

CHAPTER III

METHODOLOGY

1. Study Design

The study was action research design which divided into two parts, consisted of the questionnaire development and the main study.

1.1 Part 1: The questionnaire development

The questionnaire development consisted of content validity test and reliability test. These processes were established before the main study to obtain the questionnaire properly.

1.1.1 Content Validity is based on the extent to which a measurement reflects the specific intended domain of content. It is established by a professional or professionals selecting appropriate content for questions and statements. The questionnaire was tested content validity by four experts including two internal medicine doctors, and two hospital pharmacists. After revised questionnaire, it was pre-tested by collecting data in five outpatients who received drug allergy card at pharmacy department to perform the think aloud technique and re-adjusted the appropriateness of the questionnaire again.

1.1.2 Reliability is the consistency or the repeatability of the measurements, often used to describe a test. A measure is considered reliable if an instrument measures the same way each time it is used under the same condition with the same subjects. This study performed two types of reliability which were Test-Retest Reliability and Internal Consistency Reliability. After the content validity test, fifteen samples who were similar to the patients in the main study, received the pre-test and post-test questionnaires. Then the reliability was analyzed by Pearson's correlation and Cronbach's Alpha (α).

1.2 Part 2: The main study

The main study consisted of two parts including Phase 1 (Brochure development) and Phase 2 (Prospective intervention study). Aims of the main study

were to assess the effectiveness of the strategies used to promote the knowledge and the understanding of patients in drug allergy, and drug allergy card carrying behavior.

2. Study population

The study population involved in-and out-patients at Srinagarind Hospital, Khon Kaen University, who were classified by the main study objective including:

2.1 Phase 1: Brochure development

2.1.1 Drug allergy patients from pharmacy database who had/ or had not received any drug allergy cards from the pharmacy department at Srinagarind Hospital.

2.1.2 Patients who were diagnosed with maculopapular rash (MP), anaphylaxis, erythema multiforme (EM), Stevens-Johnson syndrome (SJS), or toxic epidermal necrolysis (TEN) and never received any drug allergy cards.

2.2 Phase 2: Prospective intervention study

2.2.1 Patients with history of drug allergy who never received any drug allergy cards.

2.2.2 Patients who developed drug allergy during their hospitalization or drug allergy caused their admission to the hospital during the study period.

3. Study sample

3.1 Phase 1: Brochure development

The subjects selected in this brochure development were in-and out-patients with drug allergy history from pharmacy database during October 1, 2006-September 30, 2008 and patients who were diagnosed with maculopapular rash (MP), anaphylaxis, erythema multiforme (EM), Stevens-Johnson syndrome (SJS), or toxic epidermal necrolysis (TEN) during fiscal years 2004-2008. (Sample size calculation was described in next session)

Inclusion criteria:

1. Patients of all ages (In case of patients aged under 15 year-old, the parents were allowed to complete the questionnaires).

2. Patients who had/ or had not received any drug allergy cards from the pharmacy department at Srinagarind Hospital.

Exclusion criteria:

1. Patient who refused to complete the questionnaires and/or answer the questions.

3.2 Phase 2: Prospective intervention study

The subjects selected in this prospective study were in-and out-patients who visited Srinagarind Hospital during June 1, 2009-August 31, 2009 including: (Sample size calculation was described in next session)

Inclusion criteria:

1. Patients of all ages (In patients under 15 year-old, the parents gave written consent prior to completion of the questionnaires).

2. Patients with history of drug allergy and never received any drug allergy card.

3. Patients who developed drug allergy during their hospitalization or drug allergy caused their admission to hospital.

4. For patients who were unable to read, closed individuals were allowed to record their answers in the questionnaires.

Exclusion criteria:

1. Patient who refused to complete the questionnaires and/or answer the questions.

4. Sample size

The sample size was calculated based on the main objective of the study which assessed the effectiveness of strategies used to promote patients' knowledge and understanding of drug allergy, and drug allergy card carrying behavior.

4.1 Phase 1: Brochure development

The sample size was determined for estimating hypothesis tests between two independent means (two groups), using the following equation (Jirawatkul, 2004)

$$n \text{ for each group} = \frac{2 (Z_{\alpha} + Z_{\beta})^2 \sigma^2}{\Delta^2}$$

n = sample size per group

α = probability of committing a Type I error (one- sided) = 0.05,

$$Z_{\alpha} = 1.645$$

β = probability of committing a type II error = 0.02, $Z_{\beta} = 1.282$

σ^2 = pooled variance of mean total score between Group 1 and Group 2
= 0.74

Δ = mean difference between Group 1 and Group 2 ($\mu_1 - \mu_2$)
= 3.23 – 3.67 = -0.44

$$n \text{ for each group} = \frac{2 (1.645 + 1.282)^2 0.74}{(-0.44)^2}$$

$$= 65.49$$

Because the lacking of prior study about patients' knowledge and understanding of drug allergy, pilot study was performed in 60 drug allergy patients to provide mean and standard deviation of Group 1 and Group 2. The pooled variance of mean total score between Group 1 and Group 2 was calculated in Appendix I, and gave the result of 0.74. Mean total score of post-test in Group 1 and Group 2 were 3.23 and 3.67, respectively. Therefore, mean difference between two groups was 0.44.

A study by Chaisrisawadsuk (2003) was carried out at Srinagarind hospital, Khon Kaen University, to identify the frequency and severity of patient self-reported ADRs of NSAIDs. The response rate was 46.3% and estimate missing of OPD card was 20%. Therefore, to achieve the 65.49 of respondents, total numbers of sample were $(65.49 \times 100/46.3) + (142 \times 20/100) = 170.4$ cases for each group of patients. Because the questionnaires were sent to the patients twice, therefore the total numbers of sample were $2 \times (170.4 \times 100/46.3) = 736$ cases. Due to the seriousness of drug allergic symptoms, all patients who were diagnosed with anaphylaxis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis were recruited without sampling.

4.2 Phase 2: Prospective intervention study

The sample size was determined for estimating hypothesis tests between dependent means, using the following equation (Jirawatkul, 2004)

$$n = \frac{(Z_{\alpha} + Z_{\beta})^2 \sigma_d^2}{\Delta^2}$$

$$n = \frac{(1.645 + 1.282)^2 0.907^2}{0.267^2}$$

$$= 98.89$$



n = sample size

α = probability of committing a Type I error (one-sided) = 0.05,

Z_{α} = 1.645

β = probability of committing a type II error = 0.01, Z_{β} = 1.282

σ_d = standard deviation of change between pre- and post-test mean total score = 0.907

Δ = mean difference of total score between pre- and post-test = 0.267

Because the lacking of prior study about patients' knowledge and understanding of drug allergy, pilot study was performed in 30 drug allergy patients to provide mean difference between pre-and post-test and standard deviation of change between pre-and post-test mean score, which were 0.267 and 0.97, respectively.

A study by Senacom (2009) was carried out at Srinagarind hospital, Khon Kaen University, to identify the frequency and severity of patient self-reported ADRs of antiepileptic drugs. The response rate from direct distribution by pharmacist was 100.0% and estimate missing of OPD card was 20%. Therefore, to achieve the 98.89 of respondents, total numbers of sample were $(98.89 \times 100/100) + (99 \times 20/100) = 120$ cases. During the study period, all patients who either had drug allergy history, drug allergy cause their hospital admission, or develop drug allergy during their hospitalization were recruited into the study.

5. Study procedure

This study was approved by the Khon Kaen University Ethics Committee for Human Research on April 7, 2009 (Appendix A). All patients received explanation about the study and gave written informed consent (Appendix B) before initiation of the data collection. The patients could also withdraw from the study at any time and for any reasons. The study was divided into two parts as follows:

5.1 Part I: Questionnaire development

5.1.1 The questionnaire used in this study was modified from other research that correlated to the patients' knowledge and understanding in drug allergy and drug allergy card carried by the patients (Chaikoolvatana et al., 2004; Dewitt, Sorofman, 1999). The questionnaire consisted of four sections as follows

5.1.1.1 Section 1: open-and close-ended questions seeking demographic details and information on concurrent therapy, disease states and previous drug allergy history.

5.1.1.2 Section 2: a list of fifteen statements to explore attitudes towards drug allergy and drug allergy card of the patients by ticking one of five likert scale, ranging from strongly agree, agree, uncertain, disagree, and strongly disagree that considered to be their first thought.

5.1.1.3 Section 3: open-and close-ended questions seeking knowledge and understanding of the patient in drug allergy and drug allergy card which were grouped in 5 domains;

1) An open-ended question to obtain name of the allergic drug (Thai or English)

2) An extensive series of symptom divided in to body systems or region, with tick boxes and spaces for addition of other symptoms; an open-ended question to elicit the most bothersome symptom severity and reporting of symptoms to the doctors

3) Multiple choice question to explore the knowledge of drug allergy management

4) Dichotomous questions to explore the knowledge of drug allergy prevention

5) Dichotomous questions to explore the importance of drug allergy card

5.1.1.4 Section 4: close-ended questions seeking patients' behavior in drug allergy card usability, the prevention of recurrent drug allergy and drug allergy management, consisting of two parts;

1) A list of seven statements to explore patients' behavior in drug allergy card usability and the prevention of recurrent drug allergy by ticking one of three-points rating scale ranging from always, sometime, and never that considered to be their first thought.

2) Multiple choice question to explore recurrent drug allergy management

5.1.2 The study selected four health professionals who experienced on drug allergy. The professional judges were two doctors, including a dermatologist and an internal medicine doctor, and two hospital pharmacists, who were responsible for ADRs monitoring in Srinagarind Hospital. They evaluated the adequacy of systematic questionnaire for clarity, meaningfulness, and appropriateness of wording for drug allergy.

5.1.3 Calculating the index of consistency (IOC) to evaluate content validity using the following equation (Rovinelli, Hambleton, 1977)

$$IOC = \frac{\sum R}{N}$$

IOC = Index of Consistency

$\sum R$ = Total scores

N = number of professors or experts

Method of calculating the index of consistency (IOC) can be computed with scores 3-point scale, ranging from -1 = no agreement or not relevant, 0 = no comment or not sure, and + 1 = perfect agreement or very relevant and succinct, individual items are evaluated by content experts; scores are used for determining whether items should be retained or rejected. If score ≥ 0.5 , it means the question related to the objective of study. If the average score was less than 0.5, the question will be revised.

5.1.4 Revised questionnaire in item IOC less than 0.5 and test content validity by the experts again.

5.1.5 After questionnaire was revised by researcher, think aloud technique was performed in 5 outpatients who had received drug allergy cards from pharmacy department to examine the clarity and the understanding of the patients in the questionnaire (Fayers, Machin, 2000).

5.1.6 Reliabilities were test as followed:

5.1.6.1 Coefficient of stability

Test-Retest method was performed by given the same questionnaire to the same group of patients twice. One-month test retest reliability was performed in 30 patients. Pearson Product-Moment Coefficient correlation was calculated using the following equation:

$$r_{xy} = \frac{N\sum XY - \sum X\sum Y}{\sqrt{[N\sum X^2 - (\sum X)^2]}\sqrt{[N\sum Y^2 - (\sum Y)^2]}}$$

r_{xy} = Pearson Product-Moment Coefficient correlation
(Coefficient of stability)

N = Number of patients

$\sum XY$ = The sums of each pre-and post-test scores

$\sum X$ = The sums of pre-test score

$\sum Y$ = The sums of post-test score

X^2 = The square of pre-test score

Y^2 = The square of post-test score

5.1.6.2 Internal consistency

Cronbach's Alpha was performed to obtain the Alpha Coefficient (α) because of the questionnaire contained dichotomous and rating scale. Alpha Coefficient was calculated by using SPSS for Window version 16.0.

Alpha coefficient ranges in value from 0 to 1. Nunnally (1978) has indicated 0.7 to be an acceptable reliability coefficient. The questionnaire is shown in Appendix C.

5.2 Part 2: Main study

5.2.1 Phase 1: Brochure development

5.2.1.1 Brochures were used to educate patients about drug allergy and drug allergy card importance. The information of drug allergy was collected from both publications and electronic sources as follows:

Publications

References in Thai

Trongpraden reung Adverse Drug Reaction, 2006

Practice guideline for adverse drug reaction monitoring: Skin disorders, 2007

Reference in English

Middleton's Allergy: Principles and Practice, 2003

Electronic sources

References in Thai

<http://www.allergythai.org>

<http://www.stkc.go.th>

References in English

<http://www.medicinenet.com>

<http://www.drugs.com>

<http://www.aaaai.org>

<http://www.mdconsult.com>

<http://www.emedicinehealth.com>

Two patterns of brochure were as follows:

Pattern 1 brochure: General information of drug allergy with mild drug allergy symptoms (Appendix D)

Color of the brochure: light green

The information including in brochure were as follows:

1. The meaning of drug allergy and side effect.
2. The basic observation of drug allergy symptoms.
3. Information of mild drug allergy symptoms i.e. skin rash
4. Figures of mild drug allergy symptoms i.e. maculopapular rash, urticaria rash, and lips edema.

5. Patient self-management of drug allergy.
6. The prevention of recurrent drug allergy.

Pattern 2 brochure: General information of drug allergy with severe drug allergy symptoms (Appendix E)

Color of the brochure: crimson

The information including in brochure were as follows:

1. The meaning of drug allergy and side effect.
2. The basic observation of drug allergy symptoms
3. Information of severe drug allergy symptoms i.e. fever, burning skin, bullous lesion, mucosal ulceration, and shock
4. Figures of severe drug allergy symptoms i.e. Stevens-Johnson Syndrome with skin peeling and mucosal ulceration, and anaphylactic shock
5. Patient self- management of drug allergy.
6. The prevention of recurrent drug allergy.

5.2.1.2 After the brochures had been created, two professionals who experienced in drug allergy including one dermatologist and one hospital pharmacist who responsible for adverse drug reaction monitoring in Srinagarind Hospital evaluated the clarity, meaningfulness, appropriateness of wording and the pattern of the brochures.

5.2.1.3 The brochures were distributed to outpatient (n = 20) to try out the patients education in drug allergy.

5.2.1.4 Revised the brochures in knowledge and patterns for clarity and convenience. The brochures are shown in Appendix D and Appendix E.

5.2.1.5 The knowledge and the understanding of patients in drug allergy, and drug allergy card carrying behavior.

The subjects were in-and out-patients with history of drug allergy from pharmacy database who had/ or had not received drug allergy cards from the pharmacy department at Srinagarind Hospital during October 1, 2006 - September 30, 2008 and patients who were diagnosed with MP rash, anaphylaxis, EM, SJS, or TEN but never received any drug allergy cards during fiscal years 2004 - 2008. This part was divided into two parts consisting of distribution of pre-test questionnaires by mail and distribution of brochure and post- test questionnaire by mail (Figure 2).

1) Distribution pre- test questionnaire by mail

The procedures of questionnaire distribution by mail were as follows:

(1) Hospital number (HN) of the patients who fulfilled criteria for the inclusion were recruited from pharmacy database and medical record and statistics database, Srinagarind Hospital, Khon Kaen University.

(2) The HNs were sorted by number, excluding the repeated HNs for each drug allergy.

(3) Because of the severity of drug allergic symptoms, all patients who were diagnosed with anaphylaxis, EM, SJS, and TEN were recruited without sampling. Drug allergic patients from pharmacy database and patient who were diagnosed with MP were randomized using systemic random sampling technique as following:

Running number of HN (1, 2, 3...229)

Calculating sampling interval from number of total patient divided by number of sample size

Randomizing start number from the random table.

Number seven was start number of sampling.

The randomized process was started at HN number five and the HN was marked to be eligible patients in every sampling interval of 3

(4) First reminders were sent to subjects during May 25-June 15, 2009. If the responses were not received within three weeks, the second reminder letters with further questionnaires were sent to non respondents during June 15-July 6, 2009. Apart from the mailing, calling by telephone was used to remind the patients as well. After another three week-period if there was still no response from the patients, no follow-up beyond the second mailing was attempted.

2) Distribution brochures and post- test questionnaire by mail

After receiving the pre-test questionnaires from the patients, the brochures and post-test questionnaires were re-distributed to those patients by mail as follow procedures:

(1) Selection of patients to receive different pattern of drug allergy brochure by simple random sampling method using table of random digits

(2) First reminders were sent to subjects during June 15 - July 6, 2009. If the responses were not received within three weeks, the follow up were attempted during July 6-July 27, 2009, with similar procedures to pre-test questionnaires.

5.2.2 Phase 2: Prospective intervention study

The subjects were in-and out-patients who had drug allergy history but never received any drug allergy card, developed drug allergy during their hospitalization or admitted to hospital with drug allergy causes at Srinagarind Hospital during June 1, 2009 - August 31, 2009. The methods used to search drug allergy patients were as follows:

1) Practical pharmacist work by asking patients' drug allergy history routinely before drug dispensing at out-patient department, pharmacy department, Srinagarind Hospital.

2) Spontaneous Reporting System (SRS) that consists of the spontaneous reporting, by health professionals, of events supposed to be adverse effects of marketed drugs.

3) Medical order screening for "tracer agents" which were used to treat drug allergy including chlorpheniramine, hydroxyzine, prednisolone, hydrocortisone, dexamethasone, and adrenaline.

4) Computerized alerting when prescribing previous allergic history drug or drug group.

This phase was divided into three parts consisting of distribution of pre-test questionnaires by pharmacist, drug allergy counseling by pharmacist with brochures and immediate post-test questionnaire distribution, and one month-period post- test questionnaires distribution by mail. (Figure 3).

5.2.2.1 Distribution of pre-test questionnaires by pharmacist

The researcher directly distributed the questionnaires in order to achieve the maximum overall response and the valid response rate. The researcher distributed questionnaires at pharmacy department and in-patient

departments at Srinagarind Hospital during July 1 to August 31, 2009. The accidental sampling method used in these studies.

5.2.2.2 Drug allergy counseling by pharmacist with brochures and immediate post-test questionnaire distribution

After completing pre-test questionnaire, the brochures were gave to all patients. Patient information on drug allergy was counseled by the pharmacist about the following aspects (Ningsanon, Yothapitak, 2006):

- 1) The different between drug allergy and other ADRs
- 2) Drug allergy information including mechanism, prognosis, complications of drug allergy.
- 3) Emphasizing patients to remembering name of the allergic drug and other drugs that possibly cause the same allergic reactions.
- 4) Advising patients to tell their closed individuals about drug allergy.
- 5) Prodome symptoms of serious drug allergy for self detection at home.
- 6) The management of drug allergy: stop taking the allergic drug and consult healthcare professionals or stop taking the allergic drug and take antihistamine for the reactions.
- 7) If suspicious adverse drug event occurred, further investigation by doctors was important to confirm whether it was drug allergy or other causes.
- 8) The patient's behavior for preventing recurrent drug allergy: avoiding drug with previous allergy history, always carry drug allergy card and show drug allergy card to healthcare professionals.
- 9) The importance of drug allergy card: reminding name of allergic drug and drug allergy symptoms, informing healthcare professional about drug allergy history.
- 10) If drug allergy card was lost or damaged, please contact the pharmacist for new drug allergy card.
- 11) If needed for further information about drug allergy, direct contact to the pharmacist could be made.

12) Receiving drug from non- healthcare professionals could possibly leading to recurrent drug allergy.

5.2.2.3 One month-period post-test questionnaires distribution by researcher

The one-month period post-test questionnaires were taken home with patients. One month after intervention, the researcher reminded the patients by telephone call during August 1-September 30, 2009 to complete and return the questionnaire by mail. If the responses were not received within one month, the second reminder calling were made to non respondents during August 15 - October 15, 2009. After another one month-period if there was still no response from the patients, no follow-up beyond the second calling was attempted.

5.3 Data validation

After receiving each questionnaire, validity of the questionnaires was assessed as the following criteria:

5.3.1 Valid questionnaire

5.3.1.1 Patients answered all four sections of the questionnaire and the answers were complete.

5.3.1.2 Patients answered section 1 of the questionnaire and some other sections (section 2, 3, or 4), of which the answers were complete.

5.3.2 Invalid questionnaire

5.3.2.1 Patients did not answer any sections of the questionnaire.

5.3.2.2 Patients answered only section 1 of the questionnaire.

5.3.2.3 Patients answered section 1 of the questionnaire, the other sections were answered but not complete.

All valid questionnaires were reviewed with OPD cards and/ or charts. Pharmacist used data collection forms to obtain medical profile data for comparison with the questionnaire (Appendix F).

5.4 Assessment of drug allergy

The literatures on ADRs were used in the process, to identify whether each symptom was previously described as an drug allergy to any of the drugs. The standard textbooks were used in attributing symptom to disease states (Figure 4).

5.4.1 The standard textbooks used are listed as follows:

5.4.1.1 Standard textbooks used for identified symptoms and disease:

1) Harrison's Internal Medicine, 2007
 2) Textbook of therapeutic drug and disease management, 8th ed., 2006

3) Applied Therapeutics, 2006

4) Pharmacotherapy, 2006

5.4.1.2 Standard textbook, computer database used for identifying adverse reactions to drugs:

1) Drug Information Handbook, 2007-2008

2) AHFS Drug Information, 2005

3) Drug Interaction Fact, 2006

4) Drug Facts and Comparison, 61th ed., 2007

5) Physicians' Desk References, 60th ed., 2006

6) Computerized Clinical Information System (CCIS, Micromedex, 2007)

7) Davies's Textbook of Adverse Drug reactions, 5th ed., 1998

8) MEYLER's side effects of Drugs, 14th ed., 2000

5.4.2 Computer database

www.fda.gov

www.fda.moph.go.th

<http://www.doublecheckmd.com>

<http://www.drugs.com>

<http://www.sciencedirect.com>

<http://www.ncbi.nlm.nih.gov>

www.medscape.com

<http://proquest.umi.com>

<http://www.springerlink.com>

<http://www.mdconsult.com>

5.5 Questionnaire evaluation

The questionnaire assessment was consisted of 2 parts as follows:

5.5.1 Knowledge and understanding part

There were 5 questions for knowledge and understanding evaluation, each of them equal one score, therefore the total score were five. The five questions consisted of:

Question 1: Name of the allergic drug

- If the patients could complete all name of the allergic drug, the score was given as 1

- If the patients could complete all name of the allergic drug including other drugs which were not existed in any database, the score was given as 1

- If the patients could partial complete name of the allergic drug, the score was given as 0

- If the patients could not tell any name of the allergic drug, the score was given as 0

Question 2: Symptoms of drug allergy

- If the patients completed all drug allergic symptoms, the score was given as 1

- If the patients could complete all drug allergic symptoms with other symptoms, the score was given as 1

- If the patients could partial complete drug allergic symptoms, score was given as 1

- If the patients could partial complete drug allergic symptoms with other symptoms, the score was given as 1

- If the patients could complete drug allergic symptoms but not relevant to any database, score was given as 0

- If the patients could complete other adverse drug effects but not drug allergy, score was given as 0

- If the patients could not tell any drug allergic symptoms, the score was given as 0

Question 3: The management of drug allergy

There were six statements in this question, which two of them were the correct answers. If the patients chose any of those two statements, the score was given as 1. If the patients chose any of the other four statements which were incorrect answers, the score was given as 0.

The correct statements were:

- Stop taking the drug and counseling healthcare professionals.
- Stop taking the drug and taking another drug for the reaction.

The incorrect statements were:

- Do nothing and continue using the drug.
- Continue using the drug and taking another drug for the reaction.
- Reduce the dose of the drug.
- Stop taking drug and doing nothing.

Question 4: The prevention of recurrent drug allergy

There were four statements in this question, answered in “Yes/ No”.

If The patients could answer all four statements correctly, the score was given as one.

If the patients answered any of the statements incorrectly, the score was given as 0.

The four statements were:

- Avoiding taking allergic drugs “Yes”
- Reducing dose of the allergic drug “No”
- Notifying healthcare professionals about drug Allergy history “Yes”
- Carrying drug allergy card “Yes”

Question 5: The importance of drug allergy card

There were five statements in this question, answered in “Yes/ No”.

If The patients could answer all five statements correctly, the score was given as one.

If the patients answered any of the statements incorrectly, the score was given as 0.

The five statements were:

- Reminding the name of the allergic drugs "Yes"
- Informing healthcare professionals about drug allergy "Yes"
- Shortcut for faster medication service "No"
- Preventing recurrent drug allergy "Yes"
- Preventing allergic reactions to drug with different combination of drug recorded in drug allergy cards "No"

All five questions were evaluated and presented as mean \pm S.D.

Also, the score were leveling in three levels as follows:

- Low level: score 0 - 1
- Average level: score 2 - 3
- Good level: score 4 - 5

5.5.2 Attitudinal part

There were fifteen statements in this part, which consisted of nine positive and six negative statements as follows.

Positive statements

- No.1 You should pay attention to drug allergy.
- No.3 You should always receive your drug allergy from healthcare professionals (Doctors, Pharmacists, or Nurse).
- No.5 You expect that healthcare professionals could prevent and reduce the recurrent of drug allergy.
- No.7 Preventing the recurrent of drug allergy would reduce your healthcare cost.
- No.9 Drug allergy card is a safety tool for the prevention of recurrent drug allergy.
- No.11 You should always carry drug allergy card.
- No.13 Drug allergy education would assure you in medication
- No.14 Drug allergy education should be a direct responsibility of the pharmacists
- No.15 Pharmacists should provide more drug allergy education.

Negative statements

- No.2 Drug allergy doesn't affect your health or quality of life
- No.4 Notifying healthcare professionals about your drug allergy was wasting your time.
- No.6 Recognizing of drug allergy is unimportant to you.
- No.8 Drug allergy limits your opportunity in drug utilization for underlying disease
- No. 10 Drug allergy card carrying is unnecessary burden.
- No. 12 The prevention of recurrent drug allergy is not your direct responsibility.

The attitudes were measured on 5-point Likert Scale; lowest score was 1 and highest score was 5. The score given in each positive and negative statement were different. For positive statements, strongly disagree to strongly agree, the scores were ranging from 1 to 5. For negative statements, strongly disagree to strongly agree, the scores were ranging from 5 to 1. The attitude mean score was classified, based on Best criteria (Best, 1959); poor (1.00 - 1.79), fair (1.8 - 2.59), moderate (2.60 - 3.39), good (3.40 - 4.19), and very good (4.20 - 5.00).

The overall scores of attitudes were calculated. The lowest possible score for attitude was 15 and the highest possible was 75. Therefore, the range (75 - 15 = 60) was divided into three equal parts, and leveled as low (15 - 35), moderate (36 - 55), and high (56 - 75). The overall level was high (57.69 ± 5.20).

6. Tools for data collection and evaluation

Tool required for data collection and evaluation are as follows:

- 6.1 The questionnaire
- 6.2 Data collection form for pharmacist
- 6.3 Outpatient Department Card (OPD)
- 6.4 Standard textbooks described in 5.4.1 and 5.4.2
- 6.5 SPSS for Window program version 16.0

7. Statistical Analysis

The data from this study were mainly extracted and analyzed using SPSS for Window version 16.0. The accuracy of drug allergy reported by patients was evaluated by the pharmacist based on data collected from OPD card. The following analyses were carried out:

7.1 The patients' demographic data, disease states and drug therapy were reported as the percentage of total patients with mean \pm S.D. or median (range), where appropriated. The percentages were determined in various categories of data such as: age, gender, education, occupation, number of underlying diseases, number of drug use.

7.2 Response rate and the frequency of allergic drug and their symptoms were reported as the percentage of the total respondents with median (range) based on patient reports and pharmacist collection form.

7.3 Attitudes of drug allergy and drug allergy card, total mean score of pre-and post-test, and drug allergy card carrying behavior were reported as the percentage of the total respondents or mean \pm S.D., where appropriated.

7.4 Independent two sample t-test or Mann-Whitney U test were used to compare post-test mean total scores between two groups of patients who received different pattern of brochures.

7.5 Dependent t-test or Wilcoxon Signed-rank test were used to compare mean total scores between pre-and post test, where appropriated.

7.6 Relationships between variables were analyzed using chi-square test for association, McNemar test, or Marginal Homogeneity test where appropriated. If expected values which were less than 5 is account for more than 20% of total cell. Fisher exact test was used, instead. The 95% confidence interval or p-value at 0.05 was chosen to accept or reject the null hypothesis. The analyzed relationships were between patients' characteristic variables (i.e. age, gender, duration of therapy, number of concomitant drugs, number of underlying disease and type of drugs) and:

7.6.1 The attitudes of drug allergy and drug allergy card.

7.6.2 The drug allergy knowledge level.

7.6.3 The patients' behavior in drug allergy card carrying and the prevention of recurrent drug allergy.

7.7 The Logistic regression analysis was used to test for independent variables considered to associate with the knowledge, behavior, or attitudes by univariate analysis (chi-square test or fisher test indicating statistical significance).

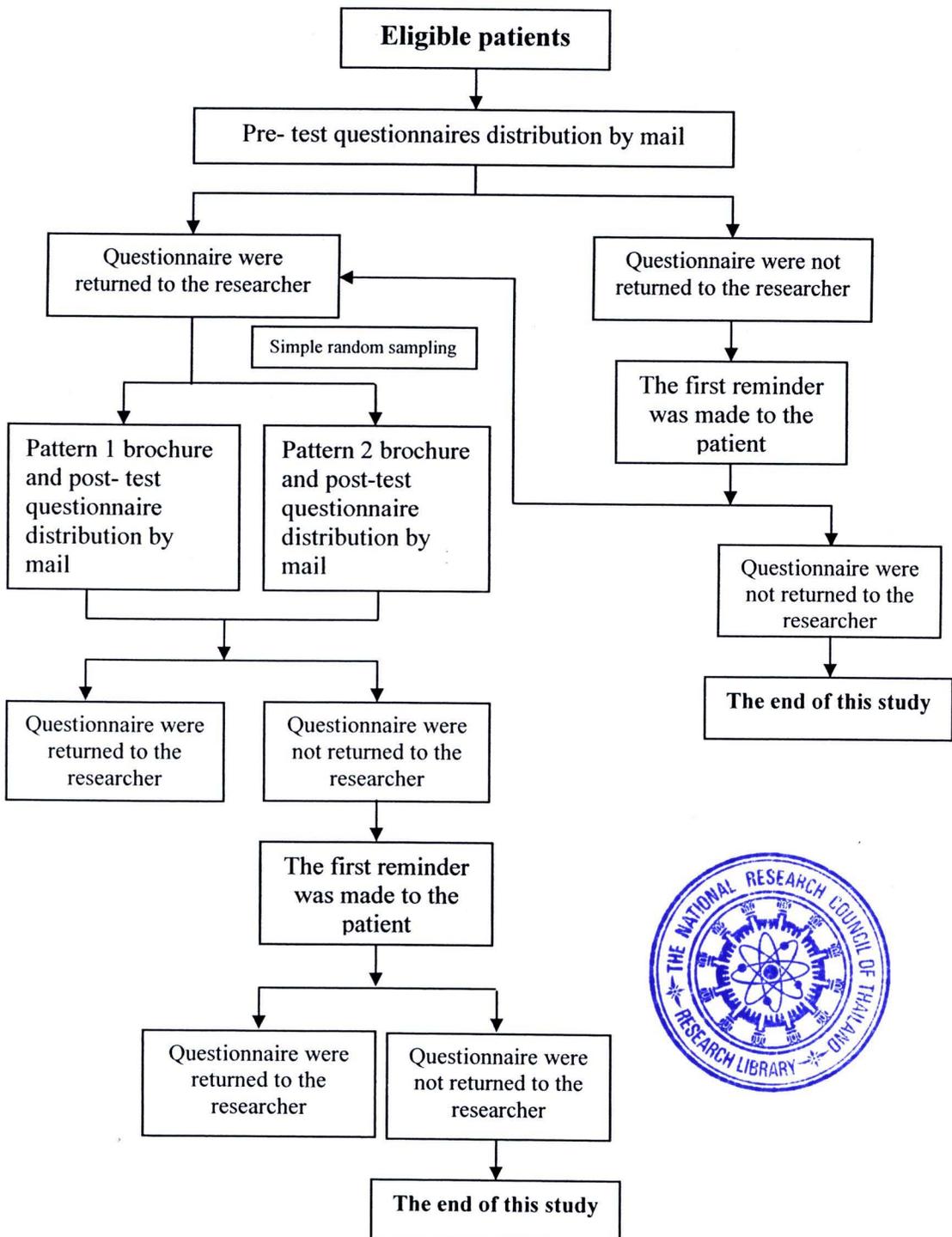


Figure 2 Flow chart of questionnaires and brochures distribution in Phase 1

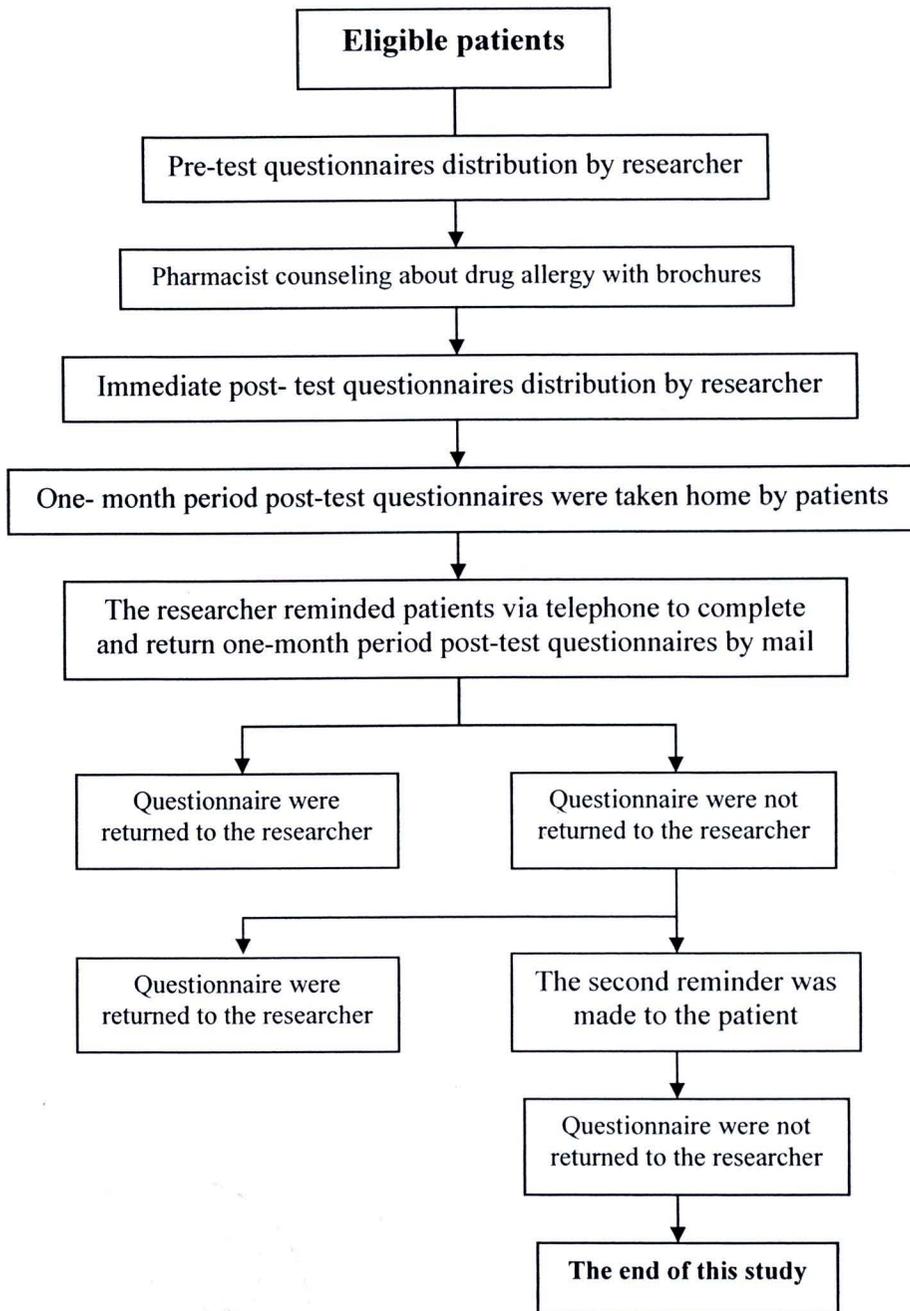


Figure 3 Flow chart of questionnaires and brochure distribution, and drug allergy counseling by pharmacist in Phase 2

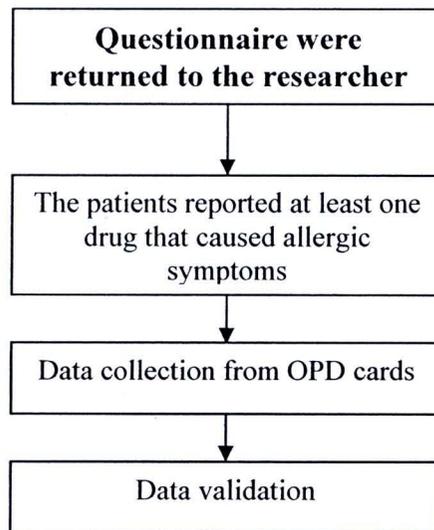


Figure 4 Assessment the accuracy of drug allergy by pharmacist

