

**THE IMPACT OF A STRUCTURED
COUNSELING TECHNIQUE BY PHARMACIST
ON KNOWLEDGE, SATISFACTION, QUALITY
OF LIFE, ADHERENCE AND CLINICAL
OUTCOMES AMONG ASTHMA PATIENTS AT
KING SAUD HOSPITAL, SAUDI ARABIA**

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by

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LIST OF ABBREVIATIONS

ACT	Asthma control test
ANOVA	Analysis of variance
ASCP	American Society of Consultant Pharmacists
ASHP	American Society of Health-System Pharmacists
AQLQ	Asthma Quality of Life Questionnaire
BMI	Body mass index
COPD	Chronic obstructive pulmonary disease
DG	Directive guidance
DM	Diabetes mellitus
DTRP	Drug therapy-related problem
ED	Emergency department
FOG	Frequency of Gobbledygook
GCP	Good clinical practice
GP	General Practitioner
GRASSIC	Grampian Asthma Study of Integrated Care
HIS	Healthcare Improvement Scotland
HIV	Human immunodeficiency virus
HRQoL	Health-related quality of life
IHD	Ischemic heart disease
IQR	Interquartile range
IRB	Institutional review board
MHRA	UK Medicines and Healthcare products Regulatory Agency
MMUH	Mater Misericordiae University Hospital
NAEPP	National Asthma Education and Prevention Program Expert Panel

NHLBI	National Heart Lung and Blood Institute
NHS	UK National Health Service
NIH	US National Institutes of Health
NSAIDs	Nonsteroidal anti-inflammatory drugs
OBRA 90	Omnibus Budget Reconciliation Act of 1990
OTC	Over-the-counter
PACP	Pharmacy Asthma Care Program
PC	Pharmaceutical care
PCNE	Pharmaceutical Care Network Europe
PEFR	Peak expiratory flow rate
PEIPB	Prince Edward Island Pharmacy Board
QoL	Quality of life
RCT	Randomized controlled trial
SD	Standard deviation
SMOG	Simple measure of gobbledygook
SPSS	A statistical analysis software package
TOM	Therapeutic outcomes monitoring
UK	United Kingdom
US	United States
WHO	World Health Organization

**IMPAK TEKNIK KAUNSELING BERSTRUKTUR MELALUI AHLI
FARMASI TERHADAP PENGETAHUAN, KEPUASAN, KUALITI HIDUP,
PEMATUHAN DAN HASIL KLINIKAL PESAKIT ASMA DI HOSPITAL
KING SAUD, ARAB SAUDI**

ABSTRAK

Ahli farmasi dijangka memainkan peranan penting dalam pengurusan penyakit kronik. Kajian semasa menyasarkan matlamat dalam membangunkan suatu alat pembelajaran (buku kecil) dan menghuraikan kaunseling pengubatan berstruktur perantara ahli farmasi bagi pesakit asma. Ia juga menentukan impak intervensi ahli farmasi terhadap pengetahuan, kepuasan, kepatuhan terhadap pengubatan, kualiti hidup, hasil klinikal (kadar alir ekspiratori puncak, PEFr), dan masalah berkaitan terapi drug (DTRP). Percubaan rawak terkawal telah dilakukan dengan memperuntuk pesakit-pesakit asma secara rawak sama ada kumpulan intervensi (n=37) atau kumpulan kawalan (n=38), menerima kaunseling pengubatan rutin di Jabatan Pesakit Luar, Klinik Dada, Hospital Raja Saud, Qassim, Arab Saudi. Daripada sejumlah 75 subjek, 58 (32 kawalan dan 26 intervensi) yang menyempurnakan kajian tersebut. Data demografi pesakit, pengetahuan mengenai asma, kualiti hidup, kepuasan, hasil klinikal dan DTRPs dinilai pada tahap asas dan selepas selesai 1, 4, and 7 bulan, justeru, tempoh kajian adalah selama 7 bulan. Penemuan kajian menunjukkan peningkatan dalam pengetahuan dari 43.1% pada tahap asas kepada 67.2%, 81%, dan 84.5% pada susulan 1, 2, dan 3, masing-masingnya. Walaubagaimanapun, diperhatikan bahawa skor kualiti hidup (QoL) pada kumpulan intervensi tidak menunjukkan sebarang peningkatan dari tahap asas ke susulan ke-1 (p = 0.526), ke-2 (p = 0.155), dan susulan ke-3 (p = 0.242). Tahap

kepuasan dalam kumpulan intervensi meningkat dengan ketara pada setiap susulan berbanding tahap asas ($p = 0.005$). Dalam kumpulan intervensi, terdapat peningkatan ketara dalam corak pematuhan pada tahap asas ke susulan ke-1 ($p = 0.002$), ke-2 ($p < 0.001$) dan ke-3 ($p = 0.005$). Suatu perbezaan signifikan ketara dapat di lihat dalam DTRP antara kumpulan-kumpulan intervensi dan kawalan pada susulan pertama ($p < 0.001$) dan ketiga ($p = 0.005$). Sama juga, terdapat peningkatan ketara dalam skor DTRP pada kumpulan terkawal dari tahap asas ke susulan ketiga ($p = 0.005$) dan susulan pertama dan kedua ($p = 0.033$). Namun demikian, keputusan menggambarkan peningkatan yang tak signifikan dalam PEFr antara kedua-dua kumpulan (intervensi, $p = 0.064$ dan kawalan , $p = 0.891$). Tambahan pula, utilisasi suplemen-suplemen herba dalam kedua-kedua kumpulan menurun dari tahap asas ke tahap ketiga pada lawatan susulan, dengan penurunan mendadak dalam kumpulan intervensi. Kesimpulannya, kajian ini menyediakan bukti tentang impak alat pembelajaran dan kaunseling pengubatan berstruktur perantara ahli farmasi dalam meningkatkan kemahiran pesakit, QoL, pematuhan, kepuasan pesakit-pesakit asma. Tambahan pula, kajian ini menyumbang pandangan dalam pelaksanaan praktis penjagaan farmaseutikal kepada pesakit-pesakit asma di Arab Saudi.

**THE IMPACT OF A STRUCTURED COUNSELING TECHNIQUE BY
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ADHERENCE AND CLINICAL OUTCOMES AMONG ASTHMA
PATIENTS AT KING SAUD HOSPITAL, SAUDI ARABIA**

ABSTRACT

The pharmacist is expected to play a vital role in chronic disease management. The present study aimed at developing an educational tool (booklet) and described a pharmacist--mediated structured medication counseling for asthmatic patients. It also determined the impact of pharmacist intervention on asthma patient's knowledge, satisfaction, medication adherence, quality of life, clinical outcomes (peak expiratory flow rate, PEFR), and drug therapy-related problems (DTRPs). A randomized controlled trial compared the conventional routine counseling [control (n = 38)] with structured medication counseling provided by pharmacist [intervention (n = 37)] at the Outpatient Department of the Chest Clinic at King Saud Hospital, Qassim, Saudi Arabia. Out of 75 subjects, 58 (32 control and 26 intervention group) completed the study. Patients' demographic data, knowledge about asthma, quality of life, patient satisfaction, adherence, clinical outcomes, and DTRPs were assessed at baseline, and after completion of 1, 4, and 7 months, thus making the study period a total of 7 months. Research findings showed an improvement in knowledge from 43.1% at baseline to 67.2%, 81%, and 84.5% at follow-up 1, 2, and 3, respectively. However, it was observed that quality of life (QoL) scores in the intervention group did not improve from baseline to follow-up 1 (p = 0.526), follow-up 2 (p = 0.155), and follow-up 3 (p = 0.242). The level of satisfaction in the intervention group were improved significantly at each follow-up

compared to baseline ($p = 0.005$). In the intervention group, there was significant improvement in adherence from baseline to first ($p = 0.002$), second ($p < 0.001$), and third ($p < 0.001$) follow-ups. A significant difference was noted in the DTRPs between the intervention and control groups at first ($p < 0.001$) and third ($p = 0.005$) follow-ups. Similarly, there was significant improvement in DTRP scores in follow-up control group from baseline to the third follow-up ($p = 0.005$) and from the first to the second follow-ups ($p = 0.033$). Nevertheless, the results revealed a non-significant improvement in PEFr among both groups (intervention, $p = 0.064$ and control, $p = 0.891$). In addition, the utilization of herbal supplements in both groups dropped from the baseline to the third follow-up visit, with a higher reduction in the intervention group. In conclusion, the research provides evidence on the impact of the educational tool and pharmacist-mediated structured medication counseling in enhancing patients' knowledge, QoL, adherence, satisfaction, and adherence for asthmatic patients. Furthermore, the research finding provides an insight into implementation of pharmaceutical care practice for asthmatic patients in Saudi Arabia.

CHAPTER 1

INTRODUCTION

1.1 Introduction

Asthma, a commonly prevalent disease in Saudi Arabia, is a common chronic respiratory condition worldwide and is characterized by reversible airway obstruction, airway inflammation and increased airway responsiveness to a variety of external and internal stimuli. These stimuli may be allergens, such as smoke, cold weather, exercise, certain drugs, and sometimes even psychological stress (Gibbs & Small, 2003), that could potentially trigger an asthma attack. Asthma affects people of all ages and patients with asthma usually present with typical symptoms that include wheezing, coughing, and tightness of the chest (Gibbs & Small, 2003). In addition, they may also have mucosal plugging and increased secretions of the tracheobronchial tree.

Saudi Arabia has an estimated population of approximately 26.1 million, of which 74.1% are native Saudis (Salam, 2013). The prevalence of asthma in Saudi Arabia is high and has been increasing in the recent past (Al Frayh, Shakoor, Gad El Rab, & Hasnain, 2001). Based on the available literature from the last three decades, Al-Moamary et al. (2012) reported an alarmingly overall prevalence of 8%-25% among children, with an increased asthma incidence over time period. Based on findings from a household survey in 2013, the asthma prevalence among Saudi Arabian adult was 4.05% (Moradi-Lakeh et al., 2015). Evidence also suggests a strong link between asthma and genetic makeup of individuals prone to develop asthma (Bener, Al-Jawadi, Simsek, & Al-Nassar, 1992).

Asthma is a chronic disease that requires specialized care and often lifelong medication; the level of care needed in asthma often go beyond care in the hospital and requiring specialized community care services from health professionals such as pharmacists. By the nature of the pathophysiology and disease prognosis, asthma requires both pharmacological and non-pharmacological therapies. The pharmacological treatment includes β_2 agonists (salbutamol, salmeterol and bambuterol), xanthine alkaloids (theophylline), anticholinergics (ipratropium), corticosteroids (prednisolone, budesonide, fluticasone, and beclomethasone), mast cell stabilizers (sodium cromoglycate), leukotriene-receptor antagonists (montelukast), and leukotriene-synthesis inhibitors (zileuton) (Gibbs & Small, 2003); in addition, anti-immunoglobulin E therapy (omalizumab) has recently been tried for asthma patients. For chronic asthma management, the medications are administered directly into the lungs; hence, the patient must use certain specialized drug delivery systems, which may need a basic level of skill and understanding. It has been noted that asthma patients often do not know how to use these devices optimally, which can lead to poor clinical outcomes (De Oliveira, Bruno, Ballini, Brito, & Fernandes, 1997; Lavorini et al., 2008; Plaza & Sanchis, 1998) resulting in impaired quality of life . In addition to the drug therapy, several non-pharmacological measures are of great importance in better disease control in asthma patients, such as smoking cessation and avoidance of allergens.

As asthma is a chronic disease often requiring lifelong treatment, the patient may not adhere to the physician's advice and often may not take the medicines regularly. Similarly, improper use of inhalation devices is known to be one of the leading causes of therapeutic failure (Newman, Weisz, Talae, & Clarke, 1991). The main reason for this

may be attributed to the poor hand-lung coordination which is critical while using these dosage forms. In addition, self-monitoring of treatment is essential in asthma so that the patient becomes actively involved in his or her own self-care, as well as a partner in disease management especially in using rescue medications (often salbutamol inhaler) appropriately.

Pharmacists, as important healthcare professionals, are expected to play a vital role in chronic disease management (Lewis, Lasack, Lambert, & Connor, 1997). There have been several studies conducted around the world that have indicated the positive role and value of patient counseling by pharmacists in asthma management (Bynum, Hopkins, Thomas, Copeland, & Irwin, 2001; Cordina, McElnay, & Hughes, 2001; De Tullio & Corson, 1987; Odegard et al., 2004; Weinberger et al., 2002). Such counseling results in several benefits: it improves the patient's understanding of his or her disease, the medication being taken, and the lifestyle modifications needed, as well as patient adherence and concordance (Hawkins, Fiedler, Douglas, & Eschbach, 1979). Patient counseling may also lead to better therapeutic outcomes and ultimately an improved quality of life (Kheir, Emmerton, & Shaw, 2001).

1.2 Conceptual framework

The research mainly involved the provision of asthma-related counseling and care by pharmacists, and evaluating its impact on various outcomes: knowledge, clinical outcomes, adherence, satisfaction, quality of life (QoL), and minimizing drug therapy-related problems (DTRPs) (Figure 1.1).

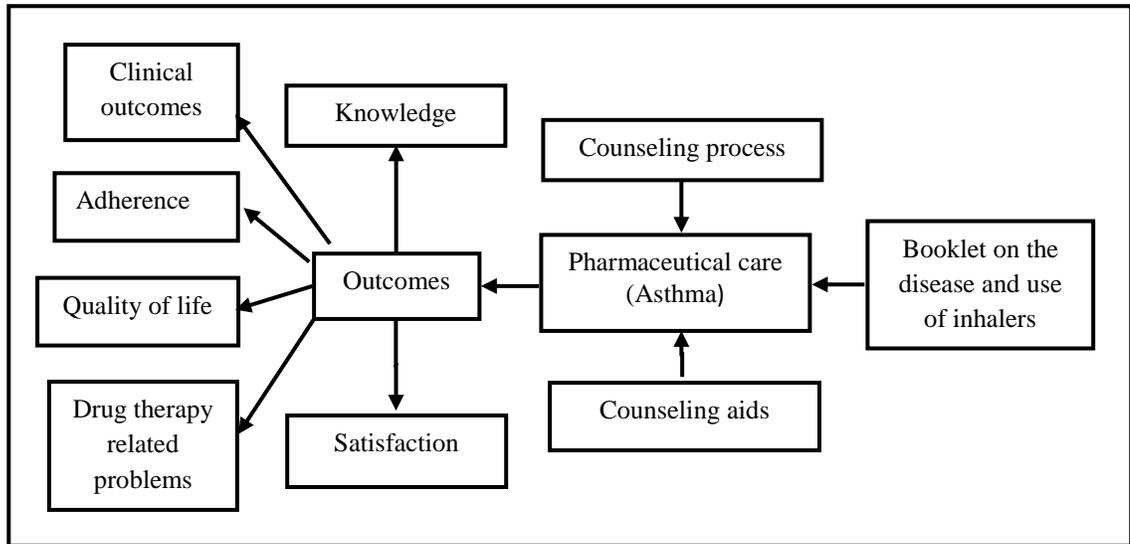


Figure 1.1. Conceptual framework of the research

Patient counseling is an important aspect of pharmaceutical care (PC) (McGivney et al., 2007), and it includes providing counseling and consultation to asthma patients. Asthma is managed using multiple therapeutic strategies with the goal of controlling the progression of the disease and preventing acute attacks. Several challenges reported in the management of asthma include patients' poor understanding of the symptoms, inhaler techniques, use of alternative medications of unproven efficacies, improper management plans, and poor medical, and medication history available to the healthcare professionals. These factors result in inconsistency and variability in clinical decision-making and practice.

PC aims to achieve definite outcomes that improve a patient's QoL (Hepler & Strand, 1990). PC provided by the pharmacist can help the achievement of goals in the management of asthma through identifying triggers, considering medication history and medication reconciliation, and providing a properly considered therapeutic regimen

(such as through clinical management plans and asthma action plans), as well as educating the patient about the disease, medications, self-monitoring, and self-management, administration techniques, and lifestyle modifications. Shanmugam et al. (2012) provided evidence about asthma control through PC and demonstrated its positive impact in improving patients' asthma-related QoL, lung function, disease control, adherence to their preventive medication, and knowledge about the disease.

During the course of counseling, the pharmacist must consider physical, psychological, socio-cultural, emotional, and intellectual perspectives, as well as respect the health beliefs and values of the patient (International Pharmaceutical Federation, 2005). The Canadian Asthma Consensus Report (1999) stated that education for asthma patients should be aimed at altering patients' behavior and achieving positive outcomes rather than simply providing knowledge. The report outlined the diverse range of educational strategies and methods that can be used, including counseling through individual teaching, small-group sessions, computer games, large-group lectures, checklists, video and audio tapes, workbooks and booklets, diaries, internet websites, problem-solving sessions, and repeated audits by health professionals (Boulet, Becker, Bérubé, Beveridge, & Ernst, 1999). Thus, there are a range of options from which the pharmacist can choose an appropriate counseling method.

It is essential to provide verbal and written information to asthma patients in a manner they understand. This aspect of counseling could involve the use of appropriately designed counseling aids tailored to the patient requirements. While developing these aids, the educator (i.e., the counseling pharmacist) should give utmost

consideration to the literacy level, eyesight, and language of comfort of the target patient. The various medication aids that can help in achieving positive outcomes in asthma education include videos, pictograms, inhaler aids, medication cards, and an asthma symptom diary (International Pharmaceutical Federation, 2005). In this research, the authors used a locally designed patient information leaflet as the tool for efficient counseling.

The present study focused on the development of a structured counseling technique for asthma counseling. This is important because, although there is a range of medication available for asthma, its prevalence is still increasing in Saudi Arabia (Al Frayh et al., 2001; Moradi-Lakeh et al., 2015). Thus, there is a need to explore options other than medication to improve the treatment outcomes of asthma patients among the Saudi population. There have been no previous studies documenting the role of structured patient counseling in asthma patients in Saudi Arabia.

It is well documented that pharmacist-provided patient counseling improves therapeutic outcomes (this is described in greater detail in Section 2.3.3). Such improvement is dependent on patient's knowledge and satisfaction with the treatment. Studies have documented that pharmacist counseling for asthma patients improves both their knowledge (Section 2.3.1) and their satisfaction (Section 2.3.4). Positive outcomes include a reduction in drug-related problems, better adherence, and improvement in the disease. A structured, systematic counseling technique, along with appropriate patient counseling and adequate use of educational aids, could improve clinical outcomes and thus, ensure a better control of disease and improved symptom-free interval and QoL.

1.3 Problem statement

In order to improve their QoL and survival rate, asthma patients require continued medical care and patient education. Asthma patients who are able to access good quality pharmacist-provided asthma education and management services have shown improved disease outcomes over standard treatment, as well as improved control of their asthma (Boulet et al., 1999; International Pharmaceutical Federation, 2005; Kheir et al., 2001; Shanmugam et al., 2012). Although there is an association between poor knowledge and poor outcomes, there has been less number on controlled clinical trials to justify the strategies for improving knowledge and clinical outcomes.

Despite the availability of a range of medication for asthma, the disease outcomes among asthma patients are often not encouraging and patient adherence is a major issue (Eakin and Rand, 2012). This suggests the need for the development of alternative measures or approaches that could address poor clinical outcomes, and underlines the need to explore possible modification to delivery of drug therapy, dispensing of medications, patient counseling, and strategies to improve concordance and adherence. These requirements for disease management strongly support further development of PC plan for asthma patients.

Often, patients with asthma are not well informed about their drug therapy and disease condition. This may lead to poor adherence to their treatment, which can ultimately lead to therapeutic failure and can therefore result in poor clinical outcomes and diminished QoL.

Physicians are often burdened with heavy patient loads and may focus their attention on the diagnosis of diseased patients and less emphasize on pharmacotherapy and lifestyle modifications. This means the role of pharmacist in providing care to institutionalized and ambulatory patients can be vital.

Patient satisfaction is an important issue when delivering healthcare, and the role of the pharmacist in improving patient satisfaction needs consideration. The usefulness of pharmacists in improving the satisfaction level of asthma patients should therefore be explored.

1.4 Research questions

This study was based on the below research questions:

1. What are the various drug therapy-related problems experienced by ambulatory patients with asthma?
2. Can structured medication counseling provided by a pharmacist have an influence on knowledge, satisfaction, medication adherence, quality of life, DTRPs, and clinical outcome?

1.5 Research hypothesis

1.5.1 Null hypothesis

The null hypothesis for this research was the following: There is no association between structured counseling provided by a pharmacist and the knowledge, satisfaction, adherence, QoL, DTRPs, and clinical outcomes of asthma patients.

1.5.2 Alternative hypothesis

The alternative hypothesis to this was the following: There is an association between structured counseling provided by a pharmacist and the knowledge, satisfaction, adherence, QoL, DTRPs, and clinical outcomes of asthma patients.

1.6 Objectives of the study

1.6.1 General objective

The general objective of this study was ‘to evaluate the impact of a pharmacist-provided structured medication counseling technique on knowledge, satisfaction, adherence, QoL, DTRPs, and clinical outcomes among asthma patients’.

1.6.2 Specific objectives

The specific objectives of this study were as follows:

1. To develop an educational tool in the form of booklet for asthmatic patients.
2. To determine the impact of pharmacist-provided intervention on patients’ clinical outcomes, as measured using peak expiratory flow rate (PEFR).
3. To describe and determine the impact of pharmacist-provided intervention on the knowledge, satisfaction, and medication adherence of asthmatic patients.
4. To assess the impact of pharmacist-provided intervention on the QoL of asthmatic patients.

5. To identify the types of drug therapy-related problems experienced by asthmatic patients.

1.7 Significance of the research

This research is one of the first in its type to be conducted in Saudi Arabia among asthma patients. It has the following significance:

1. **It provides new clinical data about asthma patients in the Saudi Arabian population**, including patient knowledge, satisfaction, QoL, adherence, DTRPs, and PEFR. These data could be useful for further research pertaining to asthma in the local population.
2. **It could be adopted as a standard approach for counseling other chronic diseases in Saudi Arabia.** The basis for asthma counseling in this study involved the development of a structured counseling program and the design of locally appropriate patient information leaflets. These concepts could potentially be adopted by pharmacists in providing care to patients suffering from other chronic diseases such as hypertension, diabetes, hyperlipidemia, thyroid dysfunction, or rheumatoid arthritis. Figure 1.2 outlines a proposed structured counseling technique for chronic diseases in Saudi Arabia.

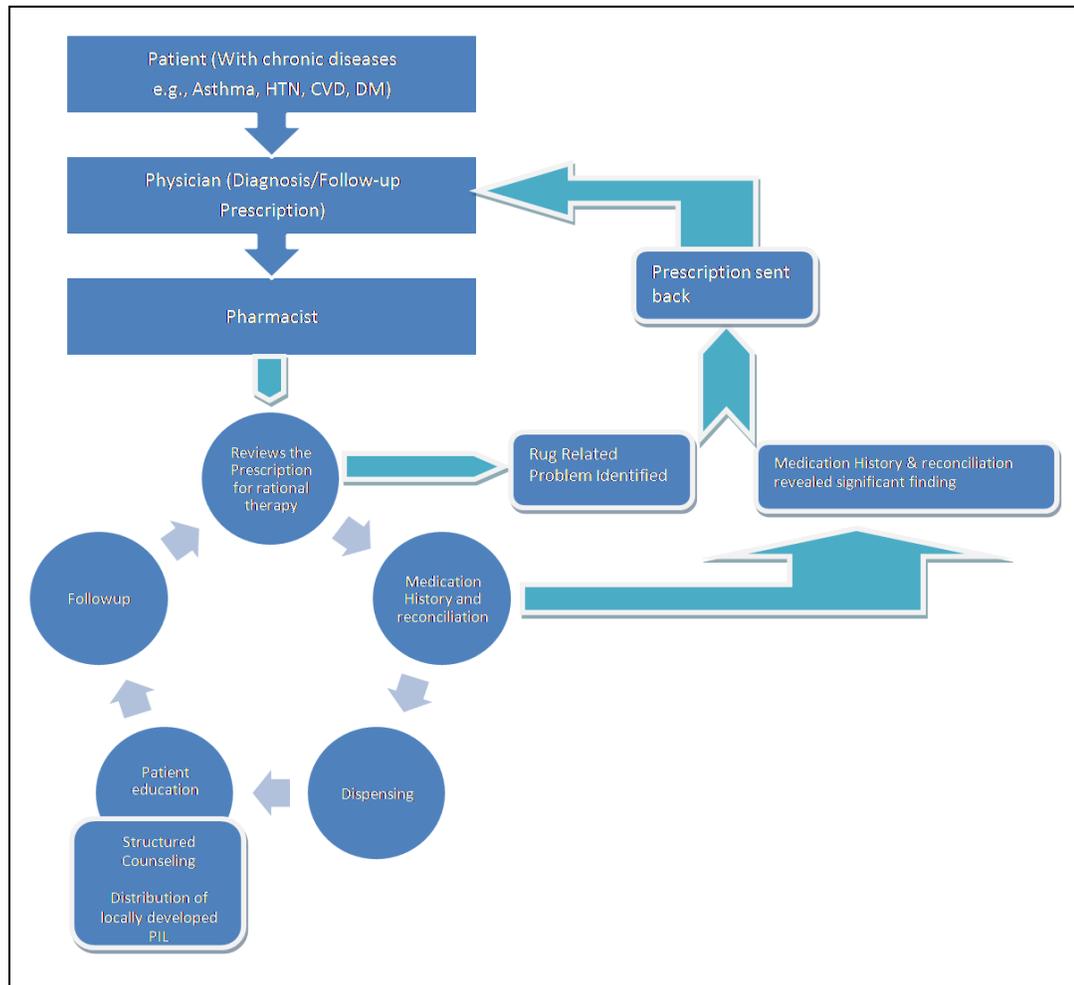


Figure 1.2. Structured counseling approaches for chronic disease management

3. **It creates a professional pharmacy practice role in helping Saudi asthmatic patients.** This research supports the professional role of pharmacists in caring for patients suffering from asthma, thus providing the opportunity for pharmacists to be more patient-focused, as well as offering professional recognition of and justification for the valuable role pharmacists can play in chronic disease management.

CHAPTER 2

LITERATURE REVIEW

2.1 Search strategy for literature

Papers for this chapter were collected by searching Google Scholar (www.scholar.google.com) using the search terms “pharmacist’s intervention,” “structured approach,” “pharmacist-coordinated medication counseling,” “knowledge,” “satisfaction,” “adherence,” “counseling,” “quality of life” and “asthma,” and PubMed/Medline using the MeSH terms “pharmacists,” “pharmaceutical services,” “knowledge,” “adherence,” “satisfaction,” “asthma,” “quality of life” and “drug therapy related problems.” The papers selected were original articles that described an intervention among asthma patients and provided the results of that intervention in any of the following outcomes: knowledge, satisfaction, adherence, counseling, DTRPs, or QoL. In few cases, studies related to other chronic diseases were also reviewed. Priority was given to the most recent articles, and in cases where there have only been limited articles on a topic, the search period was extended to up to 15 years. In addition, a manual search was conducted among the various articles that were available to the researcher, including the Central Library of the Universiti Sains Malaysia, and relevant articles were segregated and reviewed. Articles published up to June 2016 were included. This chapter of the thesis briefly summarizes these articles by subject.

2.2 Pharmaceutical care

2.2.1 Definition

In 1990, Hepler and Strand gave the pharmacy profession a new dimension by introducing the concept and practice of “pharmaceutical care,” which they defined as “the responsible provision of drug therapy for the purpose of achieving definite outcomes which improve a patient’s QoL” (Hepler & Strand, 1990). A further, more patient-centered approach was later provided by Linda Strand, who stated that PC is not only a theory but also a philosophy of practice (Strand, 1997). Carollo, Rieutord, and Launay-Vacher (2012) defined PC as “the pharmaceutical contribution to patient care in identifying PC issues (medications-related issues), and establishing and administering a PC plan.”

The American Pharmacists Association described PC as “a patient-centered, outcomes-oriented pharmacy practice that requires the pharmacist to work in concert with the patient and the patient’s other healthcare providers to promote health, to prevent disease, and to assess, monitor, initiate, and modify medication use to assure that drug therapy regimens are safe and effective”. The goal of PC is to optimize the patient’s QoL, and to achieve positive clinical outcomes within realistic economic expenditures (McLean, Gillis, & Waller, 2003).

Recently in 2013, the board of the Pharmaceutical Care Network Europe (PCNE) redefined PC as “the pharmacist’s contribution to the care of individuals in order to optimize medicines’ use and improve health outcomes” (Allemann et al., 2014).

2.2.2 Pharmaceutical care for asthma

As asthma is a chronic condition requiring lifelong medication, it is essential for patients to obtain counseling and care from their pharmacists. Several studies have demonstrated the usefulness of PC in asthma management. Many studies are mentioned in this section and others are described in Section 2.3.

Mangiapane et al. (2005) conducted an interventional study to assess the effectiveness of a PC program on clinical, patient-related, and economic outcomes of asthma patients. The study enrolled 55 asthma patients with 550 matched controls to compare the data of various subgroups of the intervention group with those of the control group. The study demonstrated improved QoL scores in the intervention group, as well as improvements in other patient-related outcomes (knowledge scores and adherence). The clinical outcomes also improved significantly in the intervention group. The study could not evaluate the effectiveness of the program with regard to economic outcomes; patients with more severe asthma may be required for such an evaluation (Bunting & Cranor, 2003).

A study by Taylor, Byrd, and Krueger (2003) assessed the effect of PC on the prevention, detection, and resolution of medication-related problems in Alabama, United States of America (USA). This was a case-control interventional study that enrolled 69 patients. Of these, 33 patients were in the intervention group that was provided with a PC plan that included drug and disease information, identifying and solving DTRPs, and monitoring the patient's response to the medications. This study showed that medication adherence scores improved in the intervention group. In addition, the participants' knowledge about the medications improved, and the

number of hospitalizations and visits to emergency departments decreased in the intervention group.

In a prospective controlled multicenter study conducted in community pharmacies in Denmark (Herborg et al., 2001), the effect of therapeutic outcomes monitoring, a community-based program for PC regarding some asthma-related outcomes, was evaluated. The study included 500 asthma patients; patients in the intervention group were provided with therapeutic outcomes monitoring, which identified and resolved the patients' drug-related problems. Beneficial effects on knowledge about asthma and their medications were found among the patients in the intervention group when compared to the control group. Other outcomes such as days of sickness, disease-related symptoms, and QoL also improved in patients in the intervention group (Herborg et al., 2001).

In a randomized controlled cluster design study by Volume et al. (2001), patient-related outcomes of asthma patients provided with PC were compared to those of patients who only received traditional pharmacy care. The study was carried out in 16 community pharmacies in Canada. The study showed that successful implementation of PC services helped improve patients' satisfaction with pharmacy-related activities. No significant improvement was seen in QoL or patient adherence in the two groups compared to baseline.

2.3 Pharmacist-provided patient counseling for asthma and its impact

The literature related to the impact of pharmacist-provided patient counseling for asthma are categorized and presented in the following sections according to the study objectives.

2.3.1 Impact of pharmacist counseling on patient knowledge in asthma

Prior to reviewing the literature on the effect of PC on asthma patients, an attempt was made to critically review studies that evaluated various outcomes among individuals other than asthma patients. This revealed that pharmacists and school teachers lack adequate knowledge about asthma. Knowledge about asthma is important for individuals other than patients such as pharmacists (Corpas et al., 2006; Osman, Ahmed, & Ibrahim, 2012), school teachers (Ones, Akcay, Tamay, Guler, & Dogru, 2006) and caregivers (Rastogi, Madhok, & Kipperman, 2013). Pharmacists hold a responsible position in hospitals and the community in which they provide information about the disease, and about medications and interventions useful for asthma. Similarly, students suffering from asthma are sometimes taken care of by schoolteachers.

A cross-sectional study in Sudan by Osman, Ahmed Hassan, and Ibrahim. (2012) evaluated the knowledge and skills of 300 community pharmacists regarding inhaler devices. The findings revealed that more than half of the pharmacists did not know all the steps involved in the inhalation technique for a metered-dose inhaler, the majority of the pharmacists did not know the proper technique for using the dry powder inhalers Turbuhaler® and Diskus®, and some had not even heard the name of such devices. This finding suggests that even pharmacists in developing countries lack adequate knowledge about inhalers and inhalation techniques.

A pretest–posttest interventional study by Corpas et al. (2006) assessed changes in knowledge of asthma among 79 pharmacists. A workshop (a single theory-practice session that lasted 3 hours and 40 minutes) was conducted as an intervention. The greatest change in the pretest and posttest scores was observed

among those who had lower test scores. The difference was statistically significant, but the results depended on the participants' prior knowledge about asthma prior to attending the workshop.

Knowledge of asthma among primary school teachers was assessed in Turkey (Ones et al., 2006). A questionnaire was administered to 792 teachers from 73 randomly selected schools. The level of knowledge of schoolteachers about the signs, symptoms, and treatment of asthma, as well as the nature of the disease was satisfactory, with a mean score of 96.7 ± 19.8 out of a maximum possible score 130 (74.3%). The authors concluded that there was a need for schoolteachers to understand about asthma and its impact so that the needs of asthmatic students can be met at the school in which they study.

An interventional study by Rastogi, et al., (2013) in New York City involved 268 caregivers. The intervention involved asthma education consisting of asthma pathophysiology, known indoor and outdoor asthma triggers, and the role and use of medications to control asthma. The study showed that the intervention group demonstrated a good retention of knowledge following one day of educational sessions, and that the number of visits to emergency departments was lower in this group than in the control group in the two years following the intervention.

Studies that assessed knowledge about asthma among patients were also reviewed. These showed that many asthma patients had poor knowledge about the disease and the medications they used. They also revealed the importance of patient education, particularly through pharmacist-provided intervention, i.e., PC that included information about disease and medications, inhalation techniques, self-management plans, and medication counseling.

Omole and Ilesanmi (2010) from Nigeria enrolled 73 asthma patients and found that asthma education strategies were important for improving patient outcomes. The researchers administered a structured interview using a questionnaire with the objective of determining the level of adherence of patients to anti-asthmatic medications. The study found that poor knowledge, suboptimal inhalation device technique, and a low level of adherence was prevalent among asthma patients. The study focused on the need for asthma education strategies among the patients with a low level of asthma knowledge to improve patient outcomes.

A prospective, randomized, controlled study in Sudan by Abdelhamid, Awad, and Gismallah (2008) assessed the impact of hospital-based pharmaceutical services on asthma patients. Of 100 subjects, 60 were assigned to the intervention group and received comprehensive medication counseling and asthma education (about the disease, life style modifications, pharmacotherapy, self-management, and inhalation technique) every two weeks. The study showed a significantly greater improvement in the patients' knowledge about asthma in the intervention group, as well as a significant reduction in acute asthma attacks, nocturnal asthma attacks and the frequency of using β_2 agonists, when compared to the control group. However, the follow-up period was too short to observe the long-term impact of the intervention. Reliance on self-documentation was another limitation of the study.

A case-control interventional study by Al-Rashed, Wright, Roebuck, Sunter, and Chrystyn (2002) assessed the value of inpatient pharmaceutical counseling in 83 patients. Pharmacist counseling (a 30-minute session for each patient) was provided as an intervention. The major findings of the study were that the patients' knowledge about their prescribed medicines improved, and there were fewer visits to their

physician and hospital admissions compared with before the intervention. However, the sample population was not large enough to generalize the results of the study.

A randomized, controlled, parallel group trial was conducted by Mehuys et al. (2008) involving 201 asthma patients. Of these, 107 were assigned to the intervention group and received information about asthma and its pharmacological and non-pharmacological treatments in the first session, and a protocol-defined intervention (the Asthma Control Test, ACT) in the first and second follow-ups. The percentage of patients with correct inhalation technique increased in the intervention group; however, no significant improvement was seen in knowledge scores. Adherence to asthma control medications was also higher in the intervention group but no significant difference in Asthma Quality of Life Questionnaire (AQLQ) score was seen between the two groups. The limitations of this study were that it did not include any steroid-naïve patients but only included patients who had used chronic asthma medications for more than a year and who were regular pharmacy customers, so the results may not be generalizable to the wider population.

A parallel, controlled design study by Saini, Krass, and Armour (2004) involving 102 asthma patients, assessed the impact of the service provided by community pharmacies to asthma patients with regard to clinical, patient-related, and economic outcomes. The intervention group (52 patients) was provided with specialized services based on an asthma care model with three follow-up visits over 6 months. This resulted in a statistically significant improvement in asthma-related knowledge in the intervention group compared with the patients of the control group.

Barthwal, Katoch, and Marwah (2009) conducted a non-randomized prospective trial that enrolled 172 patients and evaluated the impact of an asthma

education program on asthma morbidity, inhaler technique, and asthma knowledge. The program involved information about the disease and medications, self-monitoring, regular medical reviews, and a written action plan. After the program, the number of patients with satisfactory knowledge score increased from 13.9% to 69.7%. Other outcomes such as asthma morbidity and inhalation technique also improved.

A randomized, controlled trial conducted over a period of 6 months by Schacher, Dhein, Münks-Lederer, Vollmer, and Worth (2006) evaluated the effectiveness of a structured outpatient education program among asthma patients. Of a total of 120 patients, 78 were assigned to the intervention group and were provided with an education program which included peak flow meter-controlled self-medication, the correct use of medications, and detailed information about the disease and its treatment. The remaining patients formed the control group and were provided with a short education program on inhalation technique and the use of peak flow meter. The intervention group showed significantly improved knowledge of the disease compared to the control group, as well as an improvement in QoL scores and the number of patients who self-managed their asthma attacks.

A similar randomized, controlled study by Wang, Chian, Lai, Tarn, and Wu (2010) enrolled 91 patients and evaluated the impact on asthma-related clinical and health outcomes of an education program on asthma provided by nursing personnel, and asthma counseling provided by a pharmacist showed a significant increase in the knowledge scores in the first and second groups compared to the control group, but no significant difference in adherence was found between the three groups.

2.3.2 Impact of pharmacist counseling on adherence by asthma patients

An open, controlled, prospective, parallel study conducted in Brazil by Santos et al. (2010) enrolled 55 asthma patients to assess treatment adherence and the use of inhalation medications. The intervention group (28 patients) received counseling at three visits, whereas the control group received counseling only on the first visit. The inhalation technique scores were satisfactory for both groups at the first visit, the quality of inhalation technique improved and satisfactory scores were obtained by the intervention group after the counseling sessions at the next two visits.

A randomized, controlled study by Cote et al. (2001) included 98 asthma patients and assessed the impact of two different educational interventions for adult patients. The patients in the intervention group were divided into two subgroups. The first subgroup received teaching about inhaler technique and a self-action plan provided by a physician; the second subgroup received the same as the first group plus a structural educational program on self-capacity for managing exacerbations. A significant improvement between the first and third visits in adherence for inhaled corticosteroids was seen only in the second intervention subgroup; however, there was a similar percentage increase in the prescription of inhaled corticosteroids in all three groups. Other patient outcomes (knowledge, QoL, and lung function) also improved in the second intervention subgroup compared to the first intervention subgroup and controls.

A prospective, observational study in France enrolled 727 asthma patients and evaluated the effect of inhaler training provided by pharmacists on the patients' use of pressurized and breath-actuated metered-dose inhalers (MDIs) (Giraud Allaert, & Roche, 2011). The percentage of patients with optimal inhaler technique

increased from 24% to 79% and adherence also improved. However, a lack of randomization, the short period of observation, and the short duration of follow-up (1 month) were some of the limitations of the study.

Armour et al. (2007) conducted a multisite randomized intervention study to assess the impact of PACP in 396 asthma patients. The intervention included targeted counseling, as well as education about the condition, medication and lifestyle issues (such as trigger factors), a review of inhaler technique, an assessment of adherence, an investigation of whether there were any drug-related problems, goal setting and review, and referral to a GP as appropriate (e.g., for a change in medication or dose). The intervention group demonstrated improved adherence to the prevention medications and improvements in other patient outcomes (knowledge, QoL, etc.).

In a randomized, controlled cluster design study by Volume, Farris, Kassam, Cox, and Cave (2001), the humanistic outcomes of asthma patients who received PC were compared to those of patients who only received traditional pharmacy care. The study was carried out in 16 community pharmacies in Canada in which the intervention group was provided with PC services. No significant improvement was seen in QoL and patient adherence in the two groups, but the study showed that successful implementation of PC services helped to improve patients' satisfaction with pharmacy-related activities.

In addition to the aforementioned studies, there were studies by Al-Rashed et al. (2002), Mangiapane et al. (2005) and Mehuys et al. (2008), as discussed in Section 2.3.1, that also showed pharmacists involvement improving patient adherence.

Patient adherence is one of the important parameters that requires the pharmacist's intervention, as revealed by the studies described. These studies showed that many patients have low adherence to their treatment. They also demonstrated that patient education or PC that provides information about the disease, medications, and inhalation technique is an important tool in improving the adherence of asthma patients.

2.3.3 Patient counseling and its impact on the clinical outcomes of asthma patients

An interventional study carried out by Diamond and Chapman (2001) in community pharmacies across Canada enrolled 4,080 asthma patients to evaluate the impact of nationally coordinated, pharmacy-based educational intervention on asthma control. The educational needs of each individual patient were assessed and appropriate education offered to them. The study showed that the pharmacy-based intervention helped in relieving daytime asthma symptoms, and reduced the frequency of nocturnal symptoms and the use of short-acting β_2 agonists. A limitation of the study was that it included some patients with excessive health care use for asthma control; in such cases, pharmacy-based intervention may not be the only reason for the change in their clinical outcomes.

A case-control interventional study by Magar et al. (2005) enrolled 238 asthma patients and evaluated the impact of patient education programs on these patients. Patients in the intervention group were provided with a self-management program, and training sessions on the symptoms of the disease and peak expiratory flow. This group exhibited a significant improvement in a number of clinical

outcomes such as symptom-free days, number of times woken at night, consumption of corticosteroids, consumption of β_2 agonists and QoL score.

Barthwal et al. (2009), as mentioned in the Section 2.3.1, conducted a non-randomized, prospective trial that included 172 patients to evaluate the impact of an asthma education program on asthma morbidity, inhaler technique, and asthma knowledge. The education program involved information about the disease and medications, as well as self-monitoring, regular medical reviews, and a written action plan. Following the education program, there was a significant decline in the number of moderate and severe persistent asthma attacks, the number of hospital visits, and the number of patients experiencing limitation to physical activity.

Shanmugam et al. (2012) evaluated the outcome of PC service for 66 asthma patients. Patients in the intervention group received PC that included asthma education, medications counseling, lifestyle modification instructions, and an asthma care diary. The study concluded that the PC program helped to achieve the desired health outcomes as there was an improvement in the patients' lung function, asthma control, and asthma-related QoL.

A randomized controlled study by Wang et al. (2010), as mentioned in Section 2.2.2 investigated the impact on asthma-related clinical and health outcomes of an education program about asthma provided by nurses, and counseling on asthma provided by a pharmacist. The 91 patients were divided into three groups; the first group received the nurse-administered educational program, the second group received the pharmacist-provided asthma counseling and the third group acted as the control group. There was a significant improvement in health outcomes in the