was too little, because of the overcrowding of patients. This leads to increased patient shopping around and contributes to wasting more time, more money, and duplicate use of limited resources.

3. For follow-up patients, there is no effective follow-up system in current conventional care. Patients receive only a paper showing the date of the next appointment. They might lose it because they have to keep it at least 1-3 months, and ultimately they might forget the date. Patients cannot be reminded to follow the treatment with their health care providers before hand because of an ineffective recall system. According to a descriptive survey, nurses responsible for epileptic patients at community hospitals were asked about the magnitude of patients with regular follow-up and how to manage dropout patients. The result was more than

80% of patients had regular follow-up and for dropout patients, some hospitals sent a letter to patients after they missed their appointment date by two months. Up to 50% of patients missed their appointment (the detail on pages 9-10).

In conclusion, several factors can contribute to inefficient care of patients with epilepsy: i.e., limited funds and resources; limited number of physicians; a growing number of patients with chronic diseases, including epilepsy, who need long term management. There are many problems and obstacles for both GPs and specialists in the provision of continuity of care for epileptic patients including: inadequate provision of care; long waiting times; overcrowding of patients; inadequate time for patients; duplication of medical work; lack of systematic follow up; inappropriate use of polypharmacies; failure of general practitioner-patient communication; low level of patient knowledge; patients non-compliance; missing follow-up and drop out; and inappropriate use of resources.

Literature Review

Introduction

In Thailand, in addition to conventional care, there are many other health care service programs such as the home health care program to follow and monitor patients with chronic diseases or disabilities, and a diabetic-patient club to exchange experiences with each other to recognize the necessity of continuous treatment and self-care. However, those programs are limited to a minority of patients who volunteer to enroll in these programs. They neither provide equity of health care to all patients with that disease nor improve the defects of the whole health care system because they are for voluntary patients and only correct the patient side of non-compliance but not the provider side of improper practice and deficiencies in the conventional care patient registration, patient recall system.

A Structural Shared Care Scheme might strengthen every step of the whole health care system and not only correct the defects on patient's side but also on provider's side; this system is presented below.

Structural Shared Care Scheme

Definition :- Structural shared care is the joint participation of GPs and hospital consultants in the planned delivery of care to patients with chronic conditions, utilizating an enhanced information exchange over and above the routine discharge referral, letters, and the integration of primary and secondary services.

Structural shared care is one of the health care schemes whose purposes is the continuity of care for chronic diseases by a systematic approach that includes coordination, collaboration, communication and organization among patients, primary health care teams and specialists.

The objectives of this scheme are:

1. To improve the effectiveness and standard of health care service.
2. To provide continuity of care for patients with chronic disease.
3. To reduce unnecessary and improper referral rate.
4. To provide more chance for patients to receive a specialist's instruction at the proper time and to have high confidence in their primary health care team' s management under a specialist's supervision.
5. To have communication, coordination, and collaboration among primary health care teams and specialists.
6. To have proper and worthwhile efficient utilization of the limited resources at each level of the health care system.

The implementation of this plan requires a change in the role of the specialist and the creation of community sub-specialists with different skills and roles. It needs to set up a registration, recording and recall system in order to accurately transfer medical data, to retrieve it in the future and to recognize who are the risk groups and call them to visit the clinician at the predetermined time. It needs to set the whole system and assign each participants' responsibilities and the precise way in which to communicate and coordinate with each other. GPs, practice teams, and community

health staff need to take part in routine management and monitoring activities of out-patient care. The ultimate responsibility for the patient should remain with the GPs.

Structural Shared Care Scheme is comprised of:

1. Central registration
2. Call and recall system
3. Defined and agreed responsibilities
4. Shared records
5. Coordination of care and communication channel
6. Guidelines of management and referral policies
7. Patient-held records
8. Education and training

1. Central Registration

This system is for registration, recording, updating and auditing of patients, and their medical information. It is a reliable, comprehensive and fail-safe method of recording identification, essential social, demographic, clinical and therapeutic information from routine clinical contacts and can be linked with other routinely available patient health information. It will improve communication between patients, primary care physicians and specialist clinics. It is a method for automatic monitoring of the control of individuals, evaluation of the medical care for specified groups of patients, providing data for studies on the natural history of disease and

therapeutic intervention, and purposely designed statistical packages for the actuarial prediction of risk in defined subgroups of patients.

2. Call and Recall System

This systems aims:

1. To remind patients who are due for follow-up.
2. To provide continuity of treatment and care.
3. To follow risk patients.
4. To detect pre-symptomatic sub-clinical or even overt but undetected diseases.

A central hospital based computer will generate a minimum amount of information about patient identification data, clinical profile and impression of patients, details of current medications, laboratory test results, caregiver's name and the next appointment date. Letters enclosing these data will be sent to the GPs, specialists and patients at the follow-up activated date (the assigned date before the actual appointment date). The clerical persons who are responsible for this task will list the patient's name, address, and the provider's name. They will send the letters, enclosing medical records and follow-up forms, to caregivers at the predetermined appointment date (the routine follow-up interval can be set at any time, considering that best suited to the needs of the patient who then makes a new follow-up appointment). Sometimes they need to follow-up at predetermined intervals if there are some problems, such as laboratory investigation abnormalities, in order to recheck, further investigate or provide some other management.

3. Defined and Agreed Responsibilities

This task is an important structural shared care function. Each participant needs to be assigned a role and their responsibilities in order to integrate the process and avoid the duplication of medical work; particularly, who will see the patient and what examinations or tests will be done, and when they will be referred back. Therefore, the task can run smoothly and contribute to high effectiveness of care. For example, the specialist's role is to oversee and coordinate the scheme, and undertake clinical review and supervision of patients. The GP's role includes investigation and treatment of patients and ensures that GPs enjoy full clinical responsibility for the shared care patients including changes in the initial treatment.

4. Shared Records

The responsibility for recording all medical information needs to be allocated to GPs and specialists. The records will be shared between GPs and specialists.

5. Coordination of Care and Communication Channel

The aim of this component is:

- To coordinate and communicate among providers and integrate the process into a meaningful whole.
- To coordinate the approach between GPs, specialists and other providers with the purpose of delivering an agreed standard of care.
- To communicate with patients and providers and make them understand their diseases so that patients monitor themselves about diseases or adverse effects of medication.

- To improve patient's care.
- To improve interpersonal relationships.
- To improve team working.
- To improve knowledge.

Channels of communication

These channels include:

1. Liaison
2. Letters
3. Telephone
4. Meetings
5. Individual direct-contact at out-patient clinic
6. Home visits

6. Guidelines of Management and Referral Policies

Guidelines need to be provided for each level of provider in order to carry out patient management accurately and contribute to the improvement of health care outcomes and health service efficiency and to reduce levels of inappropriate practice. GPs and specialists have to prepare protocols and clinical guidelines.

7. Patient-Held Records

It is necessary for patients and providers to have effective communication and information exchange. Today, patients have the legal right to receive their medical documents, and doctors are obliged to give enough information to ensure

adequate health care and to provide a basis for informed consent to treatment. There are many problems with current methods for recording clinical information, in terms of completeness, comprehensiveness, reliability and continuity. The contents of the shared care card include computer generated medical summary details, medical knowledge and instructions and records.

What is the patient-held record?

It is a record that consists of a full case record or a summary record including structured problem lists such as diagnosis, other health problems, details of treatment, advice and information relevant to particular patient groups. The patient carries this record and he or she has automatic full access to its content.

Aims:

To improve the communication between doctors and patients.

To transfer the records in a suitable form.

Because a chronic disease is a lifelong condition, its management may be shared between GPs, specialists, nursing and other staff over the lifetime of the patient. This requires accurate information transfer between the parties concerned. To be effective, medical records must be complete and available at the time of consultation.

8. Education and Training

This is the most important task to perform in order that GPs, specialists, primary care teams and all participants understand the whole meaning of this scheme and run the study smoothly.

As mentioned above, there are many groups in shared health care that depend on methods of information exchange and technology. Up to now, there is only one paper which studied shared care in patients with epilepsy (Taylor MP, [et.al]. (1994)). The title was a district epilepsy service, with community-based specialist liaison nurses and guidelines for shared care. However this paper is not available in South East Asia. From the abstract of the study, the process of shared care produced a guideline for management by non-specialist hospital doctors and general practitioners and for the providers' role. A new feature of the study was the appointment of a community-based specialist liaison nurse. Her role was patient supervision at home, particularly in providing counseling, support, and medical instruction. This study has conducted over 5 years. The evaluation was the extent to which the services met the needs of those with epilepsy.

For other diseases, there are five randomized control trials for shared care with diabetes and one for hypertension. For those related to diabetes, one paper is not available and the other does not state the details of the study. The remaining three studies are detailed below and the results presented in Table I.

&Table I: The Result of the Shared Care Studies for Diabetes

	C%*	S%*	P-value*	C#	S#	P-value#	C$	S$	95%CI$
Regular review (≥ 1 time/yr.)	13.6	100							
Blood glucose measures (≥ 1 time/yr.)	4.8	100							
Loss to F/U	8.7	3.1		15%	3.4%				
No. of review/pt./doctor				2.2	3.2	P<0.001			
Mean No. of urine test				2.3	3	P<0.03			
Mean No. of PG estimation/pt./yr.				2.3	3.1	P<0.003			
Mean No. of HbA1C estimation/pt./yr.				0.9	2.4	P<0.001			
No of visit/2 yrs.							4.8	5.3	-0.9 to –0.1
No. of HbA1c test							1.3	4.5	-3.5 to –2.9
BP measures							1.2	4.2	-3.3 to –2.7
Cr. Measures							0.7	0.5	0.03 to 0.37
VA measures							0.7	2.6	-2.1 to –1.7
Mean random PG (mmol/L				11.2	11.2	NS			
Mean HbA1C				10.6	10.3	NS	5.3	5.3	-0.31 to 0.037
HbA1C (end of study)	10.4	9.5	P<0.02						
Change from diet to hypoglycemic drug	10.7	9.3		35%	43%	NS			
Change from diet to insulin	1	1		4%	9%	NS			
Change from hypoglycemic drug to diet	1	4.1							
Change from hypoglycemic drug to insulin	2.1	2.9		7.3 %	3%	NS			

	C%*	S%*	P-value*	C#	S#	P-value#	C$	S$	95%CI$
Admitted to hospital	24	18							
Admitted from diabetes	6.8	5.1		18%	9%	NS			
Admitted from cardiovascular	14.6	10.3							
Death	17.5	6.2	P<0.02						
Death from cerebrovascular disease	2	0							
Death from myocardial infarction	10	3							
BMI: Baseline Mean							28.3 27.9	27.6 28.7	-1.2 to 2.6 -2.4 to 0.8
Cr. (umol/L): Baseline Mean							90.4 100.6	88.9 102.2	-4.5 to 7.5 -9.3 to 6.1
Systolic BP (mmHg): Baseline Mean							153.9 156.4	155.9 161.5	-8.7 to 4.7 -11.7 to 1.5
Diastolic BP (mmHg): Baseline Mean							84.8 83.5	85.6 84.3	-4.4 to 2.8 -3.5 to 1.9

C = Control group S = Shared care group

* = The first study # = The second study $ = The third study

& Source: Hayes TM and Harries J. (1984), Hurwitz B, Goodman C and Yudkin J. (1993), and Naji S,... [et.al.]. (1994).

The first study (Hayes TM and Harries J. (1984)) is detailed below. The title was "randomized control trial of routine hospital clinic care versus routine general practice care for type II diabetics". General practitioners from the area were selected and invited to participate. The population was patients with Type II Diabetes who attended the diabetic clinic of University Hospital of Wales and resided in the area where a GP had agreed to take part in the study. The samples were patients aged 40-80 years with no complications or other necessitating continued hospital attendance with age range of 40-80 years. Two hundred patients were recruited and each gave informed consent. After that, these patients were randomly allocated into routine general practice care (103 patients) and routine hospital clinic care (97 patients). For routine hospital clinic care, patients were followed by the usual routine of the clinic, and received no special attention. For routine general practice care, the diabetic clinic was available for consultation if the GP thought this was necessary, and open access was available to the hospital laboratory, dietetic, and chiropody services As well, the GP received a leaflet from the diabetic clinic giving guidelines for the continuing care of diabetes. The investigators who evaluate the outcome of the study were employed from health visitors not related to the study. They gathered the patients' information on how often they had been seen by a doctor and problems with their diabetes at intervals of 6 months. The duration of the study was 5 years. Every patient was reviewed in the diabetic clinic at the end of the study. The result of the study, was that only 13.6% of the patients in the general practice group were regularly reviewed at least once a year, and only 4.8% had blood glucose measured at least once a year compared to 100% of patients who attended hospital clinic group. Three patients (3.1%) in the hospital clinic group and nine (8.7%) in general

practice group were lost to follow up. The mean HbA1C was 10.4 %(SD = 1.73) in the general practice group and 9.5 %(SD = 1.77) in the hospital group ($t=2.52$, $p < 0.02$). Eighteen patients (17.5%) in the general practice group died as compared to six (6.2%) in the hospital group (chi-square = 5.642; $p < 0.02$). Forty four percent in routine general practice care and 37% in hospital clinic care thought that they had problems with their diabetes during 5 years of the study. Twenty four percent in routine general practice care and 18% in routine hospital clinic care were admitted to the hospital for medical reasons. The conclusion was that there was more satisfaction in hospital clinic care. The reasons might be that the hospital clinic has more facilities and an automatic recall system. Patient-confidence and GP knowledge might be other factors explaining more satisfaction with hospital clinic care.

The second study (Hurwitz B, Goodman C and Yudkin J. (1993)) was prompting the clinical care of non-insulin dependent (type II) diabetic patients in an inner city, one model of community care. They studied patients with NIDDM who had attended a diabetic clinic at the district general hospital in the previous 2 years. The exclusion criteria were women of childbearing age, patients with significant complications and those over the age of 80 years. GP and optometrists in the area were invited to participate. Four hundred fifteen patients were recruited in this study and 215 agreed to take part. Of these, 209 were randomized into prompted (89 patients) and control hospital clinic care groups (92 patients). Twenty-eight patients were excluded after the allocation. The process in the prompted group in this study included: setting the registration and recall system; sending requests to patients

asking them to provide blood and urine samples for random plasma glucose, glycated hemoglobin, and albumin estimation; reminding patients and GPs for clinical review; providing knowledge of management to general practitioners; providing knowledge of diabetic eye disease to participating optometrists. This was a 2-year study. The results of the study were that both groups were well matched for demographic variables and for most of the important diabetic attributes. In the prompted group, all clinical processes of care measures were carried out more frequently than in the control group, including percentage of patients' review, blood test, eye test, receiving continuity of care and follow-up rate. However, there were no differences in medical outcomes between the groups especially random plasma glucose and HbA1C concentrations. The high compliance level in the prompted group suggests that the scheme was acceptable. The result of the response to questionnaire, 32/42 of patients in prompted group stated that the care was as good as hospital care. As well, 28/31 of the GPs who responded to the questionnaire wished to continue providing diabetic care within this prompted care.

The third study (Naji S,... [et.al.]. (1994)) was integrated care for diabetes: clinical psychological and economic evaluation. It was a randomized trial. The population was adult patients with diabetes attending the Aberdeen Diabetic Clinic for at least one year. The exclusion criteria were as follows: patients aged less than 18 years; women who are pregnant or planning pregnancy; serum creatinine more than 200 umol/l; patients with other medical problems. Consenting patients were stratified by treatment (insulin or other) and randomly allocated to conventional clinic care or to integrated care. It was a 2-year study in which the blood pressure,

creatinine, HbA1C, BMI, were measured and the feet were examined. Patients cost was estimated by patient completed questionnaire, interviews of the hospital accountants, practice managers, and diabetic care coordinator. The process of shared care in integrated group was the integration of care between general practice and hospital clinic with provision of the following: guidelines for management; measurement and examination of patients; assignment of the responsibilities of GP and the clinic; making an appointment with their patients together; provision to the GP of a computer generated reminder and clinical detail of patients. For conventional care, computer generated letters were sent to remind patients of their next routine appointment. 311 patients were considered for inclusion, 27 were excluded by the stated criteria and 10 declined to participate. The sample size was 274 patients, which gave 80% power of detecting differences at the 5% level of significance. One hundred thirty five patients were allocated to conventional care and 139 to integrated care. During the two years of the trial, 10 patients (7.4%) in conventional care and 11 (7.9%) in integrated care died. 10% in conventional care and only 3% in integrated care were lost to follow up (significant difference). Patients having integrated care had more visits and higher frequencies of measurement and examination. Metabolic control and number of unscheduled consultations was not significantly different between groups. The number of no measurements during the 2-year trial was significantly greater in conventional care. The annual cost per patient was 3850 Baht and 5460 Baht in conventional care and integrated care, respectively. At the final review, patients were interviewed to determine the treatment satisfaction scale, estimated cost, and advantage and disadvantage of conventional and integrated care. The advantage of integrated care

was accessibility, time saving, and continuity of care. The disadvantage was quality of care. The costs are greatly influenced by organization of care particularly maintaining the clinical database and operating the appointment prompting system in integrated care.

In summary, the studies of shared care with diabetes showed that the study populations were the patients who had volunteered and were happy to attend hospital clinics and who had no diabetic complications or serious medical conditions. The general practitioner participants were not described in terms of the degree of responsibilities for diabetic care. Some papers did not mention the statistical test for analysis of outcome. Focusing on the medical outcomes which had no statistically significant improvement between two groups, plasma glucose and HbA1C level represented the medical status in the previous few days or few weeks, but could not refer to medical status of the last three or six months. There was only one or two long-term outcomes measured such as creatinine and blood pressure levels but they were not a systematic assessment of long-term outcome. The ideal relevant outcome measurements should be all of the long-term complications of diabetes including: cardiovascular event; cerebrovascular event; neuropathy; retinopathy; nephropathy.

Concerning evaluation of the west of Scotland shared-care scheme for hypertension (McGhee SM,... [et.al.]. (1994)), the title was coordinating and standardizating long term care: evaluation of the west of Scotland shared-care scheme for hypertension. They assessed the feasibility, acceptability to patients and

GP, and cost-effectiveness, comparing the shared care scheme with two other methods of long term follow-up: a specialist outpatient clinic and nurse practitioner clinic. The study population was patients with well-controlled hypertension. The sample was patients who attended the two outpatient clinics of the Royal and Western Teaching Hospital. GP who referred patients to these clinics were invited to participate. Paired matching patients by age and sex were randomly assigned to shared care or continuing outpatient follow up and compared to patients selected from the nurse practitioner clinic. The process of shared care included: setting the central registration; recall system by using a computerized database; assignment of shared responsibility for GP, specialist, patients and laboratory services but with the GP in overall control of the patient's care; coordination; communication; referral policies; patient-held record. The database was used to generate an annually updated two-page medical record on each patient enrolled in the scheme for the GP, and a patient-held summary record for the patients. Each year, the patient was prompted by a letter from the shared care registry, to arrange a review with the GP including clinical examination, serum biochemistry, and electrocardiography. After the GP examined patients, they needed to update patients' data in the medical record and in the patient-held record and return it to the registry. The full set of results were marked by clerical staffs for abnormality according to a protocol and then scrutinized by the specialist. The updated medical record was posted to the GP with a standard letter. Any suggested changes in follow-up plans were made to the GP in this letter and, if required, an appointment at a re-referral clinic was available at short notice. The effectiveness measurement was the number of patients with a complete review in their second year of follow up, blood pressure, serum creatinine,

EEG report. The cost included direct medical cost, and direct non-medical cost. Statistical significance was determined by calculation of 95% CI for the difference between proportions and by using one or two sample t-tests for the clinical data as appropriate. 554 patients were successfully matched and randomized over a period of one year. The 277 patients allocated to shared care were cared for by 176 GPs. A further group of 277 patients with well-controlled blood pressure was selected from the nurse practitioner clinic at Stobhill hospital. The results of the study (shown in Table II), showed there was no significant difference between the three groups in terms of clinical variables including mean blood pressure levels and between the completeness of information on clinical measurements. The number of patients receiving complete review in 2 years were significantly different between shared care versus outpatient care and shared care versus nurse practitioner care. For the acceptability issue, 48.2% of respondents who received shared care preferred shared care, 22% had no preference, and 29.8% preferred out-patient care. The main advantage of shared care was greater accessibility to the doctor, better continuity of care but the disadvantage was that the visit of just annual review is not sufficient and less expertise available. For responding GPs, 61.2% wanted shared care to continue. The ideas of the GPs for shared care were fewer losses to follow-up, better communication between doctors, but difficulty in organizing in the practice and increased workload. The total cost of patients in shared care, outpatient care and nurse practitioner care were 629,204, 728,905.1 and 617,509.9 Baht, respectively. The costs per complete review in shared care, outpatient care and nurse practitioner care were 2,860, 4,992 and 3,056 Baht, respectively.

*Table II: Results of the Shared Care Study for Hypertention

	Shared care	Specialist care	Nurse practioner care	95% CI Shared VS Specialist care	p-value	95% CI Shared VS Nurse practitioner care	P-value
Mean BP (at starting point)	No difference						
Same grade or move to better grade of BP control	67.8%	63.8%	69.9%		NS		NS
Completeness of information on clinical measurement	79-97%	78-100%	93.1-100%				
Completeness of urinalysis	60%	43%	81.2%				
Still contact with clinic or scheme	96.6%	85.9%	90.7%	6 to 15.4	<.001	1.8 to 10	<.01
Received complete review	82.4%	54.1%	74.8%	20.8 to 35.8	<.001	0.7 to 14.5	<.05

* Source: McGree SM,... [et.al]. (1994) "Coordinating and standardizating long term care: evaluation of the west of Scotland shared-care scheme for hypertension". British Journal of General Practice. (44) : 441-445.

Most papers have shown that there is no statistically significant improvement in medical outcome of hypertensive and diabetic patients except process of care. Because the purpose of shared care is continuity of care for patients with chronic disease, the relevant outcome should be the long term complications of those chronic diseases. However, epileptic patients are different to these patients with DM. and HT, which is the consequence of seizure attack will occur immediately during or after the event. For DM. and HT, the consequence will emerge several years after regular treatment. Therefore epileptic patients might have clinical benefit from this scheme.

Research Question

Primary Question

Does the Structural Shared Care Scheme result in an 50% increase of epileptic patients in Nakhonratchasima Province who have a 50% seizure reduction compared to epileptic patients receiving conventional care by the closing date of the study?

Secondary Questions

1. Does the Structural Shared Care Scheme result in improvement of seizure severity of epileptic patients before and after study compared to patients receiving conventional care?

2. Does Structural shared care scheme result in improvement of QOL of epileptic patients before and after study compared to patients receiving conventional care?

Null Hypothesis

There is no difference in a number of epileptic patients in Nakhonratchasima Province who have a 50% seizure reduction between those receiving structural shared care and those receiving conventional care.

There is no difference in the change of seizure severity and QOL of epileptic patients before and after study between those allocated to structural shared care scheme and conventional care.

Objectives

1. To evaluate the effectiveness, in terms of reduction of epileptic patients' seizure attacks of conventional methods and the structural shared care scheme.

2. To evaluate the change of seizure severity and QOL during the study of epileptic patients who are treated with conventional methods and structural shared care scheme.

Research Design

A randomized controlled trial

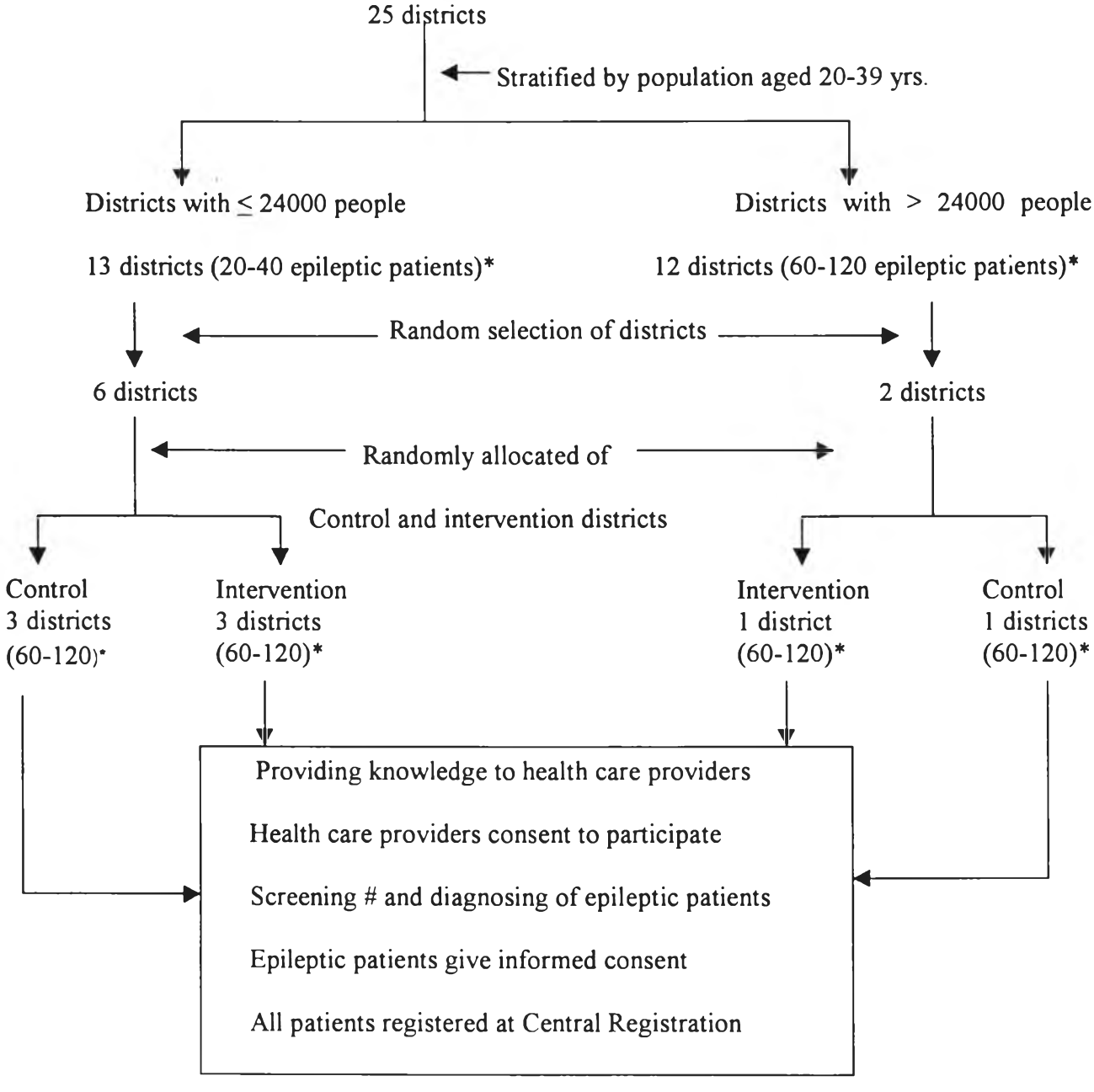
Research Methodology

Population and Sample

The target population (sampling frame) to randomly allocate to sample is all epileptic patients in Nakhonratchasima Province. The sample is selected by using a cluster sampling technique (selection of a district with its own community hospital excluding the district with its own provincial hospital). Nakhonratchasima Province has 26 districts, with the exception of Amphur Muang which has its own provincial hospital, each district has its own district hospital. All 25 districts with their own district hospitals will be stratified into 2 groups according to the population between the ages 20 and 39 years (either less or more than 24000 people). From our previous cross-sectional study (on pages 9-10), approximately 50% of epileptic patients were in this age range. From the epilepsy registration document in Nakhonratchasima Provice, the number of whole population in each district does not represent the number of patients. The number of population in each district with age range 20-39 years corresponds to the number of patients in that district.

In the group of population aged 20-39 years, less than 24000 people in each district has epileptic patients around 20-40 cases and the other group (population aged 20-39 years, more than 24000 people) has around 60-120 cases. The ratio of patients between the 2 groups is 3:1. Six districts in the first group (population less than 24000 people) and 2 districts in the second group (population more than 24000 people) will be randomly selected and each group will then be randomly allocated to the conventional and shared care group, as shown in Figure 2.

Figure 2: Sample Selection and Stratification of Epileptic Patients in Nakhonratchasima Province (25 districts)



* Based upon prevalence of 0.7/1000 population (less than the true prevalence)

#Based upon an estimated prevalence of 3/1000 population

As shown in Figure 2, each group is treated with the same care including: receiving information and instruction; patients asked whether or not they are having seizure occurrence and/or adverse drug reaction; receiving a standard treatment. In the intervention group, doctors and patients will be given a notice to remind them of the follow-up date at every next activated appointment date. In addition, the health care providers in the intervention group will have their assigned responsibilities to handle and to refer patients. As well, patients and health care providers have a liaison to exchange their experiences and help care together.

Eligibility criteria

Inclusion criteria:

1. All patients with cryptogenic unprovoked epilepsy of unknown etiology.
2. All patients with remote symptomatic unprovoked epilepsy and unprovoked epilepsy associated with progressive neurological conditions ascertained in the community.
3. All patients with seizure occurrence of at least once a year.
4. All agree to participate.

Exclusion criteria:

1. Patients with acute symptomatic or situation-related epilepsy
2. Patients with idiopathic unprovoked epilepsy of unknown etiology
3. Patients with pregnancy

Sample size:

The main outcome measurement of this study is the proportion of epileptic patients who have 50% seizure reduction.

Type 1 error, the chosen level is 5 % (significant level)

Type 2 error, the chosen level is 10 %

Power of the significance test is 0.9 (90 %)

Null hypothesis P1=P2

P1 (current percentage of patients with having 50% seizure reduction) = 30 %

P2 (anticipated expected percentage of patients with having 50% seizure reduction) = 45 %

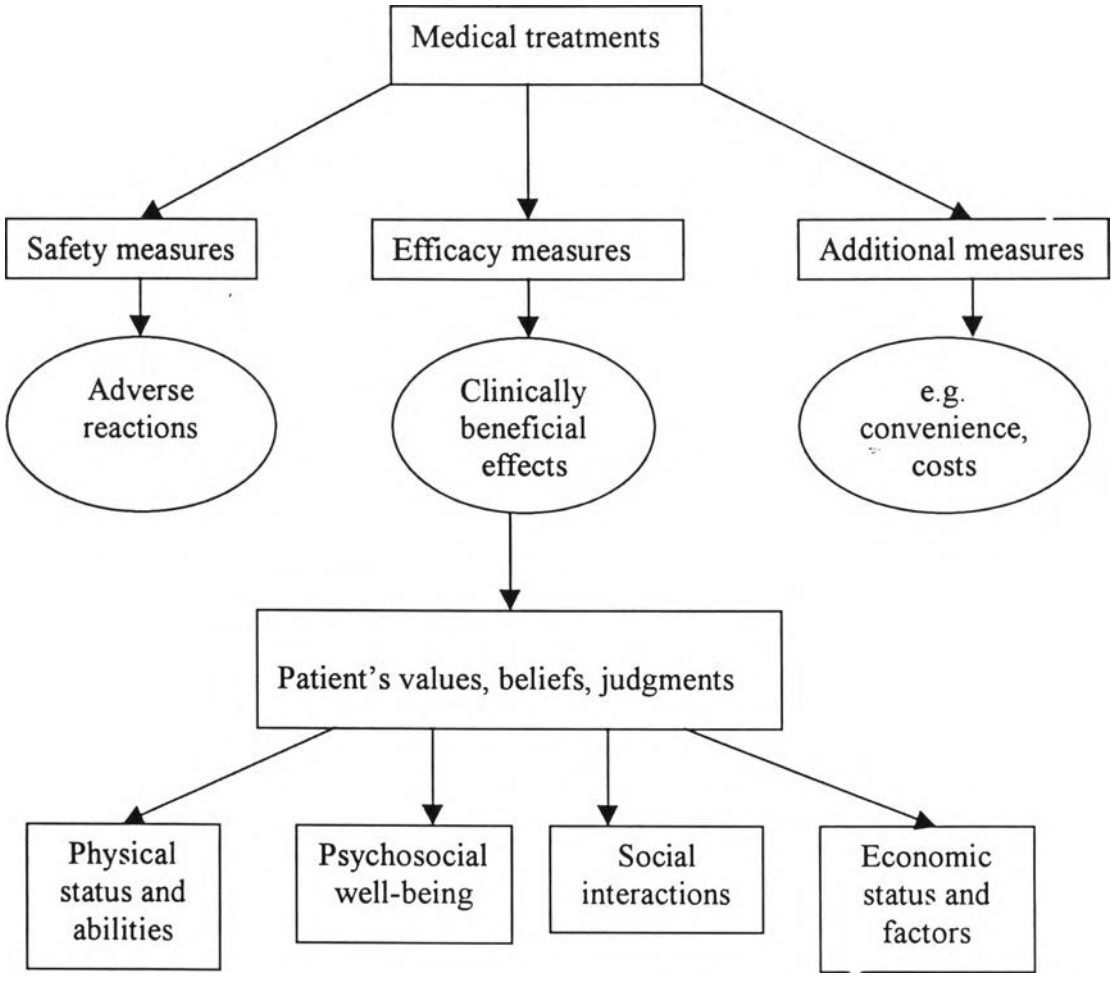
Sample size for each group is 230 subjects (calculated by the formulae of 2 independent group with categorical data).

There is a cluster effect (selecting district) from using cluster sampling technique. Individual epileptic patients in a district might not be independent from one another. As well, individual patients in a family (the smallest sub-unit of district) might be dependent upon each other. From previous study, 10% of families have a family history of epilepsy. Therefore, the minimum percentage for minimizing the cluster effect is 10%. For this study 20% was chosen. Adjusted for cluster sampling selection and for 20% dropout, the sample size will be 331 subjects.

Conceptual framework

The usual therapeutic evaluation of any disease is the physical outcome. In a real situation from the patients' perspective, physical outcome alone is not enough for the assessment of any intervention. For example, an epileptic patient who achieves his physical outcome (no seizure occurrence) still worries about an unpredictable occurrence of seizure anytime. Whenever epileptic patients are diagnosed, their work or activities (driving, swimming or working at high altitude) are restricted. Their family and relatives will treat them as an ill person from the time that the diagnosis is established. They cannot do anything alone because of their family's or relative's worry about seizure occurrence. As well, the long-term treatment with an antiepileptic drug may have some adverse effects and disturb patients' function. There are many aspects of clinical evaluation, not only physical outcome, but also psychological, social outcomes and safety measurement, as shown in Figure 3.

***Figure 3:** Health Related Quality of Life



* Source: Cramer JA. (1994). Quaility of Life for People with Epilepsy. Neurologic clinics, 12(1); p. 1-13.

The evaluation outcome of physical, mental, and social aspects like this is defined by WHO as health related quality of life (HRQOL). The definition of HRQOL is a state of complete physical, mental and social well being, not merely the absence of disease or infirmity.

WHO has developed an instrument to measure the HRQOL, which includes the following five general domains:

1. Physical health

This topic includes the assessment of seizure frequency, seizure severity, activity daily living (ADL), physical functioning, and adverse drug effects.

2. Psychological health

Cognitive function such as thinking, learning, memory, concentration and emotional state such as anxiety, depression, fear of exposure of seizure, and self esteem is assessed as a HRQOL.

3.Level of independence

The level of independence of mobility, ADL, communication capacity, work capacity and dependence on substances especially antiepileptic drugs is also evaluated.

4.Social relationship

Social relationships with family, classmates, coworkers, society, and fulfillment in marriage are assessed including family and/or social support.

5.Environment

Physically safe and secure home environment, work satisfaction, health and social care, financial resources, leisure activities and transportation are also evaluated.

There are many scales for general quality of life assessment (McDowell I and Newell C. (1996)). However, there are only four scales for disease specific assessment of quality of life of patients with epilepsy. These include:

- Quality of life in epilepsy 89 (QOLIE-89) for assessment intervention and comparing populations
- QOLIE-10 for clinical overview of highlight problem areas
- QOLIE-31 for assessment intervention and comparing populations with change overtime
- Epilepsy Surgery Inventory-55 (ESI-55) for assessment of intractable epilepsy after surgical treatment

In this study, we will study seizure frequency, seizure severity and the HRQOL assessment using the QOLIE-31, which is composed of 7 multi-item scale, 31 items according to its function. The 7 scales assessed by this QOLIE-31 (Cramer JA,... [et.al.]. (1994)) are energy-fatigue, social function, seizure worry, emotional well being, cognitive functioning, medication effects, and overall QOL.

For structural shared care, because of the current conventional care problems mentioned above, the central registration, the recall system, the coordination among primary health care teams and specialist, and line of management will be applied as an intervention in this study.

Operational Definition and Identification Subject

Seizure was defined as an abrupt, brief episode of disturbance of cerebral function that started suddenly and usually arrested spontaneously. The seizure may have altered state of consciousness that may or may not have been accompanied by characteristic body movements, by specific mannerisms, by altered sensations, intelligence, perceptions of the environment and/or autonomic symptoms.

Epilepsy is defined as a condition characterized by recurrent (two or more) epileptic seizures unprovoked by any immediate identified cause and not occurring within a 24-hour period.

Acute symptomatic epilepsy or situation related epilepsy is defined as seizures which may be: occurring within 7 days of traumatic brain injury or of any cerebrovascular accident (CVA); in the course of active CNS infection; as the presenting symptom of a CNS tumor; in the postoperative period of an intracranial neurosurgical intervention; during the time of exposure to drugs or drug overdose or elimination of drug or alcohol; related to systemic disturbances or with fever.

Idiopathic unprovoked epilepsy of unknown etiology is defined as a certain partial or generalized epileptic syndromes with particular clinical characteristics and specific electroencephalography (EEG) findings.

Cryptogenic unprovoked epilepsy of unknown etiology is defined as partial or generalized unprovoked epilepsy in which no factor associated with increased risk of seizures has been identified.

Remote symptomatic unprovoked epilepsy is defined as seizures which may be: occurring more than a week after head injury or CVA; as a sequela of CNS infection; related to alcohol with no evidence of acute withdrawal or intoxication.

Symptomatic unprovoked epilepsy associated with progressive neurological conditions is defined as seizures occurring associated with the condition characterized by a pathophysiology which is in evolution or in relation to abnormalities associated with existing damage including: incompletely treated CNS tumors or bacterial, fungal or viral infections; subacute sclerosis panencephalitis; lupus or multiple sclerosis.

Seizure type: clinical description in the criteria of the International League Against Epilepsy without recourse to EEG data is used.

Screening questionnaire for epilepsy and standardized protocols for diagnosis and classification, are used for surveying the screening population, identification, diagnosis, and classification of epilepsy patients.

Compliance is defined as a patient who strictly took medicines in terms of doses, frequency, and every day at least 80 % in the interval of follow up.

Mental retardation is defined as

- Slow psychomotor development

- Inability to attend school or to engage in age-appropriate activity without assistance

- Clumsiness in speech and movement

Severity of seizure

- Use the Chalfont Seizure Severity Scale (Chapter IV-Table 9).

Quality of life

- Use QOLIE-31 with adjusted cultural aspects.

Drop out

- Defined as patient loss to follow-up for at least 3 times of reminding by letters.

Procedure

1. Choose districts for the study: control and intervention groups

2. In each district regardless of control or intervention groups, information about how to ascertain suspected cases in a community, how to diagnose as epilepsy, how to choose and to calculate doses of antiepileptic drug, which is the seizure event and which is the AED side effects, will be provided to all primary health care teams.

3. Before commencement of the study, all patients will be registered in each district in order to follow and to evaluate the results.

4. Randomly allocate selected districts into shared care and control groups.

5. For the shared care group, computer generated recall and referral letters, shared records and responsibilities with guideline of management among health care providers, and a coordination and communication channel among health care providers will be set up. For the control group, none of above will be applicable.

For both groups (conventional and structural shared care groups) educational and training programs for all participants will include: how to screen, diagnose and handle patients; which medicines to chose; what monitoring should be done; what are the precipitating factors; how to live, to attend school, to secure employments; what is the patient's legal right; and how to obtain iinsurance. These sessions will be arranged and carried out before commencement of this study. The purpose is to minimize the confounding factors related to the caregivers. All patients in each group will be registered with a date to be sent to the central registration unit. The patient information to be recorded will include the following: patient identification; demographic data (i.e. age, gender, education); occupation; behavior, other drug taking; incomes; family history of epilepsy; past history of febrile convulsion; age at onset; frequency of seizure; age at treatment; type of seizure; cause of seizure; severity of seizure; therapeutic information; serum level of AED; quality of life.

Intervention

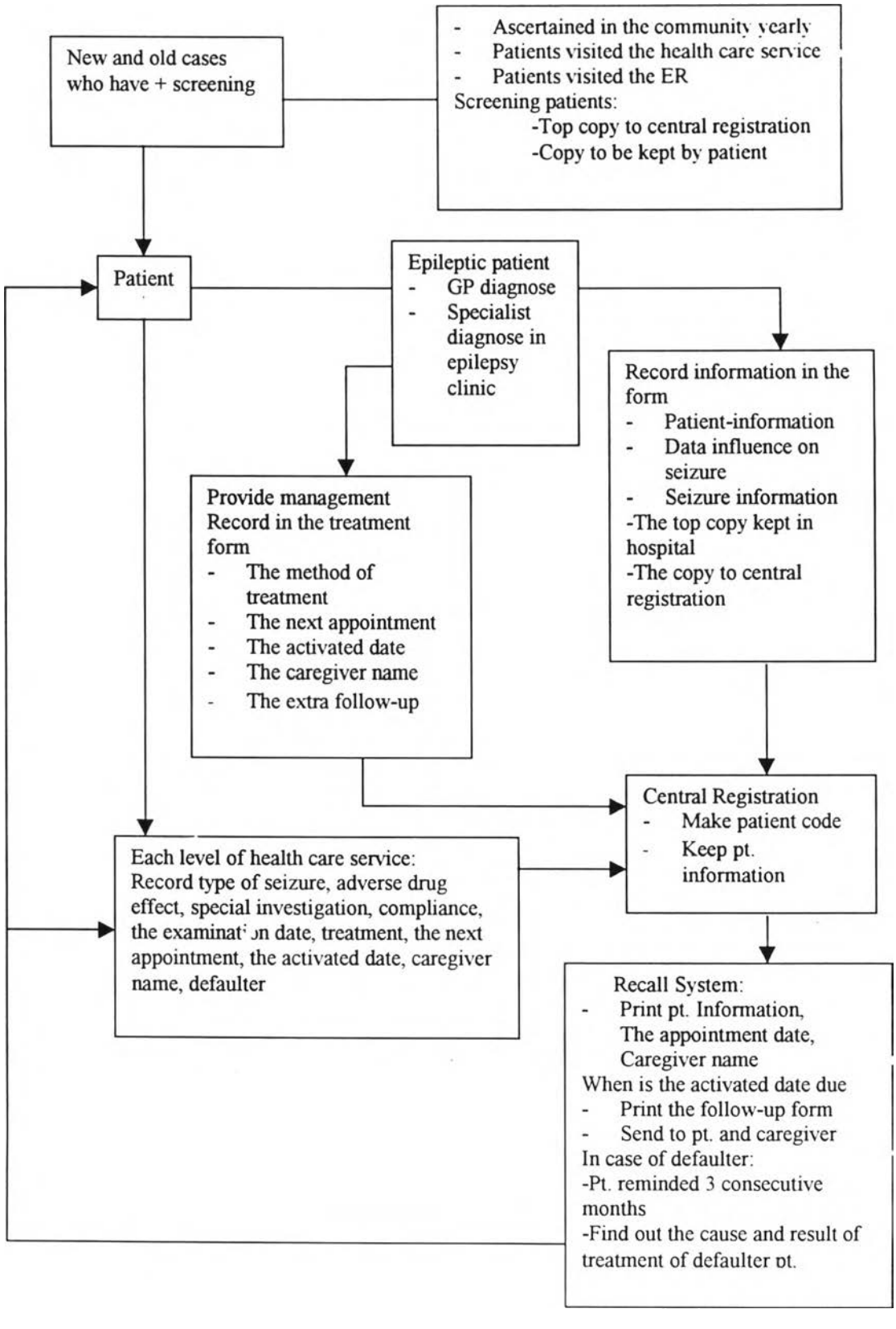
For the shared care group, district health workers, general practitioners and specialists will assemble and establish the line of management, set the coordination of care and communication channels as follow: the primary health care team and

specialist will interact and exchange their knowledge and experience or the problems faced every 6 months.

Among patients and primary health care teams, there will be regular meetings every 3 months at each district. Primary health care teams will provide the essential knowledge for patients about care taking and discuss problems or suspected matters or share ideas and try to solve the problems together. The specialist will be a moderator.

After registration (the system shown in Figure 4) and agreed next appointment date, a computerized database will create the patient's name, caregiver's name, and medical information with next appointment date and print out.The letter enclosing these data will be sent to the patient and caregivers at predetermined appointment date.

Figure 4: Central Registration and Recall System



Operation for sub-district health officer in shared care group to run the project (as shown in Figure 5).

1. Ascertainment of epilepsy patients in a community

Well-trained health officers in a sub-district area ascertain epileptic patients by using the screening questionnaire to screen the whole population in their own area, home by home. All persons who are positive on the screening questionnaire will be included as new suspected and known epileptic patients. New suspected patients retaining their positive screening questionnaire reports will be referred to GP in the district community hospital to determine if a diagnosis of epilepsy, by using the diagnostic protocol, should be made.

2. Providing care taking for epilepsy patients

All known and diagnosed epileptic patients referred back from GP will be followed by sub-district health officers every month who will ask about both seizure occurrence and adverse AED reactions. Whenever patients have either seizure occurrence or adverse AED reaction, they will be referred to GP for further care. If not, they will continue to obtain care at their sub-district health office. At six and twelve months, patients will be referred to GP and specialist for half-year and annual reviews, respectively.

Patients only taking Phenobarbital will receive their phenobarbital at the sub-district health office on follow-up time. Patients taking other AED besides

Phenobarbital will be followed without dispensing of drugs and be referred to the GP for receive these drugs every 3 months.

3. Recording patients, medical and economic information

At the epileptic patients first visit to a sub-district health office, the registration form including patients' information and epilepsy and medical information will be completed. The patient's information to be recorded includes: patient's name; address; zip code; home telephone number (if it exists); birth date; body weight; gender; education; occupation (if it exists); income; family income; alcoholic drinking habit. The epileptic and medical information to be recorded includes: a history of febrile convulsion; age at first onset of seizure; age at first treatment; family history of epilepsy; mental retardation; physical disability; frequency of seizure one year prior; seizure characteristic; current AED taken; other kinds of drugs taken; adverse AED reaction; and management at this time. The other essential information to be recorded includes: date at recording; health care provider's name and address at the recording time; a next appointment date with health care provider's name and address. After these data are completed, the top copy will be sent by mail to central registration at the Provincial Hospital for entering and generating a recall data to specific patients and health care providers addressed in the registration form 2 weeks prior to the next appointment date. The copy will be kept in the patient's OPD card. Patients will receive a patient-diary to monitor themselves about taking AED, frequency of seizure, adverse AED reaction, hospitalization from seizure, and accident from seizure and be invited to return their diary and AED-pills to the sub-district health office every visit for a pill-count.

The following visit, a sub-district health officer will fill data in the follow-up form. The data recorded will include: patient's name; address; zip code; body weight; frequency of seizure one month prior; seizure characteristic; current AED taken; other kinds of drugs taken; adverse AED reaction; management at this time; date at recording; health care provider's name and address at the recording time; a next appointment date with health care provider's name and address; number of hospital admissions from seizure and hospital's name (if it is available); accident occurrence from seizure with total cost (including medical and non-medical) of the accident (if this exists). As well as doing the registration form, the follow-up form will be done the same.

For missing patients, a sub-district health officer will report in the follow-up form and send by mail to central registration for entering and generating data to remind the patient next two times. If the patient misses appointment dates for three times, dropout-patient will be recorded for that patient and sub-district health officers need to visit them at their homes for ascertaining the causes of missing appointment and the medical consequences to make an analysis.

Operation for district community hospital in shared care group to run the project (as shown in Figure 5).

1 Ascertainment of epilepsy patients in a community

Well-trained district community hospital officers ascertain epilepsy patients by using the screening questionnaire to screen the whole population in their sub-

district area home by home. All persons who are positive on the screening questionnaire will be included as new suspected and known epilepsy patients. New suspected patients retaining their positive screening questionnaire reports will be referred from the sub-district health office and from community hospital officers to be reviewed by the GP in that district community hospital using the diagnostic protocol. If patients have an uncertain diagnosis, they will be referred to a specialist to make a diagnosis.

2 Providing care taking for epilepsy patients

All known, diagnosed epilepsy patients and patients referred from the sub-district health office will be followed by GP every one to three months, with enquiry about seizure occurrence and adverse AED reaction. Whenever patients have neither seizure occurrence nor adverse AED reaction and live outside the community hospitals' area of responsibility, they will be referred back to the sub-district health office for further care. If those patients take Phenobarbital, GP will prescribe it for one month and refer them back to get more at the sub-district health office. If the patient is taking other drugs, GP will prescribe them for three months and refer back to sub-district health officer for follow-up. If those patients are in the community hospitals' area of responsibility the GP will follow up and send them to a specialist for annual review at the twelfth month. Patients either having seizure occurrence or having adverse AED reaction will be investigated to find the causes and/or precipitating factors particularly checking a blood level of AED and to be treated in minor adverse reactions. For patients with major adverse AED reactions or no response in single therapy will be referred to a specialist for further care. The other

GP responsibilities are to review, every six months, patients referred from the sub-district health office and to follow patients who have taken other AED (besides Phenobarbital) referred from the sub-district health office every three months.

3 Recording patients, medical and economic information

At the epilepsy patient's first visit to a district community hospital, the registration form will be completed, including: patient's information and epilepsy and medical information. The patient's information includes: name; address; zip code; home telephone number (if it exists); birth date; body weight; gender; education; occupation (if it exists); income; family income; and alcoholic drinking habit. The epilepsy and medical information to be recorded includes: history of febrile convulsion; age at first onset of seizure; age at first treatment; family history of epilepsy; mental retardation; physical disability; possible cause of seizure; frequency of seizure one year prior; seizure characteristic; type of seizure; precipitating factors for seizure occurrence; current AED taken; other kinds of drugs taken; adverse AED reaction; management at this time; referring patients; investigation and result. The economic information to be recorded includes: transportation fares including cost of all relatives coming with patients; total medical cost including doctor's fees and drugs and investigation; time spent for a visit; number of relatives who come with the patient and relatives income. The other essential information to be recorded includes: date at recording; health care provider's name and address at the recording time; the next appointment date with health care provider's name and address. After these data are acquired, the top copy will be sent by mail to central registration at the Provincial Hospital where the data

will be entered and generate a recall date to specific patients and health care providers addressed in the registration form 2 weeks prior to the next appointment date. The copy will be kept in the patient's OPD card. Patients will receive a patient-diary to monitor themselves about taking AED, frequency of seizure, adverse AED reaction, hospitalization from seizure, and accident from seizure and to request that they retain their AED pills taking them to the district community hospital every visit for a pill count.

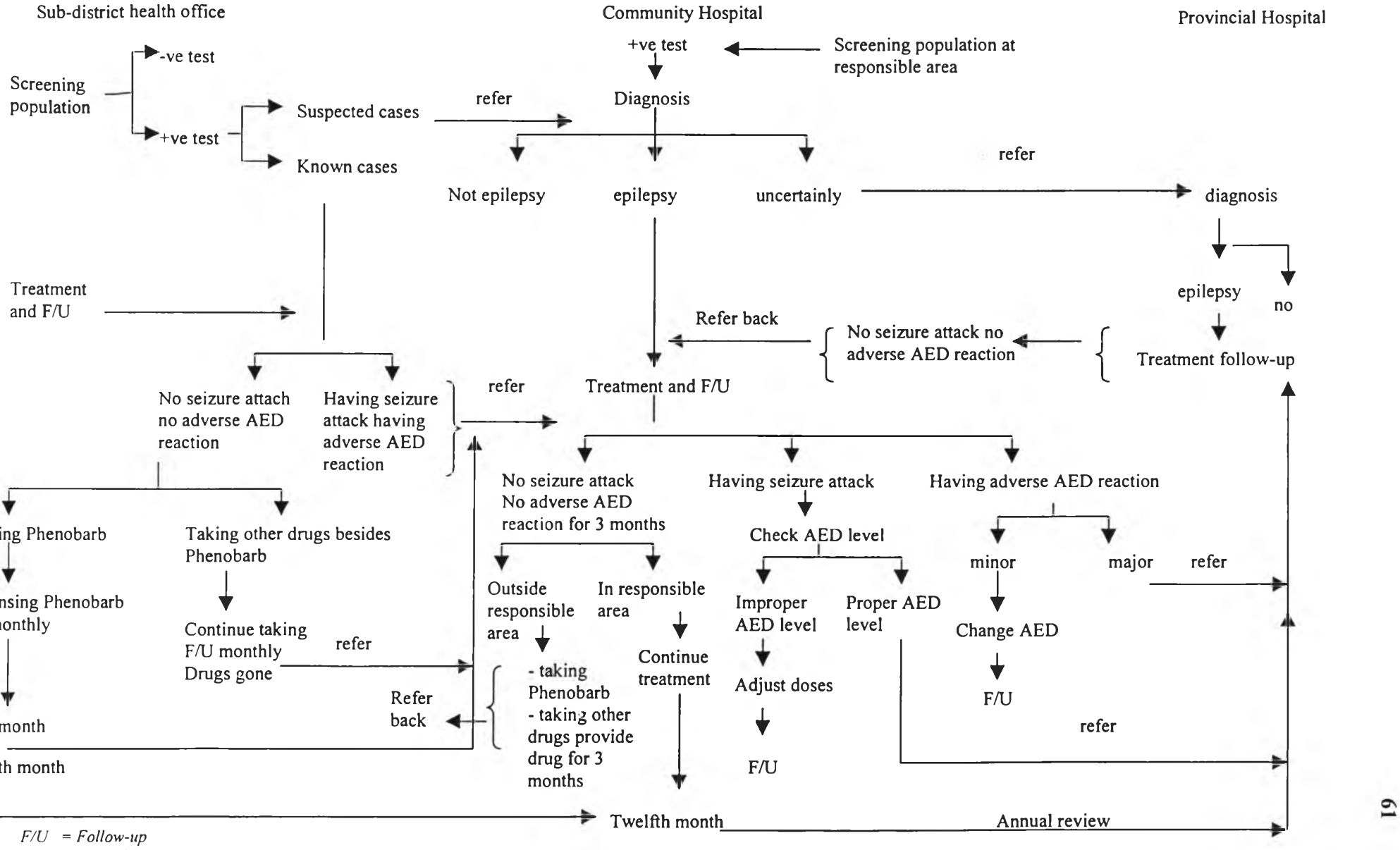
The following visit, a GP will complete data in the follow-up form. The data to be recorded includes: patient's name; address; zip code; body weight; frequency of seizure one to three months prior; seizure characteristic; type of seizure; precipitating factors for seizure occurrence; current AED taken; other kinds of drug taken; adverse AED reaction; management at this time; referring patients whether or not to specialist ; investigation and result; transportation fares including all relatives who come with the patient; total medical cost including doctor's fee and drugs and investigation; time spent for a visit; number of relatives who come with the patient and relatives income; number of hospital admissions from seizure and hospital's name (if it is available); accident occurrence from seizure with total cost (including medical and non-medical) of the accident (this is available) date at recording; health care provider's name and address at the recording time; a next appointment date with the health care provider's name and address. As well as doing the registration form, the follow-up form will be done the same way.

For missing patients, a district community hospital will report in the follow-up form and send by mail to central registration for entering and generating data to remind the patient about the next two times. If the patients missed their appointment date three times, "dropout-patient" will be recorded for that patient and community hospital officers or sub-district health officers, depending on who is responsible, will visit missing patients at their home to find out the causes for missing appointments and medical consequences.

Because all the patients will be registered, patient contamination will be immediately detected. Evaluation of these patients will be separated from others.

Monitoring is done every 3 months. If the drop out rate in the shared care group is more than 20 %, or half of patients are not in 50 % seizure frequency reduction, the cause will be examined. The study will be terminated if that cause is from the scheme.

Figure: 5 Management of Epilepsy in Each Level



Instruments

The screening questionnaire, the criteria for diagnosis and classification, the HRQOL, and the severity of seizure will be applied to patients. The validity will be done by back translation and the reliability will be assessed.

The district health workers, general practitioners and specialist line of management in epilepsy for health caregivers will be jointly developed. Later, it will be approved by expert teams and turned back to health care teams for suitable application.

Computer with suitable software programs for registration, audit, update data and recall system will be established.

Collecting Data

Data will come from primary source. Method of collecting data depends on type of data mentioned below.

1. Demographic variables: name, age, gender, address, telephone number(if it exists), district 's name, education, occupation, incomes are gathered.

2. Administrative variables: quarterly meeting, number attending, name of attendant, number of patients who have an annual review by physician is gathered.

3. Confounding variables: mental retardation, behavior and habit, other drug taking, family history of seizure, past history of febrile convulsion, age at onset, type of seizure, frequency of seizure, age at first treatment, severity of seizure, result of EEG is gathered. Compliance is measured in terms of self report, counting medicines, and serum level of AED.

4. Co-intervention variables: other drugs taken in addition to AED

5. Outcome variables:

Primary outcome variable: number of patients with 50 % seizure reduction at the closing date of the study (2-year period).

Secondary outcome variable: changing seizure severity and HRQOL during the study.

Patients' and health care providers' knowledge will be assessed before and after the study.

Drop out patient: the cause and outcome are gathered.

Death from seizure

When will we measure these variables?

- The demographic variables, confounding variables, co-intervention variables, patients' and health care providers' knowledge (using a pretest) and QOL are measured at the commencement of the study.

- Frequency of seizures, severity of seizure, compliance, co-intervention variables, health care providers' knowledge are measured every time a patient visits or is admitted during the study.

- Number of seizure reductions before and after study, patients' and health care providers' knowledge (using pre-test and post-test) and QOL are measured at the beginning and the end of the study.

- Death and drop out including reasons of drop out and outcome are measured when these events occur during the study.

Level of measurement is shown in Table III.

Table III: Level of Measurement

Variables		Level
Demographic variables	Name, gender, address	Categorical
	Age	Continuous
Confounding variables	Mental retardation, Familial history of epilepsy, Past history of febrile convulsion, Type of epilepsy, Compliance above minimum	Categorical
	Age at onset, Frequency of seizure, Age at first treatment, Duration of epilepsy, Severity of seizure	Continuous
Co-intervention Variables	Other drugs taken	Categorical
Outcome variables	Frequency of seizures reduction, Changing seizure severity, Changing QOL Patients' and health care providers' Knowledge Score)	Continuous
	Number of patients with 50% Seizure reduction Drop out Death	Categorical

Methods of data collection are shown in Table IV.

Table IV: Methods of Data Collection

Variables		Method
Demographic variables	Name, age, gender, address	Interview
Confounding variables	Mental retardation, Familial history of epilepsy, Past history of febrile Convulsion, Type of epilepsy, Compliance Age at onset, Frequency of seizure, Age at first treatment, Duration of epilepsy, Severity of seizure,	Interview Interview Interview Interview Interview, observation Interview, abstracting from records Interview Interview, abstracting from records Interview, abstracting from records Interview
Co-intervention Variables	Other drugs taken	Interview, observation
Outcome variables	Frequency of seizures Reduction, Changing QOL Drop-out Changing seizure severity, Number of patients with 50% seizure Reduction Patients' and health care Providers' knowledge Death	Prospective recording Interview Prospective recording Prospective recording Prospective recording, Pre-test, post-test death certification

Data Analysis

Design:	Experimental design, RCT
Comparison groups:	Two Independent groups
Data:	Accurate and complete
Data summary (shown in Table V):	Continuous data:- Mean, SD with SEM and 95% CI
	Categorical data:- Percentage, proportions with P(1-P)/square root N and 95% CI

Relative risk is used for comparison analysis of categorical data between two independent groups (shown in Table VI).

Mean differences are used for comparison analysis of continuous data between two independent groups (shown in Table VI).

Table V: Demonstration of Data Summary

Variables		Data analysis		
		Data summary		
		Type of data	Central tendency	Deviation
Demographic	Gender	Categorical	Percentage, Proportion	P(1-P) / square root N, 95% CI
	Age	Continuous	Mean	SD/square root N , 95%CI
Administrative	Problems and solutions	Categorical	Percentage, Proportion	P(1-P) / square root N, 95% CI
	Number of meetings, Number attending	Continuous	Mean	SD/square root N, 95%CI
Confounding	Mental retardation, Familial history of epilepsy Past history of febrile Convulsion, Type of seizure Compliance	Categorical	Percentage, Proportion	P(1-P) / square root N, 95% CI
	Age at onset, Duration of epilepsy Age at first treatment Frequency of seizure, Severity of seizure	Continuous	Mean	SD/square root N, 95%CI
Co-Intervention	Other drugs taken	Categorical	Percentage, Proportion	P(1-P) / square root N, 95% CI
Outcome	Number of seizures reduction, Severity reduction, QOL improvement Changing QOL, Changing seizure Severity Patients' and health care providers' knowledge (score)	Continuous	Mean	SD/square root N, 95%CI
	Number of patients with 50 % seizure reduction Drop out, Death	Categorical	Percentage, Proportion	P(1-P)/square root N, 95%CI

Table VI: Demonstration of Data Analysis

Variables		2 independent groups		Statistical test (Test of difference)
		Data Summary	Data analysis	
Demographic	Gender	Percentage, Proportion	Relative risk	Chi-square Fisher's exact
	Age	Mean	Mean Difference	Unpaired t-test
Confounding	Mental Retardation, Familial history of Epilepsy Past history of febrile Convulsion, Type of seizure, Compliance	Percentage, Proportion	Relative risk	Chi-square Fisher's exact
	Age at onset, Duration of Epilepsy Age at first Treatment Frequency of Seizure, Severity	Mean	Mean Difference	Unpaired t-test
Cointervention	Other drugs taken	Percentage, Proportion	Relative risk	Chi-square Fisher's exact
Outcome	Number of Seizures Reduction, Severity Reduction, QOL Improvement Changing QOL, Changing seizure Severity Patients' and Health care Providers' Knowledge (score)	Mean	Mean Difference	Unpaired t-test
	Number of patients with 50% seizure Reduction Drop out, Death	Percentage, Proportion	Relative risk	Chi-square Fisher's exact

Statistical Test

95% CI and p-value = 0.05 is used.

Statistical tests: Test of differences:- Chi-square or Fisher's exact test for proportions (relative risk)

Unpaired t-test for Mean difference

Problem Cases

1. Contamination: Data summary of outcome and the reason of changing from one to another will be evaluated.

2. Drop-out: Data summary of etiology and outcome will be evaluated.

Survival Analysis

Survival analysis will be performed if the primary outcome is not met or whenever the variation in length of times of the study's subjects exist or if defaulters or deaths exist during the study.

Benefit of This Study

There are many advantages as follows:

- GPs and specialists learn to improve the effective use of primary and secondary care.

- Improve team working and communication between GPs and specialists.

- For GPs, improve team-work and communication, increase access to services, reduce waiting time, more responsibility for care, expansion of team roles in diagnosis and treatment and access to informal advice from specialists.

- Enhances consultants' confidence in GPs' competence and increase GP 's knowledge.

- Enables more patients to receive specialist advice, increasing the knowledge of the patients' conditions.

- Reduce unplanned referring patients and re-referring patients.

- Understand the real and actual problems, obstacles and limitations of district health care provision.

Obstacles in This Study

There are some obstacles as follows:

- Operationalization: participants with their own view-point and local factors.
- Financial and operational barriers.
- Lack of time.
- Negative attitude resulting in patient resistance to change and low confidence in the nonspecialist; patients will be reassured and their confidence will be raised by quality of care provided by primary health care teams who have specialist's supervision. Convincing patients the advantages of follow-up at their community hospital or sub-district

health office particularly in terms of time lost and spending more money for travelling.

- Outcome measurements might have some problem particularly ascertaining an accurate number of seizure attacks and/or seizure severity. If patients cannot perceive attacks or severity and no witnesses are found, these outcomes will be invalid.
- For QOL assessment, it cannot be performed for all patients because some have mental problems.

Ethical Considerations

This scheme is on the basis of scientific and standard management of patients with epilepsy. Close and regular evaluation and monitoring will be continuous. This study will be terminated immediately if a poor outcome emerges. This study will be reviewed for approval by the Ethics Committee from Ministry of Public Health. Every patient will give informed consent.

Activities plan

Activities	April 43	May 43	June 43	July 43	Aug 43	Sep. 43-Aug 45	Sep. 45	Oct. 45	Nov. 45	Dec. 45	Jan. 46	Feb. 46	Mar. 46
Selection of samples and health care providers at the beginning of the study	•												
Pre-test for health care providers who gave an informed consent	•												
Providing information and knowledge of the following for health care providers - For care: Screening; diagnosis; management, follow-up and referring. - For process of care: Registration; recall system; guideline of management; coordination; referral policy. - For measurement: Recording data, seizure frequencies and adverse drug reaction; test of QOL and seizure severity;		•	•	•									
Preparing material for all recording forms, instructions, guideline for every step of running the study and for every level of participant		•	•	•									
Set up the registration, recall system and coordination	•	•	•										
Making a management guideline			•	•									
Pilot study					•								
Running the study						•							
Pre-test for patients at the first visit						•							
Post-test for patients and providers at the end of the study						•							
Gathering data						•	•	•					
Recording data						•	•	•	•				
Analysis and evaluation									•	•	•		
Conclusion											•	•	
Report													•

Budget

1.	Incentive for programmer to create and perform program	10,000 Baht
2.	Entering and auditing the data through the study	40,000 Baht
3.	Scrutinizating the data of treatment and follow-up	25,000 Baht
4.	Coordination among participants and arrangement of meetings among primary health care teams and specialist 20 times	90,000 Baht
5.	Incentive for interviewers	25,000 Baht
6.	Incentive for statistician to analyze the data	50,000 Baht
7.	Cost of typing, photocopying, postage, commodities, forms	70,000 Baht
8.	Incentive for researcher and advisor	80,000 Baht
	Total	**390,000 Baht**

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