# PHARMACY PERSONNEL PRACTICES WITH REGARD TO THE SALE OF NON-PRESCRIPTION ASTHMA MEDICATION IN COMMUNITY PHARMACIES IN THE EASTERN AND WESTERN CAPE

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**DECLARATION:**

In accordance with Rule G5.6.3, I hereby declare that the above-mentioned treatise/ dissertation/ thesis is my own work and that it has not previously been submitted for assessment to another University or for another qualification.

**SIGNATURE:** 

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## ABSTRACT

Short Acting Beta Agonist (SABA) inhalers in South Africa are available to patients without a prescription from an authorised prescriber. This study utilised a mystery shopping technique to observe, record and compare the dispensing practices of pharmacy personnel, when dispensing a reliever inhaler, to the minimum requirements set out by the South African Pharmacy Council. The results of this study indicated that there was no adherence to the minimum requirements when dispensing a reliever inhaler.

## KEY WORDS

Asthma, Healthcare professional, Pharmacist, SABA, Salbutamol, Inhalers, ICS Pharmaceutical care, Asthma management, Pharmaceutical care.

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## ABBREVIATIONS

| | |
|---|---|
| **AIDS** | Acquired immunodeficiency syndrome |
| **C : B** | Corticosteroid to bronchodilator |
| **DPI** | Dry powder inhaler |
| **GAN** | Global asthma network |
| **GINA** | Global initiative for asthma |
| **GPP** | Good Pharmacy Practice |
| **HIV** | Human immunodeficiency virus |
| **ICD** | International Classification of Diseases |
| **ICS** | Inhaled corticosteroids |
| **LABA** | Long acting $\beta_2$ agonist |
| **NCD** | Non-communicable disease |
| **MDI** | Metered dose inhaler |
| **PEF** | Peak expiratory flow |
| **RAMS** | Rural asthma management service |
| **SABA** | Short acting $\beta_2$ agonist |
| **TB** | Tuberculosis |

# CHAPTER ONE

# INTRODUCTION

## 1.1 Background

South Africa is burdened with a concurrence of epidemic infectious diseases, such as the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) and Tuberculosis (TB) and a rise in non-communicable diseases (NCDs), such as cardiovascular disease, type 2 diabetes mellitus, chronic lung disease and depression. A major struggle in South Africa is that much emphasis seems to be placed on the epidemic of HIV/AIDS and TB, which sometimes results in marginalisation of the treatment and prevention of NCDs (Mayosi, Flisher, Lalloo, Sitas, Tollman, & Bradshaw, 2009).

In Africa, it has been projected that deaths from NCDs will exceed deaths caused by not only communicable diseases, but maternal, perinatal and nutritional diseases combined by the year 2030. With these projections, NCDs are set to cause the majority of ill-health, disability and premature death. This has a negative impact on the socioeconomic development of people in the lower and middle income brackets. (World Health Organization, 2014)

Asthma is the most common chronic childhood disease affecting 13% of the population under the age of 14 years and over 7% of the adult population in South Africa (Bradshaw, Steyn, Levitt, & Nojilana, 2011). In 2013, Statistics South Africa released the findings from death notifications based on International Classification of Diseases 10 codes. Of all of the chronic lower respiratory diseases, asthma was found to be the

leading cause of death, causing 26% of the deaths. The next highest cause of death was emphysema at 6.5% (Stats SA, 2014). According to the guideline for the treatment of acute asthma in adults, published by the South African Medical Journal, acute asthma may be managed by self-medication (Lalloo, Ainslie, Abdool-Gaffar, Awotedu, Feldman, Greenblatt, Irusen, Mash, Naidoo, & O'Brien, 2013), which prompts the following question: are patients with asthma not sufficiently equipped by pharmacy personnel to self-medicate?

## 1.2 Study aims and objectives

The primary aim of this study was to establish the practices used by pharmacy personnel during the provision of pharmacist initiated therapy for the use of asthma reliever medication.

In support of this aim, the objectives of this study were to:

1. determine and describe the extent to which the minimum requirements of pharmacist initiated therapy, set out in the Good Pharmacy Practice standards, were adhered to by pharmacy personnel;
2. establish if the demographics of pharmacy personnel had any correlation with adherence to standards;
3. determine the availability of asthma screening services in community pharmacies; and
4. determine if community pharmacy personnel demonstrated the correct technique when dispensing asthma reliever medication.

## 1.3 Treatise overview

The treatise will be presented as follows:

Chapter 1: Introduction

This section highlights the higher health priority South Africa places on communicable diseases such as the HIV/AIDS and TB epidemic which can result in the marginalisation of treatment and management of non-communicable diseases such as asthma.

Chapter 2: Literature review

The literature review discusses how uncontrolled asthma is medically managed in a response to symptoms experienced by the patient and how pharmacists are in an ideal position to identify uncontrolled asthma patients. The chapter addresses

- The treatment and management of asthma
- Using SABA inhalers as targets in asthma management
- South African legislation relating to the access of SABA inhalers
- The burden of uncontrolled asthma
- A pharmacist's position in asthma care
- Pharmaceutical care
- Misperceptions and misunderstandings of asthma

Chapter 3: Methodology

This section discusses the mystery shopping technique utilised in this study to obtain data and describes the methodological processes employed.

Chapter 4: Results and discussion

This section reports the data obtained during the study and where applicable uses graphs to illustrate and present the data. It also discusses the results in the context of existing literature.

Chapter 5: Conclusions limitations and recommendations

This section describes how the study aims and objectives were met. It discusses the limitations of the study which must be borne in mind when considering the results and provides recommendations for future practice and research.

# CHAPTER TWO

# PHARMACISTS' ROLE IN THE MANAGEMENT OF ASTHMA

# AN OVERVIEW OF THE LITERATURE

## 2.1 Introduction

Asthma is the hyper-responsiveness of the bronchioles to stimuli, resulting in a chronic inflammatory disorder of the airways, with variable airflow. This inflammation causes a myriad of symptoms, such as: coughing, wheezing, tightness of the chest and breathlessness. Asthma generally develops in early childhood; however, it can develop at any stage of life. In the Global Asthma Report 2014, prepared by the Global Asthma Network (GAN), it was estimated that 334 million people are currently afflicted by this disease and over 250 thousand deaths are related to inadequate treatment. Furthermore, South Africa showed the highest mortality rate at 290 deaths per million population out of all the countries currently registered with the GAN. Putting this into perspective, the GAN is a worldwide collaborative effort with over half of the world's countries participating – including: The United States (US), United Kingdom (UK), Australia, Japan and Germany (Global Asthma Network, 2014). Despite the development of new medical management in asthma care over the past 30 years, the condition remains sub-optimally controlled and constitutes a major health burden, having implications for individuals and society (Watkins, Bourdin, Trevenen, Murray, Kendall, Schneider, & Clifford, 2016).

## 2.2 The treatment and management of asthma

After the initial diagnosis of asthma, asthma severity is then classified into four levels or categories, based on daytime and night-time symptoms (coughing, tight chest,

wheezing and night wakening) and the peak expiratory flow (PEF). A PEF is a person's maximum rate of expiration and is measured with a peak flow meter (Working Group of the South African Thoracic Society, Lalloo, Ainslie, Wong, Abdool-Gaffar, Irusen, Mash, Feldman, O'Brien, & Jack, 2007). A summary of the classification of asthma severity categories is provided in Table 2.1

Table 2.1 Classification of asthma severity as adapted from the South African asthma management guidelines (Working Group of the South African Thoracic Society et al., 2007)

| **Asthma severity** | | | |
|---|---|---|---|
| **Intermittent** | Chronic persistent | | |
| **Mild** | Mild | Moderate | Severe |
| **1** | 2 | 3 | 4 |
| **Daytime symptoms* ≤2/week** | Daytime symptoms 3-4/week | Daytime symptoms >4/week | Daytime symptoms Continuous |
| **Night symptoms** ≤1/month** | Night symptoms 2-4/month | Night symptoms >4/month | Night symptoms Frequent |
| ***PEF* ≥80%** | *PEF* ≥80% | *PEF* 60-80% | *PEF* <60% |
| ***any of cough, tight chest, and wheeze** | | | |
| ****any of cough, tight chest, wheeze and night wakening** | | | |

Figure 2.1 depicts the medical management of asthma, based on severity (the number of symptoms experienced by the patient) after the initial diagnosis of asthma has been made (Working Group of the South African Thoracic Society et al., 2007). The guidelines for the management and prevention of asthma, updated by the Global Initiative for Asthma (GINA) in 2016, similar to the South African asthma guidelines, contain a step-wise medical management approach to asthma based on symptoms experienced (Global Initiative for Asthma, 2016).

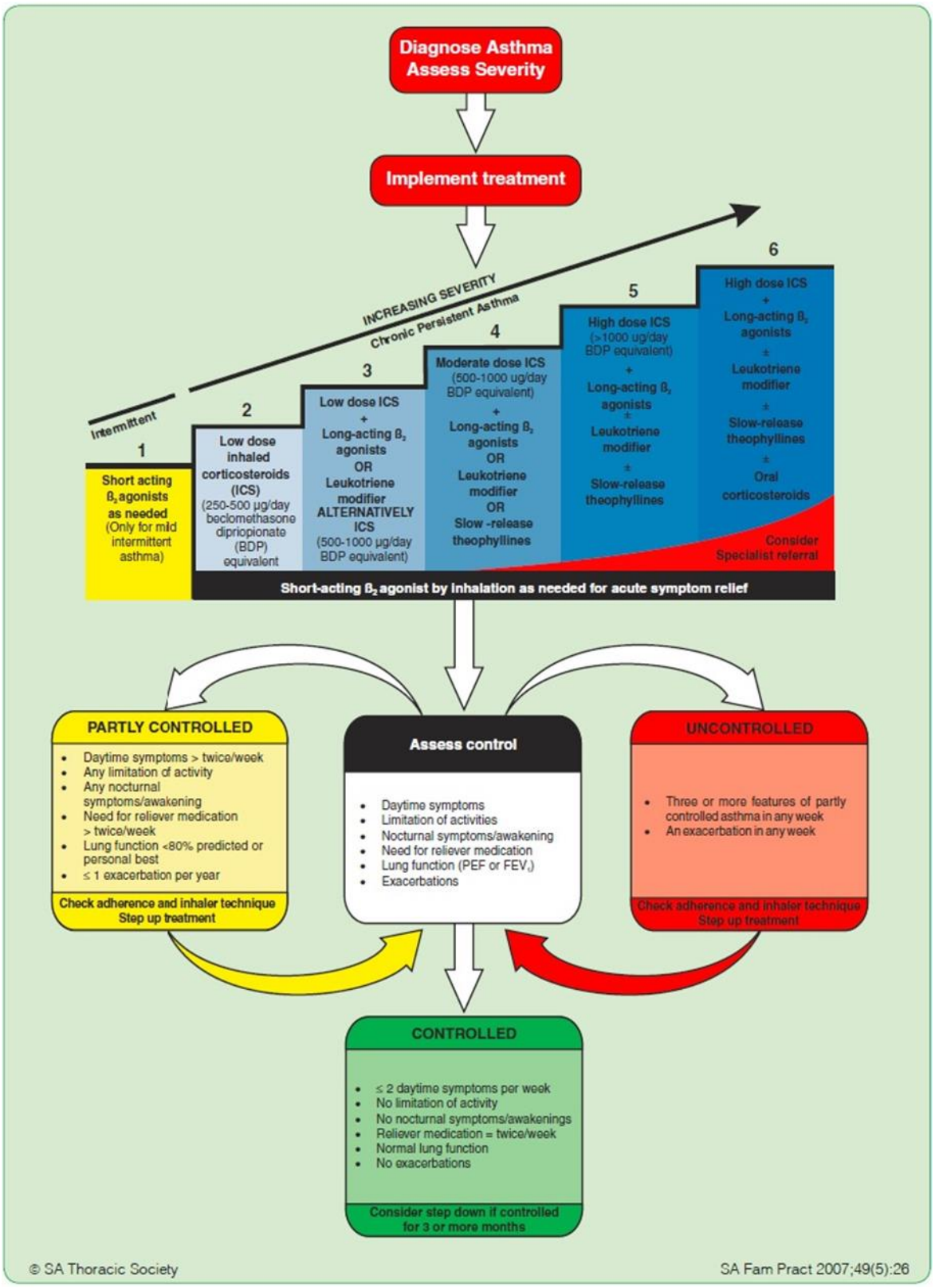


Figure 2.1 Asthma treatment algorithm, Adopted from (Working Group of the South African Thoracic Society et al., 2007)

### 2.2.1 The development of asthma management guidelines

Guidelines for the management of asthma play an empirical role in standardising timely and correct assessment of asthma symptoms, severity and provision of individualised patient management. An important component of asthma guidelines is recommendations about which asthma medications should be used in the treatment of asthma, and when these therapies should be used. Asthma treatment guidelines also promote access to quality-assured and affordable medicines within the countries in which they are used. It is imperative, however, that asthma management guidelines are free from influence and potential bias from developers and manufacturers (pharmaceutical industry) of asthma medications. Asthma management guidelines should therefore be initiated and developed by governments or non-profit organisations. (The Global Asthma Network, 2014)

The first asthma guidelines were generated in the 1980s, but were heavily sponsored by the pharmaceutical industry, which allowed bias and publishing of guidelines that were not evidence-based. In present times, asthma guidelines are more commonly developed using evidence-based medicine, with little or no support from the pharmaceutical industry. (The Global Asthma Network, 2014)

In 2011, the Global Asthma Report undertook the first worldwide survey of national asthma management guidelines. The purpose of this was to establish if countries were making use of any national asthma guidelines and whether these guidelines had been sponsored/influenced by the pharmaceutical industry. This survey was repeated in 2013 by the Global Asthma Network. The survey indicated that the use of asthma guidelines had increased over the last two years, particularly in under-developed and developing countries. It was also found that most of the asthma management

guidelines had been developed without financial incentive from the pharmaceutical industry (Global Asthma Network, 2014).

International asthma guidelines that are evidence-based and free from support from the pharmaceutical industry are freely available from sources like the World Health Organisation, which published guidelines on asthma management for children and adults in 2012 in the report entitled: “Prevention and Control of Non-Communicable Diseases: Guidelines for Primary Health Care in Low Resource Settings.” Other similar guidelines, like GINA, published the following update in 2016: “Global Strategy for Asthma Management and Prevention”. These freely available guidelines can be used with or without permission and may be adapted for specific countries to better suit medicine availability and the country’s individual needs (Global Asthma Network, 2014). In 2007, South Africa, with permission from GINA, adapted and developed GINA’s guideline into a country-specific guideline for the management of chronic asthma in adolescents and adults in South Africa (Working Group of the South African Thoracic Society et al., 2007). Both the international and South African asthma guidelines contain a stepwise medical management to asthma based on symptoms experienced by the patient (Global Initiative for Asthma, 2016; Working Group of the South African Thoracic Society et al., 2007).

### 2.2.2 Medications used in asthma treatment

Asthma medications can be administered in different ways: inhaled, orally or parenterally (by subcutaneous, intramuscular or intravenous injection). As asthma is a disease of the airways, an inhaled dosage form is preferred over oral agents. The inhaled route is a superior form of delivery as the drug can be delivered directly into

the airways with higher lung concentrations and minimal to no systemic side effects (Global Initiative for Asthma, 2016; Horak, Doberer, Eber, Horak, Pohl, Riedler, Szépfalusi, Wantke, Zacharasiewicz, & Studnicka, 2016; Working Group of the South African Thoracic Society et al., 2007). Inhaled medications are readily available in South Africa, in the form of metered dose inhalers (MDIs), breath actuated MDIs, dry powder inhalers (DPIs), soft mist inhalers and solutions for nebulisation (nebulisers are rarely indicated for the treatment of chronic asthma in adults) (Working Group of the South African Thoracic Society et al., 2007).

Asthma medications have been classified into two major categories - as relievers and controllers. This categorisation is based upon the mode of action and is summarised in Table 2.2.

Table 2.2 Common asthma medications, adapted from the South African asthma guidelines, (Working Group of the South African Thoracic Society et al., 2007)

| Controllers | | Relievers |
|---|---|---|
| **Anti-inflammatory action to prevent asthma attacks** | Sustained bronchodilator action but weak or unproven anti-inflammatory effect | Quick relief of symptoms and use in acute attacks as a when needed dosage only |
| **Inhaled corticosteroids**<br>1. **Beclomethasone**<br>2. **Budesonide**<br>3. **Fluticasone**<br>4. **Ciclesonide** | Long-acting Beta 2 agonists<br>1. Salmeterol<br>2. Formoterol | Short-acting Beta 2 agonists<br>1. Salbutamol<br>2. Fenoterol<br>3. Terbutaline |
| **Leukotriene Modifiers**<br>1. **Montelukast**<br>2. **Zafirlukast**<br><br>**Oral corticosteroids**<br>1. **Prednisone**<br>2. **Prednisolone**<br>3. **Methylprednisone**<br>4. **Methylprednisolone** | Sustained-release theophylline preparations | Anticholinergics<br>1. Ipratropium bromide |

Relievers are short-acting bronchodilators with a rapid onset of action that provide acute relief of symptoms. Short-Acting $B_2$ Agonist (SABA) inhalers are preferred over ipratropium bromide inhalers as relievers in asthma treatment. Ipratropium bromide inhalers may be used in patients who cannot tolerate the side effects of SABA inhalers (such as the elderly) and may be used as add-on treatment in patients who do not obtain adequate symptom relief from SABA inhaler use alone. In South Africa, the first reliever of choice is a SABA inhaler containing salbutamol (refer to Table 2.1 for examples). Controllers are medications that possess anti-inflammatory and/or a sustained bronchodilator action/s. As mentioned previously, Inhaled Corticosteroids (ICS) are preferred over oral corticosteroids due to decreased side effects. Leukotriene modifiers are used as add on-therapy in patients with at least mild-persistent asthma that do not show adequate control with ICS and SABA inhalers alone (refer to Figure 2.1). Slow-release theophylline preparations should not be used as monotherapy and have many disadvantages, such as: a narrow therapeutic range, drug interactions and frequent side effects (nausea, vomiting, insomnia, palpitations and seizures). All patients should be prescribed an inhaled short-acting $\beta_2$ agonist (SABA), such as salbutamol, for the relief of acute symptoms, as well as inhaled corticosteroids for the prevention and control of asthma - as baseline treatment. The only classification of asthma that does not require both SABA inhalers and ICS is mild intermittent asthma (Table 2.1 and Figure 2.1), which only requires the use of a SABA inhaler. In South Africa, the guidelines indicate that inhalers are the most commonly prescribed dosage form for asthma medications. (Working Group of the South African Thoracic Society et al., 2007)

In the most recent GINA Report (2016), it was stated that it is important for patients, who are affected with asthma, to be properly educated and to be equipped with the

necessary skills to effectively manage their condition. The GINA report was generated from data obtained from global strategies to manage and prevent asthma. One of the strategies involved the implementation of essential components, such as: skills-training for inhaler devices; encouraging adherence to medications and appointments; providing asthma information; and training patients in self-management (Global Initiative for Asthma, 2016). While the gold standard for asthma treatment remains the inhaled route (Horak et al., 2016), most patients (up to 70 - 80%) are unable to use their inhalers correctly. In addition, many health care providers are unable to correctly demonstrate appropriate inhaler technique for the products that they are prescribing (Global Initiative for Asthma, 2016).

### 2.2.3 Incorrect inhaler technique

There are multiple factors that may result in improper inhaler use, which can stem from the device itself, the patient and the healthcare professional.

#### 2.2.3.1 The device

There are many different inhaler devices, which often differ in terms of:

- the way in which the inhaler liberates the medication – in other words, is it actively or passively generated (i.e. the aerosol-generating properties which can be propellant, mechanical, or compressed air)
- the type of formulation (e.g. solution, dry powder etc.).
- whether the inhaler device is single or multiple use; disposable or refillable; or contains a reservoir.

Each of the different inhalers requires a certain level of physical skill, manipulation, dexterity, hand strength, lung capacity, inspiratory rate and/or hand-lung coordination

to ensure correct and optimal inhaler technique. Patient groups who often encounter difficulties with inhaler devices are the very young and the elderly. Therefore, these patients are at an increased risk of inhaler errors. It is recommended that all patients receiving inhaler devices need to have their individual practical abilities assessed to indicate which device would be best suited to their ability. (Price, Bosnic-Anticevich, Briggs, Chrystyn, Rand, Scheuch, Bousquet, & Committee, 2013)

#### 2.2.3.2 The healthcare professional

Healthcare professionals have a crucial role to play in ensuring correct inhaler technique, not only upon initiation of therapy, but also in ensuring that patients maintain correct inhaler use throughout therapy. However, it has been shown that only a small proportion of patients have ever received inhaler-use education; and an even smaller number of patients have had their inhaler techniques reviewed during therapy. Furthermore, it was shown that approximately half of the patients, who initially received education on correct inhaler use, were unable to maintain the correct technique over time. A critical concept in asthma education is how-, or in what form-, the information or education is delivered. The most effective strategy, in terms of training patients on how to use the correct inhaler technique, has been found to be via a combination of verbal instruction and physical demonstration. (Price et al., 2013)

#### 2.2.3.3 The patient

In addition to the physical requirements needed to utilise an inhaler device, several other patient-related factors have been found to impact on inhaler use. For instance, a patient's health beliefs or attitudes towards medications, adherence and device preferences, may influence inhaler use. Patients who believe that it is important to correctly use inhalers in asthma management, often demonstrate a higher level of

correct inhaler technique (Price et al., 2013). In order to optimise the management of asthma, patients are required to demonstrate correct inhaler technique on the initiation of treatment, as well as throughout their treatment (Basheti, Reddel, Armour, & Bosnic-Anticevich, 2007). Studies have indicated that between 40% to 60% of asthma patients were non-adherent to their medications, which may suggest that healthcare professionals are neglecting to reassess the patient's inhaler technique (Cochrane, Bala, Downs, Mauskopf, & Ben-Joseph, 2000; Cochrane, Horne, & Chanez, 1999; Rand, Nides, Cowles, Wise, & Connett, 1995)

A cross-sectional study was conducted over a 9-month period on all patients who had visited the emergency department with bronchial asthma attacks. The patients who were admitted to the emergency department had their inhaler technique assessed. The study revealed that incorrect technique was associated with irregular clinic visits and lack of asthma education, with 45% of patients showing improper asthma inhaler technique (Hamdan, Ahmed, Abdullah, Khan, Baharoon, Salih, Halwani, & Al-Muhsen, 2013).

Another important factor is the patient's preference for an inhaler, in terms of operational use (such as ease of learning to use it, holding, operating and cleaning the device); convenience (size, shape, colour, durability and weight); and oral sensation (taste, irritation) (Price et al., 2013). Patients will often preferentially choose the treatment that provides obvious and immediate symptomatic relief, like the effects experienced after use of a SABA inhaler (Watkins et al., 2016). Patients will manage asthma with various strategies developed from lived experience, to achieve a 'balance' in their daily lives, whereby the effects of asthma are tolerable and lived with. Patients centre their management of asthma on treating acute episodes with SABA inhalers

rather than preventing future exacerbations with ICS (Ring, Jepson, Hoskins, Wilson, Pinnock, Sheikh, & Wyke, 2011).

### 2.2.4 Using SABA inhalers as targets in asthma management

International and South African asthma guidelines recommend the use of a SABA inhaler, when necessary, to alleviate asthma symptoms, rather than as a regularly scheduled medication (Global Initiative for Asthma, 2016). SABA inhalers are the most important and widely used reliever treatment for asthma (Working Group of the South African Thoracic Society et al., 2007). The use of more than one SABA inhaler per month often indicates over-reliance on this drug and inadequate asthma control. The South African asthma treatment guidelines state that the patient's frequency of SABA inhaler use is a measure of asthma control. (Working Group of the South African Thoracic Society et al., 2007). The over use or regular use of SABA inhalers has been associated with increased airway hyper-responsiveness, adverse cardiovascular effects, mortality, increased health resource utilisation and worsened asthma control (Wong, Manley, Stettin, Chen, & Salmun, 2010).

A study by van Boven, Hiddink, Stuurman-Bieze, Schuiling-Veninga, Postma, and Vegter (2013) sought to demonstrate the potential value of community pharmacists by providing tailored interventions for patients suffering from asthma by making use of individual pharmacy dispensing data. Data were retrieved from 2008 to 2009 from a Dutch pharmacy database. The study population was 8,504 patients. The data were mined to identify four factors that could indicate sub-optimal asthma control, primarily associated with the use of SABA inhalers. The four factors included:

- frequent use of SABA inhalers without preventative medication;
- concomitant use of β-blockers with SABA;
- multiple short courses of oral corticosteroids without using ICS; and
- the use of a Long-Acting Beta-Agonist (LABA) inhaler without ICS

The study revealed that 21.2% of patients were receiving above the recommended dosing frequency of SABA inhalers and that 28.2% of these patients did not receive ICS. Approximately 5% of the asthma patients had been prescribed β-blockers concurrently, with 21.8% of these patients having been on non-selective β-blockers. Approximately 6% of patients received two or more oral courses of corticosteroids and 17.4% of these patients did not receive ICS. It was found that 2.9% of patients were using LABA inhalers without ICS and 8.4% of patients received both ICS and LABA, but as two separate inhalers. The study reinforced the statement in the South African asthma guidelines that SABA inhaler use can be used by healthcare providers to identify poor asthma control (Working Group of the South African Thoracic Society et al., 2007). The researchers concluded that pharmacists specifically have the potential to utilise their own pharmacy dispensing records to retrospectively identify patients with sub-optimal asthma therapy as targets for tailored interventions (van Boven et al., 2013).

Using data retrieved from the UK General Practice Research Database from 1993 to 1996, another study explored the correlation between the ratio of corticosteroid to bronchodilator (C : B) use and hospitalisation as a result of sub-optimally controlled asthma. The results of this study indicated that higher ratios of corticosteroid to bronchodilator use resulted in fewer hospital admissions, compared to patients with

low corticosteroid use. The study showed an inverse association between C : B ratio and hospital contact (Frischer, Heatlie, Chapman, Norwood, & Millson, 2000).

An increased C : B ratio has been associated with a reduction in asthma symptoms, decreased oral corticosteroid use and emergency physician visits. An intervention study was conducted in Australia in 2006/7 and involved data mining of dispensing records to identify patients who had received three or more SABAs in the preceding six months. Identified patients were split into control and intervention groups. Patients in the intervention group were contacted via mail, and were sent educational material and a letter encouraging them to see their general practitioner for an asthma management review. The intervention resulted in a threefold increase in C : B ratio, with a higher proportion of patients in the intervention group using inhaled corticosteroids compared to the control group. The study showed that dispensing records, which record SABA inhaler purchasing, can be used effectively to identify patients with sub-optimal asthma control (Bereznicki, Peterson, Jackson, Walters, Fitzmaurice, & Gee, 2008). A follow-up study was conducted in 2008 to establish the sustainability of the intervention. The improved C : B ratio was sustained for at least 12 months following the initial intervention in 2007. The sustained ratio was attributed to the significant decrease in the average daily use of bronchodilators. This study indicated the long-lasting potential that asthma interventions can have on improving asthma management and ultimately reducing burden on the health care system (Bereznicki, Peterson, Jackson, Walters, & Gee, 2011).

Another intervention study, targeting the use of SABA inhalers in the US, was conducted between 2007 and 2008. The intervention involved a written or verbal request to the prescriber to reduce the prescribing quantity of SABA inhalers to less than one inhaler per month, if the asthma patient had been dispensed more than one

inhaler per month. The results of the study indicated that a simple intervention such as a letter or a phone call, reminding the prescribing physician of guideline-suggested complaint use of SABA inhalers, can reduce the overall number of dispensed SABA inhalers without affecting asthma control (Wong et al., 2010). This intervention is possible in countries where the dispensing of a SABA inhaler requires a prescription. Watkins et al. (2016) identified a potential problem with this approach in countries where the legislation does allow for the sale of SABA inhalers without a prescription from a physician. Community pharmacists may be the only healthcare professionals who are in a position to regularly assess asthma control in patients who choose to self-medicate with reliever medication only (Watkins et al., 2016).

### 2.2.5 South African legislation relating to access of SABA inhalers

In South Africa, according to the Medicines and Related Substances Act 101 of 1965, SABA inhalers have been classified as Schedule 2 (S2) medications and are available for sale in a pharmacy without a prescription, under the direct personal supervision of a pharmacist (South Africa, 1965). For a substance to be listed as a S2 medication, it must be known to be relatively safe to use, but will still require advice, counselling and management or monitoring by a pharmacist or another health care professional. While medicines containing S2 substances may be indicated for minor diseases or symptoms, which can be recognised by the patient, these will require verification by a pharmacist, but not an initial medical diagnosis or medical management. Schedule 2 medicines, like SABA inhalers, are therefore, available without a prescription. Inhalers containing corticosteroids fall into the Schedule 3 category and require a prescription

from an authorised prescriber (South Africa, 1965). As this study focused on SABA inhalers, only the law pertaining to Schedule 2 substances will be discussed further.

During the sale of S2 medications, there are minimum legal requirements that must be adhered to and these include obtaining the following information:

- name and address of the patient;
- date of the sale;
- name of the product; and
- recommended dosage of the medicines

In 1997, the SAPC developed the Good Pharmacy Practice (GPP) standards (South African Pharmacy Council, 2010), updated in 2010, and these were produced in order to:

- provide guidelines which would enable pharmacists to evaluate their own professional services, against acceptable norms and standards of pharmacy practice; and
- encourage pharmacists to develop and improve their professional practice in order to match these standards.

The GPP provides the minimum standards for pharmacist initiated therapy for self-care products, including the supply of Schedule 0, Schedule 1 and Schedule 2 medicines and may be summarised as follows:

- The pharmacist must utilise experience to select medicines, considering product quality, efficacy and safety.

- If a medicine is supplied, the pharmacist should do his/her best to ensure that the patient or caregiver has no doubts as to:
    - the name (generic/trade) and physical description of the medicine;
    - the intended use of the medicine and expected action;
    - the route, dosage form, dosage and timing of administration;
    - any special directions or precautions for the preparation or administration of doses;
    - duration of treatment;
    - any relevant drug/drug, drug/food, and/or drug/alcohol interactions;
    - common severe side effects or adverse reactions or interactions and therapeutic contra-indications that may be encountered, including their avoidance, and the action required if they occur;
    - techniques for self-monitoring;
    - storage conditions; and
    - action to be taken in the event of a missed dose or in the event of an overdose.
- The supply of medication must be indicated in the patient's profile.

For each type of health problem that can be treated within the framework of self-care, protocols for the action of pharmacist's assistants and members of staff, who are not registered with the South African Pharmacy Council, must be established. The protocol must define when referral to a pharmacist is necessary. (South African Pharmacy Council, 2010)

Similarly, in Australia, SABA inhalers fall into a pharmacist only category of medication. A patient does not require a prescription for the medication, however, the

sale does require authorisation by a pharmacist. Pharmacists are legally responsible to assess patients' therapeutic needs and directly supervise the sale of asthma reliever medications. Watkins and colleagues (2016) suggest that in countries, like South Africa and Australia, where SABA inhalers are available without a prescription, pharmacists may be the only healthcare professionals to regularly assess patients who solely rely on reliever medication for the management of their asthma. Watkins et al (2016) made reference to 'access' and 'cost' influencing the use of ICS by patients. While most patients diagnosed with asthma are initially prescribed ICS, they choose to medicate with cheaper and more accessible SABA inhalers. The patients' choice of SABA inhalers over ICS becomes more distinct when patients are required to see a physician to obtain prescriptions for on-going ICS treatment. (Watkins et al., 2016)

SABA inhalers require no prescription from an authorised prescriber and are significantly cheaper than ICS inhalers in South Africa. The findings by Watkins et al. (2016) suggested that in a country like South Africa, where SABA inhalers are available without a prescription, asthma patients may tend to self-medicate with SABA inhalers. Asthma patients have been shown to have a different perception of asthma control to healthcare professionals who objectively perceive asthma as a chronic condition requiring long-term prevention to achieve control. Personally, patients regard asthma to be an acute intermittent condition requiring only episodic treatment. The patients' misperception of asthma as a condition often results in sub-optimal control (Ring et al., 2011). Uncontrolled asthma places a costly burden on the community in terms of lost productivity and unnecessary healthcare utilisation of healthcare resources (Watkins et al., 2016).

### 2.2.6 The burden of uncontrolled asthma

Uncontrolled asthma not only places a burden on the individual with the disease, but places a burden on society due to increased healthcare utilisation and lost man hours (Global Asthma Network, 2014).

#### 2.2.6.1 Social aspects

Uncontrolled asthma can negatively affect a multitude of daily activities, such as: sleeping, working, studying and exercising. A survey conducted in England in 2001 revealed that 16% of men and 20% of women with asthma had experienced sleep disturbances at least once a week and approximately 50% of the respondents were unable to carry out their daily activities. It would appear that asthma severity is directly related to impairment of quality of life. Surveys conducted between 1999-2001 in Europe found that 7% of patients had been admitted to hospital due to asthmatic complications in the last twelve months and 10% required a visit to the emergency department (Peters, Ferguson, Deniz, & Reisner, 2006).

#### 2.2.6.2 Economic burden

Quantification of the global economic burden of asthma is a challenging task due to variance in direct and indirect costs, however, the independent estimates of several countries are high. Direct costs are easier to measure as they are the costs that are directly associated with asthma treatment, and range from asthma medication through to hospitalisation costs. In contrast, indirect costs, which include those costs related to the loss of productivity (most commonly due to work absenteeism) are harder to quantify. Additionally, research now suggests that ‘presenteesim’, which is the

individual loss of function when at work, contributes more to economic loss than absenteeism does (Peters et al., 2006).

When reviewing studies that relate to the economic burden of asthma, most of these studies seem to have emerged from high-income countries. For example, a systematic review in 2009, showed a relative paucity of information from under developed and developing counties. This may be attributed to the fact that high income countries are more likely to conduct national surveys of disease; and have larger administrative databases that can be investigated to create a broad picture of the burden than under developed and developing countries (Global Asthma Network, 2014).

In 2005, the cost of asthma per annum in Europe was approximated to be €17.7 billion, of which €9.8 billion was attributed to indirect costs associated with the loss of productivity, due to absence from work. A later study, conducted in 2011, estimated the total cost of asthma to be €19.3 billion in Europeans aged 15-64 years (Global Asthma Network, 2014).

In addition, it has been shown that patients with poorly controlled asthma utilise a significantly larger portion of healthcare resources than patients who are controlled. A UK study recruited 13 241 asthma patients with varying degrees of severity, and demonstrated how patients with uncontrolled asthma had recurrent asthma exacerbations requiring emergency treatment. These patients were found to be three to four times costlier to manage than patients with controlled asthma (Global Asthma Network, 2014).

#### 2.2.6.3 A preventable burden

As asthma currently has no cure, the management thereof is aimed at achieving a controlled asthma state (minimal symptoms) and preventing and reducing future exacerbations. The collective effort of the Global Asthma Report has shown that when strategies are put into place to ensure optimally-controlled asthma, there is a significant reduction in the economic burden, in comparison to uncontrolled asthma. Research that is emerging from both under developed and developing income countries has repeatedly shown that adherence to controller medication is low. There is strong evidence to suggest that there is an association between controller adherence and optimal asthma control. This, in turn, makes adherence a modifiable factor and a potential target to help decrease the economic burden of asthma (The Global Asthma Network, 2014). In developing countries, like South Africa, there may be additional barriers to delivering effective asthma management strategies. These barriers include poverty, poor education and poor infrastructure, suggesting that a comprehensive approach is needed, working alongside political commitment towards better asthma care. By improving asthma control, through increased access to quality management and medications, the impact of both direct and indirect costs may be diminished (The Global Asthma Network, 2014). In 1996, the post-apartheid government developed a National Drug Policy, the purpose of which was to reduce medicine costs and improve prescribing and dispensing practices. This was the start of South Africa's political commitment towards better healthcare for the whole country (Gray, 2009).

Currently, the normal trend seems to be that asthma is managed by general practitioners (GPs) in a primary healthcare setting. They are responsible for initial diagnosis and subsequent treatment of this chronic condition. However, studies

continuously indicate a lack of guideline compliant practice and sub-optimal patient outcomes (Barton, Proudfoot, Amoroso, Ramsay, Holton, Bubner, Harris, & Beilby, 2008; Wiener-Ogilvie, Pinnock, Huby, Sheikh, Partridge, & Gillies, 2007; Yawn, 2011). Compliant practice and optimal treatment by GPs is further impeded by a lack of routine asthma visits by patients his limits the opportunity for patient education on asthma management. Watkins and colleagues (2016) identified an incongruence between patient perceptions of asthma control and actual asthma control, across a cohort study. The importance of these perceptions is that patients were unlikely to have proactively sought support from health care professionals when they considered themselves to be controlled. As a result, patients were only likely to have sought assistance from health care professionals (primarily from an emergency department) when experiencing acute exacerbations of asthma. As suggested by Watkins et al (2016), community pharmacists may be the only health care professionals, who are able to regularly assess patients who depend solely on reliever medication for the management of asthma. Pharmacists therefore have a potentially large beneficial role to play in reducing the burden of asthma (Watkins et al., 2016).

### 2.2.7 A pharmacist's position in asthma care

In Section 2.2.4, studies by Bereznicki et al. (2008), Wong et al. (2010) and van Boven et al. (2013) were alluded to and highlighted the potential benefit that pharmacists could have on improving asthma care by making use of dispensing records.

Application of an asthma care plan (or model) in community pharmacies in Australia (2004) was reviewed by Bandana Saini, Krass, & Armour to establish what benefits it could potentially have within the community. Pharmacists were trained in the

Australian Six-Step Asthma Management Plan and over 6-months, delivered the asthma care model to patients. The six-step plan consists of the following factors:

1. Assessment of patient's asthma severity.
2. Achievement of best lung function.
3. Maintenance of best lung function through avoidance of triggers.
4. Maintenance of best lung function through optimal medications.
5. Provision of a written action plan.
6. Education and regular review.

After six months, there was a significant reduction in asthma severity (symptoms experienced) in the intervention patients and an overall reduction in SABA inhaler use. Patients also demonstrated improved perceived control of asthma and asthma-related knowledge. The annual savings in medication costs for the intervention group (consisting of 52 patients) was calculated to be $100 801.20 (AU). The findings in the study showed how effective a community pharmacy setting could be to serve as a site for the provision of specialised health care for patients suffering with asthma; and that pharmacists were able to deliver efficient and quality services for patients. This could theoretically relieve some of the burden placed on prescribing physicians. However, community pharmacies were found to be a completely underutilised healthcare resource for asthma care. (Bandana Saini, Krass, & Armour, 2004)

Another Australian multi-site randomised-intervention-versus-control repeated measure study was conducted as part of the implementation of an asthma care programme (Australian Six-Step Asthma Management Plan). Fifty pharmacies were randomised into two groups: intervention pharmacies - implemented a pharmacy asthma care programme; while control pharmacies delivered their usual care. The

main outcome measures were asthma severity and asthma control. It was found that patients in the intervention group were 2.7 times more likely to have their asthma score drop from ‘severe’ to ‘moderate’. This study showed that pharmacists who delivered the asthma care programme, based on current guidelines, improved asthma control. Some of the notable outcomes in this study, included: increased adherence to preventer medications and a decreased dependence on reliever medications. There was also an increase in the patients’ knowledge of asthma as a disease state, which increased self-management ability. (Armour, Bosnic-Anticevich, Brillant, Burton, Emmerton, Krass, Saini, Smith, & Stewart, 2007)

A similar study on the provision of asthma care, in the context of a pharmaceutical care demonstration project was conducted in New Zealand. The outcome of this study suggested that some of the major reasons for the lack of asthma control were poor adherence and incorrect prescribing. Of the interventions made, the majority were revisions of the patients’ asthma care plans. This resulted in a decreased use of relievers and an overall improvement in symptom control. Emmerton, Shaw, and Kheir (2003) concluded that some of the basic principles of the asthma care service had the potential to be adopted for other conditions.

Barbanel, Eldridge, and Griffiths (2003) investigated an asthma self-care programme delivered by community pharmacists in East London (UK). Twenty-four patients visiting a community pharmacy were randomised into intervention and control groups. The intervention group received self-management advice from the pharmacist, with weekly telephone calls for three months, while the control group received no additional input from the pharmacist. The study showed how a self-management plan, delivered by community pharmacists, could improve asthma control. Studies have suggested that education for asthma is often maximised when the physician develops an ongoing

partnership with the patient (Clark, Gong, Schork, Evans, Roloff, Hurwitz, Maiman, & Mellins, 1998; Griffiths, Kaur, Gantley, Feder, Hillier, Goddard, & Packe, 2001). A similar trend was observed in the study by Barbanel and colleagues (2003) in that regular contact between the pharmacist and the patient, over a period of months, allowed for the development of trust and confidence among patients receiving the intervention. The authors proposed the following possible reasons for poor asthma care: most community pharmacies have inadequate facilities for private consultations; only a small percentage of pharmacists have received training in the delivery of asthma care; and with the increased multidisciplinary approach towards the care of a single patient, mechanisms are needed to ensure that advice given to patients is consistent across disciplines.

A study was conducted in Australia aimed at developing an asthma self-management model and implementing it in a community pharmacy to establish its impact on clinical and psychosocial outcomes. The research design of the study utilised a controlled, parallel group study. Pharmacists received training on self-management theory and intervention, patient beliefs and attitudes and communications skills. Pharmacists delivered a structured, step-wise, patient focused self-management programme to patients in the intervention group. The patients had to set asthma control goals that were facilitated by the pharmacist. The intervention group reported greater improvements in symptom control, asthma-related self-efficacy and improved quality of life. The results revealed the potential capacity of pharmacies to deliver an asthma care programme. (L. Smith, Bosnic-Anticevich, Mitchell, Saini, Krass, & Armour, 2007)

A Belgian study was conducted to establish whether pharmacist interventions, focused on the appropriate use of asthma medications and asthma plans that were tailor-made for the patient's current asthma control, would improve asthma control in adults. The

study authors stressed that while asthma care plans are typically delivered in a hospital setting and/or by a physician, a community pharmacist providing asthma care plans can make a significant contribution in asthma management. This is because of pharmacist's expert knowledge in medications, as well as frequent contact with the patient during prescription refills. The study showed that a simple intervention, focusing on inhalation technique and medication adherence, greatly improved asthma control in patients with uncontrolled asthma. (Mehuys, Van Bortel, De Bolle, Van Tongelen, Annemans, Remon, & Brusselle, 2008)

A further study conducted in Australia compared the effect of a pharmacist-delivered rural asthma management service (RAMS) with standard care that was being provided in community pharmacies. Pharmacists in the RAMS group were trained on an asthma care model that had been successfully implemented in suburban and metropolitan areas. This model was contextualised to be more suitable for implementation in rural settings. Noteworthy changes that were observed in the RAMS group, included: the mean asthma severity score, which was calculated based on the frequency of symptoms in the week; and a history of emergency room visits or hospitalisations, dropped from 'severe' to 'moderate'. Improvements were also seen in the standard care group, but these were not significant, and were attributed to patients having made fewer mistakes when using asthma devices and increased adherence to prescribed asthma medications. (B. Saini, Filipovska, Bosnic-Anticevich, Taylor, Krass, & Armour, 2008)

These studies indicated that pharmacists, with access to medical records and frequent contact with patients, are well positioned in the healthcare system to be facilitators of asthma care. However, these intervention studies were relatively short-term and not sustained once research was concluded. Sustainable roles for pharmacists in asthma

care must be developed and implemented as part of routine practice that is accepted by the broader health care system (Watkins et al., 2016).

In South Africa, all practising pharmacists are obliged to ensure that the patient care services they provide are of high quality and comply with Good Pharmacy Practice Standards, as published by the South African Pharmacy Council. The document entitled 'Good Pharmacy Practice in South Africa', indicates how that obligation can be met. What forms part of the underlying philosophy in Good Pharmacy Practice in South Africa is that pharmacists are providers of pharmaceutical care. Thus, pharmaceutical care could be considered 'routine practice' for pharmacists in South Africa. (South African Pharmacy Council, 2010)

### 2.2.8 Pharmaceutical care

Charles Hepler and Linda Strand published a revolutionary research paper in 1990 entitled: 'Opportunities and responsibilities in pharmaceutical care'. This was the first published paper to provide a definition for pharmaceutical care and to highlight its importance in the transitional stage that pharmacists found themselves in at that time. At the beginning of the twentieth century, pharmacists were known as apothecaries. During what Helper and Strand termed the 'traditional stage', a pharmacist's function to society was procuring, preparing, evaluating and selling drug products. An apothecary's primary obligation was to ensure that the drugs that were sold were pure, unadulterated and prepared *secundum artem* (Latin: according to the art or practise). A secondary obligation of an apothecary was to provide good advice to customers who asked to be prescribed drugs over the counter. This traditional stage began to diminish and the preparation of drugs, now known as pharmaceuticals, was taken over

by the pharmaceutical industry. The choice of pharmaceuticals was then passed from the pharmacist to the physician. In the mid1960s, clinical pharmacy practice was born, which shifted pharmacy closer to the patient. The emergence of clinical pharmacy gave rise to a professional transition in pharmacy where pharmacists sought self-actualisation – the full achievement of their professional potential. There was a rapid expansion of functions and increased professional diversity. Pharmacists started to perform and innovate functions new to pharmacy and make original contributions to literature. Hepler and Strand referenced an article by Brodie (1967) entitled, 'Drug use Control', suggesting that many understood Brodie's call for drug use control to advocate the profession's preoccupation with medication rather than the individual patient. Hepler and Strand stated that Brodie's presentation of these ideas in terms of social responsibility for the patient appeared to have been overlooked. Hepler and Strand suggested that another consequence of this rapid expansion of functions was the evolution of pharmaceutical services, such as clinical pharmacokinetics. While pharmacy was shifting closer towards the patient, the focus continued to be on the drug and its delivery to abstract biological systems rather than individual patients. In 1986, Cipolle wrote, "drugs don't have doses, people have doses!" Pharmaceutical practice must restore what has been missing for years: a clear emphasis on the patient's welfare, a patient advocacy role with a clear ethical mandate to protect the patient from what has been termed 'drug misadventuring'. Helper and Strand, referencing other published studies, found that clinical knowledge and skills by themselves were not sufficient to maximise the effectiveness of pharmaceutical services. An appropriate philosophy of practice and organisational structure within which to practice was required. Hepler and Strand termed this necessary philosophy of practice 'pharmaceutical care' and the organisational structure that facilitates the

provision of this care a ‘pharmaceutical care system’. Pharmaceutical care is a necessary element of health care that should be integrated with other elements. It has been defined as follows:

> “…the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life. These outcomes are (1) cure of a disease, (2) elimination or reduction of a patient’s symptomatology, (3) arresting or slowing of a disease process, or (4) preventing a disease or symptomatology” (Hepler & Strand, 1990)

Pharmaceutical care is a process in which a pharmacist co-operates with patients and other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient. This, in turn, involves three major functions: (1) identifying potential and actual drug-related problems; (2) resolving actual drug related problems; and (3) preventing potential drug-related problems. Pharmaceutical care is, provided for the direct benefit of the patient, and the pharmacist is directly responsible to the patient for the quality of that care. The fundamental relationship in pharmaceutical care is a mutually beneficial exchange in which the patient grants authority to the provider and the provider gives competence and commitment (accepts responsibility) to the patient. The fundamental goals, processes, and relationships of pharmaceutical care exist regardless of practice setting. (Hepler & Strand, 1990)

In asthma care, British guidelines (in 1990) had started indicating the benefits of a self-care management plan for asthma in improving control. For patients to self-medicate their condition, active participation from their healthcare professionals was required. An individual asthma plan was developed for the patient and then the patient was

educated on what measures to take if the condition worsened and when to contact a healthcare professional. These plans were subsequently termed ‘asthma action plans’. (Partridge, 2004). The aim of an asthma action plan is to enable patients with asthma to gain the knowledge, confidence and skills to actively manage their asthma, by forming a partnership with their healthcare professional. Patients and healthcare professionals discuss and develop a personalised written plan with set treatment goals. The plan is periodically reviewed and the level of control is established (Working Group of the South African Thoracic Society et al., 2007). The process of pharmaceutical care is comparable to the application of asthma action plans in that a therapeutic plan is designed, implemented and monitored. While guidelines promote the use of asthma action plans (Global Initiative for Asthma, 2016; Working Group of the South African Thoracic Society et al., 2007) research has shown that there is inadequate provision of asthma action plans and sub-optimal patient outcomes in asthma care (Barton et al., 2008; Wiener-Ogilvie et al., 2007; Yawn, 2011).

### 2.2.9 Misperceptions and misunderstandings of asthma

In 2011, a systematic review was undertaken by Ring and colleagues, with the aim of understanding what helps or hinders action plan use from the perspective of the healthcare professional and the patient. From the 1 665 potentially relevant studies, only 19 studies published between 1998-2009, satisfied the researchers’ inclusion criteria. The review revealed that asthma action plan use was hindered because of the differing beliefs and attitudes held by healthcare professionals and patients in asthma management. This difference resulted in healthcare professionals and patients operating in differing explanatory models as to what asthma is, how it can and should

be managed, and their respective roles in the process. Patients perceived asthma to be an acute intermittent condition requiring episodic treatment. Therefore, patients centred their management around treating acute exacerbations with a SABA inhaler rather than proactively managing the condition with ICS. Patients accepted 'tolerable' symptoms, restricted activities and did not want to use inhalers due to social stigma. Conversely, healthcare professionals perceived asthma to be a chronic condition, requiring long-term prevention and management so that patients are symptom free. Patients commonly view themselves as experts in their asthma care and actively manage their condition by making decisions for treatment based on previous experience. It was to be expected that healthcare professionals viewed themselves as experts in asthma care, who could allow patients to take responsibility for their own condition. Healthcare professionals appeared to have failed to adequately acknowledge the patients' lived experiences and focused on compliance with prescribed medications. This review reinforced the idea that was posed by Brodie (1967) and again by Hepler and Strand (1990) that healthcare professionals were working solely within a medical model of healthcare. When healthcare professionals provide asthma action plans to patients, they often do not fit the patient's explanatory model of asthma in terms of how they perceive symptoms and language that is used to describe asthma. When patients are given a medically focused plan, they perceive it as being unhelpful – as it does not reflect their asthma model – or they adapt it to suit their understanding of the condition. Healthcare professionals then interpret the patient's adaptation of the plan as ineffective or unsuitable, rather than welcoming the mutual learning process that it may offer (Ring et al., 2011).

## 2.3 Summary

Asthma is a condition that causes inflammation of the airways that results in symptoms that affect a patient's ability to carry out normal daily tasks (Global Asthma Network, 2014). The medical management of asthma is based on the frequency of symptoms (i.e. severity) experienced by the patient. The most commonly prescribed asthma medications are in the dosage form of inhalers (Working Group of the South African Thoracic Society et al., 2007). Multiple practical issues have been identified with the use of inhalers such as the device itself, the patient using the inhaler and the healthcare professional prescribing or dispensing it (Price et al., 2013). SABA inhalers are the most commonly utilised inhaler and can be used as targets for identifying patients with inadequate asthma control (Working Group of the South African Thoracic Society et al., 2007). Pharmacists are in an ideal position to identify these patients with access to dispensing records and their frequent contact with patients (Watkins et al., 2016). Healthcare professionals and patients have been shown to have different explanatory models for asthma care. Patients believe asthma to be an intermittent condition requiring treatment only during exacerbations and will live with tolerable symptoms, such as coughing. Healthcare professionals objectively view asthma as a chronic condition requiring long-term treatment for patients to remain symptom free (Ring et al., 2011).

# CHAPTER THREE

# METHODOLOGY

## 3.1 Research design

This study adopted a covert-participant observational design known as mystery shopping. Navarez (2006) described mystery shopping as a form of participant observation that can be used to lead health care professionals to believe that they are serving a real patient. Mystery shopping is also referred to as simulated or surrogate shopping or the practice of using pseudo-patients/clients (Anderson & Bissell, 2004). As a research design, the mystery shopping technique allows the observer to experience the service as it unfolds. This, in turn, ensures that the rendered service is measured in a natural environment and is not skewed or distorted for the sake of the observer. It has been shown that there is often a discrepancy between real and reported behaviours. The mystery shopping technique overcomes this weakness by documenting actual behaviours (Wilson, 2001).

When mystery shopping is used, certain factors need to be taken into consideration. A realistic scenario needs to be designed, one that mimics a natural customer/patient behaviour in order to test the service that is relevant to the topic of study. The scenario should not be overly complicated as it can result in staff guessing that they are being mystery shopped, which can compromise the value of the study. After the 'shop' is complete, it is important that the data collection sheet that the mystery shopper completes documents precisely what happened at the point of contact rather than focus on subjective data (MRS, 2014).

## 3.2 Research process

Figure 3.1 summarises the research process employed in this study. Each step is discussed in its own relevant section below.

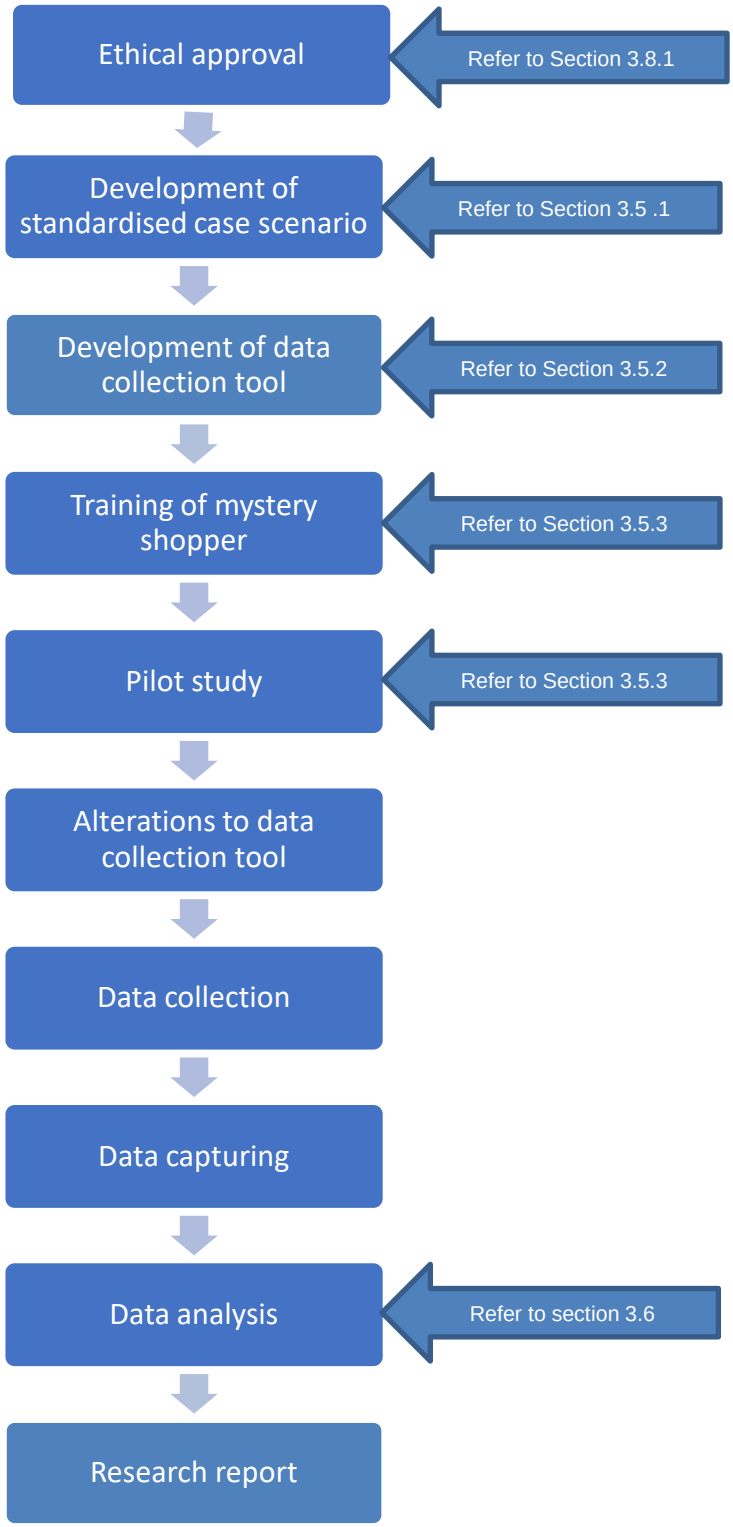


Figure 3.1 Research process

## 3.3 Research site and population

The research site included all pharmacies in the Eastern Cape and Western Cape that were situated between East London and Cape Town that were registered with the South African Pharmacy Council at the time of the study. The study population included all of the pharmacists and pharmacy support personnel that assisted the simulated patient during the mystery shop. Prior to any of the pharmacies being mystery shopped, a letter of intent (Appendix A) was emailed to allow pharmacies to opt out of the study. Any pharmacy that opted out of the study was not included in the sample. Two corporate pharmacy chains and two independent pharmacies opted out of the study.

## 3.4 Research Sample

Community pharmacy sites were selected using a convenience sampling technique. The shortest travel route was plotted between East London and Cape Town and pharmacies located on this route were included in the study. Since the researcher was well-known to pharmacist interns and students in the Port Elizabeth area, there was a great possibility that he would have been recognised whilst visiting pharmacies in Port Elizabeth. Therefore, community pharmacies in the researcher's home city (Port Elizabeth) were excluded from the study to prevent the Hawthorne effect. The Hawthorne effect has been described as a change in one's behaviour if one has the knowledge of being observed (Maher & Hughes, 2013).

## 3.5 Data Collection

According to the Mystery Shopping Guidelines (2014), when designing a scenario, it needs to be relevant to test the specific service behaviour of the topic of study. The scenario should be realistic, in that it mimics natural consumer behaviour. The simulated patient presented the case scenario to the first pharmacist or pharmacy support personnel who offered assistance. The interaction was audio recorded and immediately after the mystery shop had concluded, the simulated patient proceeded to the car to listen to the audio recording and fill in the data collection tool.

### 3.5.1 Design of the case scenario

A *Pharmaciae* issued by the South African Pharmacy Council (2007) stated: it is the pharmacist's responsibility to provide adequate advice to the patient (or the patient's care giver) to ensure the safe and effective use of medicines. The case scenario was designed to mimic a patient requesting a medication by name from a dispensary rather than the patient presenting with symptoms. The onus was on the pharmacy personnel to open the line of questioning, to take a brief history, and establish what kind of counselling the mystery shopper would require. To ensure consistency throughout this study, the following standardised case scenario (Table 3.1) was used. The aim of the standardised case scenario was to employ a mystery shopping technique to establish whether pharmacy personnel could identify incorrect and over use of a SABA inhaler. If the pharmacy personnel established incorrect inhaler technique it was also designed to provide an opportunity to identify the practices utilised when educating a patient on correct inhaler technique and give the mystery shopper an opportunity to enquire about asthma screening services available in the pharmacy.

Table 3.1 Standardised case scenario

**Mystery shopper case scenario**:

The mystery shopper will approach the counter and ask for an Asthavent® inhaler by name.
If prompted, the mystery shopper will offer the following answers to questions:

- Who is the medication for?
  - It is for me.
- Have you used the medication before?
  - Yes, but I only started recently.
- What are the symptoms?
  - Whenever I play squash, my chest feels tight and I wheeze a bit.
- How long have the symptoms persisted for?
  - They last about a few days and then disappear.
- Are you currently taking any other medication?
  - No.
- Do you have any other disease states?
  - No.
- How often do you use your inhaler?
  - Sometimes in the morning but mostly while I am playing squash.
- How many inhalers do you use in a month?
  - 2
- How do you use your inhaler?
  - A short quick breath when I press the pump
- Do you have any other questions?
  - Can you check if my asthma is getting worse?

### 3.5.2 Design of the data collection tool

The data collection tool (Table 3.2) was compiled by adopting the minimum standards for pharmacist initiated therapy provided in the Good Pharmacy Practice in South Africa manual. The minimum standards were adapted to devise a contextualised data collection tool suited towards asthma research. Demographics were recorded to establish any correlation in history taking and counselling. The history taking section was developed to see if pharmacy personnel when presented with a product request,

would ask the necessary questions to establish whether the requested product should be dispensed or not. The medical information section was included to establish if the pharmacy personnel that dispensed the requested item would voluntarily offer information on the product dispensed i.e.: what to expect from using the product. The technique of a metered dose inhaler was recorded to identify if pharmacy personnel dispensing an asthma inhaler could demonstrate correct technique to a patient. The understanding section was included to see whether pharmacy personnel gave patients an opportunity to clarify any information or misunderstandings that could occur during counselling. The availability of asthma screening services was also recorded to establish the frequency that these services were provided. For this data to be collected the following data collection tool was developed.

Table 3.2 Data collection tool

| **Demographics** | | | |
|---|---|---|---|
| **Tick as appropriate** | | | |
| **Gender:** | Male | Female | |
| **Apparent age (in years):** | | ≤ 30 | |
| | | 31 – 40 | |
| | | 41 – 50 | |
| | | ≥50 | |
| **Pharmacy type:** | Independent | Chain | |
| **Pharmacy location:** | | Shopping centre | |
| | | Street | |
| | | Medical centre | |
| | | Other | |
| **Race:** | | Asian | |
| | | Black | |
| | | Coloured | |
| | | White | |
| | | Other | |
| **Profession of pharmacy personnel** | Pharmacist | Post basic assistant /Technician | |
| | Not identifiable | | |
| **Waiting time until addressed** | < 1 min | 1-3 min | >3min |
| **Counselling time** | < 1min | 1-3 min | >3min |
| **Pharmacy business** | Staff ≥ patients | Staff < patients | |
| **Was a pharmacist apparently involved?** | Yes | No | |

| History taking and counselling offered by the pharmacist | | |
|---|---|---|
| | Yes | No |
| **History** | | |
| Who is the medication for? | | |
| Have you used the medication before? | | |
| What are the symptoms? | | |
| How long have the symptoms persisted for? | | |
| Are you currently taking any other medication? | | |
| How often do you use your inhaler? | | |
| How many inhalers do you use in one month? | | |
| **Medication information: Did the pharmacy personnel explain:** | | |
| Which symptoms will disappear and which will not disappear? | | |
| When the effect of the medication is to be expected? | | |
| What could happen if the medication is taken incorrectly or not at all? | | |
| **Medication instructions: Did the pharmacy personnel explain:** | | |
| How the medication should be taken? | | |
| When it should be taken? | | |
| How the medication should be stored? | | |
| **Understanding: Did the pharmacy personnel:** | | |
| check that everything was clear? | | |
| ask the mystery shopper to repeat vital information? | | |
| give the opportunity to ask further questions? | | |
| **Technique of a MDI** | | |
| Shake the inhaler before use. | | |
| Remove cap. | | |
| Hold canister upright. | | |
| Breathe out as far as comfortable. | | |
| Put mouthpiece between teeth without biting and close lips to form good seal. | | |
| Start to breathe in slowly and actuate the device. | | |
| Continue to breathe in slowly and deeply with inhaler in mouth and lips sealed around it. | | |
| Hold breath for 5 - 10 seconds or as long as comfortable while removing device from mouth. | | |
| Breathe out gently. | | |
| Replace cap. | | |
| **Asthma screening services** | | |
| Was an asthma screening service available in the pharmacy? | | |
| Did the pharmacy personnel advise on self-monitoring i.e.: peak flow monitoring | | |

### 3.5.3 Pilot study

A pilot study was conducted at four pharmacies between Alexandria and Kenton-on-Sea in the Eastern Cape, testing the case scenario and data collection tool. The case scenario was adequate in that it was not overly complicated and the pharmacy personnel were seemingly unaware that the mystery shop had taken place.

The data collection tool was also found to be suitable and therefore, no changes were made to the case scenario or data collection tool prior to the start of the data collection phase of the study.

## 3.6 Data Analysis

Data was encoded and captured using a Microsoft Excel® spreadsheet and analysed in consultation with a statistician. Descriptive statistical analysis was used with graphical representation, where relevant. The following was determined from data:

- Adherence to GPP standards when dispensing asthma reliever medication More specifically, the data were analysed to determine if the following had any correlation to adherence of GPP standards:
- Gender of pharmacy personnel
- Estimated age
- Identification of profession
- Type of pharmacy - independent or corporate.

The data was expressed numerically as a percentage of the total sample.

Given the categorical nature of the data collected, the intention was to perform Chi-squared tests of independence and Cramér's V tests for associations between the demographic variables and the observed counselling variables. Due to the nature of the results from the study these tests were unable to be carried out.

## 3.7 Validity and reliability of the data

Cognitive psychologists have demonstrated that memory is reconstructive. Memory can be influenced when information is encoded, stored or retrieved. Information can be added or subtracted based on previously known or intervening information (Narvaez, 2006). Audio recording pseudo-patient pharmacist interactions has shown to significantly enhance the reliability of mystery shopping as the information required to fill out the data collection tool is not reliant on memory recall (Werner & Benrimoj, 2008).

## 3.8 Ethical Considerations

### 3.8.1 Ethical approval

In order to ensure that the research was conducted ethically, a proposal of the study was submitted to the Departmental and Faculty of Post Graduate Studies' Committees for ethical approval. The Faculty of Post Graduate Studies Committee granted ethical approval on the 11$^{th}$ of November 2016 (Approval number: H16-HEA-PHA-010) (Appendix B).

As Rhodes and Miller (2012) suggested, pseudo-patient studies present two distinct ethical issues – the one being the use of deception and the other being the issue of informed consent. According to the Mystery Shopping Research Guidelines of 2014,

in order to counter the “deception” aspect, the time spent in the pharmacy by the pseudo-patient, should be kept to a minimum and should be viewed as not wasting the pharmacist’s resources, beyond what a normal customer might do. In addition, pseudo-patients should preferably buy something (MRS, 2014). For example, in this study, the pseudo-patient bought an Asthavent® inhaler from the pharmacy personnel.

### 3.8.2 Voluntary participation and informed consent

The need for informed consent is about doing no harm or protecting the “well-being” of the research subjects, whilst granting them the choice to participate or not. Pseudo-patient studies are designed to mimic real-world behaviour, however, it has been demonstrated that obtaining signed consent for a study of this nature often narrows the participant pool to such an extent that real-world behaviour is no longer measured. It has been proposed that it is less threatening to inform potential participants about the intention to conduct the study, and the possibility of including them in the sample group, but to give them the option to opt-out of the study (Rhodes & Miller, 2012). This approach has also been associated with higher participation rates. A letter of intent (Appendix A) with the option to actively opt out of participating in the study was emailed to all community pharmacies (using the email addresses on the SAPC database) in the research area. Pharmacies were identified from the South African Community Pharmacy register, and details were confirmed through a telephone directory, and a phone-call when necessary.

### 3.8.3 Confidentiality and Anonymity

A central requirement of research ethics is to minimize the risks associated with conducting research. In the case of pseudo-patient studies, central to removing or minimizing risk, is the protection of data in order to prevent identification of the

research subjects (Rhodes & Miller, 2012). The names of the participating pharmacies or the names of pharmacy personnel was and will not be disclosed before, during or after the study. The names of the pharmacies and pharmacy personnel were not recorded or reported on the data collection sheet and were not attached to the recording in any way. Each participant was allocated an alpha-numerical code.

# CHAPTER FOUR

# RESULTS AND DISCUSSION

## 4.1 Demographics

### 4.1.1 Pharmacy and Pharmacy Personnel Demographics

The study sample consisted of 100 pharmacy personnel in 100 community pharmacies that were mystery shopped. Of the pharmacy personnel who were mystery shopped, 23% were male and the remaining 77% were female. Figure 4.1 provides visual representation of the distribution of the number of male and female participants per age category.

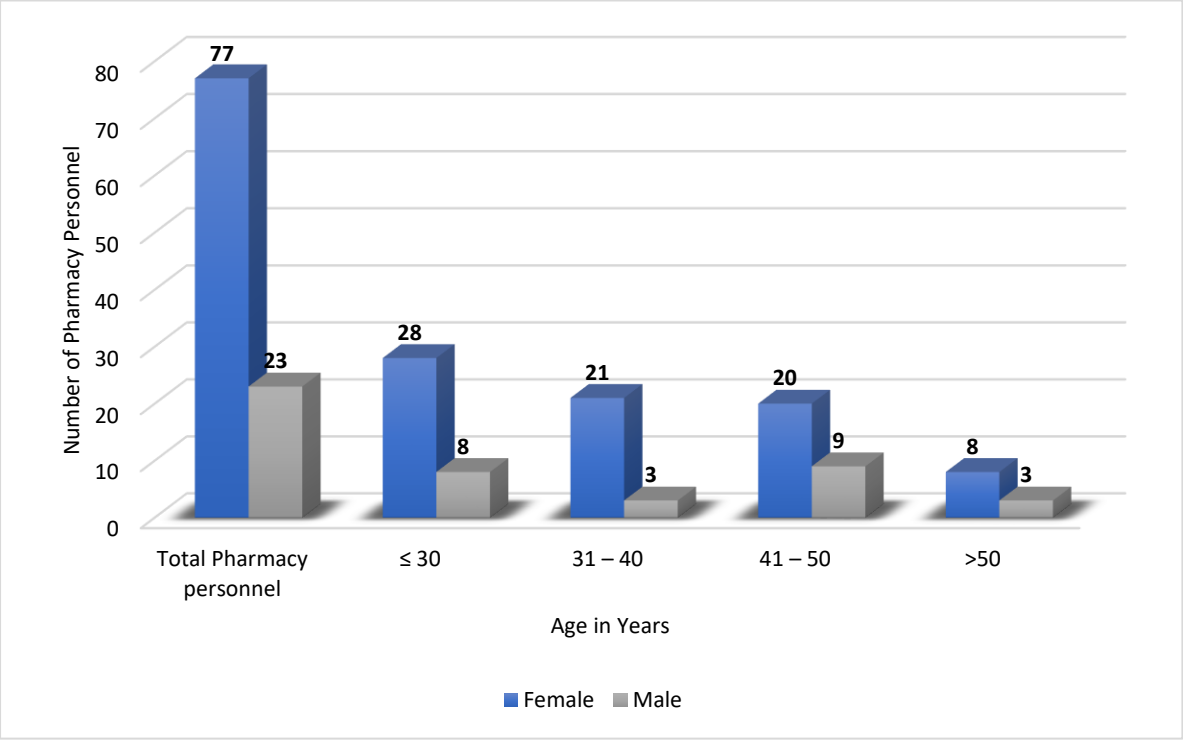


Figure 4.1 Number and age category of pharmacy personnel (*n* = 100)

According to the 2018 South African Pharmacy Council (SAPC) register, there were 41992 personnel registered to work in community pharmacies, with males

representing 33.82% of this population and females representing 66.18% of this population (The South African Pharmacy Council, 2018). The study population was reflective of the demographics of pharmacists registered with the SAPC. This number excluded assessors, community service pharmacists and specialist pharmacists. One possible explanation for this dominant presence of females in pharmacy may be partly attributed to the fact that previously, males were attracted to community pharmacy due to the entrepreneurial opportunities that were offered (e.g. ownership of a pharmacy). However, since the advent of corporate pharmacies, males may have become more disinclined to enter the pharmacy profession as pharmacy ownership prospects have been declined. As males seek other career opportunities, females have stepped in to fill the gap. Janzen Fitzpatrick, Jensen and Savage (2013) suggested that pharmacy is an attractive profession to females as it affords the opportunity to provide patient care where soft skills, such as communication and empathy, are seen as useful skills. There was a relatively even distribution of the age of pharmacy personnel that were mystery shopped.

The pharmacies that were mystery shopped were categorized into two groups: chain pharmacies and independent pharmacies. For the purposes of this study, chain pharmacies are defined as retail or community pharmacies belonging to a group of more than five pharmacy outlets, co-owned by a pharmacist, multiple pharmacists and/or non-pharmacists, business entities or corporations. The business entities or corporations can often also own wholesale and distribution companies, allowing for vertical integration. An independent pharmacy is defined as a retail or community pharmacy owned by a pharmacist or multiple pharmacists who have five or less pharmacy outlets. The majority of pharmacies that were mystery shopped (62%, *n* = 100) were chain pharmacies.

### 4.1.2 Pharmacy location

Figure 4.2 summarises the type of pharmacy (chain or independent) and the location of the pharmacies. Pharmacy location was categorised as being: in a shopping centre, accessible from the street, part of a medical centre and mixed (for example: including pharmacies that were part of a shopping centre, but that also had street access).

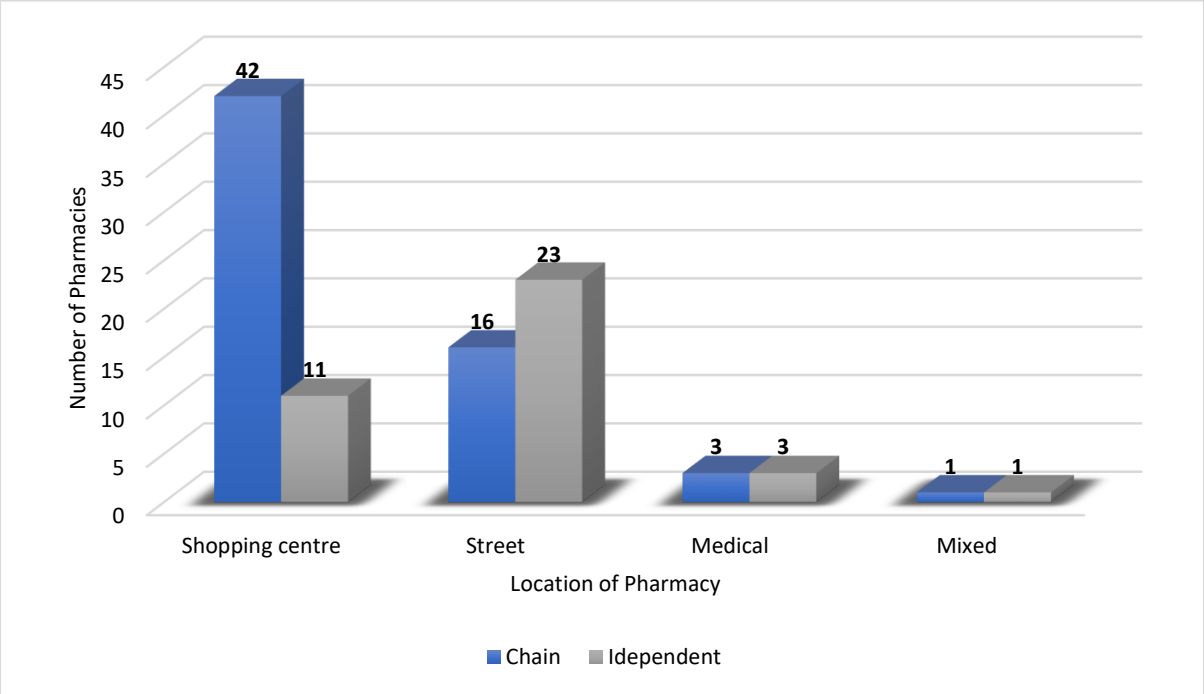


Figure 4.2 Number of chain and independent pharmacies per location (*n* = 100)

Chain pharmacies made up 62% of the total pharmacies mystery shopped. The researcher noted that shopping centres often contained more than one pharmacy. As illustrated in Figure 4.2, the majority (42%, *n* = 100) of pharmacies mystery shopped were chain pharmacies located inside a shopping centre. There were 38 independent pharmacies, 60% of which were located with street frontage. In a study to measure satisfaction by pharmacy type, it was found that patients visiting chain pharmacies were generally less satisfied with their pharmacy experience than patients who visited independent pharmacies. This difference was believed to be attributed to the notion

that independent pharmacies placed a greater emphasis on personal and professional service (Briesacher & Corey, 1997). While chain pharmacies have seen substantial growth in South Africa compared to independent pharmacies, since the deregulation in 2004, which opened ownership to corporate businesses, community pharmacies continue to be concentrated in urban provinces. This is a cause for concern in terms of accessibility to community pharmacies, as these independent pharmacies are more likely to have been established in locations that service poorer communities than corporate businesses. (Ward, Sanders, Leng, & Pollock, 2014).

## 4.2 Identifiability of pharmacy personnel

Of the 100 mystery shopped pharmacies, the researcher was only attended to by a person identifiable as a pharmacist 14% of the time. Clearly identifiable pharmacy support staff attended to the researcher 31% of the time. The attending pharmacy personnel were unidentifiable in 55% of cases. Figure 4.3 contrasts the identifiability of pharmacy personnel between chain and independent pharmacies.

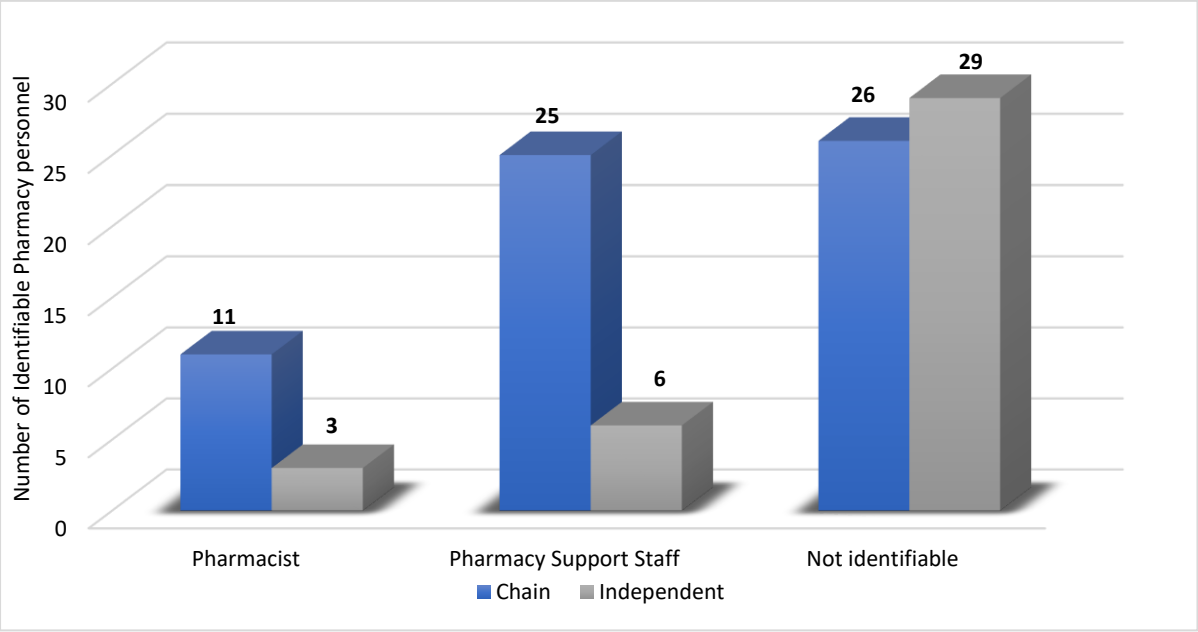


Figure 4.3 Identifiability of pharmacy personnel (*n* = 100)

In the rules relating to what constitutes good pharmacy practice, Rule 1.2.1 (e) states that all pharmacists and pharmacy support personnel on duty must wear a name tag or badge, indicating his/her name and designation for the purposes of identification of such a person by the public (South African Pharmacy Council, 2010). This means that in over 50% of the pharmacies mystery shopped, pharmacy staff were not meeting the minimum requirements with regards to the appearance of pharmacy premises. In a mystery shopping research project conducted in Port Elizabeth, Eastern Cape, in 2011, the researcher found that 74% of pharmacists were not wearing a name badge and were thus, unidentifiable (Harper, 2011). This indicates that there has not been much improvement in terms of badge wearing or identifiability of pharmacists over the last seven years. Regulations specify that not all of the pharmacy support staff are able to sell Schedule 2 medications. In the Medicines and Related Substances Act 101 of 1965, Section 22(a)(5), any Schedule 2 substance may only be sold by a pharmacist; pharmacist intern; or a pharmacist's assistant post-basic, under the personal supervision of a pharmacist, without a prescription (South Africa, 1965). Chapter Five of the Pharmacy Act of 1974, Section 35A discusses the scope of practice of pharmacy support personnel. A pharmacist's assistant basic, can only authorise the sale of Schedule 1 medications. A pharmacist's assistant post basic and learner post basic can authorise the sale of Schedule 1 and Schedule 2 medications under the direct personal supervision of a pharmacist. Direct personal supervision is defined as provision of guidance and support by a pharmacist, whilst being physically present in a pharmacy (South Africa, 1974).

### 4.3 Pricing of Asthavent® inhalers at chain and independent pharmacies

The variation between the minimum price charged (R34.45) and the maximum price charged (R50.00), when buying an Asthavent® inhaler was 31%. The minimum price was charged at chain pharmacies, while the maximum price was charged at an independent pharmacy. On average, chain pharmacies charged R37.16 per Asthavent® inhaler and independent pharmacies charged R42.67, a variation of 13%. The maximum price charged at a chain pharmacy was R40.80, which is 5.4% lower than the average price charged at independent pharmacies. This suggests that chain pharmacies, on average, were able to sell Asthavent® inhalers to the public at a reduced rate when compared to independent pharmacies.

Chain pharmacies have gained the competitive edge over independent pharmacies through vertical integration by reducing operational costs and improving efficiencies in the supply chain. This allows chain pharmacies to sell medication to the public well below the maximum price stipulated by the pricing regulation. These chains rely on a low price, high volume business model, where profits are gained from other non-pharmaceutical product lines to compensate for low profit margins from the dispensary (Ward et al., 2014).

This raises a question regarding the influence of price on patient preference when choosing a pharmacy.

#### 4.3.1 Single exit pricing

South Africa faces a health economic problem in the sense that there are unlimited health care needs but a scarcity of healthcare resources. This is partly due to the segregated healthcare system during apartheid, where the availability of quality

healthcare was dependent on a person's race. After the abolishment of apartheid in 1991 and the start of democracy in 1994, a National Drug Policy (NDP) was developed in 1996. The NDP signalled a multifarious series of interventions to reduce medicine prices and also to improve prescribing and dispensing practices. One of these interventions was the implementation of Single Exit Pricing (SEP) (Gray, 2009). The SEP can be defined as the price at which the manufacturer must sell a particular item to all dispensers, regardless of volume sold. The SEP was introduced in South Africa in August 2004 to ensure that no entity supplies medication according to a bonus system, rebate system or any other incentive scheme, including the sampling of medicines (Mngadi, 2014).

The Single Exit (SEP) of an Asthavent® inhaler at the time of the study was R29.61, with the maximum price being calculated at R57.96. None of the pharmacies that were mystery shopped charged more than the maximum price indicated for Asthavent® inhalers. The dispensing fees that may be levied on medicines are applicable, whether the service concerned is provided by the pharmacist, or any other person registered in terms of the Pharmacy Act or a healthcare professional employed in the pharmacy, provided that any such person may only provide a service or perform an act, which falls within his/her scope of practice.

In the Medicines and Related Substances Act, 101 of 1965, as amended, regulations relating to a transparent pricing system for medicines and scheduled substances include: a dispensing fee for pharmacists'. The appropriate dispensing fee, as contemplated in section 22G (2)(b) of the Act to be charged by a pharmacist, must be calculated as follows (South Africa, 1965):

(a) Where the SEP of a medicine or scheduled substance is less than one hundred and seven rands and 15 cents (R107.15), the dispensing fee shall not exceed R11.25 plus 46% of the SEP in respect of that medicine or scheduled substance. This fee, which is exclusive of Value Added Tax (VAT), represents the maximum dispensing fee and does not preclude dispensers from charging a lower fee to be added to the SEP of a medicine or scheduled substance. Thus, resulting in a final price to be paid by the consumer.

The dispensing fee is charged for 1) the interpretation and evaluation of the prescription; 2) the selection, reconstitution, dilution, labelling, recording and the actual supply of the medication; 3) the provision of information and instructions to ensure safe and effective use of a medicine by a patient; and 4) the provision of information as contemplated in section 22F (1)(a) of the Act (South Africa, 1965).

### 4.4 Outcomes of the mystery shopping experience

The researcher found that unless the mystery shopper was approached by a pharmacist directly, there was no visible “guidance or support” from a pharmacist during the sale authorised by pharmacy support personnel. The definition of direct personal supervision by a pharmacist in the Pharmacy Act allows a pharmacist’s assistant post basic (PABA) to authorise the sale of schedule 2 medication, with the pharmacist only needing to be physically present in the pharmacy (South Africa, 1974). If this is the case and a pharmacist does not need to have direct contact with a PABA or patient during the sale of a scheduled substance, then an argument can be made that, this form of supervision is in fact indirect supervision. An updated definition of direct personal supervision needs to be established, so that all parties involved in the

authorisation and sale of scheduled medications understand their responsibilities in the process.

### 4.4.1 History taking

None of the pharmacy personnel took any medication or disease history from the simulated patient before or after the request for an Asthavent® inhaler was made. In the Good Pharmacy Practice Guidelines in South Africa, Section 2.12 discusses the minimum standards for pharmacist initiated therapy. It gives an outline of the type of information that should be obtained in order for a proper assessment to take place. The information should include:

- identifying who has the problem,
- what the symptoms are,
- how long the condition has persisted,
- any action that has already been taken, and
- which medicines the person concerned is already using (South African Pharmacy Council, 2010).

Not one of these questions was posed to the mystery shopper by the pharmacy personnel in any one of the 100 pharmacies that were mystery shopped.

Although other studies internationally have suggested that history taking is poor, no other study appears to have demonstrated that there was no history taking. For example, a simulated patient study, which took place in Qatar, assessed community pharmacists' counselling practices when presented with a prescription for a salbutamol inhaler and a refill of a salbutamol inhaler and yielded the following results:

- 14.7% of pharmacists asked the patient who the medication was for;
- 24.% of pharmacists asked the patient if he/she had used the medication before; and
- 3.9% of pharmacists asked if the patient was currently taking other medications.

It is noteworthy to mention that, at the time of the Qatar study, the law did not require pharmacists to counsel (Paravattil, Kheir, & Yousif, 2017).

In Australia, when non-prescription medications are sold, the pharmacist is to provide patient assessment (history taking) and medication counselling. The Pharmaceutical society of Australia (PSA) has published standards, similar to the GPP in South Africa, for the provision of non-prescription medications in order to ensure the quality use of medicines. The PSA Assessment Elements are as follows:

- Who is the patient?
- What are the symptoms?
- How long have they had the symptoms?
- What treatment/s have they tried for these symptoms?
- How effective were the treatments?
- Do they have any other medical conditions?

In Perth, Australia, a simulated patient study assessed the counselling provided with the supply of non-prescription asthma medication. The study yielded the following results about history taking.

- 35% of pharmacists asked the patient who the medication was for;
- 36.25% of pharmacists asked the patient if they had used the medication before; and

- 17.5% of pharmacists asked the patient if they are currently taking other medications. (Schneider, Everett, Geelhoed, Kendall, & Clifford, 2009)

### 4.4.2 Medication counselling

No medication counselling was offered to the simulated patient after the request for an Asthavent® inhaler was made.

In the simulated patient study conducted in Qatar, the patient prompted the pharmacist to provide counselling on correct technique when using a metered dose inhaler. Only 7% (*n* = 65) of the pharmacists were able to correctly counsel on all the necessary steps required for proper inhaler technique. Only one step was offered by 13% of the pharmacists, namely: to insert the inhaler into the mouth before use. (Paravattil et al., 2017)

In a manner, similar to that which was used in this study, in an Australian study, the simulated patient was instructed to not offer any information or ask any questions unless prompted by a pharmacist or pharmacy support personnel. In Australia, the sale of asthma reliever medication requires the supervision of a pharmacist, but at 47% (n = 160) of the pharmacies mystery shopped, there was no discernible input by a pharmacist. No pharmacist or pharmacy support personnel offered any assessment or counselling on inhaler technique. (Schneider et al., 2009)

The outcome of the Australian study was very similar to this study in that not one of the pharmacists or pharmacy support personnel offered any assessment or counselling on correct technique when using a metered dose inhaler.

### 4.4.3 Differences between chain and independent pharmacies

There was no difference in history taking and counselling between chain and independent pharmacies, regardless of whether a pharmacist or pharmacy support personnel was mystery shopped. The only identifiable difference between the chain and independent pharmacies was the average price of the SABA inhalers (refer to Section 4.3).

A study comparing the factors that influence a patient's choice of pharmacy in Poland and the UK demonstrated that in Poland, the overall co-payment for prescription medication is relatively high, which makes medication expensive for patients. In the UK, all prescription medications incur the same costs, regardless of market prices. In Poland, the most frequently reported factors influencing pharmacy choice were 1) location, 2) professional high quality of service and 3) good prices of medicines. In the UK, the most common reported factors were 1) professional high quality of service, 2) location and 3) good advice received from pharmacist. The results of this study confirms the findings in previous studies conducted in the UK (Anderson, 1998; F. Smith, 1990) and Poland (Piecuch & Kozłowska-Wojciechowska, 2013). In other words, while price has been shown to be a determining factor when choosing a pharmacy, it is apparent that patients value quality of service and a convenient location, above a pharmacy that is able to sell medication to them at a reduced cost (Merks, Kaźmierczak, Olszewska, & Kołtowska-Häggström, 2014).

### 4.4.4 Barriers to counselling

Potential barriers to counselling that may have occurred in this study were identified. In the study, the simulated patient was briefed to not voluntarily offer information unless requested by a pharmacist or pharmacy support personnel. There was no

familiarity between the simulated patient and pharmacy personnel. The simulated patient took note of the observable “busyness” of the pharmacy by comparing the number of customers in the pharmacy with the number of visible pharmacy personnel in the pharmacy. At 80% (*n* = 100) of the pharmacies mystery shopped there appeared to be more pharmacy staff in the pharmacy than number of patients. The waiting time experienced by the simulated patient was less than one minute at 81% (*n* = 100) of the pharmacies mystery shopped. Therefore, time constraints did not appear to be a feasible barrier to counselling.

A further possible barrier to counselling could have been that the simulated patient asked for the salbutamol inhaler by name. Previous studies have indicated that product related requests for non-prescription medications resulted in less assessment and counselling than symptom-based requests (Schneider et al., 2009). A simulated patient study conducted in the UK established factors predicting the guideline compliant supply (or non-supply) of non-prescription medications. The study indicated that when simulated patients presented with symptoms, there was a greater likelihood of guideline compliant supply of medication. When simulated patients asked for a product, there was almost no or very little compliance with the guideline (Watson, Bond, Grimshaw, & Johnston, 2006).

In the Qatar study conducted by Paravattil et al. (2017), pharmacists were asked to identify potential barriers to counselling. The top ranked barriers that hindered patient counselling included: no time; disinterested patients and no private counselling area. Although Qatar law does not require patient counselling, only 2.3% of the pharmacists surveyed identified the law as a barrier to counselling.

In Australia, Schneider et al. (2009) also identified potential barriers and reasons as to why counselling was suboptimal. Reasons provided included:

- Lack of knowledge of the standards set out by the PSA.
- Consumer and/or pharmacy staff beliefs regarding the usefulness of patient assessment and medication counselling.
- Time constraints.
- Lack of privacy in the community pharmacy.
- Lack of pharmacy remuneration.

The question that must be raised now is: how can the level of counselling be optimised? One route to improve counselling would be to create further legislature to enforce proper counselling. Legal mandates can be effective tools in setting the standards of conduct in professional settings. This is because laws such as these are often accompanied by punitive measures, such as fines or incarceration. Such measures can motivate pharmacists to comply with the law. However, will new laws result in optimal counselling? New laws often translate into more regulations and paperwork requiring the pharmacist's attention. As pharmacists spend more time meeting these new legal requirements, less time will be available to the pharmacist to spend on counselling. Pharmacists may also be tempted to find loopholes in the new laws and regulations in order to continue meeting business objectives. Another issue with creating new laws is enforcing them (Resnik, Ranelli, & Resnik, 2000).

An alternative approach to improving the counselling practices of future pharmacists may be through placing a greater emphasis on the ethical aspects of practice during undergraduate education. The importance of how counselling not only protects the welfare and dignity of patients by giving them the ability to make informed decisions

but helps bring back the human element to the profession, need to be emphasised in pharmaceutical education (Resnik et al., 2000).

Placing a greater emphasis on the ethical aspects of practice during the education of undergraduate pharmacists may improve the counselling practices of future pharmacists but the question that now must be asked is how can the level of counselling provided by practicing pharmacists be improved? One possibility might be the use of educational techniques which are based on a mystery shopping approach. A mystery shopping study took place across thirty-six pharmacies in Australia, between March and October in 2015. The objective of the study was to determine whether repeated mystery shopping with immediate feedback improved pharmacy performance in the appropriate provision of non-prescription medication over time. The results of the study revealed that repeated mystery shopping visits with immediate feedback were associated with improved pharmacy performance over time (Collins, Schneider, Naughtin, Wilson, de Almeida Neto, & Moles, 2017). This study gives insight into the potential that repeated mystery shopping with immediate feedback can have on improving counselling among practicing pharmacists to a level that is acceptable.

# CHAPTER FIVE

# CONCLUSIONS,

# LIMITATIONS AND RECOMMENDATIONS

## 5.1 Conclusions

The primary aim of the study was to establish the practices used by pharmacy personnel during the provision of pharmacist initiated therapy when dispensing asthma reliever medication. In support of the primary aim of the study the following section describes how the objectives (refer to section 1.3) of the study were met:

1. *Determine and describe the extent to which the minimum requirements of pharmacist initiated therapy, set out in the Good Pharmacy Practice standards, are adhered to by pharmacy personnel.*

As no history taking or counselling occurred during the study, there was zero adherence to the minimum requirements of pharmacist initiated therapy, set out in the Good Pharmacy Practice standards.

2. *Establish if the demographics of pharmacy personnel have any correlation with adherence to standards.*

The demographics - in terms of: pharmacy type, pharmacy location and type of pharmacy personnel mystery shopped had zero correlation with adherence to standards.

3. *Determine the availability of asthma screening services in community pharmacies.*

As the pharmacy personnel that were mystery shopped did not offer the opportunity for the mystery shopper to ask any questions, the availability of asthma screening services was unable to be measured.

4. *Determine if community pharmacy personnel demonstrate the correct technique when dispensing asthma reliever medication.*

In all the pharmacies that were mystery shopped, the Asthavent® inhaler was simply just sold to the mystery shopper. Consequently, none of the community pharmacy personnel demonstrated the correct technique when dispensing asthma reliever medication.

The primary aim of the study was met as the results of this study indicated that there were no practices used by pharmacy personnel when dispensing asthma reliever medication.

## 5.2 Limitations

- The study only included pharmacies from two provinces in South Africa.
- The results of this study may not be generalisable to the rest of South Africa due to the small sample size of 100 pharmacies.
- Participating pharmacies were give prior notification that a mystery shop was going to take place, which could have resulted in altered behaviours during the

mystery shop period. If the prior notification had influenced behaviour, it could reasonably be assumed to have done so in a positive manner, however, the results obtained in this study do not suggest this.

- The case scenario required the pharmacist or pharmacy support personnel to offer history taking and counselling voluntarily.
- The results of the study did not allow for statistical testing.

## 5.3 Recommendations

The study should be extended and expanded to include a wider variety of pharmacies throughout South Africa. This would allow for multiple case scenarios to be presented to pharmacy personnel and not just one scenario that is product based. This study should also be repeated with a slightly altered case scenario where the mystery shopper requests information from the pharmacy personnel being mystery shopped. This will establish whether pharmacy personnel can correctly counsel on asthma management when requested by a patient. Before any recommendations can be made for expanding the role of the pharmacist in asthma management, further research should focus on identifying why the level of history taking and counselling is so low for the most commonly used asthma medication.

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## Appendices

## Appendix A

## Letter of Intent

• PO Box 77000 • Nelson Mandela Metropolitan University

Nelson Mandela Metropolitan University
for tomorrow

Summerstrand South Campus
Department of Pharmacy
Faculty of Health Sciences
Tel . +27 (0)41 5044212

Dear Pharmacist,

As a basis for developing and providing Good Pharmacy Practice (GPP) based professional development programmes relating to the sale of over-the-counter asthma medication, we would like to evaluate the current status of the sale of such items in community pharmacies.

This will be done through the use of mystery shopping. One or more mystery shoppers will visit all identified pharmacies and make a purchase of an over-the-counter asthma product. The interaction will be digitally audio recorded through the use of a hidden recording device. On exiting the pharmacy, observations surrounding the sale of the product will be documented by the 'shopper' on a standardised data collection form. Analysis of the recorded conversation will enable the data to be verified.

Therefore, between December 2016 and February 2017, our research team will be collecting information about the sale of over-the-counter asthma medicines in pharmacies in the Eastern Cape and Western Cape regions. Ideally you and your staff will not be able to identify these 'mystery shopper' consultations and sales, from those that you regularly encounter in your pharmacy.

We understand you may be concerned about privacy issues; therefore, no names of pharmacies or associated individuals will be recorded on the data collection forms or attached to the digital recordings, which will in no way be traceable to your pharmacy or be disclosed during or after the project, nor will they appear in any reports resulting from the study.

If you have questions regarding the project, or if you prefer not to participate, please contact us by phone or email (details provided below) prior to the end of November 2016. Alternatively if you would like feedback on the results of the study after it has been completed, please contact us and we would be happy to provide it to you.

Yours sincerely,


| | | |
|---|---|---|
| Susan Burton | and | Lia Kritiotis |
| Tel: 041-5044212 | | 041-5044334 |
| Email: susan.burton@nmmu.ac.za | | lia.kitiotis@nmmu.ac.za |

## Appendix B

## Ethical Approval for Study

Nelson Mandela Metropolitan University
for tomorrow

**Copies to:**
**Supervisor: Ms L Kritiotis**
**Co-supervisor: Dr S Burton**

**Summerstrand South**
**Faculty of Health Sciences**
Tel. +27 (0)41 504 2956 Fax. +27 (0)41 504 9324
Marilyn.Afrikaner@nmmu.ac.za

**Student number: 210052910**

**Contact person: Ms M Afrikaner**

11 November 2016

Mr B Gebers
PO Box 5570
Walmer
Port Elizabeth
6065

**FINAL RESEARCH/PROJECT PROPOSAL:**
**QUALIFICATION:** **MPHARM**
**TITLE:** **PHARMACY PERSONNEL PRACTICES WITH REGARD TO THE SALE OF NON-PRESCRIPTION ASTHMA MEDICATION IN COMMUNITY PHARMACIES IN THE EASTERN AND WESTERN CAPE**

Please be advised that your final research project was approved by the Faculty Postgraduate Studies Committee (FPGSC) subject to the following amendments/recommendations being made to the satisfaction of your Supervisor/s:

**COMMENTS/RECOMMENDATIONS:**

1. The proposal was well prepared.
2. Measuring instrument and validity (reliability)
   Add more relevant information for reliability and validity.
3. Literature review – sentence 4 change "age" to any.
4. Data collection tool.
   How will the age of the pharmacist affect the study?
5. Minor editing – line spacing not 1.5, Arial 11.
6. Time frame – date for proposal submission change to October 2016.
7. References (text)
   Check in-text references. The full stop was placed before the reference.

Please be informed that this is a summary of deliberations that you must discuss with your Supervisor/s.

FPGSC grants ethics approval. The ethics clearance reference number is **H16-HEA-PHA-010** and is valid for three years.

We wish you well with the project.

Kind regards,

**Ms M Afrikaner**
**Faculty Postgraduate Studies Committee (FPGSC) Secretariat**
**Faculty Administration**
**Faculty of Health Sciences**