APPENDICES

APPENDIX I

PROTOCOL OF A PHARMACIST INVOLVEMENT IN HYPERTENSIVE PATIENTS IN PRIMARY CARE UNITS

1. Hypertension definition and treatment guideline

1.1 Definition

The Joint National Committee on Prevention, Detection, Evaluation and Treatment of high blood pressure 1997, classifies hypertension as in Table 1

Table 1 Classification of blood pressure for adults aged 18 years and older (National high blood pressure education program, 1997)*

Category	Systolic (mm Hg)	Diastolic (mm Hg)
Optimal+	< 120	And < 80
Normal	< 130	And < 85
High normal	130-139	Or 85-89
Hypertension++		
Stage 1	140-159	Or 90-99
Stage 2	160-179	Or 100-109
Stage 3	>= 180	Or >= 110

*not taking antihypertensive drugs and not acutely ill. When systolic and diastolic blood pressures fall into different categories, the higher category should be selected to classify the individual's blood pressure status. Isolated systolic hypertension is defined as systolic blood pressure 140 mm Hg or greater and diastolic blood pressure less than 90 mm Hg and staged appropriately.

+ Optimal blood pressure with respect to cardiovascular risk is less than 120/80 mm Hg

++ Based on the average of 2 or more readings taken at each of 2 or more visits after an initial screening

1.2 Risk stratification

The risk of cardiovascular complications in hypertensive patients was assessed not only from the level of blood pressure but also from the presence or absence of target organ damage or other risk factor such as dyslipidemia as shown in Table 2. According to the BP level and the risk stratification, the patients' risk group can be determined and a therapeutic decision made as shown in Table 3.

The goal of treatment of hypertension was different depending on the presence of complications which relate to target organ damage as shown in Table 4.

Table 2 Components of cardiovascular risk stratification in patients with hypertension

Major risk factors	Target organ damage/Clinical smoking cardiovascular disease
Smoking	Heart disease
Dyslipidemia	Left ventricular hypertrophy
Diabetes mellitus	Angina or prior myocardial infarction
Age > 60 y	Prior coronary revascularization
Sex (men and postmenopausal women)	Heart failure
Family history of cardiovascular disease: women < 65 y or men < 55y	Stroke or transient ischemic attack
	Nephropathy
	Peripheral arterial disease
	Retinopathy

Table 3 Risk Stratification and Treatment

Blood pressure stages (mm Hg)	Risk group A (No risk factors; No TOD/CCD[+])	Risk group B (at least 1 risk factor, not including diabetes; No TOD/CCD)	Risk group C (TOD/CCD and/or diabetes, with or without other risk factors)
High-normal (130-139/85-89)	Lifestyle modification	Lifestyle modification	Drug therapy[$]
Stage 1 (140-159/90-99)	Lifestyle modification (up to 12 mo)	Lifestyle modification [++](up to 6 month)	Drug therapy
Stage 2 and 3 (≥160/≥100)	Drug therapy	Drug therapy	Drug therapy

For example, a patient with diabetes and a blood pressure of 142/94 mm Hg plus left ventricular hypertrophy should be classified as having stage 1 hypertension with target organ disease (left ventricular hypertrophy) and with another major risk factor (diabetes). This patient would be categorized as "Stage1, Risk Group C," and recommended for immediate initiation of pharmacologic treatment. Lifestyle modification should be adjunctive therapy for all patients recommended for pharmacologic therapy.

[$] For those with heart failure, renal insufficiency or diabetes

[++]For patients with multiple risk factors, clinicians should consider drugs as initial therapy plus lifestyle modifications.

[+]TOD/CCD indicates target organ disease/clinical cardiovascular disease

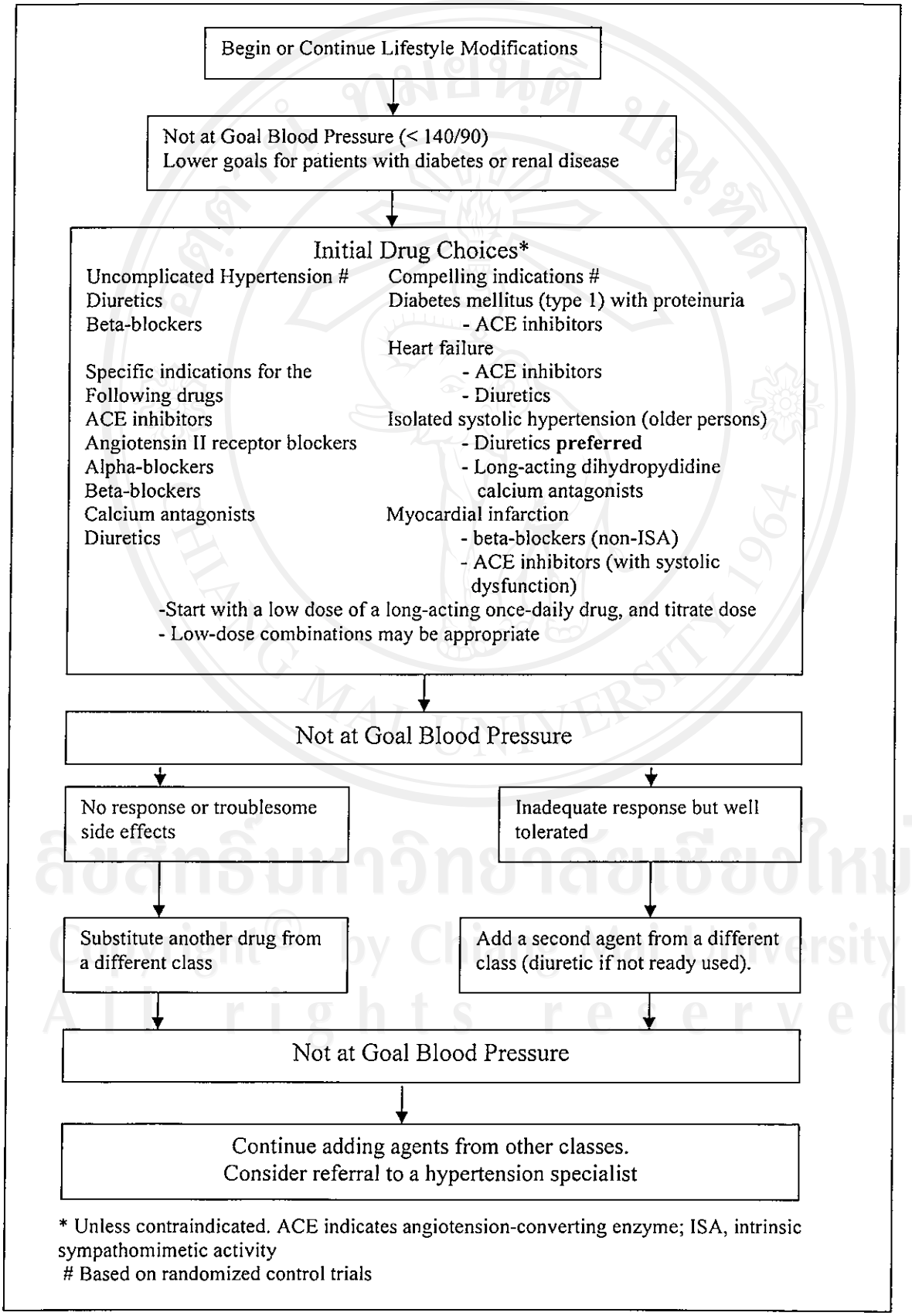
Table A.4 Goal of treatment in patients with hypertension

Hypertension	Goal of blood pressure
Uncomplicated hypertension	< 140/90
Hypertension with target organ damage or clinical cardiovascular disease (e.g. renal insufficiency, angina, heart failure)	< 130/85
Hypertension with diabetes	< 130/80 *
Hypertension with renal insufficiency with proteinuria more than 1 gram/day	<125/75

* based on current American Diabetes Association recommendations (American Diabetes Association, 1997)

Treatment follows the algorithm given in Figure 1.

Figure 1 Algorithm for the treatment of hypertension



* Unless contraindicated. ACE indicates angiotension-converting enzyme; ISA, intrinsic sympathomimetic activity

Based on randomized control trials

Cholesterol is a fat-like substance which travels in blood stream in the particle of lipid and proteins (lipoproteins). There are three major classes of lipoprotein which are found in a fasting individual: low density lipoproteins (LDL), high density lipoproteins (HDL), and very low density lipoproteins (VLDL).

LDL cholesterol was identified as the primary target for cholesterol-lowering therapy by ATP I, II and III. This is based on a wide variety of observational and experimental evidence over several decades covering animal, pathological, clinical, genetic and different types of population studies. Total cholesterol and LDL cholesterol are classified as shown in Table 5.

Lower levels of HDL are strongly related to increase risk of CHD morbidity and mortality. There are many factors which reduce HDL levels such as elevated serum triglycerides, overweight and obesity, physical inactivity, cigarette smoking, very high carbohydrate intakes (>60 percent of total energy intake), type 2 diabetes, certain drug (beta-blocker, anabolic steroids, progestational agents) and genetic factors. The classification of HDL is shown in Table 6.

Other lipids such as triglycerides were found to be an independent risk factor of coronary heart disease (CHD). Elevation of triglyceride can be confounded by significant correlation with total cholesterol, LDL and HDL. Classification of triglycerides is shown in Table A.7. Many causes elevate serum triglycerides such as 1) overweight and obesity, 2) physical inactivity, 3) cigarette smoking, 4) excess alcohol intake, 5) very high carbohydrate diets (>60 percent of total energy, 6) other diseases (type 2 diabetes, chronic renal failure, nephritic syndrome), 7) certain drugs (corticosteroids, protease inhibitors for HIV, beta-adrenergic blocking agents, estrogens), 8) genetic factors. The first recommendation for therapeutic treatment is

lifestyle modification and greater emphasis on elevated triglycerides as a marker of risk of CHD.

When pharmacists follow up lipid laboratory results, sometimes not all values of total cholesterol, HDL, LDL, triglycerides are presented. The calculation can be performed as the formula: total cholesterol = LDL + HDL + (TG/5).

Table 5 ATP III Classification of Total Cholesterol and LDL Cholesterol

Total cholesterol (mg/dl)		LDL cholesterol (mg/dl)	
<200	Desirable	< 100	Optimal
		100-129	Near optimal/above optimal
200-239	Borderline High	130-159	Borderline High
≥ 240	High	160-189	High
		≥ 190	Very High

Table 6 ATP III Classification of HDL Cholesterol

Serum HDL cholesterol (mg/ml)	
< 40 mg/dl	Low HDL cholesterol
≥ 60 mg/dl	High HDL cholesterol

Table 7 Classification of serum Triglycerides

Triglyceride category	ATP II levels	ATP III levels
Normal triglycerides	<200 mg/dl	< 150 mg/dl
Borderline-high triglycerides	200-399 mg/dl	150-199 mg/dl
High triglycerides	400-1000 mg/dl	200-499 mg/dl
Very high triglycerides	>1000 mg/dl	≥ 500 mg/dl

Physicians detect and identify cholesterol and lipoproteins and also assess overall risk of CHD. LDL lowering agent should be adjusted by an individual absolute risk for CHD. ATP III is considered in both long term (>10 years) and short term (≤

10 years) risk and risk is identified as three categories of risk for CHD in modifying the goal and therapy as in Table 8.

Patients with CHD are at very high risk of CHD events in the future (10 year-risk >20 percent). CHD risk equivalents mean patients who have peripheral arterial disease, abdominal aortic aneurism, carotid artery disease (symptomatic e.g., transient ischemic attack or stroke of aortic origin), or > 50% of stenosis on angiography or ultrasound) and other forms of clinical atherosclerotic disease (e.g., renal artery disease). ATP III counts DM as a CHD risk equivalent. If the assessment of risk by Framingham scoring shows > 20 percent, this patient can be said to have a CHD risk equivalent.

Patients without CHD or CHD risk equivalents, who have 2+ risk factors, should then have a 10 year-risk assessment in order to identify who has a risk >20 percent (CHD risk equivalents) and who has 10-20 percent. Both groups are candidates for more intensive LDL lowering therapy. ATP III stratified risk below 10 percent on the basis of the number of risk factors and not on a projection of 10 year-risk which guided the decision of therapeutic treatment. The major risk factors counting are included in Table 9.

Table 8 Categories of Risk for Coronary Heart Disease (CHD)

Risk categories	LDL-C goal
Established CHD & CHD risk equivalents	< 100 mg/dl
Multiple (2+) risk factors	< 130 mg/dl*
0-1 risk factor	< 160 mg/dl

*LDL-C goal for multiple risk persons with 10-year risk > 20 percent = < 100 mg/dl

Table 9 The major independent risk factors identified in risk factors counting

Risk factor	Definition	Comments
Cigarette smoking	Any cigarette smoking in the past month	
Hypertension	Blood pressure > 140/90 mm Hg or taking antihypertensive medications	Multiple measures of blood pressure required for diagnosis (see JNC VI for further clinical evaluation)
Low HDL cholesterol	HDL cholesterol < 40 mg/dl	
Family history of premeature CHD	Clinical CHD or sudden death documented in 1st-degree male relative before age 55 or in 1st-degree female relative before age 65	
Age	Men ≥ 45 years, Women ≥ 55 years	

The guideline for therapeutic treatment is different depending on the risk categories. Table 10, shows the therapeutic treatments in patients with CHD or CHD risk equivalents. Table 11 shows the treatments in persons with multiple (2+) risk factors and Table 12 shows the treatments in persons with zero to one risk factor. The treatment in pjatients who were evaluated beginning with 10-year risk assessment shows in Table 13. There is also a guideline to follow up cholesterol measurements when the goal is achieved as shown in Table 14.

Table 10 Therapeutic approaches to LDL cholesterol lowering in persons with CHD or CHD risk equivalents

Subcategory of LDL Cholesterol Level	LDL Cholesterol Goal	Level at which to initiate Therapeutic Lifestyle Changes (TLC)	Level at which to initiate LDL-lowering drugs
≥ 130 mg/dl	< 100 mg/dl	≥ 100 mg/dl	Start drug therapy simultaneously with dietary therapy
100-129 mg/dl	< 100 mg/dl	≥ 100 mg/dl	Consider drug options*
< 100 mg/dl	< 100 mg/dl	TLC & emphasize weight control and physical activity	LDL-lowering drugs not required

* Some authorities recommend LDL-lowering drugs in this category if LDL cholesterol < 100 mg/dl cannot be achieved by TLC. Others prefer use of drugs that primarily modify other lipoprotein fractions, e.g., nicotinic acid and fibrate. Clinical judgement also may call for withholding drug therapy in this subcategory.

Table 11 Management of LDL cholesterol in persons with multiple (2+) risk factors

10-Year risk	LDL goal	LDL level at which to initiate therapeutic lifestyle change (TLC)	LDL level at which to consider drug therapy (after TLC)
> 20%	< 100 mg/dl	≥ 100 mg/dl	See CHD and CHD risk equivalent
10-20%	< 130 mg/dl	≥ 130 mg/dl	≥ 130 mg/dl
< 10%	< 130 mg/dl	≥ 130 mg/dl	≥ 160 mg/dl

Table 12 Management of LDL cholesterol in persons with zero to one (0-1) risk factor

Risk category	LDL goal	LDL level at which to initiate TLC	LDL level at which to consider drug therapy (after TLC)
0-1 risk factor*	< 160 mg/dl	≥ 160 mg/dl	≥ 190 mg/dl +

* Most persons with 0-1 risk factor have a 10-year risk for CHD < 10 percent
+ Drug therapy optional for LDL-C 160-189 mg/dl (after dietary therapy)

Table 13 Management of LDL cholesterol in persons beginning with 10-year risk assessment

10-year risk	LDL goal	LDL level at which to initiate TLC	LDL level at which to consider drug therapy (after TLC)
> 20 %	< 100 mg/dl	≥ 100 mg/dl	See CHD and CHD risk equivalent
10-20%	< 130 mg/dl	≥ 130 mg/dl	≥ 130 mg/dl
< 10% Multiple (2+) risk factors	< 130 mg/dl	≥ 130 mg/dl	≥ 160 mg/dl
0-1 risk factor	< 160 mg/dl	≥ 160 mg/dl	≥ 190 mg/dl*

* Drug therapy optional for LDL-C 160-189 mg/dl (after dietary therapy)

Table 14 Schedule for follow-up liproprotein analysis for persons whose LDL cholesterol levels are below goal levels

Risk level	LDL goal (mg/dl)	LDL level observed (mg/dl)	Repeat lipoprotein analysis
CHD or CHD risk equivalents	< 100	< 100	< 1 year
2+ risk factors	< 130	< 130	≤ 2 years
0-1 risk factor	< 160	130-159	≤ 2 years
0-1 risk factor	< 160	< 130	≤ 5 years

LDL-lowering agent is recommended to be HMG Co A reductase inhibitors (statin) because they are the most effective and practical class to use. Statin has been proved to reduce risk for acute coronary syndromes, coronary procedures, and other coronary outcomes. Statin should be recommended as the first line therapy for lowering LDL. Bile acid sequestrants are moderate LDL-lowering agent. They are recommended for persons who need modest LDL reduction, pregnancy due to no serious systemic toxicity, in persons with very high LDL with a combination of statins. Nicotinic acid should be considered in persons without significant atherogenic dyslipidemia as a single agent or a combination with others in persons with higher risk. The cautions are with active liver disease, active peptic ulcer, type 2 diabetes, hyperuricemia and gout. Fibric acid derivatives (fibrates) are effective for lowering triglycerides and recommended for a very high triglycerides to avoid acute pancreatitis.

3. Blood pressure measurement

Schedule

- A pharmacist will schedule a monthly visit for each patient.
- If a pharmacist cannot meet the patient in that month, a call or home visit is permitted.
- A stopwatch will be used to measure the time each patient spent at the pharmacy and the data recorded.
-

Positioning of Blood Pressure Cuff

A. Center inflatable bladder over brachial artery
B. Position lower cuff border 2.5 cm above antecubital
C. Patient's arm slightly flexed at elbow
D. Position stethoscope bell over brachial artery

Technique of BP measurement (National high blood pressure education program, 1997)

A. Patients should be seated in a chair with their backs supported and their arms bared and supported at heart level. Patients should refrain form smoking or ingesting caffeine during the 30 minutes preceding the measurement.
B. Patients with diabetes, measurement of blood pressure in the supine, sitting and standing position may be indicated (to detect evidence of autonomic dysfunction and orthostatic hypotension).

C. Measurement should begin after at least 5 minutes of rest. The appropriate cuff size must be used to ensure accurate measurement. The bladder within the cuff should encircle at least 80% of the arm. Many adults will require a large adult cuff.

D. Measurements should be taken preferably with a mercury sphygmomanometer.

E. Both SBP and DBP should be recorded. The first appearance of sound (phase 1) is used to define SBP. The disappearance of sound (phase 5) is used to define DBP.

Note:

1. Take Blood Pressure at heart level
2. Inflate cuff rapidly to level above suspected SBP
3. Deflate cuff slowly at a rate of 2-3 mm Hg per second

F. Two or more readings separated by 2 minutes should be averaged. If the first 2 readings differ by more than 5 mm Hg, additional readings should be obtained and averaged.

G. Pharmacists should explain to patients the meaning of their blood pressure readings and advise them of the need for periodic remeasurement. Table 3 provides follow-up recommendations based on the initial set of blood pressure measurements.

4. Pharmaceutical process

4.1 Pharmacists' contribution in monitoring hypertensive patients

4.1.1 Measure blood pressure pulse and weight following the protocol

4.1.2 Use interpersonal and social support

- Pharmacists will make scheduled follow-up visits to evaluate patient's outcome progress and provide therapeutic outcome monitoring every month
- The research pharmacist will provide group education for patients and their families to incorporate the families with the treatment.
- Provide a private setting to repeat and clarify instructions and assess resistance to changing behavior
- Make an occasional home visit, if needed, to follow-up patients and their families and monitor their involvement in the pharmacist's monitoring

4.1.3 The method of Therapeutic outcome monitoring is quoted verbatim below (Grainger-Rousseau et al., 1997).

4.1.3.1 "Record and interpret patient information": demographic data, family history, social history, dietary pattern, life style, compliance history, current status, **review of system**, progressive notes, intervention notes, care plan for each

4.1.3.2 "Document desired therapeutic objectives for the patient and document the therapeutic plan.

The pharmacist considers two basic types of therapeutic objectives: clinical objectives (from a professional viewpoint) and quality of life

objectives (from the patient's viewpoint). If possible, the pharmacist learns the patient's objective form the patient or caregiver and clinical objectives/therapeutic plan from the physician or other health care providers.

4.1.3.3 Evaluate the therapeutic objectives and the therapeutic plan

The pharmacist evaluates potential drug-related problems (any obstacle to achieving therapeutic objectives). Keeping in mind the patient's medical problems, lifestyle and preferences, the pharmacist:

- Decides whether the patient has or is likely to develop problems with therapy
- Decides whether modifying the regimen is necessary, and if so, consults the prescriber
- Decides the evaluation, potential problems and any prescriber consultation

4.1.3.4 Design a monitoring plan.

On the basis of potential problems identified in Step 3, the pharmacist:

- Devises a procedure to obtain the data needed to monitor the patient's progress toward therapeutic objectives
- Establishes when and how the monitoring data will be collected and documents the plan in the patient record (a daily calendar diary or other reminder log may be necessary)

4.1.3.5 *Advice patients.

The clinical pharmacist includes specific information about how the patient or caregiver can monitor the progress of therapy, how to detect pharmacotherapeutic problems, and what actions to take if a possible problem is detected. The pharmacist provid supplementation written material as appropriate. Before the interview ends, the pharmacist decides whether the patient (caregiver) understands the therapeutic objective and what to do to reach it.

4.1.3.6 Implement the monitoring plan (collect monitoring data).

The pharmacist carries out the monitoring plan as decided in Step 4. (This step will usually occur some days or weeks after step 5 and may require an appointment for a visit or a telephone call or home visit*.)

a. Evaluate patient progress and identify pharmacotherapeutic problems. On the basis of monitoring data, therapeutic objectives and patient data, the pharmacist systemically evaluates the patient progress. He or she evaluates and documents the following:

- Availability. Is there evidence that the patient is receiving the therapy and intended?
- Effectiveness. Is there evidence that the patient is obtaining the intended benefit from therapy?
- Adverse effects. Does the patient show any signs or symptoms consistent with a new medical problem that could result from and adverse drug event, toxicity or side effect?

b. Respond to problems.

The pharmacist considers pharmacotherapeutic problems and follows through. He or she exercises judgment in the patient's interest. Most responses take one of two courses:

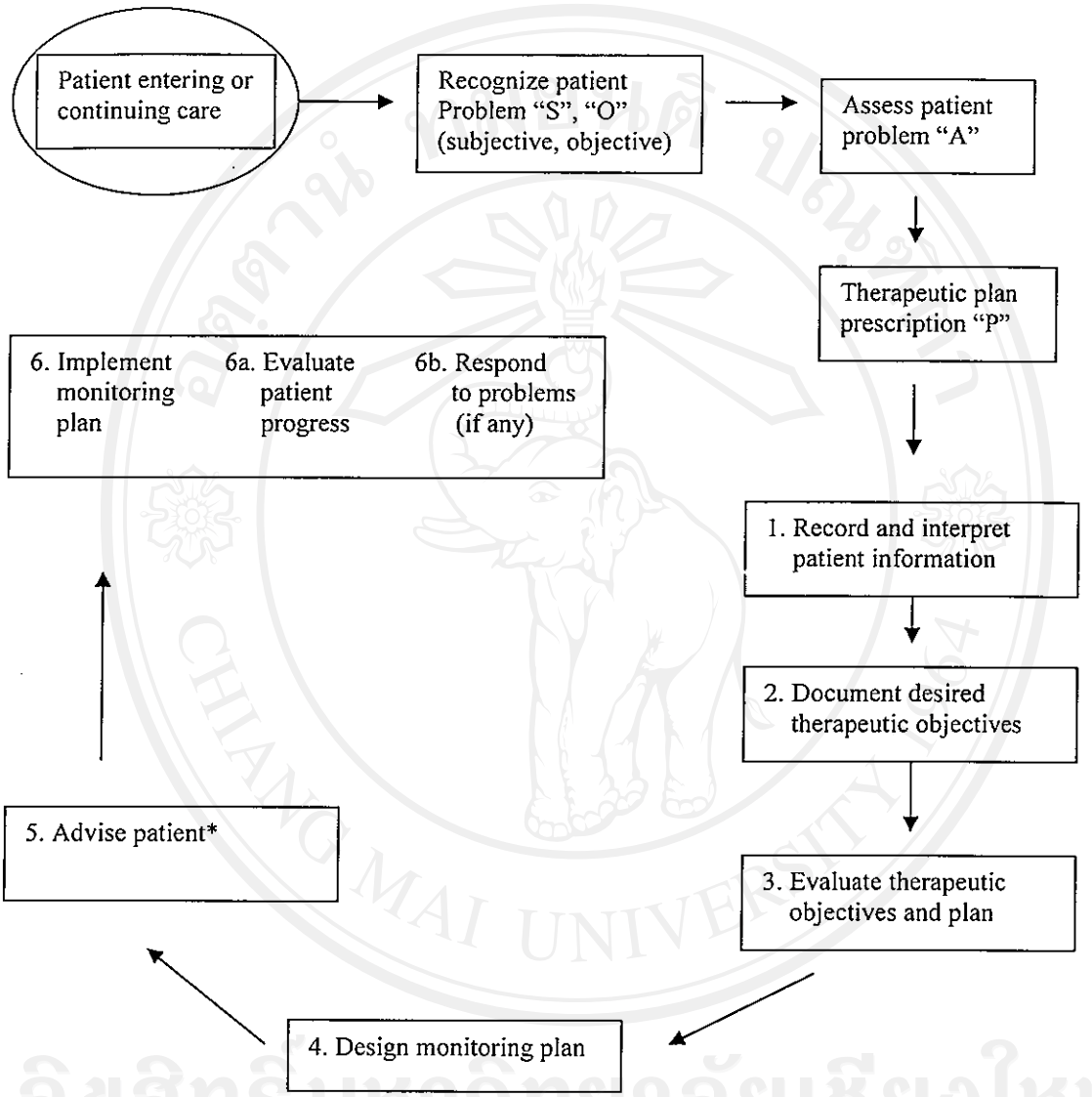
- Resolution: Resolving the problem entails five steps: defining the problem, identifying the cause (review information from Step 3 for possible causes), choosing alternative solutions, selecting the best alternative and implementing the solution. Then monitoring resumes.
- Referral: The pharmacist refers to others (e.g., physicians) problems that he or she cannot resolve alone.

c. Review the record (documentation of earlier steps) and complete documentation of episode, problems noted, and action taken

d. Report to the physician periodically as necessary.

e. Revise or update the monitoring plan as necessary."

Figure 2 Therapeutic outcome monitoring integrated into drug therapy



* This outline is taken from Grainger-Rousseau Timothy-John and others (1997) with a small adaptation at a box 5.

4.2 Review of System

Skin: flushing, rash

Head: headache

Eyes: visual disturbances

Respiratory: bronchospasm, dyspnea (rest/exertional)

Cardiac: chest pain, edema, palpitations

Urinary: dysuria, flank pain, hematuria, nocturia, polyuria

Genitoreproductive: impotence

Musculoskeletal: arthralgia, muscle cramps

Peripheral vascular: claudication, cold extremities

Neurologic: dizziness, fatigue, tingling, unsteadiness, weakness

Psychiatric: depression

Endocrine: diaphoresis

4.3 Physical examination

Physical examination should be performed on every visit with a pharmacist

1. Two blood pressure measurement in sitting position with 2 minutes apart
2. Evaluate blood pressure in both arms at the fist measurement after that follow up blood pressure with the higher arm
3. Pulse rate
4. Body weight, height

4.4 Laboratory tests

Routine laboratory tests were recommended before the treatment in order to assess target organ damage and other risk factors. Recommendations are as follows:

1. urinalysis
2. CBC
3. Blood chem. (K, Na, Cr, FBS, Total CHO, HDL)
4. 12-lead electrocardiogram

Follow up laboratory tests for every 12 month is also recommended.

1. urinalysis, BUN, Cr
2. Calcium
3. CBC with differential
4. Cholesterol, Triglyceride, LDL, HDL
5. Glucose (fasting)
6. LFT: AST, ALT, Billirubin
7. Na, K when a patient is currently on diuretics, assess the electrolyte until it is stable and follow up every 6 months
8. uric acid

APPENDIX II

RELIABILITY AND CORRELATION TESTS

1. Patient knowledge

Reliability

Patient knowledge was constructed into 14 items to cover three domains of hypertension knowledge, risk modification and the proper use of medication. It was measured at pre test, after six and 12 months. The reliability test was performed again as shown in Table 15. There were three patients who missed responding in some items of the pro forma and so there were 232 patients eligible for calculating the reliability of 14 items. Seven patients did not respond to the pro forma and three patients missed responding to one item after six months. This left 225 patients in the analysis of reliability after six months. There were 221 patients left after 12 months in whom 13 patients dropped out and another patient forget to respond in one item.

Item analyses were conducted at three times that is at the pre test, after six months and after 12 months, on the 14 items to assess active coping. From Table 15, all correlations were greater than 0.30 except for two items at pre test-No 8 and 14, two items after six months-No 2 and 8, and two items after 12 months-No 8 and 14. Item No 8 and 14 differed in the content from the other 14 items and they (8, 14) might need to be revised. Items No 8 and 14 were 'Most uncontrolled hypertensive patients have headache and blurred vision' (r = -0.06) and 'If you recognize that you have missed a dose, for example you are taking a daily dose, you do not need to take this dose at the time you remember that you missed the dose because the time has gone

by' (r = 0.27). Coefficient alphas were 0.82, 0.82 and 0.83, at pre test, after six months and after 12 months, respectively.

Table 16, shows the results of correlation in each subscale. The hypothesis on item analysis was to assess 'hypertension knowledge', 'risk factor management' and 'proper use of medications'. Initially, all items correlated well with its own scale more than other scales except item No 8 which also showed the poor correlations after six months and after 12 months. Item No2 showed a low correlation after six months (r=0.29) but at the pre test and after 12 months the correlations were higher (r=0.50, 0.60, respectively). Cronbach's alphas increased with the time of the measurement, the highest being after 12 months. The exception was for hypertension knowledge, which had a lower coefficient alpha after six months.

Table 15 Reliability test of patient knowledge at three times; the pre test, after six and 12 months

Patient knowledge scales	Mean (variance) if item deleted			Corrected item-total correlation			Coefficient Alpha		
	Pre test	After 6 mo	After 12 mo	Pre test	After 6 mo	After 12 mo	Pre test	After 6 mo	After 12 mo
1. Hypertension is a curable disease.	6.82 (10.49)	7.52 (10.34)	8.21 (10.12)	0.39	0.39	0.34	0.81	0.81	0.83
2. Medications improve better symptoms but do not extend your life longer.	7.06 (11.71)	7.73 (10.98)	8.43 (10.33)	0.64	0.28	0.34	0.83	0.82	0.83
3. Uncontrolled hypertension can cause stroke.	0.64 (9.81)	7.16 (9.81)	7.91 (9.63)	0.64	0.63	0.62	0.79	0.79	0.81
4. High salt diet makes blood pressure uncontrolled.	6.50 (9.95)	7.26 (9.92)	7.94 (9.87)	0.55	0.53	0.51	0.80	0.80	0.81
5. Uncontrolled blood pressure leads to kidney disease.	6.50 (10.12)	7.26 (9.97)	7.96 (9.48)	0.49	0.52	0.64	0.80	0.80	0.80
6. High body weight is one risk factor of uncontrolled hypertension.	6.50 (9.90)	7.26 (9.69)	7.95 (9.74)	0.57	0.62	0.55	0.80	0.80	0.81
7. Exercise in hypertensive patients should be avoided.	6.58 (9.97)	7.23 (10.21)	7.91 (10.04)	0.53	0.44	0.47	0.80	0.81	0.82
8. Most uncontrolled hypertensive patients have headache and blurred vision.	7.06 (11.87)	7.81 (12.28)	8.62 (11.50)	-0.03	-0.31	-0.06	0.83	0.84	0.84
9. Hypertensive patients can adjust doses of hypertensive medication depending of each BP measurement.	6.58 (10.11)	7.21 (10.40)	7.99 (9.96)	0.47	0.38	0.44	0.81	0.81	0.82
10. Hypertensive patients may stop medications when adverse events occur without telling their doctors or pharmacists or nurses.	6.54 (10.03)	7.18 (10.00)	7.93 (9.82)	0.51	0.55	0.53	0.80	0.80	0.81
11. Smoking and uncontrolled hypertension can cause heart disease.	6.47 (9.93)	7.26 (9.67)	7.99 (9.66)	0.57	0.62	0.55	0.80	0.79	0.81
12. Stress makes blood pressure harder to be controlled.	6.39 (10.35)	7.10 (10.24)	7.85 (9.97)	0.46	0.52	0.56	0.81	0.80	0.81
13. All medications which be taken without prescriptions should be let a pharmacist check to avoid drug interactions.	6.38 (10.17)	7.11(10.13)	7.90 (9.74)	0.54	0.55	0.59	0.80	0.80	0.81
14. If you recognize that you miss a dose, for example you are taking a daily dose, it does not need to take this dose at the time you recognize because the time has gone by.	6.75 (10.90)	7.45 (10.51)	8.18 (10.36)	0.23	0.32	0.27	0.82	0.82	0.83

Table 16 Correlations of each subscale item and with its own scale (Bold) and with the other scales

Patient knowledge scales (∝ at pre test/after 6 mo/after 12 mo)	Hypertension knowledge			Risk factor management			Proper use of medications		
	Pre test	After 6 mo	After 12 mo	Pre test	After 6 mo	After 12 mo	Pre test	After 6 mo	After 12 mo
Hypertension knowledge (∝ = 0.42/0.32/0.51)									
1. Hypertension is a curable disease	**0.65**	**0.61**	**0.64**	0.37	0.37	0.31	0.34	0.39	0.31
3. Uncontrolled hypertension can cause stroke.	**0.75**	**0.79**	**0.77**	0.62	0.65	0.60	0.46	0.44	0.44
5. Uncontrolled blood pressure leads to kidney disease.	**0.71**	**0.72**	**0.74**	0.57	0.56	0.64	0.34	0.29	0.46
8.Most uncontrolled hypertensive patients have headache and blurred vision.	**-0.02**	**0.12**	**0.14**	-0.31	-0.07	-0.10	-0.22	0.04	0.04
Risk factor management (∝ = 0.73/0.74/0.76)									
4. High salt diet makes blood pressure uncontrolled.	0.49	0.50	0.50	**0.70**	**0.72**	**0.69**	0.38	0.39	0.32
6.High body weight is one risk factor of uncontrolled hypertension.	0.48	0.56	0.49	**0.78**	**0.74**	**0.80**	0.45	0.35	0.29
7. Exercise in hypertensive patients should be avoided.	0.45	0.44	0.32	**0.57**	**0.63**	**0.57**	0.36	0.49	0.47
11. Smoking and uncontrolled hypertension can cause heart disease.	0.51	0.54	0.54	**0.77**	**0.71**	**0.78**	0.45	0.40	0.29
12. Stress makes blood pressure harder to be controlled.	0.40	0.40	0.51	**0.69**	**0.68**	**0.75**	0.40	0.31	0.32
Proper use of medications (∝ = 0.59/0.60/0.64)									
2. Medications improve better symptoms but do not extend your life longer.	0.23	0.03	0.30	0.21	0.03	0.23	**0.50**	**0.29**	**0.60**
9. Hypertensive patients can adjust doses of hypertensive medication depending of each BP measurement.	0.25	0.43	0.35	0.31	0.39	0.27	**0.66**	**0.69**	**0.71**
10. Hypertensive patients may stop medications when adverse events occur without telling their doctors or pharmacists or nurses.	0.39	0.38	0.45	0.47	0.44	0.37	**0.74**	**0.73**	**0.74**
13. All medications which be taken without prescriptions should be let a pharmacist check to avoid drug interactions.	0.42	0.47	0.50	0.57	0.52	0.57	**0.59**	**0.63**	**0.60**
14. If you recognize that you miss a dose, for example you are taking a daily dose, it does not need to take this dose at the time you recognize because the time has gone by.	0.25	0.15	0.24	0.24	0.19	0.13	**0.63**	**0.58**	**0.62**

2. Patient satisfaction

Reliability

Reliability was analyzed both in the pre test, after six and 12 months of data collection. The total number of patients in the pre test was 233 because two patients forgot to respond in some items. After six months follow-up there were seven patients who were excluded from the analysis because two patients died, two patients did not comply with the study and the other three patients were disabled during the post test time. And after 12 months there were 222 patients left in the analysis as 13 patients dropped out.

Item analyses were conducted at three times, at the pre test, after six months and after 12 months, on 16 items. Table 17 shows that all item-total correlations were higher after 12 months except item No 15, which was lower than 0.30. The worst item-total correlations were at the pretest where five items showed item-total correlations which were lower than 0.30, No 2, 3, 7, 11 and 15. Cronbach's alphas were all high and acceptable, nevertheless the highest values of coefficient alphas were seen after 12 months. The values were 0.72, 0.73 and 0.79 at the pre test, after six and 12 months respectively.

Item analyses were also conducted on 16 items to assess the six subscales: 'communication and management', 'accessibility and convenience', 'finance', 'interpersonal relationship', 'continuity of care' and 'overall satisfaction'. Table 18 shows all correlations of each subscale more highly correlated with its own subscale than with the other scales except item No 15 (r=-0.26) in the period after six months. The subscales which had only one item showed a correlation of 1.00. Coefficient alphas were produced only in four subscales, 'communication and management',

'finance', 'interpersonal relationship' and 'continuity of care', which showed the higher alphas in 'communication and management' and 'finance'. In the subscale of 'interpersonal relationship', the alphas were lower, 0.54 to 0.68, pre test to after 12 months. Whereas, the alphas in 'continuity of care' were extremely low and needed to be derived, -0.53 to -0.23, pre test to after 12 months.

Table 17 Reliability test of patient satisfaction at the pre test (N=233), after six months (N=228) and after 12 months (N=222)

Satisfaction Scale Item [a]	Mean (variance)if item deleted			Corrected item-total correlation			Cronbach's alpha		
	Pre test	After 6 mo	After 12 mo	Pre test	After 6 mo	After 12 mo	Pre test	After 6 mo	After 12 mo
Communication and management									
1. You felt satisfied with pharmacist's explanation of using medications and life style modification. (+)	45.02 (18.38)	48.59(18.08)	52.98 (19.99)	0.30	0.41	0.49	0.71	0.71	0.77
2. You understood how to use medications and life style modification better after talking to a pharmacist. (+)	44.91 (18.64)	48.59 (18.42)	52.98 (19.96)	0.28	0.32	0.46	0.71	0.71	0.77
3. Sometimes a pharmacist makes you wonder if her/his advice is correct.(-)	45.85 (18.23)	49.20 (17.10)	53.28 (19.08)	0.20	0.36	0.40	0.72	0.71	0.78
4. A pharmacist did not pay attention to your complaining about disease problems. (-)	45.69 (16.89)	49.93(17.24)	53.14 (19.27)	0.38	0.35	0.36	0.70	0.71	0.78
5. You intend to follow the details of this pharmacist's advice. (+)	44.83 (18.31)	48.57 (18.16)	52.94 (20.44)	0.39	0.40	0.39	0.71	0.71	0.78
Accessibility and convenience									
6. You have not received easy access to see a pharmacist. (-)	45.48 (17.09)	48.87(17.49)	53.26 (18.39)	0.36	0.38	0.44	0.70	0.71	0.77
Finance									
7. Although you have extra expense to see pharmacist, you receive more benefits.(+)	45.05 (18.57)	48.68 (17.23)	53.06 (19.40)	0.25	0.54	0.46	0.71	0.69	0.77
8. You felt the benefit received was not reasonable compared to the time spent. (-)	45.38 (16.47)	18.73(17.41)	53.09 (19.26)	0.53	0.47	0.50	0.68	0.70	0.77
Interpersonal relationship									
9. A pharmacist took care of you very much in medication use and life style modification. (+)	44.87 (17.54)	48.61 (17.92)	52.96 (19.62)	0.50	0.43	0.58	0.69	0.70	0.77
10. You felt better after talking to a pharmacist about medication use and life style modification. (+)	44.90 (17.77)	48.56 (18.03)	52.97 (20.47)	0.47	0.46	0.37	0.70	0.70	0.78
11. A pharmacist should smile, greet and talk more to a patient.(-)	46.00 (18.30)	49.49(19.09)	53.35 (18.17)	0.18	0.03	0.43	0.73	0.76	0.78
12. A pharmacist ignored what you to tell him/her.(-)	45.32 (16.89)	48.73 (17.92)	53.12 (19.26)	0.48	0.40	0.51	0.69	0.71	0.77
13. A pharmacist was pleased to listen to your problems not only on hypertension. (+)	45.09 (17.93)	48.70 (17.56)	53.11 (19.07)	0.33	0.45	0.55	0.71	0.70	0.77
Continuity of care									
14. You felt warm to see any pharmacist. (+)	44.91 (17.89)	48.66 (17.99)	53.06 (19.61)	0.45	0.42	0.47	0.70	0.70	0.77
15. If it is possible, you would like to see the same pharmacist.(-)	46.44 (20.48)	21.92(50.54)	55.29 (22.71)	-0.14	-0.37	-0.17	0.76	0.77	0.83
Overall satisfaction									
16. In conclusion, you felt satisfied with the pharmacy service of medication use and life style modification. (+)	44.83 (18.05)	48.60 (17.66)	52.96 (19.91)	0.39	0.48	0.58	0.70	0.70	0.77

Pre test--Alpha = 0.72; mean = 48.30; Variance = 20.07; SD = 4.48 , After 6 mo--Alpha= 0.73 ; mean = 52.14; Variance = 20.20; SD = 4.49
After 12 mo---Alpha =0.79; mean = 56.77; Variance = 22.06; SD = 4.70

Table 18 Correlation of each subscale item with its own scale (Bold) and with the other scales in pre test, after six and 12 months

Satisfaction scale item (∝ at pre test/after 6 mo)	Communication and Management			Accessibility and convenience			Finance		
	Pre test	After 6 mo	After 12 mo	Pre test	After 6 mo	After 12 mo	Pre test	After 6 mo	After 12 mo
Communication and management (∝ = 0.39/ 0.52/0.58)									
1. You felt satisfied with pharmacist's explanation of using medications and life style modification. (+)	**0.47**	**0.62**	**0.64**	0.07	0.15	0.22	0.22	0.35	0.29
2. You understood how to use medications and life style modification better after talking to a pharmacist. (+)	**0.51**	**0.52**	**0.61**	0.04	0.11	0.17	0.21	0.30	0.27
3. Sometimes a pharmacist makes you wonder if her/his advice is correct.(-)	**0.58**	**0.70**	**0.67**	0.24	0.34	0.26	0.17	0.24	0.26
4. A pharmacist did not pay attention to your complaining about disease problems. (-)	**0.65**	**0.60**	**0.69**	0.41	0.27	0.18	0.36	0.26	0.12
5. You intend to follow the details of this pharmacist's advice. (+)	**0.48**	**0.51**	**0.47**	0.06	0.08	0.20	0.31	0.35	0.43
Accessibility and convenience									
6. You have not received easy access to see a pharmacist. (-)	0.35	0.36	0.33	**1.00**	**1.00**	**1.00**	0.27	0.27	0.41
Finance (∝ = 0.16/ 0.63/0.64)									
7. Although you have extra expense to see a pharmacist, you receive more benefits.(+)	0.27	0.43	0.35	-0.03	0.24	0.29	**0.66**	**0.85**	**0.86**
8. You felt the benefit received was not reasonable compared to the time spent. (-)	0.41	0.41	0.34	0.38	0.22	0.41	**0.81**	**0.86**	**0.86**
Interpersonal relationship (∝ = 0.54/ 0.40/0.68)									
9. A pharmacist took care of you very much in medication use and life style modification. (+)	0.39	0.32	0.52	0.12	0.19	0.20	0.39	0.34	0.37
10. You felt better after talking to a pharmacist about medication use and life style modification. (+)	0.34	0.37	0.27	0.13	0.20	0.19	0.41	0.34	0.28
11. A pharmacist should smile, greet and talk more to a patient.(-)	0.12	0.01	0.36	0.11	0.12	0.36	0.11	0.01	0.26
12. A pharmacist ignored what you to tell him/her.(-)	0.33	0.37	0.43	0.36	0.32	0.28	0.44	0.27	0.26
13. A pharmacist was pleased to listen to your problems not only on hypertension. (+)	0.24	0.34	0.46	0.00	0.09	0.19	0.26	0.46	0.33
Continuity of care (∝ = -0.53/ -0.71/-0.23)									
14. You felt warm to see any pharmacist. (+)	0.39	0.33	0.36	0.15	0.11	0.29	0.26	0.32	0.44
15. If it is possible, you would like to see the same pharmacist.(-)	-0.11	0.28	-0.09	0.03	-0.10	-0.05	-0.09	0.33	-0.08
Overall satisfaction									
16. In conclusion, you felt satisfied with the pharmacy service of medication use and life style modification. (+)	0.24	0.41	0.46	0.02	0.16	0.17	0.25	0.45	0.32

Table 18 (cont.) Correlation of each subscale items with its own scale (Bold) and with the other scales in pre test, after six and 12 months

Satisfaction scale item (∝ at pre test/after 6 mo)	Interpersonal relationship			Continuity of care			Overall satisfaction		
	Pre test	After 6 mo	After 12 mo	Pre test	After 6 mo	After 12 mo	Pre test	After 6 mo	After 12 mo
Communication and management (∝ = 0.39/ 0.52/0.58)									
1. You felt satisfied with pharmacist's explanation of using medications and life style modification. (+)	0.29	0.30	0.40	0.16	0.25	0.09	0.22	0.32	0.51
2. You understood how to use medications and life style modification better after talking to a pharmacist. (+)	0.24	0.25	0.40	0.05	0.19	0.80	0.24	0.30	0.50
3. Sometimes a pharmacist makes you wonder if her/his advice is correct.(-)	0.13	0.24	0.37	0.01	0.12	0.08	0.05	0.13	0.14
4. A pharmacist did not pay attention to your complaining about disease problems. (-)	0.27	0.26	0.40	0.11	0.14	-0.03	0.02	0.22	0.24
5. You intend to follow the details of this pharmacist's advice. (+)	0.35	0.32	0.26	0.09	0.36	0.23	0.25	0.32	0.18
Accessibility and convenience									
6. You have not received easy access to see a pharmacist. (-)	0.25	0.32	0.38	0.12	0.11	0.12	0.02	0.16	0.17
Finance (∝ = 0.16/ 0.63/0.64)									
7. Although you have extra expense to see a pharmacist, you receive more benefits.(+)	0.25	0.39	0.36	-0.06	0.30	0.15	0.22	0.52	0.26
8. You felt the benefit received was not reasonable compared to the time spent. (-)	0.48	0.38	0.38	0.15	0.25	0.15	0.17	0.26	0.28
Interpersonal relationship (∝ = 0.54/ 0.40/0.68)									
9. A pharmacist took care of you very much in medication use and life style modification. (+)	**0.63**	**0.60**	**0.67**	0.10	0.39	-0.00	0.51	0.31	0.64
10. You felt better after talking to a pharmacist about medication use and life style modification. (+)	**0.62**	**0.58**	**0.52**	0.05	0.39	0.04	0.48	0.36	0.35
11. A pharmacist should smile, greet and talk more to a patient.(-)	**0.53**	**0.50**	**0.74**	0.15	-0.04	0.00	0.09	0.01	0.22
12. A pharmacist ignored what you to tell him/her.(-)	**0.64**	**0.53**	**0.73**	0.14	0.26	0.00	0.17	0.20	0.36
13. A pharmacist was pleased to listen to your problems not only on hypertension. (+)	**0.61**	**0.62**	**0.71**	0.09	0.35	0.10	0.34	0.32	0.46
Continuity of care (∝ = -0.53/ -0.71/-0.23)									
14. You felt warm to see any pharmacist. (+)	0.42	0.41	0.41	**0.43**	**1.00**	**0.46**	0.48	0.35	0.27
15. If it is possible, you would like to see the same pharmacist.(-)	-0.08	-0.27	-0.21	**0.79**	**-0.26**	**0.83**	-0.20	-0.29	-0.14
Overall satisfaction									
16. In conclusion, you felt satisfied with the pharmacy service of medication use and life style modification. (+)	0.49	0.28	0.55	0.12	0.35	0.03	**1.00**	**1.00**	**1.00**

3. SF-36

Internal consistency

Table 19 shows the evaluation of internal consistency at the pre test, after six and 12 months by Cronbach's alphas which were high and acceptable in physical function, role physical, bodily pain, social function, role emotional and mental health at the pre test, after six and 12 months, alpha >0.50 (Ware et al., 1993). Interestingly, the alphas were quite low in the subscales which had negatively worded questions which were in general health and vitality subscales, <0.50. A rewording of these questions should be done and then further evaluated.

Table 19 Results of internal consistency in each subscale at the pre test after six and 12 months

SF-36 scales	No of items	Times	Mean ± SD		Cronbach's alpha
			Treatment gr.	Control gr.	
Physical function	10	Pre test	63.36 ± 21.16	63.36 ± 22.42	0.84
		After 6 mo	66.92 ± 20.35	62.97 ± 24.17	0.86
		After 12 mo	67.86 ± 22.00	60.58 ± 24.39	0.86
Role physical	4	Pre test	50.21 ± 36.76	47.01± 36.28	0.72
		After 6 mo	49.33 ± 39.49	45.91 ± 40.24	0.82
		After 12 mo	56.88 ± 39.51	42.92 ± 37.72	0.79
Bodily pain	2	Pre test	52.29 ± 17.77	52.86 ± 20.65	0.69
		After 6 mo	56.03 ± 15.07	54.87 ± 16.02	0.55
		After 12 mo	60.16 ± 20.41	54.27 ± 18.61	0.74
General health	5	Pre test	43.56 ± 17.14	47.59 ± 17.76	0.46
		After 6 mo	47.63 ± 16.50	45.03 ± 14.84	0.42
		After 12 mo	47.56 ± 15.42	45.89 ± 17.74	0.43
Vitality	4	Pre test	56.44 ± 16.40	55.98 ± 15.05	0.33
		After 6 mo	58.97 ± 17.02	56.42 ± 16.74	0.44
		After 12 mo	60.92 ± 17.68	58.50 ± 17.24	0.32
Social function	2	Pre test	74.77 ± 19.20	71.47 ± 19.20	0.41
		After 6 mo	72.54 ± 18.90	69.61 ± 19.31	0.59
		After 12 mo	74.08 ± 19.37	69.91 ± 16.92	0.63
Role emotional	3	Pre test	36.49 ± 41.57	42.17 ± 42.07	0.82
		After 6 mo	41.96 ± 43.09	39.94 ± 41.29	0.82
		After 12 mo	49.54 ± 40.98	35.40 ± 39.91	0.78
Mental health	5	Pre test	63.39 ± 16.81	63.11 ± 16.91	0.61
		After 6 mo	63.14 ± 16.16	62.52 ± 15.23	0.61
		After 12 mo	65.21 ± 16.56	64.00 ± 17.74	0.74

APPENDIX III

PUBLICATIONS AND PRESENTATIONS

1. An article for Indochina conference during 20-23 May 2003 in Bangkok, Thailand

HYPERTENSIVE PATIENTS' SATISFACTION WITH PHARMACY SERVICES

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Abstract

The satisfaction with the pharmacy services provided by the primary care unit in a provincial hospital was assessed during a 3 month period 10 October 2002 to 10 January 2003. One hundred and eighteen hypertensive patients gave their informed consent. Patients were asked to complete an interview pro forma which was developed to provide a fixed-format of 16 statements by 6 trained interviewers. It was designed to obtain their opinions about pharmacy services on each clinic visit. The principle points of the survey dealt with the general perception of care received, communication and management, accessibility and convenience, finance, interpersonal relationships and continuity of care. The reliability of the questionnaire was tested (Cronbach's alpha = 0.69). In General hypertensive patients were satisfied with the pharmaceutical services provided, except that they would prefer to see the same pharmacist on every visit and would appreciate the pharmacists being more easily approachable by the patients.

Keywords: patient satisfaction, hypertensive patients, pharmacy services

Introduction

Patient satisfaction is one component of quality of care (Donabedian, 1980) and can also serve as a predictor of health-related behaviour (Pasco, 1983). Measuring patient satisfaction was the most important outcome measure about health services according to patients who evaluated those services (Williams, 1994). There are many concepts of patients' satisfaction with pharmaceutical care. Nau (1997) showed that patients who perceived benefit and value form pharmaceutical care showed enhanced satisfaction and returned for more services.

There was concern about the quality of care provided for chronically ill patients who frequently used hospital services, since cardiovascular disease was the most important cause of death in Thailand. The problems which occurred in these patients were closely related to their medications. Medication problems can be

minimized by pharmacists. Traditionally, pharmacists have dispensed prescribed medications but currently pharmacists also have an important role in the health care team providing pharmaceutical care to patients to help them use their medication effectively and safely. However, since providing pharmaceutical care was quite new for Mahasarakham hospital, we planned to investigate patients' opinions about the pharmaceutical care they received.

There have been many studies of patient satisfaction of medical care and some have specifically investigated pharmacy services. MacKeigan and Larson (1989) developed and validated a survey of patient satisfaction with pharmaceutical services using telephone interviews. The questionnaire used 33 statements to measure seven dimensions of satisfaction. Prior to this current investigation a satisfaction survey that was useful for face-to-face interviews had not been developed for pharmaceutical services. Our study aimed to develop a 16-item interview document by questioning respondents in order to rate specific features of the pharmaceutical services received in the hypertensive clinic at Mahasarakham Hospital.

Experimentals

This study was approved by the Ethics Review Committee, the Faculty of Pharmacy Chiang Mai University, 9 September 2002.

Phase I –development of the instrument

The interview pro forma was constructed by using the concept of satisfaction as an effect-based assessment (Shommer, 1997). Pro forma development was influenced by previous studies (Shommer, 1997 and Talbot, 1995). Multi-item scales were produced because they were more reliable than single questions (Ware, 1978). Six domains were selected to cover the pharmacy services available in Thailand. These were, communication and management, accessibility and convenience, finance, interpersonal relationships and overall satisfaction. Survey items were selected based on previous studies and 16 items were included in the pro forma. There were 7 negatively worded statements and 9 positively worded statements to reduce the inherent response set bias of the questionnaire (Risser, 1975). A 4 choice Likert evaluation scale was selected in order to make respondents decide for or against the statement and so prevent the easy option of saying they don't have an opinion. The scale was scored as Strongly Agree/Agree/Disagree/Strongly Disagree. Items for which agreement was considered desirable were scored with a 4 for "Strongly Agree" and a 1 for "Strongly Disagree." Items for which disagreement was considered to be desirable were scored in the opposite direction. Therefore a "desirable" score on each item was represented by a high numerical score.

Factor analysis was not used; however, there was evidence of content validity and reliability. Content validity was performed by submitting the 18 questions to 7 experts 5 of whom were involved in the pharmacy field and 2 were involved in health science. The experts rated each statement as to whether it was directly associated with pharmaceutical care and with what the study was designed to measure. A pilot test was performed in order to adjust the readability and understandability of the questionnaire. Sixteen hypertensive patients were interviewed on 3 consecutive visits to the hypertensive clinic at Mahasarakham Hospital. Cronbach's alpha was calculated.

Six interviewers, 2 nurses and 4 PharmD students were trained and tested in the steps of interviewing to avoid pitfalls and to understand the meaning of each question based on the method described by Guenzel (1983).

Phase II -patient selection and study sites

The interviews took place in the area outside each patient's house during 10 October 2002 to 10 January 2003. The addresses were pulled from the hospital computer database.

All 118 patients enrolled in the study were previously diagnosed with hypertension.

That is they were taking antihypertensive medications or had a systolic blood pressure equal or exceeding 140 mm Hg or a diastolic blood pressure equal or exceeding 90 mm Hg. All patients completed an informed consent form.

Phase III -Survey administration and data collection

The survey package consisted of a description of the procedure to be followed in conducting the pro forma and the objective of the study. The samples were divided into 6 groups by the location of their houses and each interviewer interviewed one group.

Data Analysis

The pro forma was assessed using Cronbach's alpha to determine the consistency of the statements. Continuous data were reported as means $\pm$ SD.

Results and discussion

The age range of the study group was 40.8 to 86.0 years. The mean age was 63.2 ± 9.5 years.

Pilot study

Content Validity

The content validity of the 18 items pro forma was assessed as in Table 1. Four domains were shown to be in the level of 'very relevant and succinct', and other 3 domains were in the level of 'relevant but needs minor alteration'. The wording of each statement was also rated for readability and understandability. One expert recommended that the time taken in relation to the value which patients received should be indicated consequently. The statements in the domain of 'time spent' were altered to include an estimate of the time spent in relation to the value the patient received. This new statement was classified in the financial aspect domain. So the 18 items were reduced to 16 items in this pro forma.

Table 1. Content validity in domains from the interview pro forma

Domains Item [a]	sample[b] Mean [c]± SD
General Satisfaction	3.28 ± .49
Time spent	3.07 ± .73
Accessibility and convenience	3.57 ± .53
Financial aspect	3.71 ± .49
Communication and management	3.54 ± .63
Interpersonal relationship	3.46 ± .70
Continuity of care	3.64 ± .50

[a] a 4 rating scale (1= not relevant, 2= unable to assess relevance without item revision, or item is in need of such revision that it would no longer be relevant, 3 = relevant but needs minor alteration, 4 = very relevant and succinct)

[b] seven experts rated the relevant to the objectives of the study.

[c] relevant level (1.00-1.50 = not relevant, 1.51-2.50 = unable to assess relevance without item revision, or item is in need of such revision that it would no longer be relevant, 2.51-3.50 = relevant but needs minor alteration , 3.50-4.00 = very relevant and succinct)

Reliability

The pro forma was tested for reliability. Cronbach's alpha was 0.66 in 16 respondents as shown in table 2.

Table 2. Domains and items from the interview pro forma (Pilot study)		
Satisfaction Scale Item [a]	Sample[b] Mean [c] ± SD	Coefficient alpha when an item is deleted
Communication and management	**3.04 ± .44**	
1. You felt satisfied with pharmacist's explanation of using medications and life style modification. (+)	3.30 ± .49	0.64
2. You understood how to use medications and life style modification better after talking to a pharmacist. (+)	3.33 ± .49	0.63
3. Sometimes a pharmacist makes you wonder if her/his advice is correct.(-)	2.64 ± .50	0.68
4. A pharmacist did not pay attention to your complaining about disease problems. (-)	2.42 ± .74	0.70
5. You intend to follow the details of this pharmacist's advice. (+)	3.40 ± .51	0.61
Accessibility and convenience	**2.67 ± .82**	
6. You have not received easy access to see a pharmacist. (-)	2.67 ± .82	0.66
Finance	**3.00 + .28**	
7. Although you have extra expense to see a pharmacist, you receive more benefits.(+)	3.20 ± .41	0.63
8. You felt the benefit received was not reasonable compared to the time spent. (-)	2.80 ± .77	0.64
Interpersonal relationship	**2.97 ± .60**	
9. A pharmacist took care of you very much in medication use and life style modification. (+)	3.33 ± .62	0.59
10. You felt better after talking to a pharmacist about medication use and life style modification. (+)	3.46 ± .52	0.60
11. A pharmacist should smile, greet and talk more to a patient.(-)	2.06 ± .70	0.70
12. A pharmacist ignored what you to tell him/her.(-)	2.64 ± .75	0.65
13. A pharmacist was pleased to listen to your problems not only on hypertension. (+)	3.36 ± .50	0.57
Continuity of care	**2.60 ± .84**	
14. You felt confident to see any pharmacist. (+)	3.20 ± .41	0.65
15. If it is possible, you would like to see the same pharmacist.(-)	2.00 ± .65	0.73
Overall satisfaction	**3.40 ± .51**	
16. In conclusion, you felt satisfied with the pharmacy service of medication use and life style modification. (+)	3.40 ± .51	0.61

[a] A 4-point scale (4 = strongly agree, 3 = agree, 2 = disagree, 1 = strongly disagree)
[b] Sample included 118 patients.
[c] Satisfaction level (1.00-1.50 = strongly dissatisfied, 1.51-.2.50 = dissatisfied, 2.51-3.50 = satisfied, 3.51-4.00 = strongly satisfied)
- negatively worded item
+ positively worded item.

Main study

Interview questions

The reliability test with the 16 patients of the pilot study and 118 patients of the main study gave the same Cronbach's alpha of 0.69. Most of the items were in the satisfied group except the 3 rd, 11 th and 15th items (Table 3).

Table 3. Domains and items from the interview pro forma

Satisfaction Scale Item [a]	Mean [c] ± SD	Coefficient alpha when an item is deleted
Communication and management	**3.04 ± 0.44**	
1. You felt satisfied with pharmacist's explanation of using medications and life style modification. (+)	3.30 ± .51	0.67
2. You understood how to use medications and life style modification better after talking to a pharmacist. (+)	3.36 ± .48	0.68
3. Sometimes a pharmacist makes you wonder if her/his advice is correct.(-)	2.50 ± .68	0.70
4. A pharmacist did not pay attention to your complaining about disease problems. (-)	2.62 ± .76	0.68
5. You intend to follow the details of this pharmacist's advice. (+)	3.43 ± .51	0.68
Accessibility and convenience	**2.92 ± .72**	
6. You have not received easy access to see a pharmacist. (-)	2.92 ± .72	0.67
Finance	**3.07 ± .13**	
7. Although you have extra expense to see a pharmacist, you receive more benefits.(+)	3.16 ± .58	0.71
8. You felt the benefit received was not reasonable compared to the time spent. (-)	2.98 ± .58	0.66
Interpersonal relationship	**3.05 ± .50**	
9. A pharmacist took care of you very much in medication use and life style modification. (+)	3.36 ± .55	0.65
10. You felt better after talking to a pharmacist about medication use and life style modification. (+)	3.40 ± .53	0.65
11. A pharmacist should smile, greet and talk more to a patient.(-)	2.19 ± .69	0.65
12. A pharmacist ignored what you to tell him/her.(-)	3.03 ± .58	0.68
13. A pharmacist was pleased to listen to your problems not only on hypertension. (+)	3.27 ± .53	0.66
Continuity of care	**2.67 ± 1.07**	
14. You felt confident to see any pharmacist. (+)	3.42 ± .51	0.65
15. If it is possible, you would like to see the same pharmacist.(-)	1.91 ± .71	0.74
Overall satisfaction	**3.42 ± .54**	
16. In conclusion, you felt satisfied with the pharmacy service of medication use and life style modification. (+)	3.42 ± .54	0.66

[a] A 4-point scale (4 = strongly agree, 3 = agree, 2 = disagree, 1 = strongly disagree)
[b] Sample included 118 patients.
[c] Satisfaction level (1.00-1.50 = strongly dissatisfied, 1.51-.2.50 = dissatisfied, 2.51-3.50 = satisfied, 3.51-4.00 = strongly satisfied)
- negatively worded item
+ positively worded item.

Our study demonstrated patient satisfaction with all domains but there were 3 statements which demonstrated patient dissatisfaction. It can be seen from Table 3 that the reliability coefficient was higher when the 15th statement was deleted.

The pro forma constructed in the study showed 'very relevant' from 4 domains and 'relevant' from 3 domains by 7 experts and also showed acceptable reliability both in the pilot test and in the main study (Cronbach's alpha = 0.69 and 0.69, respectively). This is a lower value than expected for a sample of 118 patients when compared to that obtained with 16 patients in the Pilot study. It may be related to the comparative high ages of the patients in this study, which could have led to poor understanding and the rather inconsistent opinions expressed. Although it has been reported (Larson, 1994, Sitzia, 1997, Fitzpatrick, 1991) that there is a minimal

relationship between age and satisfaction when tested using a Likert scale. The desirable level of coefficient alpha was set at a minimal of 0.50 (Larson and MacKeigan, 1994) although others have quoted higher values 0.800 (Edwards, 1970) and 0.637 (Risser, 1975). From the data above, it was concluded that this pro forma reflected the patient satisfaction with pharmacy services.

The means of negatively worded statements were quite low compared to the positively worded ones. The method using negatively worded statements may not be practical to use with elderly Thai people. Nevertheless, many studies have used this method (Monica, 1986, Risser, 1975). All interviewers complained that they had to take a considerable time to explain the exact meaning of the negatively worded statements.

The 15th statement was negatively worded and might have confused the respondents. Most of the respondents explained that normally pharmacist duties were rotated, so it was impossible to see the same pharmacist on each visit. Some patients expressed the preference to see the same pharmacist on each visit because they thought that would mean the pharmacist would know more about their personal condition. The other 2 negatively worded statements were those which showed dissatisfaction with the certainty of the pharmacist's advice and the pharmacist's relationship to patients. Overall the data showed a high level of satisfaction which indicated a good standard of service. However, statement 3, 11 and 15 reflected that the service may not adequately satisfy some patient needs. This may reflect on continuity of care aspects in that patients might not return for pharmacy services. To the statement "sometimes pharmacists made patients wonder if their advice was correct", one respondent replied that one pharmacist advised to them to take medication before meals, but another pharmacist advised them to take the medication after meals. This confused her. For the statement "pharmacists should smile, greet and talk more to patients", most of the respondents said that pharmacists were too busy to talk with them more than explaining the medication label. To the statement "if it is possible, patients would like to see the same pharmacist", most of the respondents thought that this would be an advantage because the same pharmacist would understand the progress of their disease better than seeing a different pharmacist. This last area had the strongest feelings of dissatisfaction expressed by the patients.

The responses obtained ranged between dissatisfied to satisfy with the services provided by the pharmacists. Even though most of the pharmacy services provided in the primary care units were limited to dispensing medication, patients in general were satisfied with the pharmacy services. This is similar to the results of other studies that indicated that patients were satisfied with the pharmacy services (Liu, 1999, Nau, 1997). This satisfaction was mostly due to the whole service provided in the clinic including that of physicians, nurses and waiting time involved. Such satisfaction may be related to the fact that most patients did not have a clear understanding of the ideal pharmacy service, especially in relation to optimizing medication usage. In some points, patients may have been afraid to answer negatively due to the face-face method of collecting the data. These factors may also have been a factor in the low Cronbach's alpha coefficient.

The limitations of the study were considered to be as follows. This study only sampled a specific group of hypertensive patients in order to develop a further study relating to the pharmaceutical care provided to this group of patients. As such, the study design and objectives limited the possibility of generalizing the findings to other

patients groups and other care settings. The results, however, do provide useful information of the opinions of a group of hypertensive patients' about pharmaceutical services and this group represents the largest patient group in Mahasarakham (Satayawongtip, 2002).

Pharmaceutical care in primary care units was not routinely performed by pharmacists due to the lack of time and personnel. Normally, pharmacists worked in the primary care units in health centers for only 2 half-days a week. At every interview, the interviewers had to explain to the patient who the pharmacist was in order to assess the patients' view of the pharmacist by means of the interview. This also may have affected the
Cronbach's alpha value obtained.

Conclusion

Hypertensive patients in Mahasarakham were generally satisfied with the pharmaceutical services provided, except that they would have preferred to see the same pharmacist on every visit and would appreciate the pharmacists being more easily approachable by the patient. Sometimes the patients may have had a lack of confidence in the pharmacist due to different instructions being given by different pharmacists. These matters need to be addressed and steps taken to rectify the deficiencies in pharmaceutical services.

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2. A poster presentation for ICIUM international conference at Chiang Mai, Thailand during 30 March -2 April 2004

Can pharmacists improve outcomes in hypertensive patients?

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Abstract

Problem Statement: Hypertension is an asymptomatic chronic condition that is strongly associated with cardiovascular complications such as stroke, myocardial infarction, angina, nephropathy, peripheral arterial disease, and retinopathy. It is reported in the literature that 5 mm Hg reduction in diastolic blood pressure can reduce the risk of stroke by 35%-40%, and of coronary heart disease by 20%-25%. **Objective**: To evaluate the effect of pharmacist involvement with hypertensive patients in community pharmacies and in primary care units. **Design**: Randomized, pre- post-test control group design. Analysis of covariance, multiple logistic regression and chi-square test were used to analyze blood pressure results. The p value was set at < 0.05. **Setting and Population**: Mahasarakham University pharmacy, 1 kilometer from the provincial hospital, and 2 primary care units, located in an area 3 kilometers around the University. Hypertensive patients were randomly assigned to a treatment group (pharmacist involved) or a control group (no pharmacist involved). There were 235 eligible patients (118 treatment and 117 control). **Intervention**: Individualized care by the research pharmacist monitoring blood pressure in the treatment group every month; education materials; assessment of adherence to treatment; dealing with drug related problems; and providing non pharmacological treatment. If the research pharmacist found the drug related problems, the patient would be referred to a doctor in the hospital. **Outcome measures**: Blood pressure at pre-test and post-test periods. The study began in October 2002 and ended at the end of July 2003. **Results**: From the total number of 235 patients, the 'pharmacist involved group' had a significant reduction in both SBP (p=0.037) and DBP (p=0.027) when compared with the 'no pharmacist involved group'. The results were similar for 158 patients who had high blood pressure at the beginning of the study (p=0.002 and 0.008, for SBP and DBP, respectively). The logistic regression also confirmed that the patients were more controlled in the 'pharmacist involved group' than in the 'no pharmacist involved group' (odds ratio = 1.849, in SBP). The 'no pharmacist involved group' also showed a significant improvement in blood pressure over the study period but the 'pharmacist involved group' had a significantly better reduction in blood pressure. **Conclusions**: Our results indicate a definite benefit to hypertensive patients outcomes from the involvement of a pharmacist in their care in the primary care setting. This should result in a significant increase in the life expectancy of this group of patients.

Background and setting

Hypertension is an asymptomatic chronic condition associated with cardiovascular complications such as stroke, myocardial infarction, angina, nephropathy, peripheral arterial disease and retinopathy.

It is considered that pharmacists are critical to the success of programs designed to improve blood pressure control rates (ASHP report, 2000). In fact it has been shown more than 25 years ago that community pharmacists can have an important role in assisting primary care physicians in managing patients with hypertension (McKenney et al., 1973, Carter BL, 1997).

Several studies showed that clinical pharmacist services are effective in the treatment of hypertension, as demonstrated by improvements in patients' knowledge, compliance with medication regimens and blood pressure measurements. (Monson R et al, 1981, Morse GD et al, 1986, Cookson T et al, 1997, Erickson SR et al, 1997 and Solomon DK et al, 1998).

Study question

- **Can pharmacists improve outcomes in hypertensive patients?**

Methods

- Design: randomized, pre- post- test control group design
- Setting and population: 1 Mahasarakham University Pharmacy and 2 primary care units. The patients were randomly assigned to a treatment group and a control group.
- Intervention: Individualized care by the research pharmacist monitoring blood pressure in the treatment group every month; education materials; assessment of adherence to treatment; dealing with drug related problems; and providing non pharmacological treatment. If the research pharmacist found the drug related problems, the patient would be referred to a doctor in the hospital.
- Outcome measure: blood pressure at pre-test and post-test period (6 months)
- Analysis: analysis of covariance for the blood pressure difference between groups, Paired t test for the comparison between pre and post test, Multiple logistic regression for the controlled blood pressure difference between groups, Chi square for characteristic baseline comparison between groups

Results

- There were 235 patients included in the study and there were 158 patients who had high blood pressure during the pre test period.
- Results of randomization in all variables showed no different between the control and treatment group as shown in Table 1.
- After 6 months, the mean of blood pressure reduced in both groups as in Table 2, but there was more reduction in the treatment group. When comparing between treatment and control group, we found that the treatment group showed reductions in both systolic and diastolic blood pressures compared to the control group shown in Table 3.
- The treatment group showed more control only in systolic blood pressure. In 158 patients who had high blood pressure during the pre test, the treatment group showed more control both in systolic and diastolic blood pressure as shown in Table 4.

Table 1 Homogeneity of demographic variables between groups at the baseline (N = 235 patients)

Demographic variables	Treatment group (n=118)	Control group (n=117)	P value	exp (b)
Sex			0.224	
Men	42	33		
Women	76	84		
Age, mean (SD)	63.20 (9.33)	63.23 (9.25)	0.982	
Career			0.695	
Business	21	19		
Government employee	9	12		
Farmer	31	30		
Business employee	5	2		
Retired employee	9	0		
No career (home maid)	51	53		
Education			0.229	
No education	1	2		
Primary school	83	81		
Secondary school	22	17		
Pre bachelor degree	4	2		
Bachelor degree or higher	8	15		
Marital status			0.130	
Widow	32	37		
Divorce	7	2		
Married	76	70		
Single	3	8		
SBP, mean (SD)	144.76 (19.69)	143.41 (19.81)	0.600	
DBP, mean (SD)	85.72 (13.56)	85.96 (12.94)	0.889	
SBP/DBP*			0.537/ 0.398	0.837/ 1.248
Controlled HT	32/64	36/57		
Uncontrolled HT	86/54	81/60		
Total	118/118	117/117		
SBP/DBP**			0.398/ 0.576	1.248/ 0.822
Controlled HT	5/21	7/26		
Uncontrolled HT	71/55	75/56		
Total	76/76	82/82		

HT= hypertension, *Controlled or uncontrolled definition followed JNC VI, ** in the sample of 158 patients who had high blood pressure level, > 140/90 mm Hg, during the pre test

Table 2 Blood pressure means in the pre test and post test periods

Variable	Treatment group Mean (SD)	Control group Mean (SD)
N = 235		
Pre test		
SBP	144.76 (19.69)	143.40 (19.81)
DBP	85.72 (13.56)	85.96 (12.94)
Post test		
SBP	121.47 (14.90)	124.77 (17.97)
DBP	71.55 (10.80)	74.23 (11.87)
Paired difference		
SBP	23.29 (19.10)	18.64 (17.67)
DBP	14.18 (11.20)	11.73 (10.08)
N = 158		
Pre test		
SBP	155.19 (15.51)	152.19 (16.17)
DBP	90.47 (13.85)	89.73 (12.96)
Post test		
SBP	124.16 (14.23)	130.36 (16.83)
DBP	73.08 (10.68)	76.52(12.35)
Paired difference		
SBP	26.26 (18.14)	21.83 (17.84)
DBP	15.22 (10.95)	13.22 (10.37)

Table 3 Results of the analysis of covariance model evaluating the effect of pharmacist involvement on the blood pressure of hypertensive patients after 6 months

	treatment group	control group	p value*
N=235			
SBP post test	124.16 (14.23)**	130.36 (16.83)**	0.037
DBP post test	73.08 (10.68)**	76.52 (12.35)**	0.027
N = 158			
SBP post test	121.47 (14.90)**	124.77 (17.97)**	0.002
DBP post test	71.55 (10.80)**	74.23 (11.87)**	0.008

•p value of the analysis of covariance use pre test as a covariate

** means significant difference (p = 0.000)

Table 4 Blood pressure differences between no pharmacist involved and pharmacist involved groups at the pre test period and the post test period (after 6 months)

Variables	p	exp(b)	CI(odds)
N = 235			
SBP			
Treatment group(1)	0.044	1.849	1.017-3.363
SBP pretest	0.000	6.436	2.611-15.862
DBP			
Treatment group(1)	0.088	1.852	0.912-3.762
DBP pretest	0.000	5.219	2.363-11.530
N = 158			
SBP			
Treatment group(1)	0.012	2.387	1.214-4.693
SBP pretest	0.050	8.122	1.004-65.685
DBP			
Treatment group(1)	0.033	2.208	1.066-4.573
DBP pretest	0.003	4.311	1.662-11.186

CI = confidence interval of 95%, exp (b) = odds ratio

Summary

- Our results indicate a definite benefit to hypertensive patients outcomes from the involvement of a pharmacist in their care in the primary care setting. This should result in a significant increase in the life expectancy of this group of patients.

Discussion

- Blood pressure reduction in both groups were reduced significantly. That might be because this time of the study was the time of good heart good health of the province. There were many activities such as group exercise, health education and some trips outside the province for hypertensive patients.
- We showed the results of 2 groups of total eligible patients, 235, and high blood pressure at the pre test period, 158. Pharmacists can help hypertensive patients to have better control and more reduction in blood pressure especially in the high blood pressure sample which is supported by other studies.

Conclusions and recommendation

- Pharmacists have an important role in monitoring and providing care for chronic conditions such as hypertension to achieve more control in blood pressure. This applies especially the pharmacy where patients can easily be contacted.
- If possible, pharmacists should provide care for longer period of time to see the results on morbidity and mortality.

3. A publication in The Annals of Pharmacotherapy in December 2004

RESEARCH REPORTS

Hypertension

job no. RR D605
date

Pharmacist Involvement in Primary Care Improves Hypertensive Patient Clinical Outcomes

Phayom Sookaneknun, Robert ME Richards, Jaratbhan Sanguansermsri, and Chai Teerasut

BACKGROUND: The practice of pharmaceutical care in primary care settings in Thailand is currently not generally accepted.

OBJECTIVE: To evaluate the effect of pharmacist involvement in treatment with hypertensive patients in primary care settings.

METHODS: The treatment objective was to stabilize the blood pressure (BP) of hypertensive patients in accordance with the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure guidelines. Patients were randomly assigned to a pharmacist-involved group (treatment) or a group with no pharmacist involvement (control). Pre- and post-test BPs, tablet counts, lifestyle modifications, and pharmacists' recommendations were recorded. The 6-month study was carried out in Mahasarakham University pharmacy and 2 primary care units. Patients were monitored monthly by reviewing their medications and supported by providing pharmaceutical care and counseling.

RESULTS: From a total of 235 patients, the treatment group (n = 118) had a significant reduction in both systolic (S) and diastolic (D) BP compared with the 117 patients of the control group (p = 0.037, 0.027, respectively). The 158 patients (76 treatment, 82 control) with BPs ≥140/90 mm Hg at the beginning of the study showed significant BP reductions (p = 0.002 SBP, 0.008 DBP). The proportion of 158 patients whose BP became stabilized was higher in the treatment group (p = 0.017). The treatment group showed significantly better adherence (p = 0.014) and exercise control (p = 0.012) at the end of the study. Physicians accepted 42.72% of medication modifications and 5.34% of the suggestions for additional investigations.

CONCLUSIONS: Hypertensive patients who received pharmacist input achieved a significantly greater benefit in BP reduction, BP control, and improvement in adherence rate and lifestyle modification.

KEY WORDS: blood pressure, hypertension, pharmaceutical care.

Ann Pharmacother 2004;38:xxxx.

Published Online, xx XXX 2004, *www.theannals.com*, DOI 10.1345/aph.1D605

Hypertension has a marked influence on stroke mortality and other cardiovascular problems.[1] Blood pressure (BP) reductions maintained for a number of years, especially systolic blood pressure (SBP) reductions, have been reported to be associated with 30% and 23% reductions in the number of strokes and coronary events, respectively.[2] Several investigations have shown the benefit of BP reduction or BP control in reducing the risk of cardiovascular morbidity and mortality.[3-6] Previous studies have shown that introducing pharmaceutical care to hypertensive patients improved the patients' BP control and adherence.[7-9]

Pharmaceutical care is defined as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life."[10] This type of care for hypertensive patients in a primary care setting has not previously been undertaken in Thailand. The study presented here was unique in this respect. The purpose of the study was to evaluate the clinical outcomes for patients being treated for hypertension resulting from introducing pharmaceutical care through a community pharmacy and in 2 primary care units (PCUs).

Methods

STUDY SITE

The study was carried out in Mahasarakham University community pharmacy, near Mahasarakham Hospital in the center of the provincial capital, and in 2 primary care units in Takonyung and Kharmrieng vil-

Author information provided at the end of the text.

A poster describing this work was presented at the ICIUM Conference in Chiang Mai, Thailand, March 30–April 2, 2004.

The project was supported by a research grant from Chiang Mai University, Thailand.

lages. The community pharmacy served a city area, and the primary care units served rural areas located in an area of about 3 km around Mahasarakham University.

The healthcare workers in the PCUs consisted of 2 groups. The first group rotated twice a month and consisted of a physician, a nurse, and a pharmacist from the hospital. These 2 clinic visits provided rural patients treatment equivalent to that provided to city patients by the outpatient department of the hospital. The other group of healthcare workers practicing in the PCUs worked in the PCUs every day. This group, in each PCU, usually consisted of a nurse who had qualified after 4 years of study, another nurse who had a 2-year qualification, and 2 nurses who had 1.5 years of nursing qualification plus a bachelor's degree in public health or a related subject. These 4 individuals provided nursing care and medication for common diseases and referred severe cases to the hospital. A fifth person was involved in a clerical capacity in the day-to-day organization of each PCU. The research pharmacist provided pharmaceutical care in the morning and evening for 3 days each week at the university community pharmacy and in the morning for 4 days each week in the PCUs. The pharmacists who attended the PCUs twice a month and those in the university pharmacy were not involved with caring for patients in the treatment group. Each patient in the treatment group was seen once a month. Occasionally, home visits were made in the afternoons to those few patients who missed their monthly appointment. At the pre- and post-tests, patients were separated to have their BP measured in a different area from the clinic treatment room of the hospital or the PCUs.

DESIGN

A randomized, pre-test, post-test, controlled group study was carried out between October 2002 and July 2003. The pre-test was undertaken from October through December 2002. We identified an initial sample of 235 patients from Mahasarakham Hospital. A simple randomization technique was used to assign the patients to a treatment group and a control group. BP was measured using a sphygmomanometer.

The work was conducted in compliance with the requirements of the site's Institutional Review Board/Human Subjects Research Committee, and permission was granted by this committee to carry out the study.

PATIENT SELECTION

The databases from the hospital and 2 PCUs were screened for patients diagnosed as hypertensive. They could be men or women who were >18 years of age and who signed the informed consent form. The eligible patients could also be those who were newly diagnosed during the pre-test period and had the following criteria determined by reviewing their medical records: an average diastolic blood pressure (DBP) ≥90 mm Hg or an average SBP ≥140 mm Hg, hypertensive patients with diabetes having an average DBP ≥85 mm Hg or an average SBP ≥130 mm Hg, or patients receiving current therapy with antihypertensive drugs (controlled or uncontrolled BP).

Patients were excluded if they had secondary causes of hypertension, which were determined by a review of the patient's medical history and from their other diagnoses, if they were unwilling or unable to return to the PCUs or pharmacy for scheduled appointments, if they planned to move from the area during the study, if they had another family member enrolled in the study, if their SBP was >210 mm Hg or DBP was >115 mm Hg, or if they had a serious complicating disease that was so disabling that BP control was a secondary or minor consideration (terminal cancer, New York Heart Association Class III or IV congestive heart failure, end-stage renal disease, severe hepatic condition such as cirrhosis, uncontrolled angina pectoris, ventricular arrhythmia, dementia).

TREATMENT GROUP

Patients in the intervention group were monitored by the research pharmacist for 6 months (January–June 2003). The patients' BP was measured every month as scheduled by the research pharmacist. The measurements were performed in a separate room of the clinic in the morning between 0800 and 1200, as this was the normal time of the clinic. The technique for BP measurement followed established guidelines.[11,12] An adjustable level table top for patients to rest their arms on was used, and different sphygmomanometer cuff sizes were available to ensure the appropriate size for the arm of each patient. Each patient's pharmacy record consisted of the following: demographic data, clinical and therapeutic data, patient behavior, lifestyle, and BP record.

The controlled BP in hypertension without concomitant cardiovascular disease was defined as having a benchmark of ≤135/85 mm Hg because the conditions of BP measurement were similar to the conditions for self-measurement at home as stated in Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC-6) guidelines, and all other BP goals also followed JNC-6 guidelines.[12]

The patient consultation consisted of a 30–50 minute face-to-face interview. The research pharmacist assessed the patient's understanding of his or her medications, counseled on the use of their medications, assessed adherence and lifestyle habits, reviewed for adverse events due to drug-related problems, and discussed factors associated with uncontrolled BP and disease state control. This assessment was made from the written patient history and the interview. Drug-related problems were identified, resolved, and prevented. The pharmacist's recommendations for medication regimen changes after detecting drug-related problems were made to physicians, usually by letter from the university pharmacy to the hospital, but also by recording a note in the patient's medical record in the PCUs.

The research pharmacist also adopted a nonpharmacologic approach in providing relevant information and advice for each patient. This covered exercise, fatty diet, salty diet, smoking, alcohol, and weight reduction. The patient's record was updated monthly to include medication provided from the hospital and PCUs.

Educational leaflets and a diary to record lifestyle were presented during the patient's first visit. The leaflets and diary were developed by the research pharmacist. Areas covered were information about hypertension and possible complications, as well as the medicines used to treat hypertension, and a blank table to record notes each day on food eaten, medication taken, alcohol intake, exercise undertaken, and any unusual symptoms.

CONTROL GROUP

This group had no research pharmacist involvement. Control patients received the traditional service provided by the hospital or the PCUs.

BP measurement was performed at the pre- and post-test periods. The same method of BP measurement was used as in the intervention group.

DATA ANALYSIS

Sample size was calculated from the pilot test by using the formula of 2 groups of independent subjects. We set α at 0.05, β at 0.1 (power of 90%), and the effective size of SBP change at 10 mm Hg. The target size of the study sample was thus calculated to be 95 patients. An additional 30% was added to allow for patient drop-outs, making a total of 124 patients per group.

Statistical analysis was performed using SPSS 10.0. BP reduction between groups was determined using the analysis of covariance in the multiple regression model. If interactions were found, only those with clinical significance were included in the model. BP differences between the pre- and post-tests were analyzed by using the paired *t*-test and categorical data by using χ^2. Continuous variables in demographic data were analyzed using mean and standard deviations. The significance level was set at $p < 0.05$. BP controls, adherence rate controls, and clinical factors were analyzed by multiple logistic regression using the pre-test in the model.

Adherence rate was calculated by the number of medicines taken divided by the number supplied, multiplied by 100. A rate ≥80 was considered good adherence; <80 represented poor adherence.

Intent-to-treat represented the total numbers of patients recruited, that is, a total of 235 patients' BPs were included in the data analysis. Intent-to-treat was used as the basis for inclusion in the study to reduce the bias that would occur if patients who dropped out of the study were not included in the total numbers. Patients who dropped out were determined from the most recent data on the patient history card.

A Results

PATIENT CHARACTERISTICS

From the sample of 235 patients, 118 were allocated to the treatment group and 117 patients to the group where no pharmacist was involved (control). Eight patients dropped
B out during the study: 2 in the treatment group at pre-test and 3 at post-test, and a further 3 patients in the control group at the post-test. The baseline patient characteristics at the beginning of the study are shown in Table 1. The results of randomization of hypertensive patients into groups showed no significant differences in demographic variables and baseline BP between groups, that is, the 2 groups were equal in all variables.

C BLOOD PRESSURE CONTROL

At the beginning of the study, only 27 of 118 patients in the treatment group had both SBP and DBP controlled. This was not significantly different from the number in the control group, where 21 of 117 patients had their BPs controlled ($p = 0.349$). At the end of the study, BP was controlled in 78 patients in the treatment group and 67 in the control group. This represented a significant improvement in BP control in both groups compared with the pre-test results ($p < 0.001$). However, after 6 months, the proportion of patients with BP control was not significantly different between the groups ($p = 0.061$).

The data were also analyzed after excluding patients whose BP was controlled at values <140/90 mm Hg at the pre-test. This left 158 patients who had elevated BP at the pre-test. Of these, 76 were in the treatment group and 82 in the control group. At the end of the study, 46 patients in the treatment group had both SBP and DBP controlled. This compared with 34 patients in the control group, resulting in a significant difference between the groups ($p = 0.017$).

BLOOD PRESSURE DIFFERENCE

When comparing BPs at the 6-month follow-up visit with baseline, both the treatment and control groups showed significant decreases in SBP and DBP ($p < 0.001$) in both groups. These results are shown in Table 2.

Table 2 also shows the results for the total number of 235 patients and for the 158 patients who had higher BPs of at least 140/90 mm Hg at the beginning of the study. The results for the SBPs of the 235 patients show that, when the baseline SBP, the groups, and the interaction between these 2 variables were controlled, the treatment group experienced a significantly greater decrease in SBP at the 6-month follow-up than the control group. When the baseline DBP was used as the covariate, the treatment group showed a significantly greater decrease in DBP than the control group. In the population of 158 patients, the treatment group also showed a more significant decrease in both SBP and DBP. No significant interaction between baseline SBP or baseline DBP and patient group was found.

RESULTS OF PHARMACIST'S INTERVENTION

Table 3 shows the response to the pharmacist's recommendations to modify the medica-

Table 1. Homogeneity of Demographic Variables Between Groups at Baseline

Variable	Treatment Group (n = 118)	Control Group (n = 117)	p Value
Gender			0.224
men	42	33	
women	76	84	
Age, y (mean ± SD)	63.20 ± 9.33	63.23 ± 9.25	0.982
Disease (n)			0.474
hypertension	57	54	
hypertension with diabetes	39	45	
hypertension with target organ damage*	13	7	
hypertension with diabetes and target organ damage	9	11	

*Previous stroke, myocardial infarction, left ventricular hypertrophy, angina, congestive heart failure, transient ischemic attack, renal failure.

Table 2. Mean Blood Pressures and Paired Differences in Total Group vs Patients Hypertensive at Baseline*

BP Variable (mm Hg)	Total Group (mean ± SD)			Pts. Hypertensive at Baseline (mean ± SD)		
	Pharmacist Involved (n = 118)	No Pharmacist Involved (n = 117)	p Value	Pharmacist Involved (n = 76)	No Pharmacist Involved (n = 82)	p Value
Pre-test between groups						
systolic	144.76 ± 19.69	142.41 ± 19.81	0.600	155.19 ± 15.51	152.19 ± 16.17	0.235
diastolic	85.72 ± 13.56	85.96 ± 12.94	0.889	90.47 ± 13.83	89.73 ± 12.96	0.731
Post-test between groups						
systolic	121.47 ± 14.90	124.77 ± 17.97	0.037	124.16 ± 14.23	130.36 ± 16.83	0.002
diastolic	71.55 ± 10.80	74.23 ± 11.87	0.027	73.08 ± 10.68	76.52 ± 12.35	0.008
Paired differences within groups						
systolic	23.29 ± 19.10	18.64 ± 17.67	<0.001	26.26 ± 18.14	21.83 ± 17.84	<0.001
diastolic	14.18 ± 11.20	11.73 ± 10.08	<0.001	15.22 ± 10.95	13.22 ± 10.37	<0.001

*BP ≥140/90 mm Hg.

tion. As the result of the pharmacist's letters from the community pharmacy, more than half of the suggestions to change the patient's medication were accepted. In addition, 45 of 130 recommendations made by the pharmacist in the patient's notes in the PCUs and 11 recommendations for more investigations to be undertaken were accepted. Thus, a total of 99 of 206 (48.06%) recommendations were accepted.

As shown in Table 4, at the pre-test, 58 patients in the treatment group and 61 in the control group had good adherence. At the post-test, 70 patients in the treatment group and 60 in the control group were considered adherent. There was an interaction between patient group and adherence rate control at the pre-test.

After the 6-month follow-up, participation in regular exercise showed a significant difference between the groups. The proportion of patients who participated in regular exercise was higher in the treatment group (65 of 114) than in the control group (46 of 117; $p = 0.012$). No interaction was found. The rest of the lifestyle factors did not show any significant difference between groups.

Discussion

The study was conducted during the period when the JNC-6 guidelines were currently used, 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 in diabetic patients for the target goal of treatment as recommended in JNC-7.[13] 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 middle-aged, diabetic, and older patients.[2,14,15]

This study indicated that some patients maintained a changed behavior of jogging every morning for exercise as the result of advice from the pharmacist.

For the BP control in the sample of 235 patients (Table 2), the treatment group showed significant control only of the SBP. For the sample of 158 patients with elevated BP, the treatment group showed significantly more control both in SBP and DBP. This may be because the therapeutic goal for patients with controlled BP was to maintain the BP at the same controlled level, whereas for hypertensive patients, the goal was both to reduce BP and to obtain better control.

Both SBP and DBP showed significant differences from the baseline for both groups (Table 2). We did not expect 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.[16,17] 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 hypertensive patients at the hospital, visits to special seminars with patients from other areas, and activities encouraging exercise in each community. Another possible weakness of this study resulted from an administrative procedure. This involved a label on the patients' notes to identify those who were included in the study; this may have caused physicians and other healthcare providers to monitor these hypertensive patients more closely. Having the research pharmacist as the only person measuring BPs was considered an advantage because it reduced the variation that might have occurred if more people were involved. Despite the above confounding influences on our study, the results show that significant benefits resulted from the involvement of a pharmacist with hypertensive patients. BP was better controlled and greater reductions were obtained.

It was interesting to find that 48% of the pharmacists' recommendations were accepted by the physicians (Table 3) since some physicians had misgivings at the beginning of the study as to the appropriateness of pharmacists being involved in patient care in the primary care setting.

Pharmacist involvement in providing care for hypertensive patients led to improvement in adherence (Table 4), supporting the effectiveness of such services as shown by Taylor et al.[9] It must be acknowledged that other studies of the effect of pharmacist intervention on patient adherence were not as positive; however, their protocols were less rigorous. One study used patient self-reports to measure adherence and the other used prescription refill data.[9,18] In our study, we counted patient medications at one-month intervals at the times of the pre- and post-tests.

Summary

Our results indicate that hypertensive patients who received regular pharmaceutical care provided by a pharmacist achieved a significantly greater benefit in BP reduction and control, as well as improvement in their adherence

Table 3. Response of Physicians to the Pharmacist's Recommendations on Treatment Modifications

Recommendation Tool	Total Recommendations, n (%)	Recommendations Accepted, n (%)		Recommendations Not Accepted, n (%)	Recommendations Not Seen, n (%)
		Modification	More Investigations[a]		
Letters	76	43	6	17	10
Notes	130	45	5	69	11
TOTAL	206 (100)	88 (42.72)	11 (5.34)	86 (41.75)	21 (10.19)

[a]Recommendations related to laboratory tests, such as renal function or lipid profile. Patients whose symptoms indicated they were at risk were also referred.

E rate. These findings indicate that pharmacists play a useful role in management of hypertension in primary care.

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We thank Dr. Summana Moolsarn, a lecturer at Ubon Ratchathani University, and various staff of Mahasarakham Hospital, for their valuable input.

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Table 4. Patient Adherence Rates of the Treatment and Control Groups

Group	Adherence, n (%) Good (≥80%)	Poor (<80%)	p Value
Pre-test[a]			0.534
treatment (n = 112)	58 (51.33)	54 (48.21)	
control (n = 109)	61 (56.48)	48 (44.04)	
Post-test[b]			0.014
treatment (n = 110)	70 (63.64)	40 (36.04)	
control (n = 108)	60 (55.56)	48 (44.86)	

[a]Fourteen patients were missing, 8 of whom dropped out and 6 of whom did not provide data. These were not included in this analysis at the pre-test.
[b]By the end of the study, a total of 17 patients were missing. The extra 3 missing patients were not included in this analysis.

RÉSUMÉ

INTRODUCTION: La pratique des soins pharmaceutiques en médecine familiale en Thaïlande n'est pas acceptée de façon générale.

OBJECTIF: Évaluer l'impact de l'implication du pharmacien auprès des patients hypertendus dans un environnement de médecine familiale.

MÉTHODOLOGIE: L'objectif du traitement était de stabiliser la tension artérielle (TA) de patients hypertendus selon les recommandations du JNC-6. Les patients furent assignés aléatoirement au groupe traitement (présence d'un pharmacien) et au groupe contrôle (absence d'un pharmacien). La TA pre- et post-test, le décompte des comprimés, les modifications de style de vie, et toutes les recommandations des pharmaciens furent comptabilisées. Cette étude de 6 mois fut effectuée à la pharmacie de l'Université de Mahasarakham ainsi que dans 2 unités de medecine familiale. Les patients furent monitorés aux mois en revisant leurs médications et furent suivis selon le modèle des soins pharmaceutiques.

RÉSULTATS: Des 235 patients, le groupe traitement (n = 118) a eu une réduction significative de la TA systolique (TAS) (p = 0.037) et diastolique (TAD) (p = 0.027) lorsque comparé au groupe contrôle (n = 117). Les 158 patients (n = 76 groupe traitement et n = 82 groupe contrôle) ayant une TA ≥140/90 mm Hg au début de l'étude ont démontré une réduction significative de TA (p = 0.002 TAS et p = 0.008 TAD). La proportion des 158 patients dont la TA est devenue stabilisée est plus élevée dans le groupe traitement (p = 0.017). Ce groupe a également démontré une plus grande fidélité au traitement (p = 0.014) et un meilleur contrôle d'exercice (p = 0.012) à la fin de l'étude. Les médecins ont accepté 42.7% des modifications de médications et 5.34% des suggestions relatives à des investigations additionnelles.

CONCLUSIONS: Les patients hypertendus ayant reçu un suivi par le pharmacien ont démontré une plus grande réduction de la TA, un meilleur contrôle de la TA ainsi qu'une amélioration de la fidélité au traitement et de style de vie.

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