CHAPTER VI

DISCUSSION

6.1 Methodology

6.1.1 Overall Design

In evaluating efficacy between two intervention groups, randomized controlled trials (RCT) are the standard of excellence for scientific studies (Fletcher, R.H., Fletcher, S.W., and Wagner, 1996). Randomization is the random assignment of subjects to groups. This attempts to: 1) eliminate intentional and non-intentional selection bias; 2) remove the effect of any extraneous variables (Forthofer and Lee, 1995); 3) to produce similarity in these groups in large samples, even with respect to variables which have not been anticipated, defined or measured (Elwood, 1998). These are true for large samples but it is essential in small samples to determine whether dissimilarities are present. When the units of implementation of the intervention are communities, clinics, hospitals or medical practices, cluster randomized trials are attractive in the evaluation of healthcare interventions because of logistic, ethical or practical reasons (Piaggio, et al., 2001).

This study aims to evaluate the effectiveness of two healthcare interventions, Shared Care (SC) and Conventional Care (CC) that are implemented in Community Hospitals (CHs). The research design for this study is RCT and uses cluster

randomization that is appropriate to evaluate the effectiveness of SC compared to CC for patients with epilepsy.

For cluster randomization, the size and type of clusters often vary. Stratification of units of randomization needs to be applied to guarantee the same distribution of basic baseline characteristics (Forthofer and Lee, 1995). This study uses stratification of units of randomization according to different cluster sizes in terms of number of epileptics registered at CHs. Using clusters on stratification, there are two limitations have to be noted in this study.

First, the stratification according to the different cluster sizes in terms of number of registered epileptics is incomplete. The registration does not represent the actual number because it includes non-epileptics and dead epileptics. Stratification and randomization based on incomplete registration leads to differences in number and baseline characteristics of epileptics in CC and SC. In order to make the two groups comparable, there are three ways for solving the problem. The details can be found on pages 122-126.

The second limitation is that there is no consideration on stratification of cluster types. Among CHs there are different sizes in terms of number of hospital beds, which reflect the different number and workload of health personnel. Workload has impact on effectiveness of care provision and leads to different patient's outcomes among CHs.

To improve the quality of the study, the design of a future RCT should be as follows. All of the CHs, without either or both an internist or pediatrician in Nakhonratchasima Province will be invited to participate. The registration of epilepsy of each participating CH will be verified and updated from a review of the clinical data from the hospital records. Based upon this review, the exclusion criteria will be applied; these exclusion will include: acute symptomatic or situation-related epilepsy; unprovoked epilepsy associated with progressive neurological conditions; severe mental retardation and disability; pregnancy; alcoholism; poly-pharmacy and concomitant treatments. Then, the participating CHs will be stratified according to hospital types such as 30, 60 and 90 bed hospitals. Next, each stratum will be further stratified according to the cluster sizes such as 20-50, 51-99 and $\geq$ 100 subjects with epilepsy. The cluster less than 20 subjects will be excluded because it is too small to guarantee stability of the data. After that, the CHs in each stratum will be randomly allocated into control and intervention groups. Next, the epileptics in each participating CH will be invited to join in the study and sign an informed consent. The baseline characteristics of epileptics will be collected. If some of these baseline characteristics differ from the hospital chart these will be verified, corrected and the outliners will be excluded.

6.1.2 Sample Size

Before a sample size can be calculated differences in one direction only (one-sided test) or either direction (two-sided test) must be decided. Then, the significance level (α), the power ($1-\beta$), the magnitude of the difference in outcome to be detected and the nature of the study's data have to be followed (Fletcher, et al., 1996).

This study chooses two-sided test, which would represent testing the hypothesis that the new intervention (SC) is either better or worse than the control (CC). Any new intervention can be harmful as well as helpful. For alpha error, this study wants to accept the consequences of a small chance of falsely concluding that the therapy is valuable. Therefore, a significance level of 5% is selected. This study also wants to have low chance of missing true differences, beta error of 10% is chosen, and then the power of 90% is applied. The primary outcome for this study is the percentage of regular follow-up, which is a dichotomous variable. The moderate improvement of 50% of regular follow-up is chosen for this study.

For dichotomous response variables with two independent comparison groups, the sample size calculation can be expressed by the formulae (Dupont and Plummer, 1990):

$$n = \frac{[2(Z\alpha+Z\beta)^2 \bar{P} (1-\bar{P})]}{(P1 - P2)^2}$$

where n = sample size per group (subjects) which $\bar{P} = (P1 + P2)/2$; $Z\alpha$ is the critical value, which corresponds to the significance level α; and $Z\beta$ is the value of standard normal value not exceeded with probability β. $Z\beta$ corresponds to the power $1-\beta$. Value of $Z\alpha$ when $\alpha = 0.05$ and $Z\beta$ when $1-\beta = 0.90$ are 1.96 and 1.28, respectively (Elwood, 1998). P1 is the estimate of current percentage of regular follow-up and P2 is the anticipated expected percentage of regular follow-up. According to the magnitude of difference in outcome for this study (50% improvement of the percentage of regular follow-up), P2 is equal to P1 + (P1)/2.

In this study, sample size calculation for each gender is done and the total sample size per group is the summation of sample sizes of both genders because a difference in patient-compliance between genders was found (Asawavichienjinda, et al., 2003). P1 for male and female is 55.2% and 58.1%, respectively. Therefore, P2 is 82.8% for male and 87.2% for female. The calculated sample sizes for male and female equal 57 and 46, respectively. Because of cluster effect (Piaggio, et al., 2001), 10% is added to the original sample size. Therefore, the adjusted sample size by calculation is 63 males and 51 females.

The actual sample size for this study is 94 males and 85 females in CC; and 118 males and 104 females in SC. These are larger than the calculated sample size. Large sample size in this study makes chance an unlikely explanation for what is found (Fletcher, et al., 1996). Large sample size also gives high statistical power (Altman, 1991) and allows subgroup analysis and post Hoc stratification (Marchevsky, 2000). It is appropriate to evaluate the effectiveness of SC compared to CC for patients with epilepsy.

6.1.3 Shared Care Interventions

SC interventions that are implemented in the experimental group for this study are based upon the defects of the CC in Nakhonratchasima province shown on page 31. Therefore, the interventions would solve the defects and then improve care and medical outcomes for patients. These interventions are the following: 1) communication between patients and primary healthcare teams via education and pamphlet to improve patients' self care; 2) communication, coordination and

organization between GPs and specialist via treatment review and immediate feedback, and problem-based education to improve GPs' care; 3) communication between patients and specialist via reminder letter to improve patients' regular follow-up.

After study, the usefulness of SC interventions is evaluated by patients and GPs as very useful (pages 107-109). The epileptics rate education provided by nurses as meeting most of their expectation and applied most of the knowledge to self-care. Normally, Thai patients particularly in rural area lack of knowledge about their disease and management (page 3). They need professional healthcare providers to give them education and knowledge. This intervention may improve compliance and reduce seizure(s) from precipitating factors.

Another intervention, Treatment Review and Immediate Feedback and PBE activity are also very useful to GPs (pages 107-109). The hard evidence for this benefit is the reduction of inappropriate treatments during the last three months compared to the first three months of the study (page 107). The GPs also evaluate these processes that they greatly improve their knowledge on epilepsy treatment and the content is highly relevant to the real practice (pages 107-109). In addition, at the end of the study most of the GPs suggest the PI to maintain these very useful activities.

The last one, reminder letter is the process to remind patients to visit CHs every time before the due appointment dates via mailing letters. This process except its product is not directly evaluated.

However, there are a few limitations on implementation of SC interventions. Although, all of the healthcare providers cooperate well and follow the protocol as completely as possible they do not perfectly follow because of their excessive workload. These include notable lack of communication between patients and healthcare providers and communication, coordination and organization between GPs and specialist. This may result in non-significant differences in medical outcomes between SC and CC.

Most of the CHs in Nakhonratchasima Province have many patients all day and it is very difficult for nurses to provide education to all epileptics and for GPs to attend all together the PBE activity at their hospitals over the whole section. There are a few patients receive education but do not understand the content (page 108). It is suggested that providing education should be interactive and asked about understanding during and after finishing education. For PBE activity, it is organized three times during this one-year study. Although GPs cannot attend full period of any single PBE activity they can increase their knowledge at the next activity.

Another limitation is the method to send the immediate feedback to attending GPs. This study uses nurses as intermediates to pass the feedback to the GPs. It is

suggested that the immediate feedback should be sent directly to attending GPs not through the nurses in order to avoid GPs' feeling uncomfortable.

6.1.4 Length of Study Period

Studies that systematically review published RCTs of interventions to assist patients in keeping appointment use the criteria of at least six months of follow-up (Haynes, McKibbon, and Kanani, 1996; McDonald, Garg, and Haynes, 2002). In addition, most studies have maximum follow-up of 12-month long (Macharia, et al., 1992; Dolder, et al., 2003).

This is a one-year study evaluating continuity of care in terms of the percentage of regular follow-up as the primary outcome between patients with CC and SC group according to the objective of Shared Care (McGhee and Hedley, 1996). Therefore, this one-year study is long enough for this purpose.

For medical outcomes of this study such as seizure reduction and quality of life, one-year period may be too short to evaluate the effectiveness because epilepsy needs long term treatment i.e. at least two to five years of seizure free thereafter (Medical Research Council Antiepileptic Drug Withdrawal Study Group, 1991). Therefore, the study period should be followed for more than five years if medical outcomes want to be assessed to show that Shared Care really works.

6.1.5 Analysis

6.1.5.1 Data Collection

Data being collected particularly on outcomes measurement such as regular follow-up and seizure reduction comes from primary source and uniformly uses the same definition which is well defined. Data collection is done by prospective recording and self-administered questionnaire. Data collectors are hospital officers and nurses who are not related to the results of this study. In addition, the data is re-evaluated again by the PI. The missing data for this study is also very little particularly outcomes measurement, regular follow-up and seizure reduction (pages 86, 88).

However, there are a few limitations particularly for illiterate patients without an escort to complete the self-administered questionnaires. These illiterate patients need nurses to help read and mark answers. The answers of these patients may have some error but it is the best way to do for these patients.

6.1.5.2 Data Analysis

Analysis of categorical data such as the percentage of regular follow-up, seizure reduction, inappropriate practice, overall satisfaction between two independent groups and within group uses Chi-square test (Matthews and Farewell, 1996) and McNemar Chi-square (Hicks, 1990), respectively. Survival analysis of rate of regular follow-up between two independent groups uses Log Rank statistics or Mantel Haenszel statistic test (Kahn and Sempos, 1989). Analysis of continuous data such as mean score of overall quality of life between two independent groups uses

Unpaired t-test (Altman, 1991). This study uses appropriate analysis for evaluating the outcomes.

After study, different baseline characteristics between CC and SC groups are found. To make the two groups comparable, stratification and covariate analysis with Mantel Haenszel statistic test, which is shown on pages 125-126 is used for analysis of categorical data with different baseline characteristics (Elwood, 1998).

6.2 Shared Care with Other Chronic Diseases and Shared Care with Epilepsy

By literature review, there are studies on SC with diabetes, hypertension, depression, glaucoma, mental illness and rheumatoid arthritis. However, studies on SC with mental illness (Warner, et al. 2000) and rheumatoid arthritis (Helliwell and O'Hara, 1995) are discarded because these studies only evaluate the utility of patient held SC records and of an ideal protocol of disease-modifying drug. For SC with epilepsy, there has been no published study. This is the first study ever for SC with epilepsy and therefore, comparison between this study and others is not possible.

6.2.1 Outcome in Terms of Continuity of Care

For SC with diabetes, the results of three out of five studies that evaluate continuity of care demonstrate greater continuity of care in SC than in CC group. The study of Hoskins, et al. (1992) demonstrates less decrement of attendance rate over time in SC than in CC group. The study of Huwitz, et al. (1993) shows significantly higher mean number of diabetes reviews/patient/doctor and lower percentage of

patients without doctor diabetes review in SC than in CC group. The study of Diabetes Integrated Care Evaluation Team (1994) reveals higher mean number visits of diabetes in SC than in CC.

For SC with hypertension (McGhee, et al., 1994), the result also shows the same outcome that is significantly higher percentage of patients who still contact with clinic and higher percentage of patients who receive complete review in SC than in CC.

The study for SC with depression and glaucoma do not evaluate continuity of care and, therefore, they are not compared to this study.

Compared to this study, it is found that at the end of this study the continuity of care in terms of rate of regular follow-up and the proportion of regular follow-up are higher in SC group than in CC group for both genders but did not reach the 50% relative gain as percent of CC except in male SC. Within SC group, the proportion of regular follow-up is higher after initial study than before initial study, for both genders whereas the proportion remains the same for the CC group.

In conclusion, SC interventions improve continuity of care for patients with chronic diseases.

However, aforementioned discussion is solely based on evaluation of total number of epileptics regardless of differences in baseline characteristics of the epileptics between CC and SC group.

The following is re-analysis of data taking into account differences of baseline characteristics.

6.2.2 Outcome in Terms of Regular Follow-Up of Epileptics with Different Baseline Characteristics between CC and SC

There are two significantly different baseline characteristics of the epileptics between CC and SC group that may affect the regular follow-up: 1) Poly-pharmacy of AED and 2) Concomitant treatments. To handle the outliners, there are three methods as follows: 1) exclusion (Fletcher, 1996); 2) extension of the study period and 3) stratification and covariate analysis (Elwood, 1998).

The followings are examples of analysis of epileptics with regular follow-up by exclusion and stratification of the outliners.

6.2.2.1 Result of Re-Analysis by Exclusion of the Outliners

Before analysis by exclusion, the comparison between CC and SC by sub-group analysis will be sequenced as: 1) all epileptics; 2) epileptics with poly-pharmacy; 3) epileptics with concomitant treatments; 4) epileptics with monotherapy and without concomitant treatments.

1. Comparison between All Epileptics in CC and in SC

At the end of the study, the percentages of epileptics with regular follow-up in CC and SC are 41.3% (74 out of 179) and 58.6% (130 out of 222), respectively. By intention to treat analysis, the percentage of epileptics with regular follow-up in SC is significantly higher than in CC group (p-value < 0.001).

2. Comparison between Epileptics with Poly-Pharmacy in CC and in SC

There are 44 epileptics with poly-pharmacy out of 179 in CC and 107 out of 222 in SC. The percentages of these epileptics who are regular to the follow-up in CC and SC are 45.5% (20 out of 44) and 56.1% (60 out of 107), respectively. There is no significant difference in regular follow-up between SC and CC group by intention to treat analysis (p-value > 0.05).

3. Comparison between Epileptics with Concomitant Treatments in CC and in SC

There are 50 epileptics with concomitant treatments out of 179 in CC and 24 out of 222 in SC. The percentages of epileptics with concomitant treatments who are regular to follow-up in CC and SC are 34.0% (17 out of 50) and 54.2% (13 out of 24), respectively. For intention to treat analysis there is no significant difference in regular follow-up between SC and CC (p-value > 0.05).

4. Comparison between Epileptics with Monotherapy and Without Concomitant Treatments in CC and in SC

After exclusion, there are 98 epileptics with monotherapy who have no concomitant treatments in CC and 102 in SC. Forty-four out of 98 (44.9%) in CC and 62 out of 102 (60.8%) in SC are regular to follow-up at the end of study. For intention to treat analysis the percentage of these epileptics who are regular to follow-up in SC is significantly higher than in CC (p-value < 0.05).

In total epileptics comparison the significant differences between CC and SC are found. After subgroup analysis the significant differences between CC and SC are found only in epileptics with monotherapy and without concomitant treatments. Epileptics who take poly-pharmacy of AEDs usually have a serious seizure condition and are difficult to have seizure control that may result in loss of confidence in general practitioners (GPs) leading to irregular follow-up. Patients who receive concomitant treatments may have poor compliance because of fear of drug accumulation, drug side effects or feeling bored. This is similar to the results of the studies for SC with diabetes and hypertension, whose inclusion criteria are stable cases (Diabetes Integrated Care Evaluation Team, 1994; Hoskins, et al., 1992; Huwitz, et al., 1993; McGhee, et al., 1994).

In summary, SC is effective for non-serious epileptics.

6.2.2.2 Result of Re-Analysis by Stratification and Covariate Analysis

Data are first stratified into monotherapy and poly-pharmacy and then, each stratum is stratified into two groups: with and without concomitant treatments. The four strata are shown in Appendix 8.

In CC, of the total 179 eligible epileptics, 135 and 44 take monotherapy and poly-pharmacy of antiepileptic drugs (AEDs), respectively. Of the 135 with monotherapy, 98 have no and 37 have concomitant treatments. Of the 44 with poly-pharmacy, 31 and 13 have no and have concomitant treatments.

In SC, of the total 222 eligible epileptics, 115 and 107 take monotherapy and poly-pharmacy of AEDs, respectively. Of the 115 with monotherapy, 102 have no and 13 have concomitant treatments. Of the 107 with poly-pharmacy, 96 and 11 have no and have concomitant treatments.

The percentages of regular follow-up in the groups of monotherapy without concomitant treatments in CC and SC are 44.9% (44 out of 98) and 60.8% (62 out of 102), respectively. There are 27.0% (10 out of 37) and 61.5% (8 out of 13) of patients with monotherapy and concomitant treatments in CC and in SC who are regular to follow-up. Rates of regular follow-up of patients with poly-pharmacy and without concomitant treatments are 41.9% (13 out of 31) in CC and 57.3% (55 out of 96) in SC. About 54% (7 out of 13) and 46% (5 out of 11) of the patients with poly-

pharmacy and with concomitant treatments in CC and in SC adhere to appointment (Appendix 9).

Mantel Haenszel statistic test demonstrates significantly higher regular follow-up of the patients with monotherapy in SC than in CC, regardless of concomitant treatments (p-value < 0.05) (Appendix 9). However, there is no significant difference in follow-up rate of epileptics with poly-pharmacy between CC and SC, regardless of concomitant treatments.

By stratification and covariate analysis, SC is effective for only the epileptics with monotherapy. These epileptics may have no serious seizure condition. On the other hand, SC does not add more benefit for epileptics with poly-pharmacy. These patients are usually difficult to treat.

It can be concluded that SC is more effective for non-serious epileptics than serious cases.

However, in Thailand young (< 20 years) or old patients (> 60 years) are dependent on their family and need escort by their caregivers for hospital visits. It is likely that the follow-up rate will differ among different age groups. Hence, subgroup analysis for epileptics aged below 20; 20-60 and older 60 years, was done.

6.2.3 Outcome in Terms of Regular Follow-Up with Regard to Different Ages

In the group of patients aged less than 20, there are 29 and 39 eligible epileptics in CC and SC groups, respectively. Of the 29 epileptics in CC and 39 in SC, 16 and 18 are regular to follow-up, respectively. There is no significant difference by intention to treat analysis in the percentage of epileptics with regular follow-up between CC and SC (p-value > 0.05).

In the group of patients aged above 60 years, there are 19 and 9 epileptics in CC and SC groups, respectively. Four out of 19 in CC and one out of 9 in SC are regular to follow-up. The percentage of these epileptics with regular follow-up in CC is not significantly different from one in SC (p-value > 0.05).

In the group of patients aged between 20 and 60 years, there are 127 and 170 epileptics in CC and SC group, respectively. Of the 127 epileptics in CC, 52 are regular to follow-up compared to 108 out of 170 epileptics with regular follow-up in SC group. For intention to treat analysis the percentage of epileptics with regular follow-up in SC is significantly higher than in CC (p-value < 0.001).

SC in this study, significantly improves regular follow-up of adult epileptics aged between 20 and 60 years who are mature and do not need escorts. It is inferred that family plays an important role for young and old epileptics. Consequently, care for epileptics should also involve family of epileptics by means of education so that

these people understand the guideline of epilepsy treatment, the necessity of compliance and how to take good care of epileptics.

6.2.4 Primary Medical Outcome

For SC with other chronic diseases, all of the studies measure primary medical outcome such as reduction in mean difference in percentage of glycated haemoglobin for diabetes; well controlled blood pressure for hypertension; reduction in depression scale for depression; and reduction in intraocular pressure, visual field defect and cup disc ratio for glaucoma. This study also measures primary medical outcome that is seizure reduction. These can be compared to this study.

For SC with diabetes, hypertension and glaucoma, the primary medical outcomes are not significantly different from CC. The CC group in the studies of diabetes, hypertension and glaucoma is hospital care by specialist. Therefore, SC led by GP is as effective as specialist care for these diseases. For the study with depression, patients receiving SC are less depressed than those receiving CC at the end of 9.5 months study. CC in the study of depression is GP's care. All of the results demonstrate that SC is as effective as specialist care and more effective than GP care.

For this study, the seizure reduction is not significantly different between CC and SC, for both genders at either period (three and 12 months). The reasons for no seizure improvement may be the following: 1) more serious epilepsy condition in SC, for both genders as confirmed by higher percentage of poly-pharmacy and 2)

manipulation of AED by GPs in SC to standard care. Epilepsy is quite different from other chronic diseases; seizure can be induced by manipulation of AEDs but other chronic diseases such as Diabetes, hypertension, and depression do not have any effect from drug manipulation.

If GPs have sufficient knowledge to handle appropriately at the beginning and during their stay at the same hospital long enough, seizure may be more controlled. In addition, if the study period is prolonged to at least two years, seizure reduction may be found ultimately.

6.2.5 Quality of Life

By literature review, there has been no study for SC with a chronic disease evaluating quality of life. This is the first study ever evaluating quality of life compared with CC and SC group.

At the end of the study, the mean scores of the overall Quality of Life in Epilepsy (QOLIE-31) and Short Form 36 Health Survey (SF-36) are not significantly different between CC and SC for both genders. However, mean scores of Cognitive Function domain of QOLIE-31 in female and Health Transition domain of SF-36 in male, are significantly higher in CC than in SC. Epileptics in SC, for both genders have more seizures, which may affect Cognitive Function and Health transition domains. Quality of life may be better in SC than in CC if the study period is prolonged and seizure reduction happens. However, further investigation should be performed to explore why and how gender affect these domains.

6.2.6 Overall Patient Satisfaction with Healthcare

By literature review, there has been no study for SC with a chronic disease evaluating patient satisfaction with healthcare receiving. This study is the first ever evaluating overall patient satisfaction with healthcare compared with CC and SC group.

This study shows no significant difference in overall patient satisfaction with healthcare between CC and SC and it seems to have more satisfaction expression in CC. In general, measurement of patient satisfaction with healthcare service is composed of the following factors: GPs, accessibility, nurses, appointment, and facilities (Grogan, et al., 1995). In this study, factors that affect patient satisfaction such as behavior of the health personnel, patient-practitioner relationship, facility for and access to the services are left to the original situation of each CH. The interventions cover only communication between patient and primary healthcare teams, and communication, coordination and organization between GP and specialist. In addition, health status and health outcome also affects satisfaction (Crow, et al., 2002). One reason that may explain why the epileptics in SC do not express more satisfaction than in CC is patient's false expectation that they will see the specialist every hospital visit. Therefore, the patient satisfaction with the healthcare is not different between CC and SC in this study.

6.3 Advantages and Disadvantages of This Study

6.3.1 Advantages

6.3.1.1 The First Study ever for Shared Care with Epilepsy

By literature review, there has been no study for SC with epilepsy; this study is the first ever. In addition, all published studies for Shared Care with other chronic diseases just evaluate process of care and primary medical outcomes compared with CC and SC groups. No any study evaluates quality of life and overall patient satisfaction with healthcare; this study is also the first ever. Therefore, this study is unique.

6.3.1.2 Usefulness of Shared Care Interventions

SC interventions are very useful to both patients and primary healthcare teams (pages 107-109). GPs improve their knowledge about epilepsy management, which is relevant to real practice by treatment review and immediate feedback and problem-based education (PBE) activities. Nurses improve their knowledge from the neurologist and from the pamphlet about self-care for epilepsy such as precipitating factors of seizure, impacts of not taking AED and keeping appointment, activities that should be avoided and first aid management during seizure. Patients receive education by nurses on self-care and apply the knowledge to self-care. Patients also receive reminder letters not to miss their appointment visits.

These are the ideal management not only for epilepsy but also for other chronic diseases. Patients with chronic diseases can take good care of themselves and regularly follow appointment visits, and primary healthcare teams are competent to

handle their patients. Perfect medical outcomes and quality of life will be met ultimately.

6.3.1.3 Significant Improvement of Continuity of Care

SC interventions improve continuity of care in terms of regular follow-up that is the major objectives of treatment for patients not only with epilepsy but also with other chronic diseases.

6.3.1.4 Experience of Healthcare Providers in Doing A Research

This study is quite a big project involving almost half of all the CHs in Nakhonratchasima Province. All participants in this study as well as the PI gained experience in doing research.

Primary healthcare teams learn how to do a research as follows: 1) they learn how to do a preparation phase of a study; 2) they learn steps of how to do research; 3) they learn how to invite patients; and 4) they learn how to collaborate with a study.

This study is beneficial for the primary healthcare teams to get experience in doing a research. Research and development nowadays is very essential for all level of hospital health personnel to improve healthcare service. In the future, they can conduct experiments on their own.

This study is co-operation of the PI and primary healthcare teams in applying research methodology to solve real problems of healthcare system at the CH level. This is a ideal of improving healthcare system.

Research methodology for RCT has been understood more especially research design for cluster randomization. Data and criteria for selecting and stratifying unit of randomization have to be pertinent and appropriate, respectively. After randomization, outliners of the baseline characteristics of eligible individuals between two treatment groups should be excluded and study period may be extended.

6.3.1.5 Discovery of the Real Healthcare System Situation at Community Hospitals

This study discovers the real situation of healthcare system at CHs. At the CHs, there is shortage of the health personnel. Nevertheless, the hospital health personnel are enthusiastic in cooperating as fully as possible. A limited number of nurses take responsibility to all kinds of chronic diseases such as diabetes, hypertension, epilepsy and mental diseases. There are three to six GPs at each CH responsible for about 30,000 to 100,000 population. Besides, GPs' turnover rate is high (21 out of 45 move out over one year). This will affect good healthcare service. Therefore, this should be the first priority for solving. However, this problem may need time to make solution.

6.3.2 Disadvantages

6.3.2.1 Research Design

This study uses registration, which does not represent the actual number of epileptics for stratification of the unit of randomization. This may lead to differences in number and baseline characteristics of epileptics in CC and SC. However, there are some methods that display on pages 122-126 to solve this problem.

6.3.2.2 Length of Study Period

One-year for this study is long enough to assess the primary question of regular follow-up between CC and SC (Macharia, et al., 1992). However, it is not long enough for evaluating medical outcomes in terms of seizure reduction and quality of life for Shared Care with epilepsy. Normally for epilepsy management, it needs long term follow-up i.e. at least two to five years of seizure free (Medical Research Council Antiepileptic Drug Withdrawal Study Group, 1991).

6.4 Improvement of Shared Care

6.4.1 Pamphlet and Education

Health education for this study is provided to individual epileptics. It consumes much time and may not be highly effective with epileptics because epilepsy treatment requires family support (pages 127-128). Mass education should be provided to epileptics and their family.

6.4.2 Treatment Review and Immediate Feedback

The immediate feedback for this study is sent to responsible nurses and passed to attending GPs. GPs may feel uncomfortable because nurses know their inappropriate practices. Therefore, feedback should be sent directly to the attending GPs.

6.5 Conclusions

1. Shared Care improves continuity of care in terms of rate of regular follow-up and the proportion of regular follow-up for epileptics particularly non-serious cases or adult cases aged between 20 and 60 years.

2. Shared Care improves GPs' practices for epilepsy treatment.

3. There are no differences in seizure reduction, quality of life and overall patient satisfaction between Conventional Care and Shared Care.

This study demonstrates very usefulness of Shared Care interventions (pages 107-109) that improve patients' knowledge on self-care and primary healthcare teams' knowledge of epilepsy management. Patients can apply the knowledge to self-care (page 108) and GPs improve their appropriate practice (page 107). These can improve medical outcomes and quality of life if the study period is prolonged and GPs stay at the same hospitals long enough.

The usefulness of SC interventions are ideal requirements for management of patients with chronic diseases. These may have benefit for other chronic diseases.

6.6 Recommendations

Epilepsy is a chronic disease that needs long-term treatment. Therefore, continuity of care is very essential. For this study, SC interventions are very useful to patients and primary health care teams, and improve continuity of care for epileptics with non-serious condition. It should be implemented to CHs for not only epilepsy but also other chronic diseases.

However, since a few patients do not understand the education (page 108) and epilepsy treatment requires family support (pages 127-128) the interventions should be improved by providing patients with interactive education and to their families as well. Nurses should ask epileptics during and at the end of education whether the patients understand the content, have any questions and then, let patients and family summarize all what they understand. If any error, the nurse can correct it. In case health personnel at community hospitals have excessive workload, mass education for patients and their family may be more suitable.

For treatment review and immediate feedback and PBE, these interventions require neurologist availability and regular intervention. To increase and maintain GPs' good practice for epilepsy treatment, GPs should be trained by the neurologist within workshops with common practical problems. In addition, epilepsy management and holistic care should be added in the medical curriculum, especially the necessity of good patient-compliance and avoiding precipitating factors, how to manage and modify dose of drug when seizure occurs, and when to stop AEDs.

Then, the problem of irregular care due to shortage of health personnel and GPs' relocation should be solved in the future. At this moment, a way to improve regular care is to produce and maintain good medical records including registration.

Shared Care for this study and other studies are useful for non-serious condition of chronic diseases. Chronic patients with serious condition may be too complicated to handle by GPs. These patients should be referred to specialists for further management.