CHAPTER I

INTRODUCTION

1. Rationale and Background

Adverse Drug Reactions (ADRs) are one of common Drug Related Problems (DRPs) which occurred 7.8- 8.1% of all DRPs related to hospital admissions (Hallas et al., 1990; Blix et al., 2004). Drug allergy was the immunologic reactions which responded 6-10% of all ADRs (deShazo, Kemp, 1997). In general, drug allergy accounted for approximately 3-6% of all hospital admissions (Einarson, 1993; Thong et al., 1993; Pirmohamed et al., 2004), developing in 10- 15% of hospitalized patients (Hurwitz, Wade, 1969; Thong et al., 1993). In general population, 7.8% prevalence of self-reported drug allergy was found (Gomes et al., 2004). Antimicrobial agents were commonly accounted for allergic reactions (Puavilai, Choonhakarn, 1998), which Penicillins was the most frequently causative drugs (Gomes et al., 2004; Padilla et al., 2006). Clinical manifestations of drug allergy are restricted to certain syndromes that are specifically accepted as allergic in nature, which may present in mild to life-threatening reactions (Bernstein et al., 1999). Typically, cutaneous reactions were the most commonly accounted drug allergy (Bigby et al., 1986), which usually appear in mild skin rash (Thong et al., 2003). However, 5.2% of skin symptoms could be rare and serious resulting in Steven-Johnson syndrome, Toxic Epidermal Necrolysis and generalized exfoliative dermatitis (Thong et al., 2003). Anaphylactic shock was one of the major concern severe drug allergy, and was the most potentially lethal allergic events which 0.3 cases per million inhabitants per year was estimated (Lenler-Petersen et al., 1996). Overall, it has been found that the attributable mortality due to drug allergy was 0.09 per 1000 hospitalizations (Thong et al., 2003).

In Thailand, drug allergy was found in 16.2% of all ADRs in hospitalized patients (Eaktrakoolchai, 2004). Adverse Drug Reaction Monitoring Center (ADRM) had reported that in the fiscal year 2007, general antiinfective for systemic use especially antimicrobial (69.2%), was the most encountered for ADRs. Skin and appendages disorder 57.1%) was the most effected organ systems, presented in rash

(21.2%). The majority ADRs were classified as non- serious (78.5%), whereas 21.2% was serious (Adverse Drug Reaction Center [ADRM], 2007). The re-occurrence rate of drug allergy was 77.2% of total ADRs reported in three province (Phichit, Petchabun, Phitsanulok), Thailand (Kidkeukarun, 2005).

The incidence of ADRs was frequently found in patients taken polypharmacy, elderly, multiple chronic medical problems, renal disease (Lohasuphakarn, 2000). Furthermore, ADRs often occurred in female gender more than male gender (Einarson, 1993). For patients' aspects, ADRs prolonged hospitalization (Lazarou et al., 1998), increased the cost of treatment and led to the cause of death or disability which affected their families. The study in economic effects from Beta-lactam allergy found that patients with beta- lactam allergy had higher antibiotic costs (MacLaughlin et al., 2000). Besides, it multiplied unnecessary health care professional services, government expend fund for disabled patients resulting in damaged public health and economy (ADRM, 2002).

World Health Organization (WHO) has set a patient safety policy especially medication, as primary principle for health care services. The Ministry of Public Health also campaign hospitals to improve the safety of using medication, emphasized drug administration system in 4 strategies. One of them is reducing serious ADRs which give precedence to drug group that causes severe ADRs and repeated drug allergy, approach to have the rate of repeated drug allergy as zero (The Joint Commission on the Accreditation of Healthcare Organizations [JCAHO], 2007). Drug allergy cards with fully documentation of ADRs, carried by patients, were used to prevent the incidence of repeated drug allergy which was usually more severity symptoms or life threatening. The Ministry of Public Health had specified issue drug allergy cards only for type B ADRs and serious ADRs or ADRs that patients cannot tolerate or potential to the quality of life (ADRM, 2002).

One of the most important factors preventing repeated drug allergy and life threatening ADRs is patients' knowledge and understanding of drug allergy. In general population, the study in Muang district, Ubonratchathani, 53.6% of the respondents had drug allergy knowledge in moderate level and 62.2% of them could identify the prevention of repeated drug allergy correctly by recognizing the allergic drug and always informing health care professionals about their drug allergies

(Lebnak et al., 2001). Furthermore, the study in Maesod district, Tak province found that 48.63% of the drug allergy patients could remember and recognize the name of allergic drug (Lohasuphakarn, 2000).

The role of pharmacist in counseling patients and their families about drug allergies was effective to prevent repeat allergic drug reactions. Information given to the patients including the allergic reaction that occurred and what medication caused it, drug names list that could cause similar reactions, management when the reaction occurred, and the importance of informing all health care professionals about drug allergy histories (Johnson et al., 2001). In Thailand, few studies emphasizing in pharmacists counseling of drug allergy and drug allergy cards. The Adverse Drug Reaction Prevention Program in Rasrisalai hospital, Thailand had performed in the year 2004. For this program, the pharmacists provided basic knowledge of ADRs, the management of ADRs and ADRs brochures to the patients which acquire knowledge effectively ($p< 0.05$) (Chaikoolvatana et al., 2006). Later, the study of drug allergy card services by pharmacists found that, after the services provided, the patients could recall the name of allergic drugs (60.5%), could identify drug allergic symptoms (95.4%), always carried drug allergy card (59.3%), and notified healthcare professional about their drug allergy histories (59.3%) (Wongpentak, 2008). Moreover, the evaluation of pharmacist's role on the management of in-patient with a history of drug allergy was conducted in King Chulalongkorn Memorial hospital. The majority of the patients (89.9% and 89.5%) were satisfied with additional services and required for continuation of the services by the pharmacist, respectively (Laohapojanart & Tosukhumvong, 2007). Therefore, the patients' understanding of their drug allergies is significant to patients' co-operation in carrying drug allergy cards and showing them to all health care professionals. Therefore the surveillance and the ADRs preventing program are the main issues in both government and private hospitals in medication usability safety.

Srinagarind Hospital, a 800-bed regional medical center is the tertiary care setting in North-East Thailand. There are many items of drugs use which could possibly cause drug allergy in high rate. In the fiscal year 2007, there were 383 patients who received drug allergy cards which were divided to 198 in-patients and 185 out-patients. Among these 90 patients who received drug allergy cards, had

serious ADRs. Also, the study of patients whose diagnostic records were SJS or TEN at Srinagarind Hospital during 1995 to 2008 by Jantararoungtong et al. (2009) reported that 132 and 29 cases were identified with SJS and TEN, respectively. However, there was a limit study regarding to the patients' knowledge and understanding of drug allergy and drug allergy card, also drug allergy card carrying behavior. Early studies only performed according to standard procedures that were established by The Ministry of Public Health, included providing drug allergy card and pharmacist counseling. Therefore, the purpose of this study were to explore the strategies and evaluate their effectiveness of the promotion in patients' knowledge and understanding on preventing and reducing the recurrence of drug allergy in the patients who enrolled in Srinagarind hospital.

2. Objectives

2.1 General objectives

2.1.1 To explore strategies that can improve patients' knowledge and understanding on preventing and reducing the recurrence of drug allergy.

2.1.2 To evaluate the effectiveness of the promotion in patients' knowledge and understanding on preventing and reducing the recurrence of drug allergy.

2.2 Specific objectives

2.2.1 To compare the patients' knowledge and understanding in drug allergy card between pre and post promoting patients' knowledge and understanding in the prevention to reduce the recurrence of drug allergy within pattern 1 and 2 brochure.

2.2.2 To compare the patients' behavior in carrying drug allergy card between pre and post promoting patients' knowledge and understanding in the prevention to reduce the recurrence of drug allergy within pattern 1 and pattern 2 brochure.

2.2.3 To compare the patients' knowledge and understanding in drug allergy card between pre and post promoting patients' knowledge and understanding

in the prevention to reduce the recurrence of drug allergy within brochure alone and brochure plus pharmacist counseling.

2.2.4 To determine factors attributing to patients' knowledge, understanding and behavior in drug allergy card carrying.

2.2.5 To assess patients' attitudes towards drug allergy and drug allergy card carrying behavior.

3. Scope of this Study Research

This present study was designed to evaluate the effectiveness of the strategies used to improve the knowledge, understanding, and behavior of the patient in drug allergy and drug allergy card, and evaluated the attitude of the patient toward drug allergy and drug allergy card. The drug allergic patient who had/ or had not received drug allergy card could be affected by many factors including patient characteristics (such as gender, age, education, occupation), history of drug allergy, type of the allergic drug, and the severity of drug allergy.

The outcome of this study was measured using the long form questionnaire which was developed in this study, consisted of four sections (demographic data, attitude, knowledge and understanding, and behavior). The scope of this study is shown in Figure 1.

4. Definition of Term Used

4.1 Adverse drug reactions (ADRs)

According to the World Health Organization (WHO), an "ADRs" is a noxious and unintended effects of a drug, which occurs at a doses use in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function, also cover any event that follows the administration of a drug given in the recommended dose, and is harmful to the recipient's descendants, not including any result from unintentional or accidental overdose, use or misuse (World Health Organization, 1970).

4.2 Drug allergy

According to the World Health Organization (WHO), a drug allergy is adverse reaction occurring in a susceptible patient involving an immunological mechanism. (World Health Organization, 1970) In this study defines as type B ADRs and serious ADRs.

4.3 Type B ADR

Defines as ADRs that is a non- dose related, unpredictable adverse effect of the drug, not related to pharmacological action of the drug, low morbidity rate but high mortality rate, management by withholding the drug (ADRM, 2002).

4.4 Serious ADRs

Defines as ADRs that result in death, hospitalization or prolongs existing hospitalization, persistent or significant disability, incapacity and life threatening including congenital anomaly (ADRM, 2002).

4.5 Recurrent drug allergy

Defines as a repeated similar drug allergy that occurs in patients who is received drug by self-administer, caregivers or health care professionals, even if it was recorded that patients had already experienced in the past. Excluding the intentional drug use by health care provider for pharmacotherapeutic indication or intentional drug use by the patients themselves (ADRM, 2002).

4.6 Drug allergy card

Defines as a card which is issued by pharmacists, delivered to the patients who already had an adverse drug reactions assessment (ADRM, 2002). Srinagarind hospital issues only type B ADRs.

4.7 Knowledge and understanding

Defines as patients could answer 5 questions which are;

4.7.1 The name of the drug which cause drug allergy.

4.7.2 The adverse symptoms of drug allergy.

4.7.3 The prevention of recurrent drug allergy.

4.7.4 The important of drug allergy card.

4.7.5 The management of drug allergic symptoms.

4.8 Drug allergy card usable behavior

Defines as patients carry drug allergy card in hand, showing drug allergy card or informing health care professional of their drug allergy when using health services, asking about how to prevent drug allergy and the management when drug allergy reaction occur.

4.9 Maculopapular rash

Defines as a rash that contains both macules, a flat discolored area of the skin and papules, a small raised bump. A rash may occur on only one area of the skin, or it could cover almost all of the body. Also, a rash may or may not be itchy (Chopthamsakul, 2007).

4.10 Anaphylaxis

Defines as a severe, often life threatening, generalized or localized tissue reaction occurring within minutes of an immunologic reaction after expose to an antigen. Symptoms of anaphylaxis include (Dugdale, 2008):

- Hive, Urticaria, Skin rash, itching and angioedema
- Difficulty breathing with wheeze or hoarse voice
- Nausea, vomiting, abdominal pain or cramping and diarrhea
- Hypotension, ventricular tachycardia, palpitation and arrhythmia
- Fainting, light-headedness
- Urinary retention

4.11 Erythema Multiforme (EM)

Defines as a skin disease that causes lesions and redness around the lesions, appears on the skin around arms, legs and may include the mucous membranes; majority at oral cavity more than eyes (Ministry of Public Health, 2006).

4.12 Stevens- Johnson's Syndrome (SJS)

Defines as a severe form of EM and is characterized by fever with rash all over the body, mostly bullous lesions or necrotic keratinocyte. Skin peeling is less than 10 percent of body surface area. It is marked by involvement of two or more mucosal surfaces with severe lesion (Ministry of Public Health, 2006).

4.13 Toxic Epidermal Necrolysis (TEN)

Defines as symptoms that are more severe than SJS. Skin peeling is more than 30 percent of body surface area (Ministry of Public Health, 2006).

5. Potential Benefits of this Study

5.1 To improve patients' knowledge, understanding and promoting patients' behavioral in carrying drug allergy cards.

5.2 To improve patients' knowledge and understanding in early management of drug allergy.

5.3 To prevent and reduce the occurrence of recurrent drug allergy.

5.4 To monitor patients with risk factors that lead to non-adherence in carrying drug allergy cards.

5.5 To improve hospitals' adverse drug reaction monitoring activities by effective strategy.

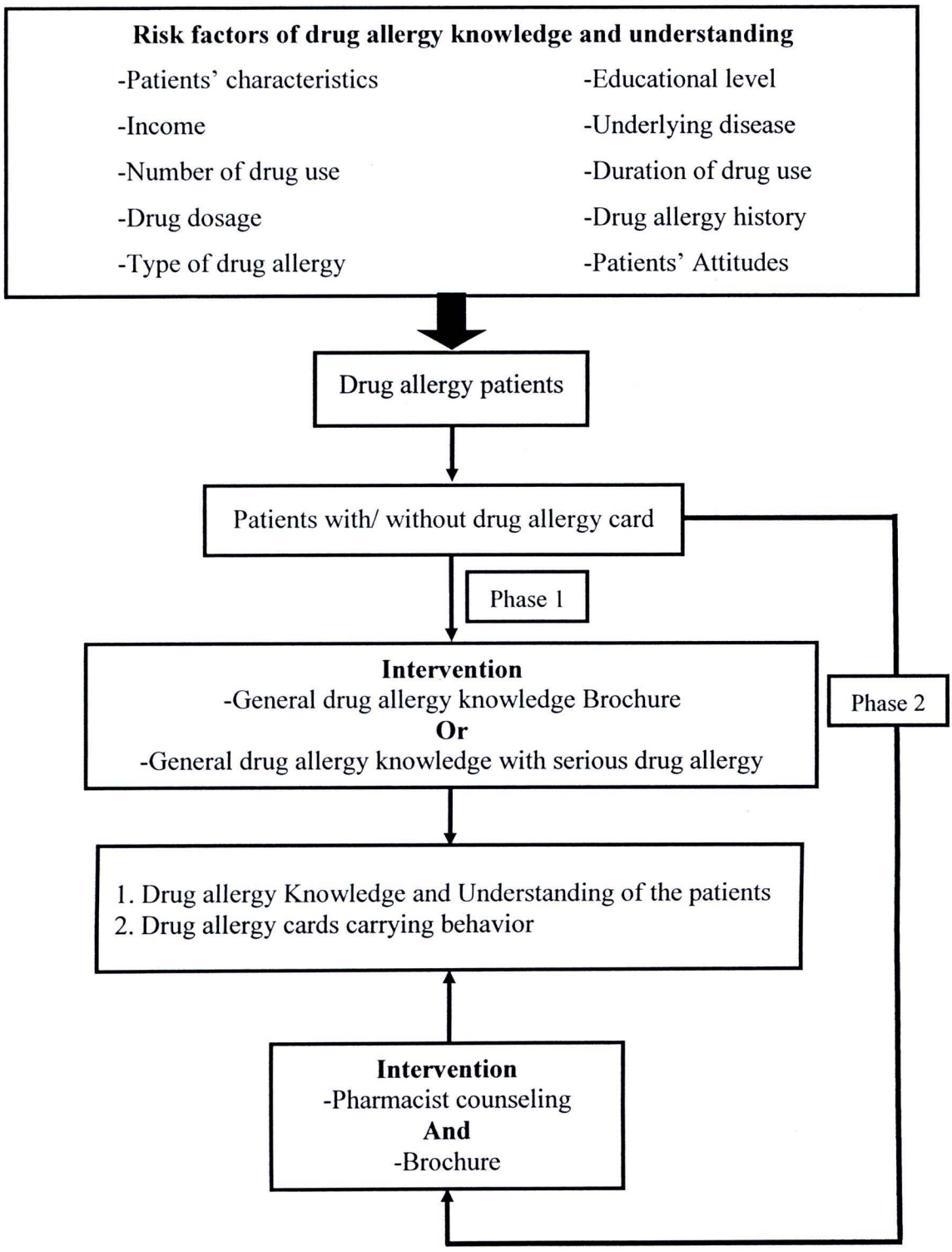

Figure 1 Scope of the study research