CHAPTER 4

GENERAL DISCUSSION AND OVERALL CONCLUSIONS

This study aimed to evaluate a pharmacist's involvement with hypertensive patients in primary care and to compare that with the traditional service offered to such patients by measuring clinical, humanistic and economic outcomes.

4.1 Design and Statistics

The study was designed as a randomized pre test and post test in treatment and control groups in which measurements were undertaken at three times, that is at the pre test, after six and after 12 months. This design was chosen because it was potentially more effective in controlling confounding factors than other designs. Thus, the results were more likely to indicate that the differences observed directly resulted from the interventions undertaken.

Sample size was calculated based on blood pressure outcome in order to be able to distinguish an effect of 10 mm Hg of SBP, with a power of 90% and an alpha of 0.05. The calculation indicated a requirement for 95 patients per group. An additional 30% was included to take account of drop outs. That is a total of 124 patients per group, which was large enough to prevent the possibility of a false-negative (beta) error. This number was also sufficient to provide the statistical power for the quality of life analysis, to detect a 10 point difference between post-intervention scores of two groups with pre-intervention scores as covariates (Ware et al., 1993).

Many kinds of statistical analyses were performed. The multiple comparisons, such as ANOVA, in the third section of the results, were more reliable in controlling alpha error which might occur with single comparisons. Although there were violations in the Levene's test for homogeneity of variance, the many observations which were made in the study (235x3=705 observations) made it reasonable to ignore this assumption. Thus the differences observed could be taken as representing the valid effects of the interventions which had been made and not the result of random error.

BP control was analyzed by the multiple logistic regression which aimed to show clinical outcome in a practical view. While ANOVA and the multiple linear regression used in BP reduction analyses showed statistical meaning of the outcomes.

4.2 Blood pressure outcomes

A sphygmomanometer was selected for use in this study instead of a digital meter because a sphygmomanometer is recommended in the JNC-6 guidelines (National high blood pressure education program, 1997). Although there might be some bias from the reading process, the accuracy of cuff size is controlled. The digital meter controls the reading and reader bias but it still has a bias with regard to the cuff size selection.

Comparison results with two measurements using a sphygmomanometer and a digital meter showed a difference of 12 mm Hg for the DBP reading. The reading was higher with the sphygmomanometer. The pulse reading was lower by 4 beats/min with the digital reading. There was no significant difference in the SBP readings. During this study, there were two sources of BP readings. One was in the hospital primary

care unit, which used a digital meter and the other was in the pharmacy and the other two primary care units which used sphygmomanometers. Sometimes doctors were unsure which readings should be used for the patients. This raises the question whether the validation once a year of the digital meter which was subject to a huge workload in each working day was adequate.

The time of this study was during the period when the JNC-6 guidelines were currently in use and we followed those guidelines for the classification, the goal and the protocol of treatment. But we also used a benchmark of <130/80 mm Hg for patients with diabetes (Tatti et al., 1998) as the target goal of treatment as recommended in JNC-7 (National high blood pressure education program, 2003).

We focused primarily on SBP because studies have shown that SBP is more valuable in predicting the risk of cardiovascular disease than DBP, especially in the middle-aged, diabetic and older patients (Adler et al., 2000; Kannel, 2000; Staessen et al., 2000).

For the BP control after six months in the sample of 235 patients, the treatment group showed a significant control only in the SBP. However, in the high BP sample of 158 patients, the treatment group showed significantly more control in both SBP and DBP. This may be because the therapeutic goal for patients with a controlled BP was to keep the BP at the same controlled level, whereas for the high BP patients the goal was both to reduce BP and to obtain a better control. However, after 12 months follow-up the BP control in the treatment group was significantly greater than in the control group in both samples.

The BP, both systolic and diastolic, also showed significant differences from the baseline for both contol and treatment groups after six and 12 months. From

previous studies it was not expected that the BP of the control group would decrease as much as it did since previous studies showed a significant decrease only in the treatment group (Garcao and Cabrita, 2002; Solomon et al., 1998). During the time of our study, however, there was a major campaign by Mahasarakham Hospital, called "Good heart and Good health", and many related activities were started such as group discussions for the hypertensive patients at the hospital, visits to special seminars with patients from other areas, and activities encouraging exercise in each community. Another possible explanation of these BP outcomes involved an administrative procedure. This consisted for the first six months of a label on the patient's notes to identify the patients who were included in the study and it may have caused doctors and other health care providers to pay more attention to these hypertensive patients. Nevertheless, it was reasonable that some improvements occurred in the control group because they were treated by a doctor. However, improvements in the control group were not observed in previous studies.

Having the research pharmacist as the only person taking the BPs was considered to be an advantage, because it reduced the variation that might have occurred if two or more people were involved in making the measurements.

4.3 Compliance

Medication compliance was investigated by counting pills twice at approximately monthly intervals between the interview at the patient's homes and a visit to the pharmacist at the university pharmacy and the primary care units. However, a pill count does not indicate the accuracy of the timing of doses. Other methods have been used to measure compliance; patient reports, refill adherence and

electronic monitoring using bar code or microchip technologies (Murray et al., 2004). A pill count was selected for this study as the most reliable method that could economically be achieved and it provided an objective measure which was believed to be more accurate than a subjective one such as a recall questionnaire. Moreover, at each visit during the first six months, patient diaries were used in both groups, but there were only a small number of patients who kept recording such details each day and this record was hard to implement.

The improved compliance results obtained over a period of a year supported the effectiveness of pharmacist services and supported a previous study (Taylor et al., 2003). However, it should be noted that other studies into the effects of pharmacist interventions on patient compliance were not as positive as the results reported for this study but it should also be noted that the other test protocols were less rigorous. One study used patient self-reports to measure patient compliance (Taylor et al., 2003) and another used prescription refill data (Mehos et al., 2000).

4.4 Lifestyle modification

Many studies showed that with ageing sodium intake strongly related to cardiovascular mortality and high BP and have recommended a reduction of sodium intake to control BP in hypertensive patients as well as the change of other lifestyle factors including; exercise, smoking, caffeine, stress, fatty diet and minerals (Hu et al., 2004; Kastarinen et al., 2002; National high blood pressure education program, 1997; Roberts et al., 2002; Sacks et al., 2001; Whelton et al., 1998; Whelton et al., 2002). In a big survey study, NHANES I, in 20,729 US participants aged between 25-75 years in the period 1971-75 reported that sodium intake was inversely correlated with all-

cause and CVD mortality (Alderman et al., 1998). Another systematic review of 11 trials showed that the degree of sodium intake reduction was not related to changes in BP (Hooper et al., 2002). These contradictory findings might be because of confounding influences or different sensitivities to salt intake. Nevertheless, JNC-6 recommended controlling salt intake in moderation accompanied with moderate consumption of other minerals, K, Mg and Ca, and smoking cessation, caffeine intake reduction, weight reduction and dietary fats control (National high blood pressure education program, 1997). Another interesting study showed the effect of exercise on reducing BP. The study design was matched pairs with 207 hypertensive participants. Aerobic exercise of 30-60 minutes per week was sufficient to have an influence on BP reduction (Ishikawa-Takata et al., 2003). In this current study exercise was evaluated by the pharmacist at each visit. If a patient exercised for more than 20 minutes at least 2-3 times per week, they achieved their exercise goal.

The results of this study following the JNC-6 guidelines indicate that patients who received a pharmacist's involvement changed their lifestyle e.g., increased their exercise, decreased their sodium intake and reduced their stress, helping to produce BP control and BP reduction over 12 months. These patients would also tend to get more benefit from the long term treatment of hypertension in morbidity and mortality reduction resulting from cardiovascular diseases.

4.5 Patient clinical outcomes (visits, hospitalization, death and disabling)

The results of hospital and clinic visits showed that patients in the treatment group had more contacts in terms of total and non hypertension clinic and hospital visits after six and 12 months. Visits in this study were counted when patients came to

receive medications, whether from doctors, or from nurses, or from pharmacists. The more frequent contact in the treatment group might have resulted from the pharmacist consultations resulting in changing medication and/or asking for further investigations to be undertaken.

The number of hospitalizations, deaths and becoming disabled were not analysed statistically due to the small numbers involved when compared to the total sample. During October 2002-February 2004, the number of hospitalizations were equal between both groups, but there was one patient in the control group who was admitted to the hospital due to chronic renal failure resulting from hypertension on six occasions between October 2002-June 2003 and also eight times between July 2003-February 2004. Patients in the treatment group had a maximum of two admissions.

4.6 Pharmacist intervention

Pharmaceutical care is a model of broad intervention which is associated with many steps as shown in Appendix I. In this study, it consisted of patient education (slide show, oral information, booklet and leaflet), counseling, and pharmacist communications to physicians by letters or notes. A meta-analysis study commented that a complex intervention is more likely to be successful than a single one (Weingarten et al., 2002) although it begged the question as to whether all these elements were necessary in a real situation of cost-containment and staff reductions (Haynes et al., No date). Important findings of this study a pharmacist's extra involvement with patients showed benefits in clinical and humanistic outcomes, better blood pressure control, better compliance rate and better quality of life. This implied

that in making good use of limited staff, pharmacists' involvement in patient care could provide extra benefits to patients and might also be cost-effective.

The pharmacist's recommendations which were accepted ranged between 48-50% of suggestions during the 12 months follow-up. Some doctors had misgivings at the beginning of the study as to the appropriateness of pharmacists being involved in patient care in the primary care setting. This was not the case in the study of Bogden which showed 92% acceptance of pharmacist recommendations in a situation in which the physician and pharmacist cooperated and respected each other's differing opinions due to appreciating their differing roles (Bogden et al., 1998). Nevertheless, the results of this current study could well represent the actual circumstances pertaining in the general primary care settings. It should be noted that the accepted recommendations occurred more frequently in the setting of the university pharmacy. That is 64.5%, compared with 38.5% in the primary care units. This is despite the number of interventions not seen by the doctor being higher in the former setting than the latter settings, 13.2% compared with 8.5% respectively.

The reason for the recommendations being unseen or ignored might be because the pharmacist's notes written in the primary care units were unfamiliar for doctors to recognize, the recording paper in the patient medication profile was hard to review and the doctors involved were different every week. Sometimes the letters from the university pharmacy, which were given to patients to give to their doctors at their next visit, got lost or were forgotten.

4.7 Cost

Costs were analyzed by both the nonparametric Mann-Whitney U test and by the ANOVA parametric methods. The results of the Mann-Whitney showed that all cost variables were not different between groups but the results of ANOVA showed significant difference between groups. The Mann-Whitney analysis might not have power to reject the null hypothesis and show a significant difference between groups but the parametric ANOVA analysis did.

This study evaluated whether a pharmacist's extra involvement would reduce medication costs. Unexpectedly, after 12 months following patients' health status, patients in the treatment group spent more money on total costs and non hypertensive medications, but not on hypertensive medication, when compared with the control group. This was similar to the finding that more hospital/clinic visits were made by the treatment group than by the control group with respect to total and non hypertensive visits. The higher number of visits was probably the reason for the higher costs in the treatment group. In general patients who came to see doctors expected to get at least one medication even though that medication prescribed might be a multivitamin. Nevertheless, the main aim of this study was to improve patients' clinical outcomes, the consultations were not limited to only hypertensive medication modifications but also included medication for other coexisting diseases such as dyslipidemia and diabetes for which medications were quite expensive, e.g., atrovastatin, simvastatin, NPH injection.

4.8 Patient knowledge

A patient knowledge pro forma was set as a single construct and a three item construct of hypertension knowledge, risk factor management and the proper use of medication. Cronbach's alpha which is widely used for testing the internal consistency of pro formas was used. The alpha for a single construct of 14 items from the pilot study was acceptable at 0.60, and the alphas for a multiple construct in each subscale were also acceptable, except in the hypertension knowledge subscale after six months which was <0.50. The reliability values were all acceptable after 12 months when compared with a previous publication, which accepted >0.50 (Ware et al., 1993). Item No. 8, which had a negative or lowest correlation to its own scale would seem to be in need of revision or deletion (Appendix II).

The results of patient knowledge of a single construct showed a significantly higher total score after 12 months in the treatment group when compared with the control group. A multiple construct also confirmed that patients in the treatment group had more relevant knowledge than in the control group after 12 months. This positive result in patient knowledge resulting from a pharmacist's extra involvement was consistent with the findings of another study (Gourley et al., 1998). Nevertheless, it was somewhat unexpected to find improved knowledge in the proper use of medication after six months in the control group, but this did not happen with other subscales. Both groups however, had more knowledge after 12 months in all the scales. Possible reasons to help explain this are the education provided during the period of this study by health personal from the hospital in their campaign of 'Good Heart Good Health', nursing students undertaking home visits and health care providers giving group education to hypertensive patients. Patients' discussion with

doctors' at clinic visits would also be a source of improving their knowledge. Even the interviewers could improve patient knowledge. They mentioned to the research pharmacist that patients asked for answers, especially to item No. 14 which asked what a patient would do after he or she recognized that he or she had missed a dose. Thus interviewers could be a source of relevant knowledge. Another possible reason was that all patients signed the consent form. This would alert them that they were involved in the research study and they knew they would be followed up by the pharmacist. This might make the patients in the control group pay more attention to the use of their medications. Nevertheless, all these sources of additional relevant patient information were blinded as to which groups the patients were in.

4.9 Patient satisfaction

A patient satisfaction pro forma was constructed with four rating scales which aimed to make the respondents decide as to which direction their satisfaction was moving. A single construct was reliable throughout the three times of measurement. A multiple construct reliability was also acceptable and showed greater reliability after 12 months, except in continuity of care where alpha was <0.50. Thus the results in continuity of care can not be considered reliable. The improved alpha values over time might also be a result of the increased familiarity of the interviewers in administering the pro forma (Appendix II).

The overall results from both a single and the multiple construct showed clearly that patients had more satisfaction with a pharmacist's extra involvement after 12 months when compared with patients who received the traditional service. Unexpectedly, patients in the control group also had increased satisfaction when

compared with the beginning of the study but this has been found by others (Carter et al., 1997). Carter's study, however, showed more satisfaction in the treatment group as indicated by the differences found in 4 of 13 items after six months while in this study increased satisfaction was found in 1 of 16 items after six months and in 12 of 16 items after 12 months. This would again point to the necessity of long term provision of the extra services by the pharmacist in order to archive the best patient benefit.

When considering the increased satisfaction observed in the control group it is necessary to note the following factors which could have had an influence. The research pharmacist spent time informing all patients about the study, measuring their BP and explaining the meaning of the values obtained. The patients had not experienced anything like this before. In addition personal carrier bags and drinking glasses were provided to each patient at the pre test and after six and 12 months. This was aimed at providing something in which the patients could keep their medications and bring them back for the pharmacist to observe at each visit and also to encourage them to be involved until the end of the study. These things could have been sufficient to increase patient satisfaction in the control group.

Another explanation could be that the patients might answer in such a way as to try and please the interviewer and they did not necessarily express their true feeling. The patients might even have been afraid that the health care providers wouldn't take care of them if they did not answer positively. Nevertheless all patients were assured that the answers given in the interview would not influence their regular treatment. Despite the possibility of this potential bias, the study design with pre test and post test and with treatment and control groups was considered to be acceptable for the purpose of this study. The results obtained have confirmed that decision.

4.10 Patient quality of life (SF-36 and Digit Span test)

The SF-36 Thai version, which was used in this study was validated in 569 normal Thai people, Cronbach's alpha coefficients ranged between 0.63-0.77 (Leurmarnkul and Meetam, 2000). However, the results obtained in our study ranged between 0.33-0.87 (Appendix II). From the manual and interpretation guide of Ware and colleagues (1993), group comparisons do not require as a high reliability as 0.90 – as required for comparisons among individuals or across administrations to the same individual. Values of 0.50 or 0.70 as well as higher values have been concluded to be acceptable (Ware et al., 1993). In fact on this basis, there were only two scales in the work reported here which were found to be unacceptable, that is, general health and vitality. Values for these had a Cronbach alpha value of lower than 0.5 throughout the study. Interestingly, two studies which reported using two different Chinese SF-36 versions both showed very low reliability in the social functioning scale. The respective coefficient alphas were 0.39 in 1,316 normal samples (Li et al., 2003) and 0.54 in 156 normal samples (Ren et al., 1998). Although the validation of the Thai version showed that the coefficient alpha was reasonable, the authors of that study commented that the vitality scale scores were particularly highly correlated to the mental health scale score. This could indicate that the SF-36 Thai version might need further cultural modification in order to more accurately measure Thai health status, especially in hypertensive patients in Northeastern Thai people.

With reference to the results obtained in this study which were shown to be reliable it can be concluded that patients in the treatment group had a better quality of life, especially in physical function, role limitation due to physical problems, and in social functioning than patients in the control group. Patients in the treatment group

also had less limitation due to emotional problems over 12 months than in the control group. Interestingly, in most of the scales, mean scores of patients in the treatment group were increased, except in the social functioning, while they decreased in most of the scales in the control group except for bodily pain, vitality and mental health scales. Nearly similar patterns were found in the study of Carter and colleagues. That is, most of the mean scale scores were higher after follow up in the treatment group, with some decreased mean scale scores in the control group (Carter et al., 1997). This contrasted to the five months study of Erickson, which found decreased mean scores in the intervention group. This was explained as resulting from a 'labeling effect' which caused the patients to perceive that they were sick and led them to give answers of poor self-reported health. Nevertheless, no statistical difference was found between groups after five months in that study (Erickson et al., 1997).

The work reported here would suggest that a five month investigation would be unlikely to give reliable results. The results obtained after six months in our study did not show any improvement or deterioration from the baseline and this is also similar to other short term studies (Erickson et al., 1997; Gourley et al., 1998; Krska et al., 2001; Mehos et al., 2000). This could be explained by the short duration of intervention or the too small number of samples in each group as mentioned in the manual of the SF-36 health survey (Ware et al., 1993). Another explanation could be the frequency of intervention. When the pharmacists' visits were less frequent, for example, two visits, the results did not tend to show a difference between the groups in the HRQOL compared with when there were more frequent visits, as in some other studies including our study (Carter et al., 2000). When the length of the study was greater, as in this study of 12 months, then the patients' quality of life in physical functioning,

role limitation due to physical problems and the social functioning scale showed significant improvements. This might indicate that a sustained interaction in providing pharmaceutical care was necessary in order to have benefits on patient's quality of life (Kheir et al., 2004). Moreover, for producing a difference between groups, a regular schedule in seeing patients in order to provide pharmaceutical care would seem to be essential. Thus a good mutual relationship between patients and the pharmacist and good communication enabled the pharmacist to empathize with the patients' emotional difficulties (Foppe van Mil et al., 2004).

High blood pressure leads to the risk of vascular dementia and cognitive dysfunction. The Digit span test was used to test and monitor for cognitive function during one year of antihypertensive medication with pharmacist involvement. The results of the Digit Span (forward) test showed the decline of the mean scores over 12 months in both groups. Inversely, the scores of the Digit Span (backward) test increased over 12 months but without significant differences in both groups. The average mean scores of backward numbers were lower than the normal range of 4-6 digits. This seems to be contrast with other studies in the mean scores of the forward numbers. One study which was undertaken in 30 patients over 16 weeks showed the igit span forward increased in both groups, one group received atenolol with HCTZ and another group received enalapril with HCTZ, but the digit span backward showed a decrease in the group received atenolol with HCTZ but an increase in the group received enalapril with HCTZ. Nevertheless, there was no significant difference between groups (Blumenthal et al., 1990). Another study in 306 black men and women showed the increased mean scores after eight week follow-up in all three groups of medications, atenolol, captopril and verapamil SR. As with the study of Blumenthal

and colleagues (1990), in both male and female groups, there was no significant difference between groups of medications on the Digit Span test (Croog et al., 1990).

The possible explanation of the decrease in forward number but not backward number might be as follows. (1) patients might have paid attention to the first interview because of the new beginning but then did not pay much concern at the two post interviews, (2) patients might not be ready to respond at the beginning of the test, forward numbers, thus they were better at the later numbers, that is the backward numbers, (3) alternatively the patients may have been confused by the procedure.

From this study, it could be interpreted that patients in both groups were not different in their cognitive function due to the pharmacist involvement. Nevertheless, it cannot be concluded that patients in both groups had their cognitive function decline because the medications' groups were also related to cognitive dysfunction, moreover, diabetes, insulin resistance and age are also correlated to cognitive impairment (Kilander et al., 1998).

4.11 Is a pharmacists' contribution, as described here, practical in primary care units in Thailand? What might the impact of the results be on the system as a whole?

The pharmacists' contribution to health care provision has changed since the emergence of pharmaceutical care in the 1990s. Although some countries use the description 'pharmaceutical care' some use 'medicines management'. The important factor is that patients know exactly what they are getting from the pharmacists. The provision of pharmacists which is referred to in the above descriptive terms pharmaceutical care and medicines management is the provision of the kind of

practice which is distinctive to the pharmacist and can be compared with and differentiated from that of a doctor, a dentist or an optician. In order to conveniently provide pharmaceutical care it is considered by some that there is a need for a consulting room to be available for appointments between the patient and the pharmacist (Mason, 2001).

Nowadays the situation in primary care units, away from the hospital in Thailand, generally provides for a team of health professionals consisting of a doctor, a resident nurse, a pharmacist and a nurse from the main hospital. They will meet once or twice a week to provide advice and treatment for both minor and chronic illnesses during a 2-3 hour morning clinic. It was our experience in the study reported here that there were nearly 40 to 50 patients at each clinic and from this it could be implied that the quality of care possible from a 3-5 minutes talk with a doctor was not likely to be optimum. The resident nurse at each PCU normally provides nursing care for minor illnesses and this is not directly related to patient monitoring of chronic illness such as those patients with diabetes and hypertension. The rest of the health providers at the clinics were trained to work in a health promotion role. Most patients visit the clinics in preference to the crowded provincial hospital to seek care for their condition whether their condition is currently stable or unstable.

The involvement of pharmacists in several studies over the past 10 years, including this study, has shown great benefits in clinical outcomes for hypertensive patients. Most of the studies have involved just one or two pharmacists (Bogden et al., 1998; Borenstein et al., 2003; Braybrook et al., 2002; Carter et al., 1997; Garcao and Cabrita, 2002; Mehos et al., 2000; Okamoto and Nakahiro, 2001; Vivian, 2002). In two studies more than two pharmacists were involved and both studies showed

significant differences between the intervention and the control groups (Erickson et al., 1997; Solomon et al., 1998). One of these studies was undertaken in a multicenter setting (Solomon et al., 1998).

The previously mentioned findings from the 1990s have influenced the pharmacist's overall responsibility to not only include dispensing but to be involved with patient centered outcomes. The evidence confirms the usefulness of pharmacists in identifying, resolving and preventing drug therapy problems and that pharmacists have a beneficial influence on patients' clinical and humanistic outcomes. The role for pharmacists has been said to be to provide care directly to patients and take responsibility for a definable set of problems. In addition they should evaluate the quality and impact of their service and in some situations be involved with negotiating payment based on patient needs (Mason, 2001).

In the report of a conference in Minnesota by Manson (2001), pharmacists were said to see patients one at a time by appointment in a consulting room. Pharmacists were paid based on documentation of pharmaceutical care by a variety of payers, such as insurance companies and health maintenance organizations. In New Zealand, when a pharmaceutical care plan is submitted, a fee of NZ$160 is paid for each plan. It is paid partly by third party payers and patients but mainly by the government. Although pharmacists in the Netherlands are not paid as a result of the pharmaceutical care process, the income from dispensing is good and pharmacies are large and can help support such activities. In Britain, there is a process of medicines management services which links to the government National Health Service, NHS. There is little parallel with payment for pharmaceutical care but nevertheless, there is the same focus on the patient and medication related problems.

Pharmacists in Thailand generally work in the role of dispensing medicines in the hospital or they work as part time pharmacists in pharmacies. The role of pharmacists in PCUs is quite new and much more knowledge is required about this role to make clear the appropriate role of the pharmacist in this part of the Thai health care system.

Although regulations in Thailand have not been fully enforced to provide a full time pharmacist in each primary care unit, the rotation of pharmacists providing pharmaceutical care during the interval between doctor visits, e.g., three to six month intervals, is an interesting possibility. This is a challenging choice for the director, or the minister, of the Public Health Ministry to consider in relation to the cost benefit and effectiveness of treatment in the long term. Nevertheless, having a full time pharmacist with a full time doctor would be the preferred choice.

In Thailand, it is beyond the power of the Public Health Ministry at present to have a full time pharmacist in every community pharmacy, although there has been some promoting and encouraging of this idea by the government. The remuneration from health maintenance organizations and health insurance companies has been used in other countries to link pharmacies to be an integral part of the health care system. This may be achieved in Thailand through a development of the 30 baht scheme which may attract the backing of the owners of community pharmacies, or the pharmacist owners, to be involved as a part of the system and receive remuneration per patient for the pharmaceutical care provided. It would be a practical possibility with the cooperation of hospitals to arrange the schedule of management and provide other facilities.

Pharmaceutical care is an individual care in which pharmacists need to be trained in order to care effectively for patients. To achieve this, the university curricula of faculties of pharmacy need to be adapted in cooperation with medical schools (Foppe van Mil et al., 2004). In the current situation in Thailand, the pharmacy profession is evolving at the educational and practice levels led academically by Mahasarakham and Naresuarn Universities. In addition, the Thai Pharmacy Organization has been asserting the need for the development of the pharmacy profession in the area of community pharmacy and has been encouraging community pharmacists to achieve a high standard in their quality of service.

This is the current challenging social agenda in Thailand in which the pharmacy profession currently has the opportunity of changing to patient centered care in the primary care setting.

4.12 Limitations of the study

This study was limited to the characteristics of the sample used. For example the results could not be generalized to patients under 18 year old or pregnant patients or patients with other conditions excluded by the exclusion criteria.

The initial study was quite novel. Home visits were carried out to inform patients about the study and to request patients to return to the primary care units at the follow up periods when communication by telephone and post mail was not possible. Nevertheless, there was only a small number of < 20 patients.

Blinding to other health care providers or interviewers as to which groups patients belonged to was not 100 per cent possible. Although the research pharmacist's patient consultation was held separately from the clinic, other health care providers

might recognize patients who came to see the pharmacist every month for extra consultations. Moreover, the label sticker placed on the patient's medical card which was done over the first six months for easy retrieval when updating the data might make other health care providers pay more attention to those patients. It should be noted that these factors would favour the control group and not the treatment group.

4.13 Conclusions and further research

In conclusion, this study indicated that in general after one year those hypertensive patients who received a pharmacist's monitoring of their medication and health benefited from a positive influence on their BP control, disease state and medication knowledge, their ability in the areas of physical, mental and social well-being and in their satisfaction of their treatment. Further research is needed over a longer time period to determine the impact of pharmaceutical care on patient morbidity and mortality endpoints and on the cost effectiveness of full time pharmacists being involved in the long term monitoring of medication outcomes in patients with chronic diseases. The results of this initial study endorse the effectiveness of this role of the pharmacist and the considerable benefits to patients.