

## CHAPTER II

# LITERATURE REVIEW



This chapter is comprised of the review of the literature on pharmacy practice, good pharmacy practice, pharmaceutical care and its implication, pharmaceutical care in Thailand, measuring pharmaceutical care- based pharmacy practice, and factors influencing pharmaceutical care. The theoretical and conceptual framework of this study is also described.

### **Pharmacy Practice**

#### **Historical of pharmacy practice**

Pharmacy practice is the total practice delivered by a pharmacist, an individual who has acquired formal knowledge of the profession. The existing pharmacy practice has been proposed during various practices in different stages of pharmacy's evolution, which is traceable as a series of stages, including manufacturing pharmacy, compounding, distribution, clinical pharmacy, and pharmaceutical care. The role of pharmacy can be defined as including professional pharmacy services that promote and assure rational drug therapy, in order to maximize patient benefits and minimize patient risk. The term 'clinical' became attached to pharmacy to distinguish these functions and these pharmacists from other pharmacists who had not developed in the way that avoided performing standardized, mass- produced services like drug distribution. Clinical pharmacy, the first (but still incompletely established) practice specialty, emerged in the late 1960s. It marked the

first time that pharmacists played a direct role in advising physicians in selection and management of drug therapy for patients. Further, it was clearly defined as responsibilities instead of functions. It also suggested the social value of clinical pharmaceutical services, however, it was pointed out that technique alone would not make pharmacists professionals. Acceptance of a share of responsibility for drug use was addressed. Pharmacy and medicine have yet to agree on the integration of roles of the clinical pharmacist in the patient care setting, although progress has continued. At present, the term of Good Pharmacy Practice (GPP) represents an international attempt to unite the conceptualization of practice related to Pharmaceutical care and also to provide the foundation for a model to explain current practices. (Wertheimer, 1989; Holland and Nimmo,1999)

Although pharmacy is a universal profession, the practice can vary dramatically from country to country. However, this practice has been evolving in the United States and elsewhere, over the past 140 years. From 1860 until the late 1990s, the paradigm had shifted from manufacturing to compounding, compounding to distribution, distribution to a more clinical role, and a clinical role to pharmaceutical care. The Pharmaceutical care in the current era is emphasized by information and is patient-orientated. Since the health care system changed, the concept of practice has shifted to be more patient-centered. The pharmacist thus has an adaptive response to the emergence of Pharmaceutical care in their practice.

In 1952, one of the major changes in pharmacy practice in the USA was the supporting of drug distribution in the organization. According to the Durham-Hamprey Act, the community pharmacists had limited functions. The pharmacist lacked access to the full scope of patient- specific clinical information, patients' care

givers and drug literature and their social function role. Pharmacy had become a channel of distribution for the pharmaceutical industry and the task of the pharmacist was dispensing only. At the same time the hospital pharmacist functioned primarily in a support role for the management of drug products only. Then, in 1960, the role of the clinical pharmacist extended to counseling practice, indicating the shift of the pharmacist's role to the counseling and dispensing era.

In the counseling and dispensing era, the community pharmacist resumed providing drug information by way of advice and the counseling of medication. Although their practice was product-oriented, the community pharmacists added on their dispensing functions by providing consultations on generic substitution and advice on the use of non prescription medication. Some community pharmacists moved toward patient - oriented self care. However, the social value of community pharmacists, as a whole, remained fairly weak. While the hospital pharmacist provided a valuable supporting service, found in their specialized knowledge of the action and use of medication, the adoption of the clinical pharmacy practice model could be viewed as the beginning of social value for hospital pharmacists.

Since 1990, the concept of Pharmaceutical care has been established ( Penna,1990; Farris and Kirking 1998; Holland and Nimmo,1999 ) which has reflected the shift of pharmacy practice to disease management activities. The pharmacists' practice of pharmaceutical care demonstrated the responsibility of the outcome of medication therapy. In addition, pharmaceutical care is the philosophy for practice implication as Hepler's notion of **“synergy of the drug product itself and intelligence to control its use”**. The adoption of this new practice model could be viewed as opportunities for pharmacists and they began to exercise them

In the USA, during the twentieth century, pharmacy practice was influenced by changes in education, organization and economics. Three main challenges occurred in the pharmacy profession: (1) the conflict between commercialism and professionalism, (2) the isolation of pharmacy education from the practice of pharmacy, and (3) the choice between the drug product or the patient as pharmacy's object. Sleath and Cambell (1998) concluded that the pharmacy profession approached the stage of choosing to be either a patient-centered profession or a new technical field. However, regarding the pattern of the health care system, the pharmacists still have authority only in dispensing, while prescribing is fully authorized by the physician. In a study (Bell, McElnay, and Hughes, 2000), patients' perceptions towards the current role of pharmacist were investigated, and it revealed that the pharmacists' services were quick and efficient, with little effort to provide pharmaceutical care.

In most Latin American countries (Leyva, Bronfman, and Erviti, 2000), such as in Mexico, pharmaceutical products are sold with less restrictions than in other regions. This fact, in addition to difficult geographic terrain and economic barriers to health services, make drug store attendants to be an important source of diagnosis and the prescription of medical drugs. Consequently, medical drugs are sold nearly everywhere. The main places where medical drugs are obtained are drug stores. Thus, anyone who established a pharmacy could sell the medication with less government restrictions. It was also found that some of the owners of these private drug stores could be anyone as well as a doctor who could prescribe and sell drugs at the same time. Not surprisingly, the attendants in any drug store could be anyone who could read and write. They could work as legal practitioners in a pharmacy. It was

found that 43% of all drug store attendants had only a college degree. Yet, research involving pharmacy practice has not been addressed. During the 1990s, the number of private drug stores, particularly chains of drug store, increased substantially in the country. Additionally, the health centers, clinics and public hospitals owned by social security and social assistance institutions have their own pharmacies. A total of 15,653 pharmacies supplied prescription drugs for their patients. Although, most prescriptions were prescribed by doctors in these situations, these prescriptions were not dispensed at these pharmacies, especially in the case of health ministries' clinics. It was observed that 56% of these patients bought medicine in private drug stores.

In Great Britain, over 12,000 community pharmacies had two dimensions to their practice; a professional dimension and a retail dimension. As an independence contractor within the NHS (National Health Service), community pharmacists delivered pharmacy services and these services were remunerated. The majority of the dispensing of prescribed medicines could be remunerated. The traditional pharmacists compounded and dispensed prescribed medications. This function has now largely involved into the **dispensing** activities of **counting, pouring and labeling**, assessing and monitoring prescriptions to ensure that they are appropriate and safe (Ruston ,2001). This resulted in a re-examination of the professional role of the pharmacist. Community pharmacists found themselves over - qualified for what they did and under- utilized in relation to their knowledge. The response of the community pharmacy profession has been to engage in the process of **re-professionalization**, which has taken the form of a role expansion, a phenomenon which is now occurring all over the world. The study showed that the involvement in extended role activities is more to do with their professional orientation than the

settings in which they work. According to several constraining factors, for example, the lack of pharmacists' autonomy, knowledge, skill and confidence for them to extend their role, it is suggested that it will a long time before the extended role becomes a reality for most community pharmacies.

In Denmark (Yan, 2000), generally, pharmacists worked to serve the growth in the industry sector. Sixty percent of graduated pharmacists of the Royal Danish school of pharmacy went to work in all areas of drug manufacturing in the pharmacy industry sector, while 20 % of new graduates chose to practice in community pharmacy. They are regulated jointly by the Pharmacy Proprietors Association (PPA) and the National Board of Health (NBH). All community drug stores were privately owned by individual pharmacists. No one was allowed to own more than one store, nor could an owner sell his or her store. Corporations could not own pharmacies. Therefore, chain drug stores could not exist in Denmark. Denmark had the fewest pharmacies per person of all European countries, with each community pharmacy serving an average of 16,000 people.

In East Asia, the health care systems mostly had the tradition of oriental medicine and the roles of physician and pharmacists were not differentiated. It had the effect on the practice of medicine that physicians both prescribed and dispensed drugs in China, Hong Kong, Japan, Korea, Vietnam, and Taiwan (Chue, 2002; Kwon, 2002). In Vietnam, currently, in more than 6000 private pharmacies, prescriptions by pharmacy staff or pharmacists without prescriptions, most patients can purchase drugs including antibiotics without prescriptions, or with just some medication instruction advice. Also in Thailand, multi-interventions have been studied to improve the quality of pharmacy services in the Good Pharmacy Practice among

these countries. (Pumtong,1998; Suttajit, 2000; Chue, 2002; Kwon ,2002; Lee, 2003). Further, in Thailand, pharmacy development projects, standard practice guidelines, and community pharmacy accreditations were addressed to improve the quality of pharmacy services. In Korea, in the pharmaceutical sector, where there was no separation of drug prescribing and dispensing, physicians and pharmacists both prescribed and dispensed drugs. Missing was the mechanism of checking and balance between the pharmacist and the physician in the prescription of drugs, that resulted in inappropriate drug use. To correct this problem, the Korean government carried out health care reforms by launching a new policy ( Lee, 2003; Kang, Park, and Kim, 2002), called the '**separation of dispensing and prescribing**' authority which redefined professional roles of the physician and pharmacist with respect to medication therapy and altered the way of providing or receiving pharmaceutical care, effective from 1 July, 2000. Pharmacists were no longer allowed to prescribe and physicians were prohibited to have medicine in their office and hospitals for out-patients. This reform attempted to change the provider's economic incentives by eliminating the providers' profit from drugs that had been a major source of their income. It also influenced the pharmaceutical industry that had thrived on offering margins to physicians rather than on producing high – quality drugs. However, recently the physician strike forced the government to modify some critical elements of the reform package and to raise medical fees substantially to compensate for the loss of the physician's income. Despite a decreasing of drug expenditure (302 billion won between 2000 and the first half of 2001) in regard to self medication and pharmacist consultation, the highest-priced drug had increased (Lee, 2003). It was found that the failure to appreciate this paradigm of health policy process and also the

failure to convince consumers of benefits of the reform resulted from the lack of a strategy plan of implementation. This historic reform has resulted in greater social cost than was expected. Nonetheless, the separation of prescribing and dispensing allowed pharmacist to have specific role in providing full function on dispensing.

### **Pharmacy practice in Thailand**

The evolution of Thai pharmacy practice (Aswavitai, 2002; Aswavitai, 2003; Jantarasukul,2003) began with the traditional herb and pharmaceutical product pattern in the Sukothai- era (1238-1350), to the compounding era in 1914, and the dispensing era in 1982 , until the current era (twentieth century) of **dispensing with counseling**, where the concept of Pharmaceutical care has been addressed. Eventually, some community pharmacists and clinical pharmacists shifted to pharmaceutical care practice. Because irrational drug use was mostly found in the drug store outlet among developing countries and also in Thailand ( Rattanawijitrasin, 1997; Suttajit, 2000; Wiboonpornprasert, 2002), the WHO, in cooperation with FIP in 1993-1994, set a standard practice guideline for good pharmacy practice. Also pharmacy practice in Thailand shifted to complementary and alternative care. Support of the use of traditional herbs in countries and also the primary care giver in self-care was established. Further, the Thai Community Pharmacy Association set the standard practice guideline relating to Good Pharmacy Practice (GPP). The study of Tiennguan in 1994 showed positive attitudes among community pharmacists to this standard practice guideline. In 2002, Tongrod developed and validated the Thai community pharmacy standard practice guideline for adaptive responses to the changes of the Thai health care system (universal coverage policy). The study's



objective was to be the standard pattern of an accreditation of the community pharmacy, for preparing to be the sub-contractor (out - source) of the medication from out-patients' prescriptions of clinics and hospitals. This guideline was composed of three standard issues, structure, quality management for good pharmacy practice, and ethics with social responsibility. Despite its validation, reliability and clarity, the result revealed that, although most of pharmacists welcomed this guideline, some thought it had restrictions concerning the competitiveness of community practitioners doing this practice in a real setting. So it was recommended to be voluntary, and step by step towards change.

Like some other countries in Asia and Latin America, existing pharmacy practices in the Thai health care system had the community pharmacists having **both the role of prescribing and dispensing**. Most drugs were dispensed without prescriptions. Among the 11,037 pharmacies in the country, there were two types of drug stores, namely type 1 and type 2. Modern medicine was available for type 1 and only the traditional drug was available for type 2. There were about 5000 of each type in this sector, and about 1200 of type 1 pharmacies belonged to pharmacists, which had full time and part time pharmacists. The ratio of a drug store to the population was 1:6000 ( Puntong, 1998) and for a type 1 drug store, the ratio to the population was 1:12551 in 1996. In the last two decades, the business trend of pharmacies has shifted to a more competitive market; chain and franchise drug stores were mostly found in department stores. In this holistic drug system, inappropriate drug use has been found to be rampant throughout these outlets. The professional associations included the Community Pharmacist Association, the Pharmaceutical Association, Hospital Pharmacy Association and the Pharmacy Council, they had applied

enforcement to encourage pharmacists to extend their role, especially among the community setting in regard to providing more patient care. Continuing education, academic meetings and pharmacy development project participation were the trigger that community pharmacists engaged extensively to the role.

For hospital pharmacies, clinical practice and providing pharmaceutical care were the marks of the professions relating to pharmacy practice. Some clinical pharmacists had been well recognized from colleagues amongst health teams, and also from the patients. Still, community pharmacists did not emphasize professional care, besides dispensing. Several studies (Prachachalerm et al., 1998; Sripa, 2000; Chaiutithkul et al., 2003) stated that pharmaceutical care terms only dispense with counseling, regardless of the novel care practice, including patient monitoring or patient medication records. Pharmaceutical care- based pharmacy practice has not been identified or documented, except for the studies regarding the attitude toward pharmacy services just dispensing and some influencing factors being addressed.

## **Good Pharmacy Practice**

A standard is important in quality service assessments. In the pharmacy profession, many standards have been set up to assure the quality of pharmaceutical services or products. Good Manufacturing Practice (GMP) was used to assure the quality of manufacturing product or even a production sector in hospital. However, the Good Pharmacy practice (GPP) established by the International Pharmaceutical Federation (FIP) was a standard for qualification of pharmacy services in direct contact with patients. In addition, this standard was further adopted by both the FIP in

1993 and the World Health Assembly in 1994, which it based on a pharmaceutical care concept, (Hepler and Strand, 1990) regarding the responsibility for drug therapy to achieve a definite outcome that would improve the patient's quality of life. This guideline included the national standard activities for pharmacists concerned with health promotion and ill health avoidance, supply and the use of prescribed medicine and other health care products. For self care, it is regarded to advise appropriately the medicine or other treatments for symptoms of minor ailments that can properly be self treated and also influenced prescribed medicine ( WHO, 1993; Pumtong,1998; Suttajit, 2000 )

In 1993, the charter of collaboration between the Pharmaceutical Group of European Community (PGEC) and the European Proprietary Medicines Manufacturers' Association (AESGP) noted the terms as follows;

“The pharmacist is an adviser to the public on every day health care and the key figure in the supply and delivery of medicines to the consumer. He is a partner of the manufacture of non- prescription medicines. Both share the common goals of service of high quality for the patient and encouragement of the rational use of medicines. The pharmacist in his professional capacity and in direct contact with patients is component to provide sound advice on the medicines he supplies”  
( WHO, 1998 )

In regard to the Tokyo FIP congress (1993), Good Pharmacy Practice (GPP) needed to be established, to keep the pharmacy service high enough for the public. GPP suggested 3 major functions of pharmacy practice ( Lee, 2003);

- 1) Provision of drugs through dispensing and sales.
- 2) Provision of advice and information for effective use of drugs by the public and society.
- 3) Participation into public health promotion and disease prevention through pharmacy service. To achieve this, community pharmacists with their professionalism should work for the well being of their patients.

It therefore would be necessary to introduce GPP to strengthen the pharmacy practice so that it could provide enough good quality pharmacy services among the public in the context of possible separation dispensing and prescribing.

## **Pharmaceutical Care and Its Implications**

Pharmaceutical care was the philosophy practice that Hepler and Strand (Hepler and Strand, 1990; Holland and Nimmo, 1999; and Penna, 2000) defined as “the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient’s quality of life”. Hepler further differentiated pharmaceutical care from clinical practice in that the former emphasized the purpose of the functions over simply performing them. Professionals accepted responsibility rather than merely provided functions. The clinical pharmacy shifted to pharmaceutical care as a practice model in which attention was paid more than previously before on the professionalism of pharmacists. For some pharmacists that have already embraced a clinical pharmacy practice model, the shift to

pharmaceutical care was primarily the change in attitude. For others, still in the distributive role, it signaled a major change in knowledge and skill as well.

Decades ago, the notion of pharmaceutical care was defined in various terms including the definitions, missions, activities, dimension and domains. However, each term and understanding from several researchers had the same focus of care in regard to patient-centered practices. To date, the current issue of this care has been recognized in pharmacy benefit management of the managed care system. Several studies have revealed drug expenditure decreasing through pharmaceutical care activities.

Several studies have implied the concept of pharmaceutical care. (Hepler and Strand, 1990; Odedena, Segal and Hepler, 1995; Odedena and Segal, 1996) A qualitative study of attitudes and opinions of community pharmacists towards this care showed that the pharmacists had knowledge regarding various terms of 'pharmaceutical care (Bell, Mc ElNay, Hughes et al.,1998). Definitions ranged in complexity and indicated the varying extents of understanding of the concept. Some pharmacists considered pharmaceutical care to be a basic customer service function, whilst others considered it to be primarily an advice-giving role. The examples of some opinions towards pharmaceutical care were '*Customer care, looking after the customer from when they come into the shop until they leave.*', or '*It is really advice, making sure the patient has understood the instructions.*', or '*It is complete patient care, where the pharmacist takes responsibility for the drug therapy of the patient, ensuring the correct outcome of medication is achieved.*'

Despite most pharmacy professional associations incorporating this concept of pharmaceutical care defined by Hepler and Strand, it has not been widely adopted into daily practice. The question arose; how could the extent of pharmaceutical care of pharmacists be measured? Several quantitative studies (Odedena, Segal and Hepler, 1995; Odedena and Segal, 1996; Farris and Kirking, 1998; Bell et al., 1998; Bell, Mc ElNay, and Hughes, 2000; Hanson, 2003, and Volume et al., 2001) regarding pharmaceutical care provision measurements were implied and established. For example, the study of Odedena in 1996, defined a scale for measuring pharmaceutical care was performed. The development and validation of a behavioral pharmaceutical care scale (BPCS) was also addressed. Revisions of behavioral pharmaceutical care scale were established (Appendix V) whilst scales were used as a tool for measuring pharmacists' efforts to provide this service (Odedena and Segal, 1996; Bell et al., 1998). The construction of behavior appeared to represent three dimensions of pharmaceutical care scale; 1) direct patient care activities, 2) referral and consultation, and 3) instrumental activities. The direct patient care dimension was proposed to represent five domains, including documentation, patient assessment, implementation of therapeutic objectives and monitoring plans, patient advising and counseling, and the screening of patient records. The referral and consultation dimension was proposed of domains of referral and consultation, which consisted of nine items. Finally, the instrumental dimension was proposed to consist of seven single item domains that included counseling location, validation of filled prescription, information support, evaluation of patient satisfaction, competency improvement, performance evaluation, and provision of medical information. Conclusively, fourteen domains were constructed to these three

dimensions and overall levels of pharmaceutical care are shown in Table 2.1. However, at present, the provision of pharmaceutical care within the community setting is not extensive ( Bell, et al., 1998; Bell, Mc ElNay, and Hughes, 2000; Rossing, Hanson, and Krass, 2002 ).

Additionally, several authors evaluated community pharmacists' views and opinions toward pharmaceutical care provisions. Those were the missions of insight success cases of pharmacy practice and several opinions related to pharmaceutical care concepts, in Europe, USA, and also in Thailand. Considerably summarized various definitions and measurements of pharmaceutical care are shown in Table 2.1.

Table 2.1: Summarized pharmaceutical care definition & measurement

Year	Authors	Concepts/ Definitions/ Missions	Dimensions/ Domains/ Activities
1990	Hepler, C.D.& Strand, L. M.	'Responsible provision the drug therapy involving dispensing, implementing and monitoring therapeutic plans to achieve specific outcomes that improve a patients' quality of life'	<b>Outcomes:</b> 1) Cure of disease 2) Elimination /reduction of patients' symptom, 3) Arresting/slowing of disease process, 4) Preventing a disease or symptomology
1993	WHO	'The philosophy of practice in which the pt. is the primary beneficiary of the pharmacist action p' care focuses the attitudes, behaviors, commitments, concerns, ethics, functions, knowledge, responsibilities & skills of the P' cist on the provision of drug therapy with the goal of achieving definite therapeutic outcomes toward pt. Health and quality of life'	<b>P' care for individual patient:</b> *Obtain & maintain medication records and relevant health information. *Identify, evaluate & assess DRP, symptom described by pts , self diagnosed conditions *Initiate or modify drug / non drug therapy: i) independent action that drug can be provide by pharmacist without prescription eg., life style changes, medical devices. ii) collaborated action for prescribed drug. * Prepare & supply medication for use



Year	Authors	Concepts/ Definitions/ Missions	Dimensions/ Domains/ Activities
			<ul style="list-style-type: none"> <li>* Prepare &amp; supply medication for use</li> <li>* With prescriber / patients., set goal of therapy</li> <li>* Design &amp; implement pharmaceutical care plan( education, counseling)</li> <li>*Monitor for therapeutic outcomes &amp; take appropriate medication.</li> <li>*follow up action( begin with pharmaceutical care cycle again)</li> </ul>
1996	Odedena, F.T. & Segal, R.	<p>The provision of pharmaceutical care entails pharmacist increasing their share of responsibility for the drug therapy outcomes of their patients. While the implementation of pharmaceutical care may be facilitated by several changes in the organization of work &amp; payment system, it appeared that pharmacists must show ‘psychological commitment’ &amp; ‘effort’ for true implement to be realized. One approach to defining a scale for measuring pharmaceutical care may be based on an assessment of pharmacists efforts to provide such care. Development and validation a behavioral pharmaceutical care scale ( BPCS ) to measure pharmacist effort were proposed.</p>	<p><b>Dimensions:</b></p> <p><i>Direct Pts care activity</i> Documentation, Pts. Assessment, Therapeutic monitoring plans, Pts. Record screening, Pts. Advising /counseling, Pts. Understanding verif.</p> <p><i>Referral / consultation activities</i> Referral/ consultation.</p> <p><i>Instrumental activities</i> Pts. Satisfaction evaluation, Competency improvement, Counseling location, Filled prescription. validation, Performance evaluation, Provision of medical info., Info. Support</p>

Year	Authors	Concepts/ Definitions/ Missions	Dimensions/ Domains/ Activities
1997	Yarborough, P.C.	Specific activities and services through which an individual pharmacist co-operate with a pts' and other professionals in designing, implementing & monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patients	a.) Pt. assessment, b.) Pt. Education & counseling, c.) Pt.- specific pharmacist care plan, d.) Drug treatment protocols e.) Dosage adjustment, f.) Selection of therapeutic alternatives, g.) Selection of therapeutic alternatives, h) Prescriptive authority h) Preventive service
2000	Prapanwatana, M.	It is a specific method of patient care to get to the complicate problem and adverse effect of medication.	*Drug therapy problem management *Drug information center *Adverse drug reaction monitoring.
2001	Arvipunth, R.	It is a patient care related to a pharmaceutical task with health team in regard as a patient- centre oriented.	1) Drug monitoring, 2)ADR monitoring, 3)Drug & disease info.4)Drug interaction, 5) TDM, 6) TPN, 7) Home Health Care, 8) DRP, 9) unit dose one day dose
2002	Pummangura, Ch.	'Responsible for patients' medication as in direct and indirect which is the important service for preventing the ineffective dr. therapy.'	1) drug counseling, 2) ADR monitoring with intervention 3) Therapeutic drug monitoring and assessment, 4) Drug utilization evaluation, 5) Drug info. Service, 6) Aseptic dispensary care

Year	Authors	Concepts/ Definitions/ Missions	Dimensions/ Domains/ Activities
2002	Tindall W., Millonig M. AphA.	<p><b>5 Process steps approach:</b></p> <ul style="list-style-type: none"> <li>* A professional relationship with patient</li> <li>* Patient-specific medical information must be collected, organized, recorded, and maintained.</li> <li>* patient-specific medical info. must be evaluated &amp; drug therapy plan developed mutually with pts.</li> <li>* Pharmacists ensure that pts. has all the supplies</li> <li>* Pharmacists must review, monitor, and modify therapeutic plans necessary &amp; appropriate in concert with the pt. &amp; health team</li> </ul>	
2002	Hanson, J.S	<p><b>Mission Statements:</b></p> <p>To provide patient with superior customer service when preparing and dispensing their medication. Highly trained pharmacist in drug therapy management to provide comprehensive pt. counseling, education services, and medication monitoring to ensure safe and effective medication use. It is our commitment to help pt. achieve better health through this service.</p>	

Year	Authors	Concepts/ Definitions/ Missions	Dimensions/ Domains/ Activities
2002	Graf, E.	<p><b>Embarking on the pharmaceutical care:</b>  Pharmaceutical care can be built by becoming the primary source in health care matters that are important to consumers. Satisfied consumers bring success to those from whom they have gotten help.</p>	

## **Pharmaceutical Care in Thailand**

The concept of pharmaceutical care in Thailand has been introduced for more than ten years, bringing questions of whether this pharmaceutical care service has been established or not, what the dimensions, and what activities are. To date, there is no research explaining the specific term of this service among community pharmacists in dimensions/activities explicitly, besides the general terms, particularly the traditional pharmaceutical care regarding dispensing with drug counseling (Kanjanakantika, 1996; Chayakul, 1997; Sripa, 2000; Prachachalerm et al., 2001; Chaiutithkul et al., 2002). The pharmaceutical service within the community setting is still not extensive nor has it been evaluated. The study of novel care such as the service related to drug monitoring and patient medication profile among community setting has been limited (Supaporn et al, 1996; Sripa, 2000; Lungsopaparn, 2000). Nonetheless, studies revealed the barriers influencing the attitudes and intentions to provide pharmaceutical care emphasizing on novel care.

With regards to the Thai drug system, the community pharmacists have both authorities including prescribing and dispensing. The services they provided relate to pharmaceutical care, for example, medication with counseling to the patients of primary ailments and also information of health promotion and disease prevention. The study (Sripakorn and Hemayakorn, 1995) of the perception toward the term of “pharmaceutical care” among community pharmacists and hospital pharmacists in Thailand was addressed. Additionally, few studies related to pharmacy services among community pharmacists, including refill medication provisions in chronic disease cases (Laungsopaparn, 2000), the counseling activities (Kanchanakantika et

al., 1996; Areekul, 2001), opinions of pharmacist and patients in patient medication records (Supaporn et al.,1996), and the referral system for diabetic patients by the community pharmacists (Jarupongsa et al., 2001) were addressed. Rather, factors influencing attitudes on general terms of pharmaceutical care practice regarding dispensing with counseling among community pharmacists in Thailand were also investigated (Sripa,2000; Prachachalerm et al., 2001; Chaiutithkul et al., 2002).

However, to date, Pharmaceutical care – based pharmacy practices in Thailand have not been identified in specific terms and dimensions. Yet, we can not evaluate whether community pharmacists provide pharmaceutical care activities. Providers or non- providers of pharmaceutical care could not be justified. What types or what levels of pharmaceutical care they provided are issues. Thus, it needs to identify and determine those activities. To get the dimensions and activities in a Thai context, the behavioral pharmaceutical care scale (BPCS) could be applied. Explicit services should be explored which are beneficial to implementing pharmaceutical care among community pharmacists throughout the country. Indeed, during the past decade there were several researches into pharmaceutical care, most of which had proposed the definition of general patterns of pharmacy practice among community pharmacists, relative to some domains of this care, including drug counseling, health prevention and promotion advice. Rather, it has not been investigated what the dimensions and items of real practice are in a Thai context. To know and explore these specific terms or the dimensions of Thai Pharmaceutical care, qualitative studies regarding the focus group study should be alternative performed. (Kitzinger, 1995; Britten, 1995; and Gibbs, 1997). Additionally, qualitative study will allow the

discovery of Thai pharmaceutical care concepts and components not anticipated by the researchers.

From several researchers of other countries (Table 2.1), the various terms, activities, dimensions and also the mission statements related to pharmaceutical care were addressed. Most of this research addressed behavioral pharmaceutical care scale (BPCS) was based on pharmacy practice among community pharmacists. Yet, among community pharmacists in Thailand, pharmaceutical care has still not been addressed or clarified in any specific terms or domains in the real setting. Decades ago, besides the perception of community pharmacists toward pharmaceutical care, the prevalence of this care had not been identified and had not been widely adopted into practice. Although some studies concerning community pharmacy practice have been performed, the validity and reliability of instruments of pharmaceutical care-based pharmacy practice were not available. Studies that addressed pharmaceutical care service in term of the community pharmacists' perspective toward the concept of pharmaceutical care and explicit activities were limited. Rather, the prevalence of pharmaceutical care practice among community settings in Thai context has not been addressed. It is therefore, the first step, it needs to gather some opinions or knowledge from the practitioners at the practice site. Meanwhile, pilot interview studies and semi- structure topic guide probes might be appropriately used to get an insight into community pharmacists' opinions of the real practice ( Britten, 1995; Bell, Mc ElNay, and Hughes et al.,1998).

## **Measuring Pharmaceutical Care –based Pharmacy Practice**

Awareness of variation in the delivery of pharmaceutical care- based practice has resulted in considerable research activities being focused on developing measures to assess the appropriateness of this service. Ideally, pharmaceutical care should be provided to all patients on a continuous basis to achieve the desired therapeutic outcome. However, during this transition in pharmacy practice, it may be unrealistic to expect pharmacists to provide every component of pharmaceutical care to all patients at all times. Thus, to address this issue, behavioral pharmaceutical care scale ( BPCS ) items were described on the basis of specific patient care services provided to patients with chronic conditions. Regarding this approach to defining a scale for measuring pharmaceutical care that were based on pharmacists' efforts by using a multiple- item scale to assess behavioral activities in pharmaceutical care. BPCS was developed (Odedena and Segal, 1996). The instrument was found to be reliable, sensitive and valid.

The BPCS includes domains and items of pharmaceutical care activities as shown in appendix V. Several studies (Odedena and Segal, 1996; Bell et al., 1998) used this BPCS instrument to assess the provision of pharmaceutical care by community pharmacists. Additionally, qualitative measurement of some domains in pharmaceutical care, for example, the criteria to measure the appropriateness of advice provided by community pharmacists, and also the qualitative investigation of the opinions of community pharmacists toward pharmaceutical care were addressed ( Bell, Mc ElNay, and Hughes, 1998; Bissell et al., 2000 ). However, in comparing to the qualitative measurement, BPCS would be a more potential application in



pharmacy service measurement and it can help determine the outcome of intervention programs related to pharmaceutical care service.

Due to the Thai drug system being different from the USA and Europe, the BPCS would not be practically used to predict or evaluate the extent of pharmaceutical care provision in the Thai context. The study that capitalized on communication between research participants in order to generate data, including pharmacy practice activities in the real setting of Thai context should be the focus group methodology, by which the method is particularly useful for exploring a person's knowledge and experiences, and can be used to examine not only what people think but also how they think, and why they think in that way (Kitzinger, 1995; Gibbs, 1997).

The focus group or a form of group interview is thus appropriate to reach the parts of pharmacy practices that other methods cannot reach, so that it might reveal the dimensions of understanding, such as the domains or activities of pharmaceutical care based pharmacy practice that really often remains untapped by more conventional data collecting techniques. Therefore the explicit activities besides dispensing with counseling will be explored.

## **Factors Influencing Pharmaceutical Care**

The limited success of past attempts to influence pharmacist consultation activities was the evidence in the difficulty in changing pharmacists' practice patterns. However, most pharmacists were eager to develop their professional roles, many barriers were identified including lack of time, little financial incentive, lack of

private counseling areas and low public perception. The study of Rossing, Hanson, and Krass in 2002 revealed that the most significant barriers influencing the pharmaceutical provision among Danish community pharmacists regarding the lack of resources, included a lack of pharmacists ,technicians, and financial resources in pharmacy; also most initiatives or facilitators taken to implement pharmaceutical care were addressed, including post graduated training of pharmacy staff, external promotion, and changes in the general operation of the pharmacy. In addition, the characteristics of pharmacists were identified, that influenced the adoption of an extend role. Shortage of time was cited by 96% of respondents and 92 % of them reported insufficient remuneration as barriers (Ruston, 2001). Moreover, other major structural barriers that included a shortage of staff and a lack of contact with other health professionals were identified. It was similar in the study (Bell et al.,1998); two related factors identified as hindering pharmacists' provision pharmaceutical care were lack of staff and lack of remuneration, while the qualitative investigation of attitudes and opinions toward this service (Bell, Mc ElNay, and Hughes,1998) showed that lack of time, little financial incentive, lack of private counseling areas and low public expectations were factors influencing this provision.

Sleath and Campbell (1998) noted that economic factors influencing pharmacy practices in moving toward being more patient- oriented, there were powerful commercial forces in the health care system that will either help or hinder pharmacy in making the patient the social object of the profession. When the unit of pharmacy productivity is a prescription, the pharmacist's evaluation and reimbursement is based upon the rate of prescriptions dispensed.

In 1995, Odedena, Segal, and Hepler investigated the provider and non provider of pharmaceutical care by an interview study. The factors of those groups that they believed influenced their behavior relative to pharmaceutical care were identified. It was found that the physical layout of the pharmacy, qualified personnel, practice orientation, patient expectation, physician cooperation, computer support, patient medical information and competency influenced this care.

## **Theoretical and Conceptual Framework**

### **Theoretical background**

The pharmacy practice literature has used the theoretical approaches which included the health behavioral model in consideration of pharmacy practice behavior changes. Regarding factors that have contributed to the change of pharmacy service in the past decades, besides the external factors, such as lack of time, staff, competition, and remuneration that have influenced the provision of pharmaceutical care, other internal factors concerning the behavioral mediating variable are the important factor that also affect the practice behavior. Several behavioral researches have been studied, theory of health behavior has been established to predict and explain the behavior change. Hereby, a theory of planned behavior, a self- efficacy model and a KAP model were used to get the theoretical framework.

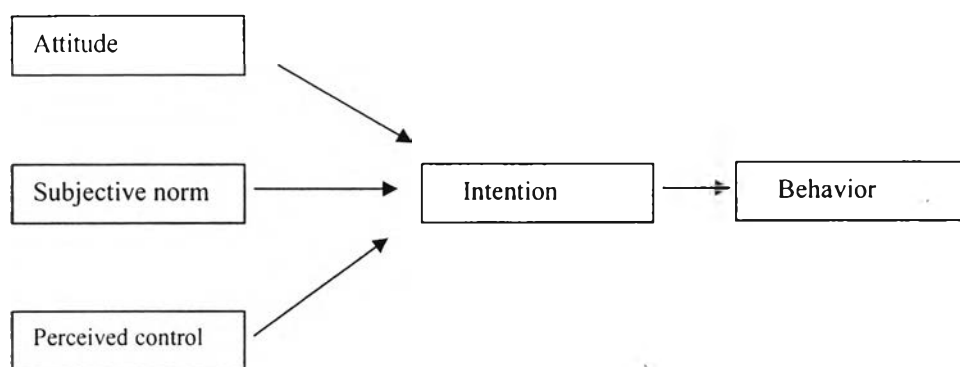
#### ***Theory of planned behavior (TPB)***

Regarding the health behavioral researches, especially in the behavior change related to the pharmacy practice, the planned behavior theory is a

considerable theoretical approach and mostly found in several studies. The theory focuses on theoretical constructs concerned with individual motivation factors as determinants of the likelihood of performing a specific behavior. An extension of the theory of reason action (TRA) (Ajzen and Driver,1991) included a measure of attitude and social normative perception that determined the behavioral intention; the theory of planned behavior (TPB) added a construct concerned with perceived control over performance of behavior that in an effort to account for factors outside the individual control may affect his intention and behavior, as illustrated in figure 1. A person's perception of control over behavioral performance, together with intention, is expected to have a direct effect on behavior, particularly when his/ her perceived control is an accurate assessment of actual control over the behavior and when volitional control is not high. The effect of perceived control declines and intention is a sufficient behavioral predictor in situations where volitional control over the behavior is high.

The practice philosophy has been explicitly advocated since 1990. However, its adoption by community pharmacists has been slow (Carter and Barnette, 1996; Sisson and Israel, 1996; Posey, 1997; Farris, 1999). Several barriers to providing clinical pharmacy have been identified including such as economic structure of retail pharmacy, inter-professional conflicts etc ( Baker, 1979; Bell, Mc ElNay, and Hughes, 1998). Besides these barriers, several studies have examined pharmacists' intentions and behaviors in implementing pharmaceutical care. Some studies used goal direct behavior model to predict the goal behavior and ones' behavioral intention to try to provide pharmaceutical care ( Farris and Kirking,1998; Farris and Schopflocher, 1999). Some studies showed that although pharmacists have

good attitudes, they did not intend to provide a pharmaceutical care service. Not only the attitude but also the intention should thus be the important predictors influencing pharmacy practice.



*Figure 2.1: Schematic presentation of the Theory of planned behavior*

### *Theory of self-efficacy*

The self- efficacy theory (Bandura, 1977) proposed the concept of self- efficacy as a fundamental component of the social cognitive theory. Bandura defined self- efficacy expectations as a person's belief or confidence in her or his ability to perform a given behavior or set of tasks. Bandura posited that self efficacy expectations determine whether or not a person will initiate a behavior, how much effort he or she will expend, and how long he or she will sustain the behavior in the face of obstacles. Hundreds of studies have shown that self-efficacy beliefs are good predictors of behavior. In academic settings, it refers to the students' beliefs concerning their capability to perform given academic tasks at designated levels (Schunk, 1991; Bong, 2001). Students with strong senses of self-efficacy willingly engaged in challenging tasks, invested greater effort and persistence, and showed superior academic performance than those who lacked such confidence (Bandura &

Schunk,1981; Betz & Hacket 1981). Evidence convincingly demonstrates the critical role of self-efficacy perceptions play in determining ones' achievement-related cognition affect and action. Self-efficacy is highly relevant to career behavior ( Hacket & Betz. 1981).

Additionally, the studies (Odedena, Hepler, and Segal, 1997; Farris and Kirking 1998) showed self-efficacy was a strong predictor of practice regardless of the terms of instrumental belief and effect toward means. Moreover, the study of intention and behavior: an application of community pharmacists' assessment of pharmaceutical care (Farris, 1999) showed that adoption of pharmaceutical care behavior was predicted by pharmacists' self-efficacy, beliefs, evaluations and behavioral control. Ajzen's construct of perceived behavioral control is very similar to Bandura's construct of self –efficacy, an individual judgment of how well he can perform behavior under inhibiting conditions. However, operating the construct is somewhat different in TPB. The study (Farris, 1999) showed that the only direct predictor of behavior was self –efficacy. Self- efficacy thus would be used to be one important predictor of the pharmacy practice behavior in this study.

### ***The Knowledge- Attitude – Practice model ( KAP)***

This model focuses on the cognitive mechanisms underlying the acquisition and representation of knowledge. Sripa (2000) claimed that in the Schwartz study there are four models of the relationship among knowledge, attitude and practice of behavior. All four models revealed the attitude and knowledge that has affected the practice behavior both directly and indirectly. From the study among community pharmacists, revealed **knowledge** has both directly / indirectly (through

attitude) affected the intention toward the general term of pharmacy service in Thai context, with the correlation coefficient 0.162 and 0.233 significantly. The participation of pharmacists in development projects are likely to have a positive relationship with knowledge to perceive ease to provide this care.

Regarding this study's objectives to assess the extent of pharmacy practice among community pharmacists in Thai context of non-separation prescribing and dispensing (NSPD), and to determine the factors influencing the theory of self-efficacy combined with the planned behavior theory. It should be implied to predict the pharmacist behavior via the behavioral construct, including **attitude, self efficacy**, via **intention , and behavior**. Additionally, **knowledge** and **attitude** from KAP model would also be the predictor of the practice behavior. Thus, the theoretical framework of this research would include **attitude, knowledge, self- efficacy**, via **intention** to the **practice behavior**.

Furthermore, professional socialization was the process by which an individual selectively acquires the value, attitudes, interest, skills and knowledge current in the profession. **Professionalism** was identified as one of the characteristics of a fully socialized professional that focus on the patient welfare which is the basis of emergence of pharmaceutical care (Almardottir et al., 2001; Lerkiatbundit, 2000). Professional scales were developed, the change of professionalism in Thai pharmacy students as the outcome of pharmacy socialization was focused upon. The level of professionalism and variables were measured. Social, academic integration and socioeconomic status were significant of professional commitment, and professionalism scales were addressed (Lerkiatbundit, 2000). Thus we would also

employ the **professionalism** as the social cognitive variable in the conceptual framework.

According to the concept of pharmaceutical care involving the pharmacist- patient relationship, similarly to the research related to physicians in caring of patients, the positive role of **empathy** in interpersonal relationship was agreed upon. Despite physicians mediating roles, in patient - physician relationships and clinical outcomes, operational measurement of empathy should be employed. Empathy has been described as the concept involving cognitive as well as affective or emotional domains. The empathy was defined in patient-care situations as the cognitive attribute that involved an ability to understand the patient's inner experiences, feelings and a capability to view the outside world from the other person's perspective. ( Hojat et al., 2002; Gardner, Boyce, and Harrier, 2000 ). Thus, the component of the physician **empathy** scale, that considered the grant factor of physician's view from patient's perspective, should be developed and applied to pharmacists in pharmaceutical care provision. Therefore it would be employed as another social cognitive variable influencing pharmacy practices.

Additionally, this theoretical framework would be implemented effectively if the comprehensive barriers were overcome. The intervention program would be generated, the model should have factors that influence pharmacists' underlying intentions toward the provision of pharmaceutical care directly or indirectly to the practice (Odedena and Segal, 1996). Regarding several studies ( Odedena, Segal and Hepler, 1995; Odedena, et al.,1996; Bell, Mc ElNay, Hughes,1998; Rossing 2002; Sripa 2000; Prachachalerm et al., 2001) besides the predisposing factors including age, gender, year graduated, year practice, practice pattern and owner status, etc.; they

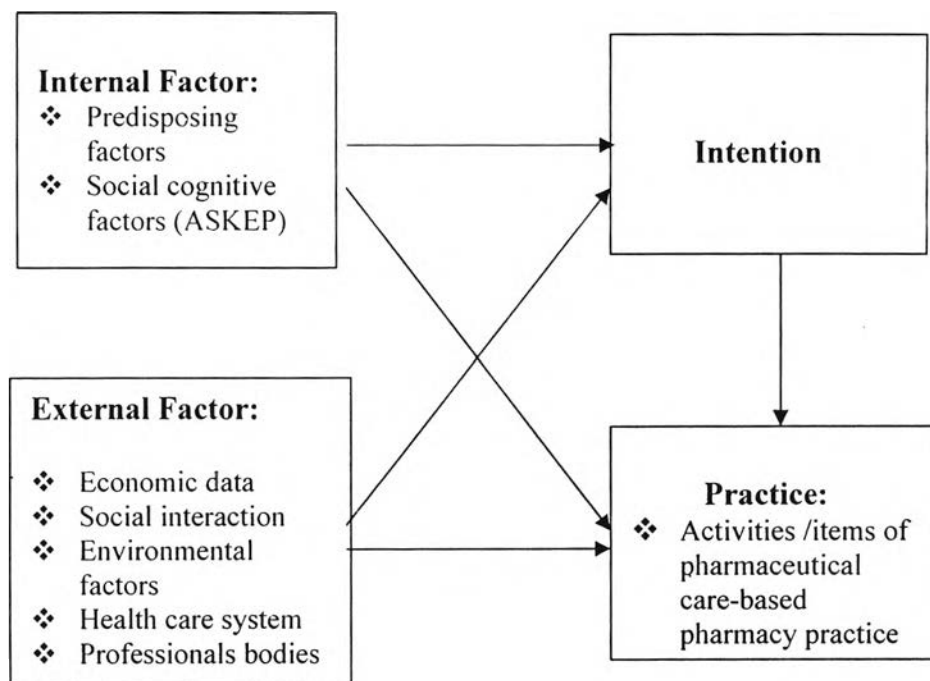


revealed the external factors that considerably influenced the intention and practice; including the number of pharmacists, number of assistants, workload, knowledge of pharmacist, participation in pharmacy association meeting, remuneration, lack of co-operation with physicians, in service training for pharmacists, patient's expectation, patient's time, patient's medical information, policy of government, IT utilization ( computer program), and price competition.

### **Conceptual framework**

From the theoretical framework, empirical studies and pilot interview, it was shown that attitudes toward pharmaceutical care behavior, self - efficacy, intention, knowledge were important factors in the establishment of pharmacy practices. From the pilot interview, some traces of pharmaceutical care provision as concept, understandings and some activities of pharmacy practice in Thai community settings, were found. In addition, other social cognitive factors included professionalism and empathy were also important factors to predict or assess the extent role of pharmacy service related to pharmaceutical care. Furthermore pharmacists' encouragement to ensure that medication- related health outcomes would be successful, by decreasing the barriers. The specific objectives were to identify the factors influencing intention of community pharmacists to provide pharmaceutical care – based pharmacy practice, and to identify the factors influencing community pharmacists to provide their current pharmaceutical care– based pharmacy practice. The conceptual framework of this study was mainly aimed to determine the degree of pharmaceutical care in the Thai context. In addition, many

factors including individual factors, economic data, social interaction, environment factors, health care system, and professional bodies might also affect the intention and practice. Therefore the conceptual framework of this study would comprise four parts. Factors (IV) were divided into two group of internal and external factors toward practice. The pharmacy practice and intention (DV) would be investigated as illustrated in the following figure 2.2.



**Figure 2.2: Conceptual Framework:**

**Note: Internal Factor:**

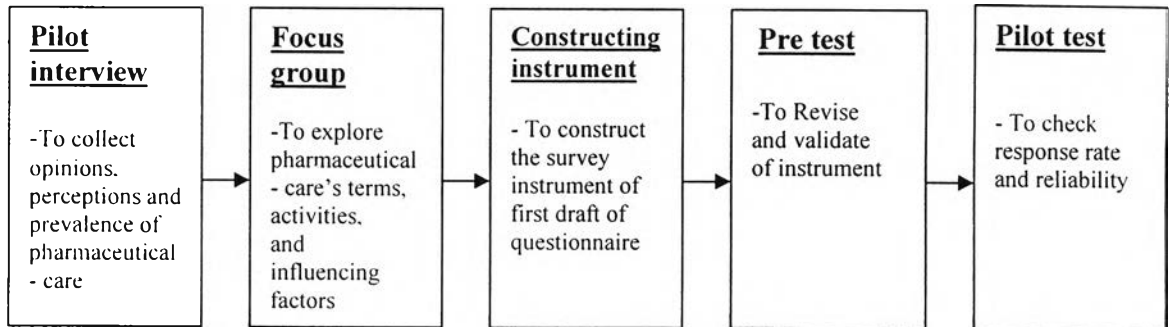
- ❖ Predisposing factors
  - Age, Gender,
  - Year graduate, Degree
  - Year practice, Practice pattern
  - Owner status
- ❖ Social cognitive factors
  - Attitude (A)
  - Self efficacy (S)
  - Knowledge (K)
  - Empathy (E)
  - Professionalism (P)

**External Factor:**

- ❖ Economic data
  - Price competition, setting type, location.
- ❖ Social interaction
  - Participation in CE, drug store dev. project, com. pharmacy accreditation
- ❖ Environmental factors
  - Pharmacist assistants, workload, utilizing of computer in dispensing ( eg., computer program used in service) and pts' time.
- ❖ Health care system
  - Perception of the influence from 30 baht policy, perception of the usefulness of SPD toward pharmaceutical care.
- ❖ Professional bodies
  - Perception of supports from pharmacy professional bodies including community pharmacy assoc., pharmacy council, university.

Pharmaceutical care- based pharmacy practice in Thai context were still not considerably addressed, and yet, the degree of this service was not determined. Exploration of the extent of pharmaceutical care- based pharmacy practice was needed. The method of the focus group is an alternative method, particularly useful for exploring pharmacists' knowledge and experiences of their practice in a real setting. As mentioned before, the focus group should be used to reveal the terms, explicit activities and factors influencing pharmaceutical care based pharmacy practice in Thailand. Therefore, this method was an alternative method, particularly useful for the survey research in construction of the tool or instrument of survey study in next step. Thus, the process of instrument development to measure the pharmaceutical care- based pharmacy practice in survey research would be employed by this method, which comprised the following steps as illustrated in figure 2.3.

The first step was a pilot interview to collect some opinions and to explore the prevalence of pharmaceutical care among the community pharmacist. The second step, a focus group was set to explore the components of pharmaceutical care activities and some factors influencing in Thai context. Further, the first draft survey instrument was developed. Then, evaluation of the instrument process on validity and reliability was performed by pretest (validated by experts) and a pilot test was performed to assess response rate and reliability of the instrument.



**Figure 2.3: Study Instrument Developing Process**