AN EXPLORATIVE STUDY ON PHARMACEUTICAL CARE PRACTICE FROM THE PERSPECTIVE OF PHARMACISTS IN MALAYSIA

By

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Thesis submitted in fulfillment of the requirements for the Degree of Master of Science (Pharmacy)

July 2008

DEDICATION

This dissertation is dedicated ……

……To the memory of ……..

My beloved father, who strived to give me the best; prepared me to face challenges with faith and humility. Although he is not here to give me strength and support I always feel his presence which motivates me to strive to achieve my goals in life. May ALLAH (SWT) forgive him and make the paradise his permanent residence.

..... To my own "soul out of my soul", and the essence of my life …

My beloved mother, Alrawdda Othman Hj. Ali, for her prayers, doaa', unflagging love, difficulties and pains. She was a constant source of inspiration to my life.

Your supports have pulled me throughout my difficult times ……

…….. To my best friends ……..

My beloved brothers, Ahmed, Yasir, Omar, Mohamed who kept my spirit up when the endurance failed me. Without their lifting me up when this thesis seemed interminable, I doubt it should ever have been completed.

…… To my wonderful friend……

My beloved sister, Sahar, her joy in others and unconditional love and be loved touches my heart. Thank you for not only being my little sister, but also my friend. I love you.

I ask ALLAH Almighty may bless all of you …….

ACKNOWLEDGMENTS

First and foremost, I would like to give my greatest glory to ALLAH (Subhanahu Wa Ta'ala) that I had courage and willingness to complete my dissertation and for the greatest and every things He has done for me all over my life. Thanks my merciful ALLAH, May Your name be exalted, honored, and glorified.

A journey is easier when you travel together. Interdependence is certainly more valuable than independence. This thesis is the result of four years of work whereby I have been accompanied and supported by many people. It is a pleasant aspect that I have now the opportunity to express my gratitude for all of them.

The first person I would like to thank is my supervisor Assoc. Prof. Dr. Azmi Sarriff, Pharm D, The Head of Clinical Pharmacy Department, School of Pharmaceutical Sciences, Universiti Sains Malaysia (USM) for his constant invaluable guidance, support and encouragement that helped me in all the time of research and writing of this thesis. His overly enthusiasm and integral view on research and his mission for providing 'only high-quality work and not less', has made a deep impression on me. I really appreciate his intellectual capabilities and constructive criticisms. He could not even realize how much I have learned from him. I owe him lots of gratitude for having me shown this way of research.

I warmly thank Puan. Zalila Ali from School of Mathematical Sciences, USM, for her guidance in the statistical analysis and friendly help. Her valuable advice and fruitful discussions around the statistical filed have been very helpful for this study.

I would like also to acknowledge with thanks the valuable contributions of Dr. Norbane Tangue, Department of Community Medicine, School of Medical Sciences – USM; Dr. Mohd. Ayub Sadiq, School of Dentistry – USM; Dr. Mohamed Izham Mohamed Ibrahim, School of Pharmaceutical Sciences – USM; Dr. Rahmat Awang, School of Pharmaceutical Sciences – USM. Dr. Yuen Kah Hay, School of Pharmaceutical Sciences – USM. Indeed their guidance in statistics has immensely contributed to the success of this work.

I owe my most sincere gratitude to my faculty lecturers, Dr. Noorizan Abdul Aziz, Dr. Yahaya Hassan, Dr. Syed Azhar, Dr. Mohamed Izham, Dr. Mohd Baidi, for the valuable revisions to establish the validity Phase of this research.

I wish to thanks my sponsor, Ministry of Health, Khartoum State, Sudan for providing me with the financial assistance throughout my research. In addition, special thanks to Training Department, pharmacy Directorate, and Revolving Drug Fund (RDF), Khartoum State, Sudan.

I cherished the prayers and generous support of Engineering. Hashiem Suliman Saad throughout the research time; this dissertation is simply impossible without him.

I wish to thank Mrs. Zeehan Shanaz Ibrahim, Florsent, and Ahmed Safwan, Center of Languages - USM, for revising the English of my manuscript.

My sincere thanks to all the staff at Institute of Post-graduate Studies (IPS), and Librarians in the USM main library for their valuable assistance

I also appreciate deeply the help and support of my family, uncles, aunts, cousins, relatives, and friends, especially Abd Elwahab Osman Hag Ali, Ali Alshibli, Mohammed Elmahadi Mandour Elmadadi, Isam, Imad, Atif, iman, Alia, Hanan, Dr. Mohamed Othman, Eng. Tarig Mubark, and Mr. Nemmour Yazid.

Special appreciation goes to my Brother, Sisters and friends postgraduate students, especially the Sudanese family in USM for their support and continuous Doaa'.

To all those that did not mention here, due to my short memory, I am grateful to all your contributions towards this research.

Last but not least, I feel a deep sense of gratitude for my mother who formed part of my vision and taught me the good things that really matter in life. The happy memory of my father still provides a persistent inspiration for my journey in this life. I am grateful for my four brothers Ahmed, Yasir, Omar, and Mohammed, and my sister Sahar for rendering me the sense and the value of brotherhood. I am glad to be one of them.

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LIST OF ABBREVIATIONS

ACCP	American College of Clinical Pharmacy
ADRs	adverse drug reactions
APhA	American Pharmaceutical Association
ASCP	American Society of Consultant Pharmacists
ASHP	American Society of Health-System Pharmacists
BP	Blood Pressure
CACDS	Canadian Association of Chain Drug Stores
CP	Clinical pharmacy
CPC	comprehensive pharmaceutical care
DRNs	Drug Related Needs
DRPs	Drug Related Problems
DTDM	Drug therapy decision-making
DTPs	Drug Therapy-Problems
FIP	International Pharmaceutical Federation
MCPA	Malaysian Community Pharmacists Association
MOH	Ministry of Health
NHS	National Health Service
OTC	over the counter

PC	Pharmaceutical Care
PCP	Pharmaceutical Care Practice
P&T	Pharmacy and Therapeutic (P&T) Committees
PSNZ	Pharmaceutical Society of New Zealand
QoL	quality of life
TPN	Total Parenteral Nutrition
TTM	Trans-theoretical Model
UKM	University of Kebangsaan Malaysia
UM	University of Malaya
USM	Universiti Sains Malaysia
WHO	World Health Organization

GLOSSARY

Action stage of Transtheoretical Model	At the point of action the individual has made the commitment to change and has ceased the problem behavior.
Contemplation stage of Transtheoretical Model	A person in the contemplation stage is considering the possibility of change the problem behavior, operationally defined as within six months.
Drug	The term drug and medicine are used indicating substances, which potentially heal or prevent disease.
Drug-use-control	Sum total of knowledge, understanding, judgments, procedures, skills, controls and ethics that assures optimal safety in the distribution and use of medications.
Maintenance stage of Transtheoretical Model	After six month of successful change, the person is consider in the maintenance stage and working toward resisting the temptation to revert back to the old behavior.
Precontemplation stage of Transtheoretical Model	The individual is not thinking about changing his or her behavior.
Preparation stage of Transtheoretical Model	The change in the preparation stage intends to change the problem behavior within the next 30 days.
Transtheoretical Model	Transtheoretical Model (TTM) of Change to explain, predict, and change multiple human behaviors. The Transtheoretical Model, which suggests that five stages of voluntary behavior change exist from precontemplation, contemplation, preparation, action, and maintenance.

MENGKAJI PRAKTIS PENJAGAAN FARMASI DARI PERSPEKTIF AHLI FARMASI DI MALAYSIA

ABSTRAK

Objektif kajian ini adalah untuk meneroka dan mengumpul informasi dasar yang diperlukan untuk melaksanakan praktis penjagaan farmaseutikal (PC) di Malaysia. Kajian ini juga menilai kefahaman, persepsi, sikap dan penghalang terhadap konsep PC, dan pada masa yang sama untuk menunjukkan situasi praktis farmasi dalam konteks pelaksanaan PC. Ini adalah suatu soal-selidik keratan rentas yang melibatkan ahli-ahli farmasi hospital dan komuniti di Malaysia yang menggunakan pendekatan mengeposkan borang-borang soal-selidik yang beserta setem. Dalam aspek kognitif, lebih 70% dan 60% ahli farmasi hospital dan komuniti mempunyai kefahaman yang tepat mengenai proses PC manakala hanya 17% dan 19%, masing-masingnya, gagal bersetuju dengan penyataan yang tepat. Situasi praktis semasa menunjukkan, kebanyakkan responden di hospital dan komuniti melakukan aktiviti-aktiviti praktis farmasi, tambahan pula, mereka juga kompeten untuk menjalankan aktiviti-aktiviti tersebut dan mengakui kepentingan aktiviti ini. Namun, data menunjukkan tidak ramai ahli farmasi komuniti (32%) menjalankan aktiviti pendispensan, hanya 34% mengaku kompeten dan 43% daripada mereka bersetuju tentang kepentingan aktiviti tersebut. Berkaitan dengan taburan masa dalam praktis farmasi menunjukkan bahawa kedua-dua respondens daripada farmasi hospital dan komuniti memerlukan peruntukkan masa yang lebih dalam melaksanakan aktiviti-aktiviti penjagaan pesakit. Tambahan lagi, responden daripada komuniti memerlukan masa yang lebih untuk melakukan aktiviti mendispens. Secara

keseluruhannya, responden-responden dari farmasi hospital dan komuniti menunjukkan persepsi dan sikap positif mengenai kepentingan dan praktikaliti dalam membangunkan praktis penjagaan farmaseutikal. Namun demikian, data menunjukkan bahawa kurang daripada 50% responden-responden hospital dan komuniti berkompeten untuk membangunkan praktis PC. Halangan-halangan yang membantut pelaksanaan PC adalah berkaitan dengan suasana praktis seperti kekurangan masa dan tiada garis panduan yang piawai bagi praktis PC. Untuk menentukan variable-variabel responden yang dapat meramalkan implementasi praktis PC, nilai R^2 daripada tiga analisis regresi lelurus yang di lakukan secara berasingan telah di hitung sebagai 0.62, 0.61, dan 0.42 untuk persepsi-persepsi responden berkaitan dengan kepentingan, kompetensi, dan praktikaliti, untuk membangun praktis seumpama itu. Penemuan ini menunjukkan bahawa responden-responden mempunyai tekat untuk melaksana praktis PC, tetapi, mereka mempunyai beberapa kemusykilan tertentu berkaitan dengan praktikalitinya. Justeru itu, kajian ini memberikan suatu natijah dan pengertian tentang pemikiran dan perhatian ahli-ahli farmasi tentang implementasi praktis PC di Malaysia.

AN EXPLORATIVE STUDY ON PHARMACEUTICAL CARE PRACTICE FROM THE PERSPECTIVE OF PHARMACISTS IN MALAYSIA.

ABSTRACT

The objectives of this research were to explore and gather baseline information that is necessary for the implementation of pharmaceutical care (PC) practice in Malaysia. It went further to evaluate the understanding, perceptions, attitudes, and barriers towards the concept of PC as well as to describe the current pharmacy practice situation from the context of PC implementation. This is a cross-sectional survey of hospital and community pharmacists in Malaysia, employing the self-administered mailed questionnaire approach. In the cognitive aspects, over 70% and 60% of the hospital and community pharmacy respondents respectively, had a correct understanding of the PC process with only 17% and 19% respectively, failing to agree with correct statements. The current practice situation revealed that, most hospital and community pharmacy respondents performing the pharmacy practice activities; in addition, they were competent to carry out these activities and perceived its importance. However, the data collected revealed 32% of the community pharmacy respondents performing the dispensing activities consequently, 34% of them were competent to practice the dispensing activities and 43% of them agreed about its importance. Regarding the distribution of time of the pharmacy practice revealed that both the hospital and community pharmacy respondents would like to spend more time in performing the patient care activities. In addition, the community pharmacy respondent had the intention to spend more time engaging in dispensing activities. In general, hospital and community pharmacy respondents perceived

importance and practicality of developing PC practice and skills to practice it. In spite of this, the data revealed less than 50% of the hospital and community pharmacy respondents were competent to deliver the PC practice. The barriers impeding the provision of PC seem to be related to practice settings such as insufficient time and no standard guideline for PC practice. In order to determine the respondent's variables which could be the predictor for the implementation of PC practice, R^2 values of three separate linear regression analysis were computed as 0.62, 0.61, and 0.42 for the respondent's perception of the importance, their competence, and the perceived practicality to develop and implement such practices in the local pharmacy settings. These findings indicated that the respondents had the intention to render pharmaceutical care but, they had certain doubt about the practicality of such practices. Thus, the study provides an insight into the pharmacists' thoughts and concerns regarding the implementation of PC practice in Malaysia.

CHAPTER 1

INTRODUCTION

1.1 Introduction

Over the past few decades, with the health care environment worldwide especially in the United States witnessing the gradual and remarkable growth of the managed care system and pharmacy practice becoming more medically sophisticated, pharmacists are employing innovative patient care strategies such as pharmaceutical care practice. The philosophy of pharmaceutical care has been accepted worldwide as the primary mission of pharmacy. Pharmaceutical care mandates that practitioners not only to dispense medications, but also to assume responsibility for improving the quality of patients' outcomes (Helper and Strand, 1990). The traditional role of the pharmacist that involves in the preparation, dispensing and selling of medications is no longer adequate for the pharmacy profession to survive. Additionally, it has been argued that pharmacists have assumed a paternalistic role in discussions with patients about therapeutic options. Under this “pharmaceutical care” model, the patient delegates decision-making authority to the pharmacist. Implicit assumptions in delegating this authority include the perception that the “pharmacist knows best” and would be in the best position to make a therapeutic decision in the patient’s best medical interests for the purpose of achieving definite results that improve a patient's quality of life (QoL) (Hepler and Strand, 1990). To achieve these results, pharmacists need to co-operate with patients and other healthcare providers in designing, implementing, and monitoring a care

plan aimed at preventing and resolving drug therapy problems (DTPs) (Bell *et al*, 2006; Haugbølle and Sørensen, 2006; Blix *et al*., 2006; Soendergaard, 2006; Sturgess *et al*., 2003).

For the pharmaceutical care to achieve its goals it needs the traditional pharmacy to evolve and transform (Winslade, 1994; Winslade, 1993; Duncan-Hewitt, 1992). The perception and understanding towards pharmacy need to be changed, evolved, and transformed as well as to reorient the practising pharmacists to meet the challenges of the contemporary health care system. This is vital as the pharmacists are the main drive and main factor behind this transformation and application of pharmaceutical care practices. Hence, pharmacists' knowledge, perception, and attitude about the new emerging philosophy of pharmaceutical care are important.

1.2 A historical perspective of pharmacy practice

The practice of pharmacy, in a historical sense, has evolved from a state of none or minimal patient contact to a level where the pharmacists provide an individual patient-oriented service as depicted in (Figure 1.1). Pharmacy practice has been aptly described as evolving in three distinct stages. These stages are namely; (1) the traditional or drug distribution stage; before 1960s, generally, pharmacists are known as apothecaries, their function was to procure, prepare, and compound medicinal products. However, this role was gradually waned and taken over by the pharmaceutical industry. (2) the transitional or clinical pharmacy stage; born in the mid-1960s, The notion of the pharmacy practice had shifted to place much less emphasis on compounding and considerably more emphasis on clinical service delivery (Higby, 2003). (3) The patient-focused or pharmaceutical care stage (Hepler and Strand, 1990; Hepler, 1987) began in 1990 and continues to the present time. It

is the "patient care" era in which the pharmaceutical care reached maturation and became the mainstream function of pharmacists. Patients and their effective treatment with drugs are now central to the pharmacists' role. The pharmacist's role as a "therapeutic advisor" subsequently began to emerge.

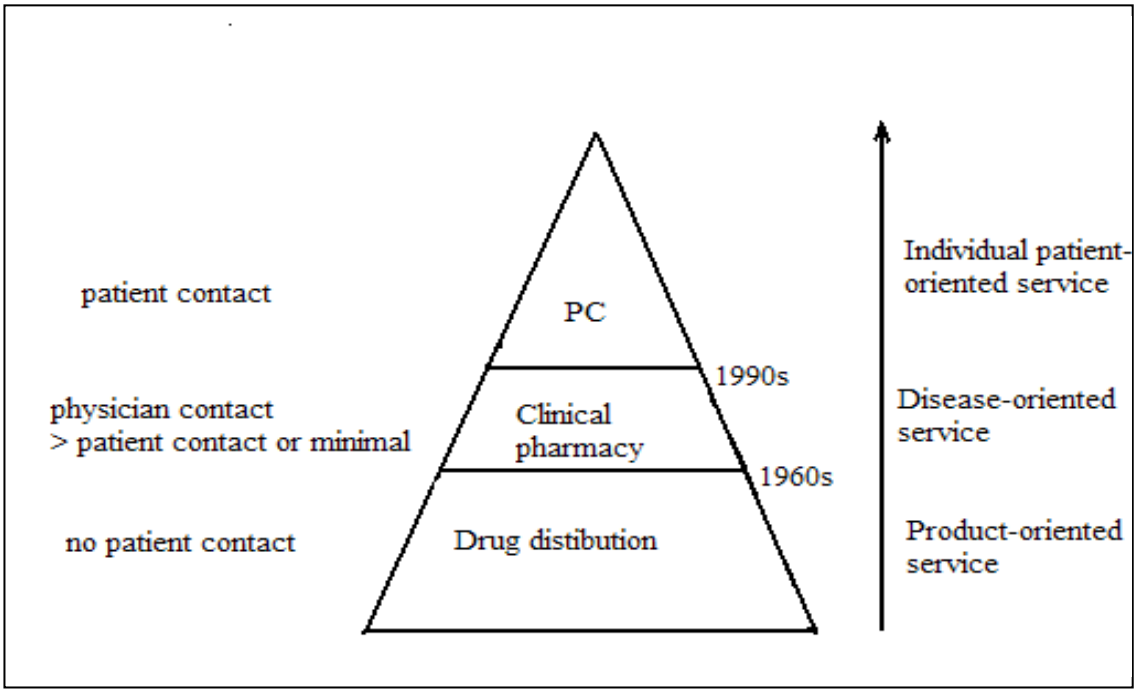

Figure 1.1: Evolution/ transformation of pharmacy practice

1.3 The clinical pharmacy era

The clinical pharmacy era, represents a period of rapid expansion of functions, professional transition, and development of clinically oriented pharmacy. This era is best characterized as a transitional period between the years of count-and-pour practice and the current era of pharmaceutical care. The notion of the pharmacy practice had shifted to place much less emphasis on compounding and considerably more emphasis on clinical service delivery (Valuk and Nair, 2003). Conceptually, clinical pharmacy is drug use controlled in which Donald Brodie (1967) expounded and stated his theory:

The ultimate goal of the service of pharmacy must be the safe use of drugs by the public. In this context, the mainstream function of pharmacy is clinical in nature, one that may be identified accurately as drug-use-control.

By "drug-use-control" Brodie meant the sum total of knowledge, understanding, judgments, procedures, skills, controls and ethics that assures optimal safety in the distribution and use of medications (Brodie and Benson, 1976). The overall goal of clinical pharmacy activities is to promote the correct and appropriate use of medicinal products and devices (Table 1.1).

The growth of clinical pharmacy in hospital has lead some people to incorrectly conclude; that clinical pharmacy is a variety of hospital practice and or limited to hospital only (Hassan, 1993). Community pharmacy shift to clinical practice coincided with hospital pharmacy transformation. Unlike hospital pharmacy, the burdens of business nature like of the practice and the distance from the clinical environment made the transition slower and more difficult (Higby, 2003; Posey, 1997; Carter and Barnette, 1996; Sisson and Israel, 1996).

In the local scene, transition occurred in the 1980s; in a large part because pharmacy educators, who initially lagged behind practitioners as advocates of clinical practice, saw the prospects for the future. Clinical pharmacy restored meaning to their teaching. Rather than just supporting their own scientific disciplines. The pharmacy authorities have given a lot of emphasis on clinical pharmacy. In a continuing effort to advance, expand, and promote the practice of clinical pharmacy in Malaysia, the School of Pharmaceutical Sciences, (USM) began adapting its curriculum to focus on the patient and on clinical practice. Many of these changes had been brought about by new faculty members returning from the United States with Pharm.D degrees beginning in 1983. Curriculum changes were made

thereafter; the proportion of clinical components increased (Ab Rahman and Bahari, 2004). The concept of clinical pharmacy practice in hospital settings comprises functions require pharmacists applying their scientific body of knowledge to improve and promote health by ensuring safety and efficacy of drug use and drug use- related therapy in seven major categories: prescribing drugs, dispensing and administrating drugs, documenting professional activities, direct patient involvement, reviewing drug use, education, and consultation (Hassan, 1993). Community pharmacy practice in Malaysia varies from one pharmacy to another. Chain-store pharmacies usually offer a significant proportion of non-professional services and activities alongside the traditional professional services. Smaller independent pharmacies normally focus on professional pharmacy services. Both types are representative of community pharmacy practice in Malaysia (Wong, 2001). In general, the application of clinical knowledge and skills although necessary, are not sufficient for effective pharmaceutical care (Todd *et al*., 1987). There must also be an appropriate philosophy of practice called pharmaceutical care and an appropriate organizational structure to facilitate providing that care called pharmaceutical care system (Hepler and Strand, 1990).

Table 1.1: The overall goal of clinical pharmacy*

Clinical pharmacy activities	Goal
Using the most effective treatment for each type of patient	Maximizing the clinical effect of medicines
Monitoring the therapy course and patient's compliance with therapy	Minimizing the risk of treatment-induced adverse events
Trying to provide the best treatment alternative for the greatest number of patients	Minimizing the expenditures for pharmacological treatments born by the NHS and by patients

* Source: Alminana et al., (2007)

1.4 The pharmaceutical care

1.4.1 The definitions and the concept of pharmaceutical care practice

Since the landmark description of the concept of pharmaceutical care by Hepler and Strand (1990), there have been numerous definitions of the concept (Hepler, 1993) and suggestions and also evaluations of models for implementing pharmaceutical care practice. These include the Therapeutic Outcome Monitoring (TOM) model of Grainger-Rousseau *et al*., (1997); and the Pharmacists Implementation of Pharmaceutical Care (PIPC) model of Odedina *et al*., (1997) among others. Currently, pharmaceutical care is widely understood as "the direct, responsible provision of medication-related care to achieve definite outcomes intended to improve the patient's quality of life", The principal elements of pharmaceutical care are that it is medication related; it is care that is directly provided to the patient by pharmacist in collaboration with the patients and healthcare professionals. This role requires pharmacists to apply a higher level of drug knowledge, clinical skill, and independent judgment to their work which involves designing, implementing and monitoring a therapeutic plan. The care provided is to produce definite outcomes; these outcomes are intended to improve the patient's quality of life; and the pharmacists who practice PC have accepted personal responsibility for their patients' outcomes. These therapeutic outcomes are: cure of a disease, elimination or reduction of a patient's symptoms, arresting or slowing a disease process or symptoms, outcomes is the goal of pharmaceutical care. Pharmaceutical care involves identifying, resolving, and preventing drug-related problems (Strand *et al*., 1993; ASHP, 1993). A drug-related problem was defined as "an event or circumstance involving medication therapy that actually or potentially interferes with an optimum outcome for specific patient. Drug-related problems have

been categorized as follows: untreated indication, improper drug selection, sub-therapeutic dosage, over-dosage, adverse drug reaction, drug interaction, failure to receive drug, and drug use without indication (Strand *et al*., 1993; ASHP, 1993).

The experience of pharmacists seeking to incorporate this philosophy into everyday practice have led Strand and her colleagues in (1997) to redefined pharmaceutical care, it is considered more pragmatic definition, as "a practice for which the practitioner takes responsibility for patient drug therapy needs and is held accountable for this commitment. This later definition has three components which comprise of: (1) a philosophy of practice, (2) a consistent and systematic patient care process, and (3) a practice management system. Most major pharmacy organizations in developed countries (e.g., the American Pharmaceutical Association [APhA] and the American Society of Health-System Pharmacists [ASHP]) have since adopted the pharmaceutical care philosophy.

World Health Organization (WHO), (1998) defined pharmaceutical care as a patient care system that continually observes the short-term results of the therapy in progress and helps to make corrections to improve management outcomes. The term requires multidisciplinary approach and the term would normally consist of a patient, a pharmacist, and a general practitioner.

1.4.2 The significance of the pharmaceutical care

The concept of pharmaceutical care evolved to help maximize the contributions of pharmacists in reducing and combating the drug-related morbidity and mortality to improve outcomes and decrease health care costs, since drug-related morbidity and mortality is costly both from human resource and a financial perspective. Research demonstrated that; where pharmaceutical care services are applied, they contribute significant benefits to social, humanistic and economic

groupings (Ernst et al., 2003; Manasse and Thompson, 2003; Ernst and Grizzle, 2001; Classen et al., 1997; Johnson and Bootman, 1995). Pharmacists significantly can help satisfy drug related needs, optimize patient outcomes through pharmaceutical care services by identifying, detecting, resolving, and most importantly, preventing drug-related problems (Strand *et al*., 1990).

A drug-related problem was defined as "an event or circumstance involving medication therapy that actually or potentially interferes with an optimum outcome for specific patient. Drug-related problems have been categorized as follows: untreated indication, improper drug selection, sub-therapeutic dosage, over-dosage, adverse drug reaction, drug interaction, failure to receive drug, and drug use without indication (Strand *et al*., 1993; ASHP, 1993).

Drug-related problems that are not identified, detected, resolved, or prevented may result in drug-related morbidity and mortality. A drug-related morbidity can manifest as a treatment failure or as a new medical problem. Some cases of drug-related morbidity, if unattended, can result in drug-related mortality (Planas *et al*., 2005).

Studies conducted over the past decades indicated that drug related problems are widespread and cause significant injury and death. Bates and colleagues (1995) found that almost 2% of hospital admissions experienced a preventable adverse drug event. This resulted in an average increase in length of stay of 4.6 days and a $4700 increase in hospital costs per admission.

A landmark study by Johnson and Bootman, (1995) used a pharmacoeconomic model to identify that, in the USA, the expenditure on treating drug-related morbidity and mortality is the same as the expenditure on the medicines themselves, and this was the second most costly disease after cardiovascular disease.

They prophesied that 25–50% of the drug-related morbidity and mortality might be prevented through improved medicines management. In a 1997 follow-up study published in the American Journal of Health-System Pharmacy, Johnson and Bootman noted that pharmacist intervention could reduce drug-related morbidity and mortality and could reduced health care costs. In 2001, Ernst and Grizzle updated Johnson and Bootman's cost-of-illness model to estimate that drug-related morbidity and mortality cost over $ 177 billion in the year 2000.

More recent studies estimate 58.9% (range, 32% to 86%) of drug-related hospital admissions are preventable (Winterstein *et al*., 2002). Causes of preventable drug-related hospital admissions have included adverse drug reaction, over-dosage and under-dosage, lack of a necessary drug therapy, patient non-adherence, inadequate follow-up, and problem with nonprescription drug (Heelon *et al*., 2007; Pit *et al*., 2007; NANs, 2006; Sorensen *et al*., 2005; Gurwirtz *et al*., 2000; Dartnell *et al*., 1996; Schneitman-McIntire *et al*., 1996; Lindley *et al*., 1992; Bero *et al*., 1991).

In the context of Malaysia, the drug related problems have received much attention during the past years. Through this period; several studies had been conducted, using many variables to investigate the existence of different categories of drug-related problems for different disease conditions in different practice settings. One study conducted by Sarriff *et al*., (1992) in outpatient pharmacy demonstrated that a significant proportion of patients unable to understand prescription instructions, and only 21% of patients were able to comprehend complete antibiotics instructions. The problem of poor patient adherence has been extensively researched over the years (Aziz *et al*., 1999; Othman, 1991; Hassan *et al*., 1990b; Hassan *et al*., 1990c; Hassan *et al*., 1989). Other study detected an alarmingly high prevalence of drug related problems on medication prescribed to

outpatients with type II diabetes (NIDDM) and hypertension. Since out of 392 prescriptions, DRPs were detected in 272 (69%) of anti-diabetics and 319 (81%) of antihypertensive prescribed (Sararaks, 2005). The problems of adverse drug reaction reporting have been given more importance lately. Another study was conducted in Malaysia to determine the frequency and types of drug administration errors in a hospital ward found that a total of 1118 administrations were observed in 66 inpatients with 135 drug administration errors recorded. This means 12.1 errors per 100 drug administrations. The most common types of drug administration errors were incorrect time (25.2%), followed by incorrect technique of administration (16.3%). Others included incorrect drug preparation, incorrect dose and omission errors (10.4% each) (Chua *et al*., 2005; Chua *et al*., 2003)

The problem of drug related therapy is a well- recognized problem in the local literature. Therefore, provision of pharmaceutical care in the local setting should target local problems and the outcomes of this service should be investigated, so that the significance of pharmaceutical care at the local level can be appreciated.

1.5 Issues in implementing pharmaceutical care

The concept of pharmaceutical care is capturing the attention of a growing number of practitioners. There are urgent needs to clarify a number of issues that shape and direct the implementation of pharmaceutical care.

1.5.1 Understanding, knowledge, and awareness of pharmaceutical care practice

Pharmaceutical care is the crucial philosophy and mission of pharmacy practice. Understanding and knowledge of this philosophy must precede efforts to implement pharmaceutical care, which merits the highest priority in all practice

settings. Studies on pharmacists' knowledge and understanding of pharmaceutical care are scarce and not consistent in their findings

Dunlop and Shaw (2002) established New Zealand community pharmacists' level of understanding of the pharmaceutical care process. The study involved 377 respondents who were younger and older, proprietors and employees pharmacists. Over 60% of the pharmacists had a correct understanding of pharmaceutical care.

Study by Van Mil (1999), used the results of International Pharmaceutical Federation (FIP) questionnaire. One of the questions specifically asked for the definition of pharmaceutical care used internationally. Six out of 30 responding countries indicated in that they used Hepler and Strand definition as their current working definition, 12 countries gave their own description or definition, which in all cases significantly different from Hepler and Strand definition. Twelve countries did not give a definition of pharmaceutical care.

One study has described the current practice of hospital pharmacists in Kuwait revealed that, the lack of uniformity in the responses regarding the focus and objectives of pharmaceutical care indicates a lack of appropriate understanding in this matter. All respondents have shown high willingness towards the implementation of pharmaceutical care services in their practice (Awad, 2006).

Yet, very little is known about pharmacists' knowledge on pharmaceutical care in this country. One study in Malaysia involved 282 pharmacists practicing at the outpatient pharmacy of 13 state hospitals, 67 district hospitals, and 7-health clinic in West Malaysia revealed that, knowledge about pharmaceutical care in general is unsatisfactory. Although pharmaceutical care is regarded as, highly important, only 5% of the pharmacists were considered to have adequate knowledge on pharmaceutical care (Othman, 2004).

1.5.2 Competence and skills needed for pharmaceutical care

In essence pharmaceutical care is that component of pharmacy practice that can be performed by no one other than a competent pharmacist. Competence comprises adequate knowledge and skill to perform a particular function, and an attitude of commitment to the patient's valued interests (Meyer, 2003). In that context, the future direction of the pharmacist in hospital and community will continue to evolve towards patient-directed services that apply scientific knowledge and clinical skills to the prevention and resolution of drug-related problems.

Subsequently, the pharmaceutical care literature has demonstrated numerous references to the expanding the role of "expert" pharmacists for different disease conditions in a variety of pharmacy settings. As an example, in one thyroid clinic, a pharmacist can initiate, maintain or modify the drug therapy of a selected group of patients under the guidelines of approved protocols. In this clinic, patients treated by the pharmacist include those receiving thyroid - suppression therapy, anti-thyroid drugs for Graves' disease or thyroid hormone supplementation after surgery or after radioactive iodine therapy. The pharmacist assesses patients, prescribes medications, orders laboratory tests, charts visits and therapeutic plans and educates patients about their conditions. Physicians may refer those noncompliant patients or those desiring additional information also are referred to the pharmacist. Joint therapeutic management between the pharmacist and endocrinologist is necessary when there are major changes in thyroid status (Dong, 1990).

Another pharmaceutical care program called a practice enhancement program (PEP) was designed by Farris *et al*., (1999) as part of the pharmaceutical care research and education project to help pharmacists acquire the necessary competencies, including skills, knowledge, and attitude to provide a comprehensive

pharmaceutical care to elderly ambulatory patients. The tools and processes used in the project increased community pharmacists' competency for providing pharmaceutical care.

Thus, it is anticipated that the pharmaceutical literature will continue to provide evidence references to identify the unique contribution that competent pharmacist can make to disease management for patients with certain specific and chronic conditions. for example several studies have been conducted to evaluate the effectiveness of PC with regard to clinical, humanistic, and economic outcomes in patients with asthma (Hounkpati et al., 2007; Mangiapane *et al*., 2005; Gonzalez-Martin *et al*., 2002; Kheir *et al*., 2001; Shaw *et al*., 2000). Pharmaceutical care sets out to maximize the benefits and minimize the risk of medicines and improve health by working in collaboration with diabetes patient and other health care providers (Morello et al., 2006; Clifford *et al*., 2005; Odegard *et al*., 2005; Armor and Britton, 2004; Sarkisian *et al*., 2003; Cranor and Christensen, 2003; Grant *et al*., 2003; Nowak *et al*., 2002; Renders *et al*., 2001; Jaber *et al*., 1996). Numerous studies were conducted to evaluate the pharmacists capacity to positively influence the results of antihypertensive drug therapy through pharmaceutical care (Matowe *et al*., 2008; De Castro *et al*., 2006; Chabot, 2003; Carter and Zillich, 2003; Garcao and Cabrita, 2002; McAnaw *et al*., 2001; Sen and Thomas, 2000; Paul *et al*., 1998; Dong *et al*., 1997; Lip and Beevers, 1997; Erickson *et al*., 1997). A study by Okamoto and Nakahiro, (2001) measured clinical, economic, and humanistic outcomes associated with a pharmacists-managed hypertension clinic compared with physician-managed clinics. The results found that pharmacists can be a cost-effective alternative to physicians in management of patients, and they can improve clinical outcomes and patient satisfaction. Pharmaceutical care positively affects lipid values, quality of

life, and patient satisfaction through provision of comprehensive pharmaceutical care (Pauos *et al*., 2005; Tsuyki *et al*., 2002; Nola *et al*., 2000; Shibley and Pugh, 1997).

A number of studies have proved the benefit of competent pharmacists providing pharmaceutical care in psychiatry area (Bryce *et al*., 2004; Jenkins and Bond, 1996). Other studies aim to investigate the impact of a pharmacist-lead pharmaceutical care program, involving optimization of drug treatment and intensive education and self-monitoring of patients with heart failure (Sadik *et al*., 2005; McMurray, 1999; Gattis *et al*., 1999). Li and Kendler, (2004) reported that community pharmacists managed postmenopausal osteoporosis through comprehensive pharmaceutical care. One study revealed the impact of a pharmaceutical care specialist HIV service provided by pharmacists to sample of patient with HIV infections (Gilbert, 2005; Bramble *et al*., 1999). In a similar context, the profession of pharmacy has a unique opportunity to contribute effectively to gerontological care especially during the past 40 years whereby the elderly population has increase dramatically (Lyra Jr *et al*., 2007; Grymonpre et al., 2001; Beyth and Shorr, 1999; Stein, 1994). Several studies revealed pharmacists ability to positively affect drug-use management and contribution provides care to pediatric patients (Stergachis *et al*., 2003; Botha *et al*., 1992).

In Malaysian context, the competent pharmacist's taking a more active role in patient care is a well- recognized in the local literature. Study analyzed clinical pharmacists' interventions in the ICU of the Penang General Hospital (Penang, Malaysia) and assessed the pharmaco-economic impact of these interventions. In this study Pharmacists recommendations and interventions in the ICU of a Malaysian hospital resulted in significant cost savings in terms of drug expenses (Zaidi *et al*., 2003). Other study conducted in Penang General Hospital to evaluate the medication

compliance and the impact of pharmacist intervention in patients with congestive heart failure. More than 50% of the pharmacists' interventions and recommendations were accepted in this study (Akhali *et al.*, 2002). Several studies dealt with the pharmacists' ability to influence outcomes of diabetes mellitus therapy (Mathialagan *et al*, 2007, *Khalid et al*., 2007; Hoe *et al*., 2004). Other studies were conducted to evaluate the pharmacists' capacity to positively influence the results to quit smoking in Malaysian (Babar *et al*., 2007; Magzoub, 2005; Mohamed, 2004; Mohamed, 2003).

1.5.3 Perception, behavior, and attitude about the pharmaceutical care

A positive pharmacist perception, behavior, and attitude are pivotal towards the implementation of pharmaceutical care. A key aspect towards improving or preventing the occurrence of drug related problems is changing the attitude, behavior, and perception of pharmacists as health care professionals to know their physical and mental limitation, and to behave in a professional and courteous manner whilst at work.

The concern about human behaviors, which spurred the formulation of the Transtheoretical Model (TTM) of Change to explain, predict, and change multiple human behaviors in the 1970s and 1980s, (Prochaska and DiClemente, 1984), incited Berger and Grimley, in the 1990s, to apply the TTM to measure pharmacists' readiness for rendering pharmaceutical care. It also identified and measured factors that facilitate rendering pharmaceutical care and factors that are barriers, as well as the strength of these factors for each stage of readiness. The Transtheoretical Model, which suggests that five stages of voluntary behavior change exist from precontemplation, contemplation, preparation, action, and maintenance. Their findings support the theory behind the TTM; that is, with any behavior change,

individuals will fall into several stages of readiness for change, and the vast majority will not be ready to take action within the next six months. Also consistent with the theory, the cons of engaging in a behavior tended to be more salient for individuals in the pre-contemplation/contemplation stages than for those in the action/maintenance stages (Berger and Grimley, 1997).

An attitude can be defined as a learned disposition to respond in a particular manner to a given object (Campagna and Newlin, 1997). The important influence of attitudes on the practice behavior of pharmacists has been noted and discussed in the literature (Fjortoft and Lee, 1994; Hansen and Ranelli, 1994; Lee and Fjortoft, 1993; Kirking, 1984; Baker, 1979; Knapp, 1979). These studies suggest that a pharmacist's choice to perform at a particular level of drug therapy decision-making (DTDM) may be influenced by her or his attitude towards the role of pharmacy in the health care process towards the perceived appropriateness of specific action, towards her or his ability to effectively perform in a particular role, and towards a number of other issues.

Several approaches to examine pharmacists' intentions and behaviors in implementing pharmaceutical care have been pursued. A Pharmacists' Implementation of Pharmaceutical Care (PIPC) model was developed by Odedina *et al*., (1996) from 617 community pharmacists in Florida (USA), These PIPC model included factors (attitude, perceived behavioral control, social norm, intention, psychological appraisal processes and past behavior recency). The PIPC model incorporates these variables or factors which proposed by Theory of Reasoned Action (Fishbein and Ajzen, 1975), Planned Behavior (Ajzen, 1985), Theory of Trying (Bagozzi and Warshaw, 1990), and Theory of Goal Directed Behavior (Bagozzi *et al*., 1992). Although community pharmacists report low provision of

pharmaceutical care at their pharmacies, they have high behavioral intention to provide pharmaceutical care. Study results suggest that the discrepancy between behavioral intention and actual behavior may be due to (i) low perceived social norm by physician (ii) low perceived behavioral control (iii) low self-efficacies with respect to the means involved in the provision of pharmaceutical care and (iv) low effect towards the means involved in the provision of PC. The PIPC model could be used to design successful intervention procedures for implementation of PC.

Farris and Kirking, (1995) used the theory of goal-oriented behaviors and showed that attitudes were generally positive and intention to try preventing and correcting drug-therapy problems was high. Intention to try was predicted, however poorly, by attitude and social norm towards trying after controlling for recency of past trying. Another study also by Farris and Kirking, (1998) showed that behaviors requiring medium effort were directly predicted by pharmacists' self-efficacy, instrumental beliefs and affect towards means.

An assessment of Canadian community pharmacists' attitude and behavior towards pharmaceutical care found that they have moderate to high intentions practice and conceptually see its benefits but believe that there was currently lack of appropriate framework in place for the adoption of pharmaceutical care (Faris and Schopflocher, 1999).

1.5.4 Support personnel

New pharmaceutical care and rapid changes in health care system are imposing new demands on hospital and community pharmacy which results in a need for increased supportive personnel (manpower). These demands dictate for the pharmacist a multifarious role which he can assume only when there are an adequate number of personnel within the pharmacy. Studies have indicated that many of the

tasks performed in pharmacy could be delegated to supportive personnel under the supervision of pharmacists (Skrepnek *et al*., 2006). If pharmacist could be freed to a greater extent from performing routine tasks which could be delegated with supervision to trained supportive personnel, he or she would be able to direct more of his or her attention to professional tasks only, thereby expanding professional pharmacy service in the interest of patient care. This emphasizes the need for supportive personnel to assume many of the nonjudgmental duties traditionally associated with delivery of pharmaceutical service (ASHP, 1983; ASHP, 1971) Hospital and community pharmacies must do likewise if it is to make maximum use of pharmacists' unique body of knowledge, and provide an opportunity for developing a scope of pharmaceutical care.

1.6 Practicality of application the pharmaceutical care

Pharmaceutical care has universal appeal because drug-related morbidity and mortality knows no boundaries. The consistent and systemic process of providing pharmaceutical care holds true without regard to the language spoken. Pharmacists in at least 24 countries are prepared to deliver pharmaceutical care (Isetts and McKone, 2003).

The concept of pharmaceutical care was converted into the practice of pharmaceutical care in an action-oriented research project called Minnesota Pharmaceutical Care Project (Tomechko *et al.*, 1995). A tremendous Minnesota Pharmaceutical Care Project was a 3-year, practice-based initiative conducted from June 1992 through November 1995 by Cipolle, Strand, and Morley. It included 54 pharmacists from 20 community pharmacy practice sites through the state of Minnesota. The intention of the project was to explore the relationships between the theory and practice of pharmaceutical care. The word "practice" is

important in the Minnesota model; it means pharmacists having a practice just like a doctor, a dentist, or an optician. The demonstration project was divided into four major phases: (1) the pre-study period involved selection of a representative sample site. (2) The pilot-study year to determine if a new practice of pharmaceutical care could be developed. (3) The implementation or development phase was dedicated to disseminating the practice developed in pilot-study phase. (4) The evaluation phase was developed to the evaluation of the care pharmacists provided to patients through the project. The participants have a prescribed structure (training, equipment, consultation area and reimbursement system which rewards them for identifying, preventing or responding to drug related problems), adhere to processes (planning, patient monitoring, interview, recording) to achieve patient outcomes. In this project 45,000 pharmaceutical care encounters have been documented for over 15,000 patients and over 19,000 drug therapy problems identified, prevented and resolved (Mason, 2001). Part of the result shows that, the most frequent indications for drug therapy in patients receiving pharmaceutical care services were sinusitis, bronchitis, otitis media, hypertension, and pain. It is interesting that the most frequent problems were that patients needed additional drug therapy (23%) and adverse drug reactions (21%). In common with Minnesota model, it focuses on the burden of medication-related problems and aims to ensure that medicines are used appropriately, safely, effectively and conveniently.

Another study has provided evidence to support the further development of Pharmaceutical care concept in New Zealand. In 1994 the Pharmaceutical Society of New Zealand (PSNZ) adopted quality standards for the practice of comprehensive pharmaceutical care (CPC), after the landmark paper published by Hepler and Strand

(Hepler and Strand, 1990). 28% of community pharmacists and 16% of all the pharmacists in New Zealand working in conjunction with the (PSNZ) expressed a keen interest in pharmaceutical care application (Isetts and McKone, 2003). The number of pharmacists providing pharmaceutical care has been cited as a reason that the government in that country encouraged to fund the process (Dunlop, 2001). This funding was achieved by separating funding from a previously profitable dispensing remuneration into a fund for cognitive services.

1.7 The levels of pharmaceutical care

Pharmaceutical care is applicable and achievable by pharmacists in all practice settings. The provision of pharmaceutical care is not limited to pharmacists in inpatient, outpatient, home care setting or community setting. The care provided may differ among practice settings and to distinguish in its delivery, theoretical aspects in the level of pharmaceutical care have been described by Strand *et al*., (1991). Their view that patient needs must differentiate the level of care required by and provided to a patient and not specific pharmacists activities. Distinguish can be expressed in term of the risk associated with patient's pharmacotherapy, so they identified three categories of risk factors that can affect the type and level of pharmacotherapeutic risk (1) risk factors associate with the patient's clinical characteristics, (2) risk factors associate with the patient's disease, and (3) risk factors associate with the patient's pharmacotherapy. The interaction of these three types of risk factors ultimately determines the level of risk associated with patient's pharmacotherapy and therefore the level of pharmaceutical care required of the pharmacist. The pharmacist then transforms these data into relevant information through application of knowledge, judgment, and experience.

Smith and Benderev, (1991) described a "theoretical model" in which models of health-care provision are organized according to level of care, namely, primary, secondary, and tertiary levels. Each level of care differs in the magnitude of the four factors involved in pharmaceutical care needs by the patient. This patient needs is influenced by 1) the patient medical condition, 2) the drug therapy the patient is receiving, 3) the degree of action required of the pharmacists, and 4) the inter-professional relationships between pharmacists and healthcare providers. As explicated by Smith and Benderev, primary pharmaceutical care arises when the drug therapy needed by the patient is not for a condition that necessitates hospitalization, the patient's medical conditions is non-acute, chronic, or episodic, the drug therapy the patient is receiving is easily observed, the degree of action required of the pharmacist is minimal, and the interaction between the pharmacist and the physician are infrequent. Primary pharmaceutical care is practiced in outpatient pharmacies in hospital, and community pharmacies. Secondary pharmaceutical care starts with the initial drug therapy for a more complex medical condition. The medical condition requires hospitalization, the drug therapy the patient is receiving required monitoring, patient responsiveness is not as easily observed as in primary care, and the pharmacist communicates with physician at regular intervals. Secondary pharmaceutical care is practiced in acute-care hospitals, and specialized-care programs such as oncology and pain control. The most comprehensive clinical services are offered for tertiary pharmaceutical care, whereby patients will require intensive monitoring by pharmacists and this can only occur in critical care service. In tertiary care the medical condition required hospitalization, drug therapy must be closely monitored by pharmacist as well as frequent inter-professional interactions

are required. Tertiary pharmaceutical care is practiced in hospitals that provide inpatient critical care services.

In Malaysian context, the ambulatory settings such as health clinics and community may require a primary level pharmaceutical care while the hospitals may involve secondary and tertiary levels of pharmaceutical care (Othman, 2004).

1.8 The pharmacy practice in Malaysia

Most of the reports concerning future pharmacy practitioners' perceptions, understanding, and attitudes towards pharmaceutical care are based on experience in developed countries. As the philosophy of pharmaceutical care spreads to other parts of the world, there is a need to build on professional literature by incorporating evidence from the developing countries.

Malaysia is one of the front-runners amongst developing countries, where clinical practice and pharmaceutical care is gradually dominating the picture of professional pharmacy practice. The population of Malaysia is approximately 23.95 million (in year 2005 population census). Malaysia heavily subsidizes its health care service; the Ministry of Health is the major health care provider in the country. The second major provider of health services is the private health sector. There are two types of pharmacy practice, government and private. Government pharmacy practice takes place mostly in government hospital and health care facilities (Ab Rahman and Bahari, 2004). In year 2002, according to Pharmacy Board Annual Report, only about 18% of the more than 3000 registered pharmacists in the country worked in government sector and 82% worked in private sector.

Practitioners are capable of implementing clinical pharmacy services in hospital pharmacy settings. The important activities in clinically oriented pharmacy practice include improvement of the drug-control process, development of physical

and human resources, clinical pharmacy skills, and the training of practicing pharmacists. A number of Malaysian pharmacists have already developed a unit-dose drug distribution system, patient counseling, therapeutic drug monitoring, drug information, and total parenteral nutrition services (Hassan, 1993). A continuing effort to advance, expand, and promote the practice of clinical pharmacy and patient care in Malaysia had been brought about by clinical educators and new faculty members of the School of Pharmaceutical Sciences (USM), returning from the United States with Pharm.D degrees (Ab Rahman and Bahari, 2004; Hassan, 1993; Hassan, 1990a).

On the other hand, the status of patient-orientated activities beyond dispensing of prescriptions revealed that there is no widespread implementation of such activities as part of daily practice among the local community pharmacy in Malaysia (Sarrif, 1994). In addition, pharmacy practice in the community setting varies from one pharmacy to another. Private (Community) pharmacy practice is mainly represented by chain store pharmacies and independent pharmacies (Wong, 2001). Chain-store pharmacies usually offer a significant proportion of non-professional services and activities alongside the traditional professional services. Smaller independent pharmacies normally focus on professional services (Wong, 2001). Community pharmacies operate under very unfavourable conditions imposed by legal and historical limits. Many community pharmacists do not have full control over the supply of medicines, since the medical doctors' control a large percentage of medicines supplied to patients (MCPA, 2006a; Wong, 2001). Malaysian pharmacists need to remedy this unhealthy situation in order to be able to contribute more meaningfully, as an important healthcare team member of pharmaceutical care practice.

1.9 Barriers to implementing pharmaceutical care

All new concepts confront barriers and challenges, and the concept of pharmaceutical care is no exception. As plentiful barriers to providing clinical pharmacy have been identified, these barriers are also presented when considering the adoption of pharmaceutical care. Although there are many different environments in which pharmaceutical care is provided within the practice settings (e.g., hospital and community pharmacy settings), the barriers experienced by the pharmacist are often shared among these different settings.

There is universal interest in pharmaceutical care (PC) practice. However, its uptake as daily practice by different pharmacy settings has been hindered by a number of barriers to implementation (Ozolinaa, 2007; Berger and Grimley, 1997; Posey, 1997; Odedina *et al*., 1996). Several pharmaceutical literatures tried to categorize the barriers to provide pharmaceutical care as: system-related, resource-related, educational, legal, professional and administrative barriers, financial, information-related, communication-related, structural, leadership-related, pharmacist-related, pharmacy management or pharmacy department-related and demand-related barriers (Al-Shaqha and Zairi, 2001; May, 1993; Swift, 1993) and there are numerous subcategories of these barriers categories.

A plethora of barriers to providing clinical pharmacy have been well-known including the gap in pharmacy training, information restrictions, divergences of interprofessional, economic structure, and uneven patient demand (Smith, 1988; Baker, 1979). These barriers are also present when considering the implementation of pharmaceutical care (Venkataraman *et al*., 1997; Hagedorn *et al*., 1996; Raisch, 1993; Knapp, 1992 Nelson *et al*., 1984). Specifically, attitudinal factors may