DESIGN AND EVALUATION OF ILLUSTRATED INFORMATION LEAFLETS AS AN EDUCATIONAL TOOL FOR LOW-LITERATE ASTHMA PATIENTS

A thesis submitted in fulfilment of the requirements for the degree of

Master of Pharmacy
Rhodes University

by

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February 2012

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ABSTRACT

Asthma is a chronic non-communicable disease associated with an increase in morbidity, mortality and economic burden. Globally 300 million people have asthma and it is estimated that one in every 250 deaths worldwide are due to asthma. South Africa has the highest asthma prevalence (8.1%) in Africa and the disease is 18th in the top 20 causes of death. Inadequate home management, poor availability of health care, and poor transport and emergency services are recognised as important contributing factors. Patients with a low level of education and limited literacy skills may be unable to understand instructions on frequency and use of asthma medicines, which could result in unintentional non-adherence leading to serious complications and increased health care costs.

The aim of this study was to investigate the impact of a tailored educational intervention on low-literate patients with asthma. Objectives to achieve this aim included designing patient information leaflets (PILs) containing information on asthma, management of asthma and asthma therapy, and using the PILs to educate low-literate asthma patients. A before-and-after intervention type design evaluated self-reported selected health-related quality of life measures, self-reported self-efficacy, knowledge of asthma and asthma management, knowledge of the use of metered dose inhalers (MDIs) and MDI technique. The acceptability and understanding of the tailored PILs was also investigated.

Two simple, readable PILs containing pictograms were developed in English and then translated into isiXhosa, the home language of the majority of the target population. Various guidelines on the design of health-related information for people with low-literacy were consulted and input on the design was received from health care providers, patients and graphic artists. A pilot study was conducted at a local primary health care (PHC) clinic to evaluate the PILs and final modifications to the PILs were made based on feedback received.

For the main study, patients were recruited from the KwaNonqubela PHC clinic in Alexandria in the Eastern Cape, South Africa. Patients were 18 years or older, dependent on public sector health care facilities, diagnosed with asthma, prescribed a MDI (beclomethasone and/or salbutamol) for at least one month and English or isiXhosa-speaking. The exclusion criterion for patients in this study was involvement in any other asthma educational intervention during the period of study. Interviewer-led structured questionnaires were administered to 55 patients at the baseline and follow-up. Data collected include demographics, brief medical history and current asthma medications. Self-efficacy and

health-related quality of life were assessed. Knowledge of asthma and asthma management was evaluated, and the use of beclomethasone and/or salbutamol metered dose inhalers was assessed. The PIL ‘Understanding asthma and trigger factors of asthma’ formed part of the educational intervention to explain asthma and aspects related to its management. Inhaler technique was evaluated and corrected using the PIL ‘How to use your pump’ together with a demonstration of correct technique by the investigator. Follow-up interviews were conducted approximately four weeks after baseline. PIL acceptability, readability and understanding of each pictogram were investigated at follow-up only.

The educational intervention resulted in a significant increase in mean knowledge of asthma from 52.7% at baseline to 75.5% at follow-up. Gender was not associated with knowledge, but there was a significant age effect at baseline only, with the younger patients achieving better knowledge results. In both phases, patients with higher education had improved scores. A significant increase (2.4% to 38.6%) in the number of patients taking the minimum recommended adult dose of beclomethasone was noted but it is a matter of concern that the majority of patients were taking less than this. Patient self-reports suggested a significant increase in adherence, with the number of patients taking beclomethasone daily increasing from 33.3% to 61.3%. Self-reported management and control of asthma improved and this was reflected by the enhanced HRQOL results. MDI technique also improved significantly with an increase in the mean number of correct steps from 4.6 ± 2.2 to 7.9 ± 2.7. Education had a significant effect on MDI technique with more errors associated with lower educational status. There were no significant age or gender effects on the total number of correct steps in either phase.

The illustrated PILs were received favourably with the majority of literate patients reporting that they were easy to read. Patients commented positively on the inclusion of pictograms and stated that the pictograms had served as aids in the understanding of asthma, trigger factors of asthma and correct MDI technique. The results of this study show that specially designed illustrated PILs can be an effective tool in educating low-literate patients with asthma.

“Experience is a hard teacher because she gives the test first, the lesson afterwards.”

Vernon Sanders Law

This thesis is dedicated to my beloved family and to all patients with asthma.

ACKNOWLEDGEMENTS

Funding for this study was received from the Rhodes University Joint Research Council, for which I am most grateful.

I would like to thank the following people for their contribution to this thesis:

- My Supervisors, Prof Sunitha Srinivas and Prof Ros Dowse, for believing in me and for their insight, guidance, encouragement, support and patience throughout this study.
- The asthma patients at the KwaNonqubela PHC clinic in Alexandria and the Settlers Day Hospital PHC clinic in Grahamstown, for their enthusiasm and readiness to participate in this study.
- The health care providers at the KwaNonqubela PHC clinic in Alexandria and the Settlers Day Hospital PHC clinic in Grahamstown for all their assistance in implementing this study.
- Ms Primrose Moya, my interpreter, for her commitment and assistance.
- Mr Mohamed Docrat, District Pharmacist for the Makana Local Services Area, for his help and guidance.
- The Eastern Cape Department of Health for approving the study in the two public sector PHC clinics.
- Professor Sarah Radloff, Department of Statistics, Rhodes University, for her assistance with the statistics in this study.
- Ms Lillian Smit, Graphics Services Unit, Rhodes University, and Ms Susan Abraham for their expert advice and endless patience with the design of the patient information leaflets.
- Ms Pamella Maseko and her colleagues at the School of Languages, Rhodes University, for translation of the patient information leaflets.
- All the staff members in the Faculty of Pharmacy, Rhodes University, particularly Dr Carmen Oltmann, Ms Yoland Irwin and Ms Tanya Kent. Also, my former colleague, Dr Kazeem Yusuff.
- Ms Tracy van Aardt, Transport Department, Rhodes University, for arranging transport to and from the clinics.
- Ms Sheila Hicks for her prompt and valuable feedback after proof-reading this thesis.
- Ms Eileen Shepherd and Mr Wynand van der Walt for their assistance at the Rhodes University library.
- Lastly, to my family (particularly Murray, Peter and Jenna Wrench, and Dr Karen Bradshaw), Nozodwa Singata and friends (particularly Morny le Roux) for their constant support and encouragement.

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LIST OF ACRONYMS

ADMIT	Aerosol Drug Management Team
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
AQLQ	Asthma Quality of Life Questionnaire
ANOVA	Analysis of Variance
CFCs	Chlorofluorocarbons
CHW	Community Health Worker
EML	Essential Medicines List
FAIFE	Freedom of Access to Information and Freedom of Expression
FEV_1	Forced Expiratory Volume in 1 second
FVC	Forced Vital Capacity
GAPP	Global Asthma Physician and Patient
GARD	Global Alliance against Chronic Respiratory conditions
GINA	Global Initiative for Asthma
GOAL	Gaining Optimal Asthma control
HCPs	Health Care Providers
HFAs	Hydrofluoroalkanes
HIV	Human Immunodeficiency Virus
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
HRQOL	Health-related Quality of Life
IFLA	International Federation of Library Associations
ISO	International Standards Organization
LHS	Left Hand Side
MDI	Metered Dose Inhaler
MDG	Millennium Development Goals
NAEPP	National Asthma Education and Prevention Program
NAEP	National Asthma Education Program
NC	Not Calculated
NCD	Non-communicable Disease
NIH	National Institutes of Health
PEF	Peak Expiratory Flow
PHC	Primary Health Care
PIL	Patient Information Leaflets
PTC	Pharmacy and Therapeutics Committee
QEI	Quality Enhancing Interventions
RCT	Randomised Control Trial
SD	Standard Deviation
SMOG	Simple Measure of Gobbledegook
STGs	Standard Treatment Guidelines
TB	Tuberculosis
TENOR	The Epidemiology and Natural History of Asthma Outcomes and Treatment Regimens
UK	United Kingdom
UNICEF	United Nations Children's Fund
US	United States
USA	United States of America
USP	Unites States Pharmacopeia
WHO	World Health Organization

CHAPTER ONE
INTRODUCTION

1.1 Background to Research

My current position as a lecturer in the Faculty of Pharmacy at Rhodes University (Grahamstown, South Africa) involves taking final year pharmacy students to interview patients with chronic non-communicable diseases (NCDs), namely asthma, hypertension and diabetes, who are dependent on public sector health care facilities. Problems that have been identified during the interview process of patients with asthma include an inability to read and comprehend the medicine information in the package inserts[1] accompanying asthma medicines, a lack of understanding of what asthma is, the trigger factors of asthma, medication non-adherence (either not taking the prescribed medicines as directed or not taking the prescribed medicines at all), an inability to differentiate the difference between metered dose inhalers (MDIs) used for prevention of asthma and those used for managing asthma symptoms and exacerbations, and incorrect MDI technique. These can all contribute to poor adherence and suboptimal health outcomes which prompted me to investigate why these problems are occurring and to develop and test an educational intervention which could assist patients with self-management of asthma.

The 2002 World Health Organization (WHO) Global Report on Chronic Conditions states that NCDs and mental disorders are accelerating globally and in 2020 these will account for 60% of the global burden of disease. [1] The success of public health initiatives have resulted in people living for longer, often with one or more NCDs. Urbanisation, unhealthy lifestyles and global marketing of risk factors such as tobacco have also played a role in the increase of NCDs. Developing countries face two major and urgent health concerns: the growing burden of NCDs and persisting communicable diseases, which are referred to as the double burden of disease. [2,3] South Africa has a quadruple burden of disease in that there is an increase in NCDs together with maternal, newborn and child health disease, violence and injuries, as well as HIV/AIDS. [4] Abegunde et al. [5] reported that in a study of the 23 countries that account for 80% of the total burden of disease in developing countries, as little as a 2% annual reduction in mortality rates from NCDs from 2006 to 2015 would avert 24 million deaths, with almost 80% of these being in people younger than 70 years. It would also save approximately 10% of the projected loss of income, which amounts to US$8 billion for the 23 countries.

[1] In South Africa, package inserts contain medicines information intended for health care providers and are produced by the manufacturers of the medicine product.

Asthma, together with diabetes, heart disease and depression, is one of the most prevalent NCDs [1] and has been associated globally with a sharp increase in morbidity, mortality and economic burden. [6] Most asthma deaths occur in people older than 44 years of age and are largely preventable. [6,7]

Patient education that can assist with long-term self-management is becoming more important as the incidence of NCDs increases. [8] It has been shown that giving patients written medicines information containing simple, understandable text and visual aids such as pictograms, can positively influence adherence. [9] If pharmacists are actively involved in patient education about asthma, patient outcomes including quality of life are improved. [10] Patient education emphasising self-management plays an important role in reducing the incidence and severity of asthma exacerbations. [11]

1.2 Field of research

This study involved a patient education intervention for patients with asthma. Patient information leaflets (PILs) were designed for a specific target population and formed the core component of an educational intervention, the aim of which was to improve patients' knowledge of asthma, improve knowledge of and adherence to beclomethasone and/or salbutamol MDIs as well as to improve MDI technique, all of which are important aspects in self-management of asthma.

1.3 Overview of chapters

Chapter 2 is a literature review that includes the characteristics and management of asthma. Challenges of chronic care management are highlighted as factors that hamper the implementation of health as a human right. Patient education, its use by health care providers (HCPs) in the health care system and its effects on patients' knowledge of disease, adherence and health related quality of life (HRQOL) are also addressed. Health literacy is explored and the communication of health-related information between HCPs and low-literate patients is considered. The issue of patient self-management is assessed as a means to reducing the exacerbations of asthma.

In Chapter 3, details of the setting in which the study took place are presented. The health care system in South Africa, with particular emphasis on the public sector health care system in the Eastern Cape, is described. The development and evaluation of the pilot PILs are also addressed.

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Methodologies used to achieve the aims and objectives of the pilot and main studies are described in Chapter 4. The results obtained from the study are presented in Chapter 5. Chapter 6 consists of a discussion of the results, together with the limitations of the study. Conclusions of the study are presented in Chapter 7, along with recommendations, and suggestions for future research.

CHAPTER TWO
LITERATURE REVIEW

2.1 Non-communicable diseases

During the 20th century, a significant reduction in communicable diseases in developed countries occurred due to improved sanitation and living conditions together with the introduction of immunisation and antibiotics. [12] While communicable diseases remain a problem in developing countries, an urgent health care challenge for the 21st century in both developed and developing countries is that the incidence of NCDs is increasing among people of all ages. [1,13] In 2001, NCDs together with mental disorders, HIV/AIDS and tuberculosis accounted for 54% of the global burden of disease. It is anticipated that this will increase to 65% in 2020 and that poor people will be affected more than wealthy people. [14] The increase in NCDs has long-term implications for health care systems and will become the most expensive component of health expenditure if the incidence of NCDs is not curtailed. [1]

It is estimated that globally, the number of deaths due to NCDs, e.g., cardiovascular diseases, diabetes, some types of cancers and chronic respiratory diseases, increased from 34 million in 2004 to 35 million in 2008. [13] According to the 2010 World Health Statistics, more deaths are caused by NCDs than by other causes. Out of every 10 deaths, six are caused by NCDs, three by communicable, reproductive or nutritional conditions and one by injuries. [15]

Between 2004 and 2030, considerable declines are expected in deaths as a result of communicable, maternal, perinatal and nutritional causes. In contrast, a significant increase in deaths due to NCDs is predicted in low- and middle-income countries with just over three-quarters of deaths being due to NCDs. [1,16] Globally, NCDs cause twice the number of deaths than the combined total caused by infectious diseases, maternal and perinatal conditions and nutritional deficiencies. [17] Deaths due to NCDs increased from 867 per 100 000 population in 2004 to 983 per 100 000 population in 2008 in South Africa. [2,13]

2.2 Asthma

2.2.1 Introduction

Asthma has been known since ancient times. According to the South African Thoracic Society 2007 guidelines for the management of chronic asthma in adolescents and adults, “Asthma is a chronic inflammatory condition of the airways which is usually allergic in origin

and is characterised by hyperresponsive airways that constrict easily in response to a wide range of stimuli." [18]

2.2.2 Epidemiology of asthma

It is estimated that globally, 300 million people have asthma. [7,19] Since the 1970s, the incidence of asthma has been increasing continuously [20,21] and by 2025, it is estimated that the global prevalence of asthma will increase by an additional 100 million. [7] South Africa has the highest asthma prevalence (8.1%) in Africa [7] and it is 18th in the top 20 causes of death. [22] The South African Department of Health has identified asthma as one of the priority NCDs. [23] An increase in atopic sensitisation, increased urbanisation, inadequate home management of acute asthma, poor availability of health care and poor transport and emergency services are recognised as important contributing factors. [6,7]

The incidence of asthma is greater in people <18 years old (6.1%) than for those in the 18-64 year age group (4.1%). Before puberty it is higher in males, but thereafter it is higher in females. [20] Asthma is the most common chronic disease among children, [24] causes the majority of paediatric admissions to hospital and is the chronic condition causing the most absenteeism from school. [20] The incidence of asthma is higher in urban areas. [20,21] If families with a low prevalence of asthma move from a rural area to an urban area, then the prevalence of asthma in that family is likely to increase. [21]

2.2.3 Pathophysiology of asthma

Asthma is characterised by reversible inflammation throughout the airways except the alveoli and lung parenchyma. Inflammation is the underlying reason for smooth muscle hyper-responsiveness of the airway. [25,26,27] Bronchial inflammation is characterised by "swelling" of the airway linings and "increased sticky secretions lying in the airways" [26] as a result of T-helper type 2 lymphocyte cells, eosinophils, mast cells, $CD4^+$ subtypes and neutrophils forming an extensive inflammatory infiltrate in airway epithelium and smooth muscle which leads to desquamation, subepithelial fibrosis and smooth muscle hypertrophy. [20,21,27] Hypertrophy narrows the airway and increases reactivity to allergens, infections, irritants, parasympathetic stimulation and other bronchoconstrictive triggers. Desquamation and mucosal oedema may also cause a reduction in inhibitors of bronchoconstriction and other substances that metabolise endogenous bronchconstrictors. [20,28] Mucous plugging is prevalent in severe asthma and is often found in the lungs of patients who die of asthma. [21] Recurrent inflammation may result in structural changes, known as airways remodelling. These changes are irreversible and are a result of hypertrophy and hyperplasia of the epithelium and smooth muscle, as well as an increase in goblet cells and mucous plugs in

the lumen. A serious consequence of airways remodelling is the development of chronic obstructive pulmonary disease. [25,27]

There is a genetic predisposition to asthma and it is often passed down through females. [21,25] Exposure to trigger factors of asthma causes reversible airway obstruction and non-uniform lung ventilation. In severe exacerbations, diffuse bronchoconstriction reduces the ability of the respiratory muscles to generate inspiratory force, resulting in hypoxia, hyperexertion and an increase in $PaCO_2$. Respiratory and metabolic acidosis may result, which if not treated, can result in respiratory and cardiac arrest. [20]

2.2.4 Etiology of asthma

The development of asthma is dependent on interaction between multiple susceptibility genes and environmental factors. [20,21,25] There is evidence that household (e.g., dust mite, cockroach and pets) and other environmental (pollen) allergens play a role in the development of asthma in older children and adults. The following are also linked to the development of asthma: perinatal factors such as young maternal age, poor maternal nutrition, prematurity, low birth weight and lack of breastfeeding; diets low in omega-3 fatty acids, Vitamins C and E and obesity. [20,29] Smoking during pregnancy increases the risk of childhood asthma. [21] Smoking also increases the risk of persistent asthma in children whose parents smoke. [30]

2.2.5 Trigger factors of asthma

Trigger factors (Table 2.1) are not the same for all patients with asthma. [25] Exercise-induced bronchoconstriction can occur in patients with or without asthma. If bronchoconstriction only occurs as a result of a brief period of exercise or increase in ventilation, it is known as exercise-induced bronchoconstriction and not asthma. [31] The eucapnic voluntary hyperpnoea test and provocative testing with mannitol are used to confirm exercise-induced bronchoconstriction. [32,33] If trigger factors are avoided, the incidence and severity of asthma exacerbations is reduced. [18,21,34] Atopic patients should avoid the allergic trigger factors to which they are sensitised. [25] The control of trigger factors includes the following: use of synthetic fibre pillows and impermeable mattress covers; frequent washing of linen and blankets in hot water; removal of upholstered furniture, carpets; avoidance of cigarette smoke, strong odours, irritant fumes, cold temperatures, high humidity and exercise, as well as cessation of smoking. [20,21,30,35] House dust mites feed off human skin scales, with the allergen being found in their faecal pellets. The mites are prevalent in bedding, furniture, carpets and soft toys and thrive in moist, warm conditions, so moving to a cooler, drier climate may improve asthma. [21] The acquisition of furry pets,

particularly cats, should be avoided and pets should not be allowed onto soft furnishings or into bedrooms of people with asthma. [18,21]

Table 2.1 Common triggers of asthma [18,20,21,34,36]

Trigger factor classification	Examples
Environmental allergens	House dust mites; animal dander from pets; grass pollens and spores; Cold and/or warm weather
Occupational allergens	Chemicals; vegetable sources such as latex and cotton flax and hemp dust; enzymes; animals such as laboratory rodents and shellfish, and manufacture of medicines such as penicillin, salbutamol and cimetidine
Infections	In young children: respiratory syncitial virus which causes lower respiratory tract infections, and parainfluenza infection
	In older children and adults: upper respiratory tract infections and pneumonia
Exercise	All forms (particularly those in cold or dry environments)
Inhaled irritants	Air pollution; smoke (including cigarettes); dust and fumes
Food allergies	Milk, eggs, nuts, wheat, food additives such as preservatives and colourants
Emotions	Anger, anxiety and excitement
Medicines	Use of beta-blockers (including eye drops), non-steroidal anti-inflammatories and aspirin; some asthma medicines, e.g., aminophylline, ipratropium bromide, sodium cromoglycate and $beta_2$-agonists (in infants)
Chemicals and solutions	Propellants and contaminants of the valve apparatus in MDIs; hypotonic solutions; some preservatives in nebuliser solutions
Medical conditions	Gastroesophageal reflux and possibly allergic rhinitis and sinusitis

2.2.6 Signs and symptoms of asthma

Symptoms include dyspnoea, chest tightness, audible wheezing and coughing [18,20,21,25,27] all of which can worsen during the night and may result in nocturnal awakenings. They are often worst at around 04h00 with deaths from asthma being more likely during the early hours of the morning. [20,21,27] No audible wheeze may be present in patients with severe bronchospasm. In patients with long-standing, uncontrolled asthma, hyperinflation of the lungs may change the chest wall resulting in a barrel-shaped thorax. Inflammation of the airway wall can be found even in remission. [21] Signs and symptoms of asthma between acute attacks include audible soft wheeze during forced expiration, after exercise and at rest. [20]

2.2.7 Diagnosis of asthma

Diagnosis of asthma is more difficult in very young people, older people and those with mild asthma. Breathlessness often has other causes that must be excluded such as reflux diseases, vocal cord dysfunction and sleep apnoea. [21,37] Patient history, physical examination and pulmonary function tests such as spirometry, are used to diagnose asthma. [20,37,38] Spirometry tests are conducted to check for reversibility of airway obstruction, the

major physiological characteristic of asthma. [18,20,21] Forced expiratory volume in one second (FEV_1) results indicate the volume of air that is exhaled in the first second. [39] Patient age, height, ethnicity and gender are used to calculate expected normal values, with results that are <80% of the expected value being considered abnormal and indicative of disease. [40] A reduced FEV_1 prior to administration of a bronchodilator indicates airway obstruction. [18,20,21] If there is an increase in FEV_1 of >12% or >0.2 L 15-30 minutes after a bronchodilator, e.g., 200-400 mcg of salbutamol is given, then reversible airways obstruction, i.e. asthma, is confirmed. [18,20] Forced vital capacity (FVC) refers to the maximum volume of air that can be exhaled after inhaling deeply. [41] In asthma, the FVC may be normal or abnormal. If the ratio of FEV_1 to FVC is <70%, then this indicates obstructive disease. The more severe the asthma, the lower the FEV_1 to FVC ratio. [18]. It is advised that spirometry be done annually to monitor the progression of the disease in asthmatics. [20]

If spirometry tests are normal, provocative testing can be used to confirm asthma. These tests indicate if there is hyperresponsiveness to stimuli (e.g., inhaled metacholine, mannitol or histamine, or an exercise test) which are known to cause bronchoconstriction. [18,20,21,33,37] Peak expiratory flow (PEF) is a measure of the maximum flow rate of air that can be exhaled after full inhalation. [41] Using spirometry, baseline PEF and/or FEV_1 are measured and if these stimuli cause a reduction of 20% of PEF or 15% of FEV_1 from the baseline, the diagnosis of asthma can be confirmed. [18]

Although spirometry is the preferred method for diagnosing asthma, PEF meters can also be used. This measurement of PEF is dependent on patient effort and therefore the results may not be reliable. [38] Diurnal variation in PEF of more than 20% can be used to confirm asthma. Early morning PEF readings are done before medicines are taken (when PEF values are usually low) and then again late at night (when PEF values are usually higher). This is done for two weeks and the differences in the average morning and evening values are compared. [18,43] PEF meters are also used to monitor asthma. The highest of three readings is measured against accepted norms. Age, gender and height are taken into account when interpreting the results. [20,21] If PEF values drop below an individual's previous highest value, then this indicates worsening of asthma. [44] The monitoring of peak flow would assist in patient self-management of asthma but PEF meters are not readily available or used in resource-poor regions such as sub-Saharan Africa. [45]

2.2.8 Classification of asthma severity

After the initial diagnosis, asthma is classified according to severity with mild, intermittent asthma being the least severe followed by chronic persistent asthma that is mild, moderate or severe. This classification is advocated by the South African Thoracic Society and is based on the frequency of day- and night-time symptoms as well as PEF and is used for patients who have not received any treatment for asthma (Figure 2.1). [18] Classification of severity may change, e.g., when pharmacotherapy is optimised and asthma symptoms improve.

INTERMITTENT	**CHRONIC PERSISTENT**		
Mild	Mild	Moderate	Severe
I	II	III	IV
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

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Figure 2.1 Assessment of asthma severity using symptoms and PEF in patients presenting with asthma for the first time on no treatment [18]

2.2.9 Asthma management

Although the use of inhaled corticosteroids has had a positive effect on the health outcomes of asthma, globally the condition is still underdiagnosed and undertreated. [6,24,34,46] The criteria for the selection of essential medicines used in the public sector in South Africa are based on the WHO guidelines for developing a national essential medicines list (EML). [47] Standard treatment guidelines (STGs) using the medicines listed in the EML have been implemented in the public sector in South Africa and for managing asthma they include preventer medicines (inhaled corticosteroids, e.g., budesonide and beclomethasone) and/or reliever medicines (inhaled $beta_2$-agonists, e.g., salbutamol). [43]

The following are important in the management of asthma: control of trigger factors, the use of medicines specific to the classification, monitoring the response to treatment and progression of the disease as well as patient education to allow for self-management of asthma. [20] Nasal mucosa often respond to the same trigger factors that cause asthma and it is therefore important to treat nasal symptoms, e.g., allergic rhinitis, as well as the asthma. [21] Weight loss in obese patients results in a reduction of asthma symptoms and lung

function also improves with exercise. [30] Smoking is associated with reduced effectiveness of treatment in adults. [30]

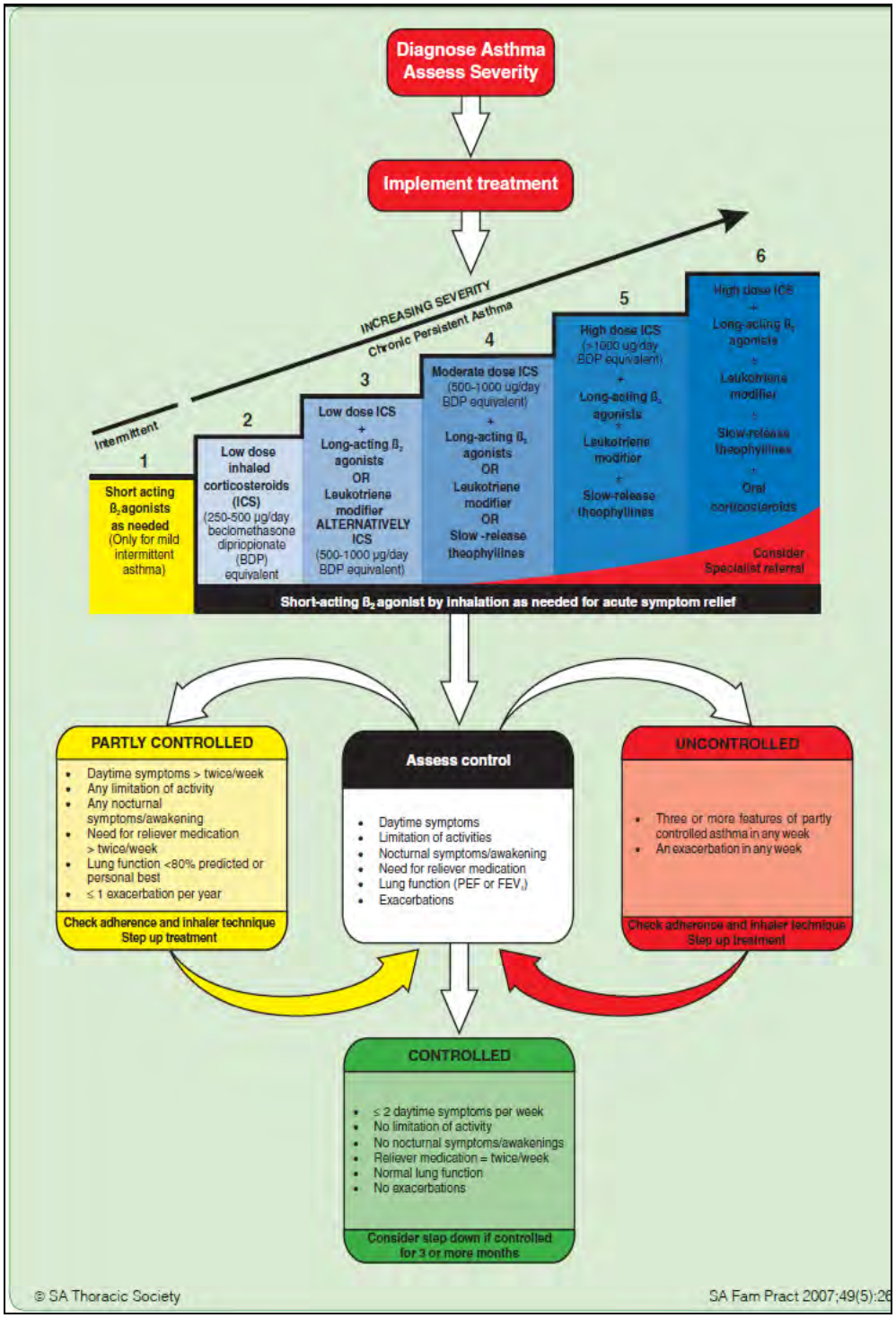

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Figure 2.2 Algorithm for diagnosis and management of chronic asthma [18]

Various international and national organisations have published guidelines for the management of asthma [6,48] with broad agreement between most guidelines. To be effective, local needs must be taken into account and guidelines should be adapted,

reviewed and updated regularly. [21] In South Africa, guidelines for the management of chronic persistent asthma were published by the South African Thoracic Society in 1992, and revised in 2000 and again in 2007 (see Figure 2.2). [18] The South African guidelines are similar to those advocated by the GINA and the British Thoracic Society. [38,49] Globally, asthma control remains poor despite the availability of guidelines and effective medicines. [49,50] This indicates poor adherence to the recommendations in the guidelines by both doctors and patients. [49,51,52] However, the guidelines fail to take the following into account: individual response to treatment and severity of adverse effects, availability and cost of medicines in different countries, the best device for delivery of medicine to the lungs, and difficulty in understanding and implementing complex guidelines. [49]

2.2.10 Pharmacotherapy in asthma

Asthma can be controlled with medicines and its management is dependent on the use of bronchodilators (beta$_2$-agonists and anticholinergics), corticosteroids, leukotriene receptor antagonists and methylxanthines. [53] Asthma medicines are classified according to their mode of action, i.e., relievers, which are short-acting bronchodilators (e.g., salbutamol) are used to provide rapid relief of asthma symptoms, while controllers have anti-inflammatory (e.g., beclomethasone) and/or sustained bronchodilator action. [18,53] Leukotriene receptor antagonists are used as “add-on therapy” for patients on inhaled corticosteroids. [38,53] Because of their side-effect profile, only short courses (i.e., 7-14 days) of oral corticosteroids should be used for deterioration of asthma control. [53]

This research was conducted in a public sector PHC clinic and according to the South African 2008 PHC STGs, the following medicines should be used for adults depending on the classification of asthma. [43]

Step 1: Mild, intermittent asthma

- Beta$_2$ agonist, e.g., salbutamol, inhalation, 1-2 puffs 3-4 times daily as needed until symptoms are relieved.

Step 2: Mild, persistent asthma

- Budesonide or beclomethasone, inhalation, 200 mcg 12 hourly regularly,

and

- Beta$_2$ agonist, e.g., salbutamol, inhalation, 1-2 puffs 3-4 times daily as needed until symptoms are relieved.

Step 3: Moderate, persistent asthma

- Budesonide or beclomethasone, inhalation, 200 mcg 12 hourly regularly. If no response, refer to doctor to uptitrate to 400 mcg 12 hourly regularly.

and

- $Beta_2$ agonist, e.g., salbutamol, inhalation, 1-2 puffs 3-4 times daily as needed until symptoms are relieved.

Step 4: Moderate, persistent asthma not controlled on these dosages

- Add slow release theophylline (doctor initiated).

If patients are not controlled on the medicines offered at PHC level, then patients are referred to a public sector hospital where the addition of ipratropium bromide MDI, a long acting $Beta_2$ agonist (salmeterol or formoterol) MDI and/or oral prednisone (5-10mg daily) can be initiated. [54]

Inhalation of corticosteroids and $beta_2$-agonists is preferred to oral administration because of the faster onset of action and fewer adverse effects as smaller doses are required and there is less systemic bioavailability. [18,49] The medicines most commonly used in this research were salbutamol and beclomethasone MDIs, and these are therefore reviewed in detail below.

2.2.10.1 Inhaled salbutamol and beclomethasone

Early inhaled short acting $beta_2$-agonists such as salbutamol (Table 2.2) are the medicines of choice for relief of mild to moderate attacks of bronchoconstriction. Salbutamol (Table 2.2) should not be used regularly, daily for long-term. [53,55] Inhaled corticosteroids such as beclomethasone (Table 2.2) have been studied widely and are the anti-inflammatory of choice for controlling asthma. [18,30] A significant improvement in symptoms can take 1-4 weeks. [36,53]

Table 2.2 Use of salbutamol and beclomethasone MDIs [18,21,53,55]

Medicine	Medicines information	Dosage	Adverse effects
Salbutamol	Uses: Asthma symptoms, prophylaxis for exercise-induced asthma Effect: Relaxation of bronchial smooth muscle	Asthma symptoms: 100-200 mcg every 4-6 hours as needed Prophylaxis of exercise-induced asthma: 200 mcg 15-30 minutes before exercise	Tachycardia, tremor headache and irritability
Beclomethasone	Use: Long-term control Effect: Reduction of inflammation in the airways N.B. Washing the mouth out with water and use of a spacer reduces local adverse effects and systemic absorption	400-800 mcg daily taken twice daily but can be reduced to once daily	Local: Dysphonia and oral candidiasis Systemic: >800 mcg per day may result in adrenal suppression, osteoporosis, cataracts, skin atrophy, hyperphagia and easy bruisability

2.2.10.2 Types of inhalers

Pressurised MDIs were the first inhaler devices introduced in 1956. Originally chlorofluorocarbons (CFCs) were used as propellants but these have been replaced by hydrofluoroalkanes (HFAs). [56] All pressurised MDIs need to be primed to check that the MDI is working correctly. This involves shaking the MDI and then actuating 1-4 times into the air. The number of actuations varies depending on the active pharmaceutical ingredient, the formulation, the type of propellant used and the manufacturer. Priming should take place before the MDI is used for the first time or if the MDI has not been used for more than a few days (1-2 days for CHC-containing MDIs and 4-7 days for HFA-containing MDIs [57-59]

MDIs which are commonly used and inexpensive are the most cost-effective treatment for asthma. Other inhalation devices include breath-actuated pressurised MDIs which release a metered volume of active ingredient on the in breath and dry powder inhalers whereby the powdered active ingredient is dispersed into droplets during inspiration. [56,60] If inhaler technique is taught correctly, there is no difference in patient ability to use MDIs and other inhaler devices. If used correctly, there is also no difference in clinical effectiveness between nebulisers and alternative inhaler devices compared to standard pMDI with or without a spacer device. [56,60,61] Patients will require specific devices dependent on their individual needs. [56,62,63]

Dry powder inhalers are unlikely to be used in developing countries as they are more expensive to produce. [64] Where possible, only one type of inhaler should be prescribed as patients on more than one type are more likely to make errors in inhaler technique. [65] MDIs are more convenient to use than nebulisers as they are less cumbersome [66] and nebulisers require complex assembly and cleaning. [58] MDIs should be stored at room temperature. If the temperature drops to below 15°C, the dose emitted is substantially reduced. To prevent this, the patient should warm the MDI in their hands before use, although this is more important for the older CFC-actuated MDIs. [58] The MDI should always be stored with the cap on to prevent the entry of foreign objects and to reduce humidity and microbial contamination. [64] MDIs must not be broken or punctured and must not be kept near hot objects. [58]

Patients are not always able to identify if a MDI is empty or nearly empty and this could have disastrous consequences. Having built-in dose counters eliminates this problem for most people except those with poor eyesight. [58,62,66,67] Counters are also useful for HCPs to monitor adherence to preventer medicines and may serve as reminders if patients forget their dose. [62] If counters are not available, it has been suggested that patients or HCPs

take note of the date of dispensing, calculate the date when the inhaler should be discarded and record the date on the inhaler device. This method is appropriate for the use of controller medicines such as inhaled corticosteroids. Patients should be encouraged to keep a record of the number of doses of reliever medicine used. [64] However, requesting patients to count the doses is impractical, inconvenient, unrealistic and unreliable. [58]

Canisters should not be immersed in water to estimate the number of doses in the canister as this method is unreliable and if water enters the nozzle, subsequent doses are considerably reduced. [58,64] MDIs should be discarded when the total number of doses have been used to avoid the administration of propellant only. [64] There is a need for "intelligent devices" that inform patients if dose emission and correct inhalation have occurred, and to monitor adherence. [63]

2.2.10.3 Inhaler technique

Correct inhaler technique is vital when using MDIs. [21] The success of an inhaler depends on the type of inhaler used, the patient's psychosocial status, cultural beliefs and language skills, and continuous and consistent instruction on inhaler technique. [68] Poor MDI technique is one of the reasons for admission to hospital in patients with asthma exacerbations. [69,70] Even when technique is correct, only about 10% of the active ingredient reaches the airways below the larynx. [21,53,71]

Many patients are unable to implement correct MDI technique with a consequent negative effect on asthma control. [58,62,70,72] Approximately 25% of patients experience difficulty when using MDIs. [21,71] An increase in age, dementia and arthritis are some of the contributing factors. [21,70,71,73,74] Less education is associated with poor inhaler technique. [70] Patients overestimate their ability to use MDIs correctly [63,75] and are therefore unlikely to associate symptoms with incorrect technique or request that HCPs check their technique. MDI technique should be checked regularly, especially if asthma control worsens and symptoms develop. [21,63,76,77]

2.2.10.4 Use of spacers and valved holding chambers

Spacers and valved holding chambers are devices that can be attached to MDIs and are used to improve the delivery of active ingredient to the lungs. [18,58] The main difference between these two devices is that the spacer does not contain a valve whereas the holding chamber does. Both these devices provide an increase in the space between the nozzle of the MDI and the mouthpiece. The particles emitted from the nozzle evaporate and reduce in size resulting in a decrease in oropharyngeal deposition of the active pharmaceutical

ingredient which is more pronounced in holding chambers than in spacers. The devices are made of various materials and are of different volumes. [58] One-way valves in holding chambers allow the particles to be inhaled with any air that is exhaled is directed out of the holding chamber. [66] If inhalation is too rapid, a whistling sound can be heard which is an indication for the patient to breathe in more slowly. [78] The valves in the holding chambers should be checked regularly and should be replaced if they have changed shape as a result of extended use or cleaning. [58]

Spacers are either home-made or manufactured. Spacers are also a useful alternative to nebulisers for acute attacks. [21,79] A study in South Africa found that 500ml plastic cold-drink bottles can be used effectively as low cost spacers. [79] The use of a spacer together with an MDI is as effective as using a dry powder inhaler. [18] There are different types of spacers and these must be compatible with the particular MDI. [18,21,58] The spacer volume that is recommended for adolescents and adults is 750 ml. [43] When using spacers, inhalation must occur within 30 seconds of actuation to prevent deposition of medication on the inside of the spacer. [21,67,71] At beclomethasone doses ≥ 800 mcg per day, large spacer devices should be used routinely to reduce pharyngeal deposition. [21,71] The use of spacers and holding chambers results in a reduction in local adverse effects of beclomethasone such as oral candidiasis and dysphonia as well as a reduction in systemic absorption. [18,21,71] Although spacers and holding chambers can be cumbersome, this should not be a problem for twice daily doses of inhaled corticosteroids or use of inhaled $Beta_2$ agonists in patients' homes. [21,58,71]

Electrostatic discharge on the inside of spacer devices and holding chambers results in a reduction of active ingredient reaching the airways. To reduce this, spacers and holding chambers should be washed using detergent and left to air dry. [18,21,58,66,67,71] Towels must not be used to dry them as these are a source of contamination and can also play a role in the build-up of electrostatic discharge. [71] Spacers must be cleaned once a month and should be replaced every 6-12 months. [21,58,67,71] More recently, manufacturers have started using plastics that do not result in electrostatic discharge or are using a conducting metal which allows static discharge to dissipate. [58]

2.2.11 Asthma control

In the past, the focus of treatment decisions was based on asthma severity. Control of asthma is based on the achievement and maintenance of the goals of asthma. The South African Thoracic Society has adopted the following goals for asthma treatment: [18]

- Achieve and maintain control of symptoms

- Maintain normal activity levels, including exercise
- Maintain pulmonary function as close to normal as possible
- Prevent asthma exacerbations
- Avoid adverse effects from asthma medications
- Prevent asthma mortality

According to the British Guideline on the Management of Asthma, control of asthma should be assessed against the following standards: “Minimal symptoms during the day and night; minimal need for reliever medication; no exacerbations, and normal lung function (in practice FEV_1 and/or PEF >80% predicted or best).” [21] The 2007 NIH National Asthma Education and Prevention Programme (NAEPP) guidelines emphasise the achievement of control of asthma symptoms as well as a reduction of the risk of exacerbations, decline in pulmonary function and adverse effects associated with long-term use of treatment. [80]

All patients returning to health care facilities should be assessed for asthma control. [18,30,53] Asthma symptoms can be assessed objectively by asking patients the same set of questions relating to symptoms at each visit and scoring the responses. Changes in scores give an indication of asthma control. [81] If asthma control is poor, adherence should be assessed. [18,30,53] Inhaler technique should be assessed as well as exposure to trigger factors. [18,30,53] The following should be excluded: gastro-oesophageal reflux diseases, rhinitis and sinusitis, the use of medicines that may aggravate asthma, e.g., aspirin, non-steroidal anti-inflammatories and beta-blockers, and other medical conditions, e.g., cardiac disease. In the absence of these, treatment should be increased (step up treatment). If control has been achieved and maintained for a minimum of three months, then step down treatment is recommended. [18,30,53]

2.2.12 Prognosis

Most asthma deaths can be prevented by treatment provided that there is continuous access and adherence to treatment. The use of inhaled corticosteroids has been shown to reduce hospital admissions and mortality rates. In established asthma, the occurrence of 2.14ling (permanent structural changes in the lungs as a result of long-term inflammation) is not reduced by using inhaled corticosteroids. [82]

2.2.13 Economic cost of asthma

When calculating the economic cost of asthma, both direct (e.g., hospital admissions, cost of medicines, cost of doctor’s visits) and indirect costs (e.g., inability to work, premature

retirement, time spent by others caring for sick relatives, premature death) need to be included. [7,83] Studies conducted in various countries including Australia, United Kingdom (UK), Sweden, USA, Canada and France found that direct and indirect costs were almost equal. Three-quarters of the total costs were due to poorly controlled asthma, and interventions such as patient education and prophylactic therapy reduce the incidence of poorly controlled asthma, thus reducing the economic burden of asthma. [83]

2.2.14 Asthma deaths

It is estimated that one in every 250 deaths worldwide are due to asthma, with many of these deaths potentially preventable if adequate long-term medical care had been available and if there was no delay in receiving appropriate care when experiencing the final asthma attack. [7] Approximately 25% of deaths as a result of asthma occur within an hour after the start of the exacerbation. Patients who are known to deteriorate quickly are at a greater risk and should therefore have appropriate treatment with them at all times. [21]

Asthma occurs in all countries regardless of the level of development although more than 80% of asthma deaths are in low and lower-middle income countries. [24] Figures reported in the Global Burden of Disease and Risk Factors reports of 2006 [84] and 2008 [16] are shown in Table 2.3. An increase of 61 000 deaths was reported from 2001 to 2004 in low- and middle-income countries.

Table 2.3 Asthma deaths as reported in the Global Burden of Disease and Risk Factors reports of 2006 and 2008 [16,84]

	Globally	Gender		Country Income	
		Male	Female	Low & Middle	High
2006 Report (data from 2001)	233 000	119 000	114 000	205 000	28 000
2008 Report (data from 2004)	287 000	151 000	136 000	266 000	21 000

The majority of asthma deaths occur in those >75 years old. [16,21] Southern Africa has the fifth-highest case fatality rate in the world with the majority of deaths occurring outside hospitals. [7,85] According to Statistics South Africa, there were 4763 deaths from asthma and 1020 from status asthmaticus which accounted for 33.5% and 7.2% of the total number of deaths due to chronic lower respiratory diseases which were among the ten leading causes of natural causes of death in 2008. [86] According to Poyser et al, living in poverty is associated with an increase in asthma severity whereas improved socio-economic conditions are associated with an increase in the incidence of asthma. [87] Asthma symptoms are unacceptably high, despite the availability of inhaled corticosteroid inhalers from public and private health care facilities. Under-prescribing and incorrect use of inhaled

corticosteroid inhalers may play a role in preventable morbidity and mortality. [46] Not following guidelines for treatment and non-adherence further compound the problem. [88]

2.3 Health care system

2.3.1 Health as a human right

Member states of the United Nations pledged themselves to the Universal Declaration on Human Rights in 1948. Human rights are protected by law and international human rights law lays down obligations of how governments must protect human rights and basic freedom of individuals or groups. All human beings are entitled to human rights and there should be no discrimination. [89] Article 25 of the Declaration includes the right to health and states that:

> Everyone has the right to a standard of living adequate for the health and wellbeing of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control. [90]

Governments have a responsibility to provide essential health and social services, and to promote human rights which must be included in health-related policies. [91] The right to health care is included in Section 27 of the Bill of Rights, which forms part of the 1996 Constitution of South Africa. [92] Since its inception, there have been many health reforms that have resulted in improved health outcomes for South Africans. [93]

2.3.2 Primary health care globally and in South Africa

In 1978, the Alma-Ata Declaration was accepted by 134 countries whereby cost-effective interventions in PHC were envisaged as the means to attain health for all by the year 2000. [94] Although a decision was made to address the main health problems of communities through the provision of promotive, preventive, curative and rehabilitative services, the essential elements identified did not include the treatment of NCDs. [3,95,96] If patients with NCDs are to be treated and managed effectively, they need to have access to HCPs and medicines. [97] In developing countries, the majority of patients with NCDs are treated at PHC facilities, which in the past focused more on acute conditions. [1]

South Africa was one of the pioneers in the global development of PHC. The Pholela Health Centre, established in 1940, provided holistic care. The health care needs of the community were identified and addressed and interventions to address vulnerable and high risk groups,

such as women and children, were implemented. Community involvement was encouraged and local members of the community were trained as health assistants and educators resulting in empowered communities. The Gluckman Report of 1944 proposed that this model be implemented throughout the country, but a change in government and lack of funding prohibited this. By 1960, the founding members of Pholela left the country and continued to lobby for community-oriented primary care, a forerunner to PHC.

During the apartheid years, the focus on health in South Africa was on hospital care. Churches played a role in health care services and missionaries from many countries tried to provide services in rural and peri-urban areas but could not meet the overwhelming demand. In 1994, under the first democratically elected government, the National Health Plan was introduced and this was based on the PHC approach. Health care services were decentralised and the establishment of more PHC clinics was viewed as a priority. A shortage of medical practitioners has hampered the functioning of the decentralised health care system and PHC and this, along with other factors such as HIV/AIDS and the increase in NCDs, has resulted in the health care system not being able to meet the health care needs of the population. [98]

It has been proposed that PHC be the main focus of the National Health Insurance system to be implemented in South Africa. [97] There are 4 500 PHC clinics, which are staffed mainly by nurses, several thousand of whom have completed a postgraduate PHC course recognised by the South African Nursing Council. [98,99] Patients with NCDs are encouraged to attend these clinics as factors such as transport costs and getting time off work make it difficult to attend hospitals. This should then reduce overloading of hospitals. [97] Most patients dependent on public sector health care have their asthma diagnosed by nurses at either PHC clinics or at district hospitals where spirometry testing is not done.

2.3.3 Millennium Development Goals

By 2000, the Alma-Ata vision of health for all had not been achieved. In September 2000, a pledge was made by 189 countries to free people from extreme poverty and multiple deprivations. Eight millennium development goals (MDGs) were agreed on and the attainment of these goals by the year 2015 is being co-ordinated and monitored by the United Nations Development Programme. Four of the eight MDGs relate to health: MDG 4 is to reduce child mortality; MDG 5 is to improve maternal health; MDG 6 is to combat HIV/AIDS, malaria and other diseases; and MDG 8 is to develop a global partnership for development, which includes providing access to affordable essential medicines in developing countries. [100,101] It is anticipated that by 2015, none of the MDGs will have

been achieved in sub-Saharan countries and that NCDs will continue to increase, further exacerbating poverty which will be particularly problematic for the health and economies of under-resourced middle- and low-income countries. [102,103] Social determinants of health include living and working conditions and generally, poor socio-economic status is associated with poor health. Social and economic policies that address social determinants of health can improve the health of a population. [104]

2.3.4 Health care services in South Africa

South Africa has a large public sector health care system that provides health care to about 80% of the population. The private health care system caters for the remaining 20%, 18% of whom are on medical aid. The public health care system provides basic care and is under-resourced and over-used, while the private health care system has many resources including technologically advanced and specialised services. In the public sector, health care is free at PHC level. [98] According to the 2008 South African Health Review, “Differentials in health status have been observed between population groups, wealth groups, urban-rural and education levels.” Reasons cited for this include high rates of migration of health workers, shortages of health workers, inequities in the distribution of personnel, an imbalance of resources, an increase in infectious diseases and NCDs, a curative-orientated health service and deficiencies in managerial capacity and health system leadership. [98] At the National Health Insurance Conference held in 2011, it was stated that “The current health system is unconstitutional, inefficient, not accessible, and unequal and undermines human dignity.” [105]

In 2009, the total expenditure on health as a percentage of gross domestic product was 8.5%. [106] Government contributes approximately 40% of the total expenditure on health to address the health care needs of 80% of the population. Approximately 11% of the total government budget is spent on health and this is distributed to the nine provinces in South Africa. [107] The STGs and the EML were developed for use in the public sector as a means of addressing the lack of equity of access to essential drugs in South Africa. [43,47] Despite this, there are discrepancies in public sector health care services between and within the nine provinces in South Africa. [108,109]

In South Africa, if an adult (18-59 year old females and 18-60 year old males) has a physical or mental disability which makes them unfit for work for longer than six months, they can apply for a disability grant from the South African Social Security Agency. The maximum grant (February 2012) is R1 140 per month and to qualify, applicants are required to undergo a medical examination by a doctor appointed by the State. Continuity of these grants is

based on review and may result in suspension thereof if there is an improvement in the applicant's health. [110]

2.3.5 Challenges in health care

The top 20 challenges in addressing NCDs were identified by a panel of 155 culturally diverse stakeholders from 50 different countries and include: [17]

- allocating health resources based on burden of disease
- health professional training and practice moving towards prevention
- increasing the number and skills of professionals who prevent, treat and manage NCDs especially in developing countries
- screening and prevention being incorporated into health systems
- access to medicines being improved to prevent complications of NCDs.

Other challenges are:

- raising public awareness of NCDs
- enhancing social and economic health policies
- reducing risk factors by reducing tobacco and alcohol use as well as promoting healthy eating habits and physical activity
- involving business and communities
- studying how poverty and urbanisation impact on NCDs.

Many of the above involve policy changes, which will need to be monitored. Individual countries need to identify their own priorities, taking disease patterns and resources into account. The WHO, World Bank, all governments, health agencies, business communities and civil society organisations are important role players in meeting the challenges of NCDs in a co-ordinated way. [17]

A shortage of HCPs is one of a multitude of challenges in implementing access to health care. [1,97] Data from the 2009 World Health Statistics indicate that for the time period 2000-2007, there were the following number of doctors per 10 000 population: globally (13), European countries (32) and African countries (two). South Africa fared better than other African countries with eight doctors per 10 000 population. [2] According to the 2008 World Health Statistics for the time period 2000-2006, the ratio of HCPs per 10 000 population in South Africa was eight doctors, 41 nurses and three pharmacists. [111] It is a matter of concern that for the time period 2000-2010 (2011 World Health Statistics), the ratio of HCPs per 10 000 population in South Africa decreased to 7.7 doctors, 40.8 nurses and 2.8

pharmacists. [13] The shortage of doctors and nurses in South Africa has a negative impact on quality of care. [99]

2.3.6 Asthma care by various health care providers

The NAEPP guidelines recommend that HCPs educate patients with asthma every time they see them. [35] However, several studies have shown that HCPs are not always capable of demonstrating correct MDI technique. [42,58,112-114] In a study in Spain, only 9% of patients, 15% of nurses and 28% of physicians were able to demonstrate correct MDI technique. Of the physicians, scores for correct use by general practitioners and paediatricians were significantly lower than those of chest physicians and allergists. [42] Table 2.4 presents the results of a Canadian study showing that respiratory therapists had better MDI technique and were more knowledgeable about asthma than physicians and registered nurses. [112]

Table 2.4 Comparison of asthma study results for HCPs in Canada [112]

HCP	Mean knowledge score (%)	MDI technique scores (%)
Physicians	48	69
Registered nurses	39	82
Respiratory therapists	67	97

2.3.7 The role of pharmacists in the health care system

According to the South African National Drug Policy the role of pharmacists includes “the safe and effective administration of drugs” and pharmacists “have a central educational role in instructing patients in the correct use of drugs.” [47] South Africa is a member of the Commonwealth Pharmacists Association. At a meeting held in Durban, South Africa in 2011, the “Durban Declaration on the Commitment of Pharmacists to Combating Non-communicable Diseases in the Commonwealth” was released. It was stated that pharmacists should provide patients in both the public and private sector with health promotion information aimed at reducing common risk factors for NCDs such as tobacco use, harmful alcohol use, unhealthy diets and physical inactivity. Pharmacists should also engage with policy makers and other HCPs to strengthen health care systems for effective management and care of NCDs. [115]

The provision of pharmaceutical care requires that pharmacists take responsibility for the provision of medicines in order to achieve specific outcomes that improve a patient’s health-related quality of life (HRQOL). [116] If pharmacists show an interest in disease progression, patients may become more motivated to assume responsibility for improving and maintaining their health. [117] Pharmacists are accessible and can work together with patients to devise therapeutic plans that result in positive patient health outcomes. [118-123]

2.3.7.1 The role of pharmacists in asthma care

Pharmacists can play an important role in educating parents, children, teachers and other members of the community. [35,38] Results from studies implementing asthma pharmaceutical care show a reduction in asthma symptoms, hospital admissions, emergency department visits and costs related to asthma. Results also indicated an improved HRQOL and improved self-management capabilities due to improved inhaler technique, increased knowledge and increased self-efficacy. [8,35,66,119,120,123-129]

The inappropriate over-use of bronchodilators in South Africa has resulted in a decrease in asthma control and an increase in exacerbations. [91] Use of one or more canisters of salbutamol per month, increased dosing or a reduction in effect suggest inadequate control of asthma. The pharmacist, as an accessible, informed health professional, is ideally positioned to educate the patient and if necessary, refer the patient to a doctor. [18,20,30,53,114]

Pharmacists are able to assess and teach inhaler technique, but may require training to do so. [62,112,124,130-132] A study in Canada found that most pharmacists taught themselves MDI technique, provided education and assessed MDI technique for new prescriptions, but did not check these regularly thereafter. [133] It is recommended that when new supplies of medicines are collected, patients first demonstrate technique using a placebo inhaler and that the pharmacist corrects any errors or commends correct technique. [35,129,130,134-137] Repeated education and regular rechecking of inhaler technique are necessary to maintain long term correct usage of MDIs. [129,130] Despite being ideally situated to assist with monitoring of asthma, pharmacists are underutilised for this service. [114,126]

2.4 Patient behaviour

2.4.1 Adherence

When diagnosed with an NCD, patients are expected to adopt and learn new and sometimes complex behaviours. They are expected to accept the need for change and to learn and implement new skills after a brief interaction with an HCP. For patients with pulmonary disease, this often occurs when a patient is experiencing an asthma exacerbation and they may not be able to assimilate information given due to being distressed and unable to breathe. Most HCPs assume that patients will carry out their instructions, even after minimal interaction, in order to improve their health. If patients do not follow instructions, they are thought to be either self-destructive or stupid. [58]

Adherence is defined as “the extent to which a person’s behaviour (taking medicine, following a diet, and/or executing lifestyle changes) corresponds with agreed recommendations from a health care provider”. [14] It has been reported that adherence to long-term therapies averages 50% in developed countries and 20% in developing countries. [1] Non-adherence has a negative impact on national health economies and also results in poor health outcomes at a very high cost to society and families. [1,14,138]

Interventions that are effective at improving adherence may improve the health of populations more than improvements in specific medical treatments. According to the 2001 WHO report: Adherence to Long-term Therapies: Policy for Action, there are four interacting elements that cause non-adherence: [138]

- Health care system and team – knowledge, attitudes and skills of members of the health care team; the health care system’s capacity to provide patient education, access to treatment and follow-up; the ability to establish community supports and to train providers to carry out chronic care protocols and interventions to assist patients with self-management.
- Condition-related factors – symptoms; level of disability (physical, psychological, social and vocational); disease severity; progress rate of the disease; availability of effective treatments.
- Therapy-related factors – access to medicines; complexity of therapy; the time it takes to notice benefits of treatment; adverse effects and the availability of HCPs to address them; association of treatment with stigma.
- Patient-related factors – resources, attitudes and perceptions of patients; patient knowledge about their disease; motivation to deal with the disease; confidence to partake in behaviour to manage it; expectations regarding the effect of treatment.

Socio-economic factors are also important, for example, poorer patients from developing countries may use their limited funds for the needs of other family members and not for their own health-related needs. [58,138]

Patients are often blamed for non-adherence but the health care system should accept some responsibility for reducing non-adherence. [1,14] The provision of appropriate information, support and regular follow-up can improve adherence which would result in an improvement of patient health outcomes together with a reduction in the burden of NCDs. [1] Regular reinforcement of information takes time, but is needed to promote adherence. [21,58,139]

Support from family and members of the community can affect the health outcomes and behaviours (e.g. adherence) of people with NCDs. [14]

2.4.2 Non-adherence in asthma

Non-adherence with asthma therapy is widespread and is a significant risk factor for asthma morbidity and mortality. [7,21,140] In a literature review of articles between January 1966 and 1997 on adherence with inhaled corticosteroids (measured by an electronic device), it was found that patients took the recommended doses on 20-73% of days. Underuse (24-69% of days) was more common than overuse (2-23%) and average adherence ranged from 63-92%. [72] Reasons for non-adherence in a South African study on asthma included being concerned about adverse effects of medicines (45.4%), discontinuing medicine when "feeling better" (45.2%) and sometimes forgetting to take medicines (28.5%). [141]

Medicine-related reasons for non-adherence to asthma therapy include delays in acquiring medicines from the pharmacy, inability to use inhalers, complex regimens, concern about adverse effects and taking corticosteroids on a long-term basis, cost, reluctance to take medicines or difficulty in accessing medicines. [21,49,52,58,76,142] When the cold aerosol plume (which can be as low as -30°C) reaches the back of the mouth, many patients stop inhaling. This is known as the "cold-FREON" effect and may affect adherence. [64] Patients do not feel any immediate benefit when using inhaled corticosteroids and this may reduce adherence. [76,143] Adherence is also affected by periods when the patient is well and they might not see the need to take corticosteroids. [21,52,142,144]

Reasons for non-adherence which are not medicine-related include not being able to understand instructions, lack of trust in the prescriber, lack of supervision to check adherence as well as anger and resentment due to feeling unwell. [49,76] Patient ability and motivation also need to be considered as unintentional non-adherence can occur when patients are unable to open the medicine package, they do not understand how to use the medicine, they cannot read the instructions and/or cannot use the medicine. Intentional non-adherence may be due to lack of motivation because of disliking the appearance of the medicine, regarding taking the medicine as too much bother or feeling that taking the medicine causes other problems. [68] Cultural, religious and ethical issues also play a role, as does objecting to being labelled with asthma. [49]

In developing countries many people believe in the use of traditional medicines, which may reduce adherence to prescribed medicines. In some countries, both traditional and modern medicines are used simultaneously. [145] Sometimes non-adherence is simply due to

forgetting to take the required medicines and/or underestimating the severity of their asthma. [49,52,76,142] Stress and secondary gain from persistent symptoms, e.g., to ensure the continuation of disability grants, can also contribute to non-adherence. [76]

2.4.2.1 Promoting adherence

Improved adherence has been associated with stronger beliefs in the benefits of treatment, avoidance of trigger factors, increased perception of asthma severity, having had asthma for a longer period of time, having more people giving instructions on MDI use and better general health. [146] Adherence should be assessed at each visit to a health care facility. [14,18,76] Barriers to adherence need to be addressed by health care systems and HCPs. Patient-specific interventions to reduce non-adherence must be implemented. To improve adherence, co-ordinated action from HCPs, researchers, health planners and policy-makers is required. [14]

2.4.3 Health-related quality of life

HRQOL focuses on the impact health status has on quality of life. It is a multi-dimensional concept that includes physical and mental perceptions, social functioning, health risks and conditions, functional status and socioeconomic status. [147] HRQOL and well-being have been used by public health officials and clinicians to measure the effects of chronic illness, treatments, and both short- and long-term disabilities. HRQOL assessment is a particularly important public health tool in helping monitor the progress of nations in achieving their health objectives. [148]

At an individual patient level, measurement of HRQOL is a non-invasive, patient-centred way to assess management. [147] Disease severity and treatment given for the disease are not the only factors affecting HRQOL. The environment, cultural and personal socio-economic factors also affect HRQOL and these vary in different regions and in different countries. [149,150]

Asthma, and particularly exacerbations of asthma, have a negative effect on HRQOL, with one of the goals of asthma treatment being to improve HRQOL. [83,151] The Global Asthma Physician and Patient (GAPP) survey was conducted in 16 countries (including South Africa) and involved 1 726 asthma patients and 1 733 physicians. [52] In this study, 41% of patients reported that asthma limited their daily activities. The more severe the asthma is, the greater the reduction in HRQOL, [147] and the presence of a concomitant NCD affects HRQOL and limitation of activity more than asthma does alone. [152] In asthma, HRQOL is negatively affected as age increases. [147,152] Monitoring of HRQOL is important as it reflects

patients' concerns and perceptions. [153] In South Africa, higher levels of education and higher levels of income were associated with improved HRQOL in patients with asthma. [154]

When used with other forms of assessment, HRQOL assessment can assist HCPs in making the best choices for their patients and changes in HRQOL as a result of treatment can be a valuable indicator of treatment success. If doctors have a better understanding of how diseases affect HRQOL, they are likely to have better relationships with their patients who may then find interactions with their health providers more meaningful. [155] A study conducted in South Africa showed that a pharmaceutical care intervention resulted in improved HRQOL. [156]

HRQOL can also be used as one of the predictors of adherence. There is a relatively weak correlation between lung function and HRQOL, indicating that HRQOL outcomes focus on different aspects of asthma. Monitoring lung function together with HRQOL may present a more complete picture of a patient's health status. [153]

Patients can also use HRQOL questionnaires as a means to self-manage asthma. [147,142] Studies that have addressed asthma control and HRQOL include GOAL (Gaining Optimal Asthma controL) and TENOR (The Epidemiology and Natural History of Asthma: Outcomes and Treatment Regimens). The GOAL study found that improvements in asthma control using the Global Initiative for Asthma (GINA) goals for management of asthma resulted in improvements in HRQOL. [158] TENOR results established that when asthma control in patients with severe or difficult to treat asthma improved, HRQOL improved as well. [159] If asthma control is sustained, patients and their families can enjoy a better HRQOL and continue with their daily activities without interruption. [30,34]

2.4.3.1 Measuring HRQOL

Several instruments have been developed to assess HRQOL. The WHOQOL-100 and the WHOQOL-BREF are international, cross-cultural instruments that have been translated into more than 20 different languages to assess HRQOL. [155,160] One of the most commonly used methods to assess asthma HRQOL is the Asthma Quality of Life Questionnaire (AQLQ), which was developed in the UK, consists of 32 items and assesses four domains: activity limitation, symptoms, emotional function and environmental stimuli. It is a validated interviewer-administered instrument designed for use in adults for assessing the effect of interventions in clinical research. [161,162] The Mini Asthma Quality of Life Questionnaire (Mini-AQLQ) is self-administered and comprises 15 items covering the same four domains

as the AQLQ. It is useful for larger clinical trials, group patient monitoring and large surveys. [163] Other AQLQ instruments used in specialised settings include the acute AQLQ, paediatric AQLQ, standardised AQLQ, AQLQ 12+ and asthma impact survey (AIS-6). [164-166]

2.4.4 Patient self-management

Patient well-being improves with effective treatment, support for self-management and regular follow up. [1,9,169] Partnerships and discussions between the patient and HCP should enable the acquisition of knowledge, confidence and skills needed to empower patients in the self-management of their asthma. [9,18,30,38]

In a systematic review of 71 self-management trials involving multiple NCDs, it was found that self-management educational interventions were only beneficial in certain conditions such as asthma. Conditions for which goals can be set and objectively measured are more likely to benefit from self-management programmes, with the most successful of these being face-to-face interventions. [168] Self-management of NCDs involves teaching patients problem-solving and self-diagnosing skills for monitoring and interpreting changes in health. Patients are taught how to find resources in the community, to manage medication and to take the initiative when deciding about their health and when interacting with HCPs. Group sessions to facilitate this have been shown to improve self-efficacy and reduce stress and depression. [169]

Self-efficacy refers to the patient's belief (confidence) that they are capable of a specific behaviour. [167,169,170] People will only act and persevere in the face of difficulties and setbacks if they believe that their action will produce the effects they were hoping for. [169] There is an association between confidence in using MDIs and correct MDI technique. [70]

According to social cognitive theory there are four ways of developing self-efficacy:

- The first is through mastery experiences whereby a person experiences success. Easy experiences of success result in people expecting quick results and being easily discouraged when not successful. Resilient efficacy is obtained by overcoming difficulties that require perseverance.
- Secondly, if others (models) are seen to succeed, people feel that they can also succeed. The model's behaviour and thinking teaches observers effective skills and strategies.

- Social persuasion is a third way of strengthening efficacy. If people are persuaded verbally that they are capable, they are more likely to be able to deal with problems than if they rely on their own feelings of self-doubt and/or personal deficiencies.
- Lastly, if people are taught how to reduce their reactions to stress, change their tendencies to negative emotional states and correct any misinterpreted physical states such as fatigue, their self-efficacy will improve. [169]

According to social learning theory, behaviour can be learned and is dependent on different experiences. [120] The Health Belief Model suggests that patients will be adherent if they perceive their disease to be a moderate or severe threat. They will also be adherent if they perceive that the treatment is effective and that the benefits of treatment outweigh the costs. Changes in behaviour take place over a short or long period of time and in different stages. Some people do not change while others go through stages of thinking about change, preparing for change, taking action and then maintaining the change in behaviour. [120]

Self-monitoring can result in a change in patient behaviour although regular reinforcement of the required behaviour is important to maintain the changed behaviour. [120] HCPs should assess patients' self-monitoring systems and if necessary, offer corrective feedback in a positive way together with advice and encouragement. The ability and willingness of patients to take responsibility varies and thus the information and training given to different patients will also vary.

Personalised asthma management plans that are well-written and include self-monitoring (symptom control and/or peak flow monitoring) are recommended and result in fewer days away from school and work, fewer hospital admissions and emergency room department visits, fewer night-time symptoms, reduced use of reliever medicines and improved HRQOL. [18,171] Evidence from a Cochrane review suggests that symptom-based written asthma plans are better than peak flow written asthma plans for preventing exacerbations of asthma in children and adolescents. [172] Each patient should receive a written plan summarising their medicines and the actions they have agreed upon if asthma symptoms are experienced. [18,30,35,38,58,173-175]

Asthma self-management plans can be patient-driven where the patient makes changes without informing the doctor but in accordance to what was agreed upon, or they can be doctor-driven whereby patients refer most major treatment changes to a doctor. [38] Any changes to medication regimens must be discussed and agreed upon. [30] Asthma diaries can play a role in assisting in the self-monitoring of asthma. [35] The formulation of action

plans may also promote enablement. The original Patient Enablement Instrument has been adapted for use in patients with asthma. Patients are asked if they are able to cope with life, if they understand their illness, are able to cope with their illness, are able to keep themselves healthy, are confident about their health and are able to help themselves. Improvements in enablement scores were associated with clinical improvement as measured by the AQLQ. [176]

2.5 Patient communication and education

2.5.1 The importance of providing information

If positive patient outcomes are to be achieved, HCPs need to be able to communicate effectively with patients, provide patient education and counselling and should ideally be able to influence behaviour change. [1,18,58] Reliable health information is needed for individuals to make good decisions about their health and information is available from many sources. [177]

The following statement was made by the International Federation of Library Associations and Institutions (IFLA) and the Freedom of Access to Information and Freedom of Expression (FAIFE) initiative in support of Article 19 of the United Nations Universal declaration of Human Rights.

> The right of access to information and ideas is vital for any society. If citizens are to participate and make informed choices, they must have access to political, social, scientific and economic information and cultural expressions. They need access to the widest range of ideas, information, and images. Freedom, prosperity and the development of society depend on education, as well as on unrestricted access to knowledge, thought, culture and information. [178]

With reference to this statement, Nicholson [179] commented that:

> This ideal is unfortunately unattainable for most developing countries in the sub-Saharan region of Africa, in their current circumstances. Throughout this region, illiteracy and dire poverty are serious problems and as a result, millions of people are deprived of access to information and knowledge, and hence to a better life.

The South African National Drug Policy, in pursuit of its objective of promoting safe, effective medicines use, states that:

> The public will be provided with access to objective, validated and practical information on drugs and their proper use, written in lay language, and including appropriate self-diagnosis and treatment. [47]

According to the Empowerment Model, the provision of knowledge is necessary to allow people to make informed decisions about their health. The Knowledge-Attitude-Behaviour model suggests that if people acquire knowledge about the health consequences of their behaviour, their attitude and behaviour are more likely to change. [180] Although it has been shown that knowledge does not always result in a change in behaviour, basic knowledge is essential to guide appropriate health behaviour and to avoid undesirable, harmful health behaviour. [120,180]

According to Fink [114], “successful asthma management is 10% medication and 90% education.” If patients are to be successful with self-management, they must be educated about their asthma [20,30,68,181] as patient education has been shown to be effective in managing bronchospasm thereby improving asthma control and HRQOL. [182] Various forms of information and different methods of communicating this information should be developed to facilitate access to medicines information by all patients. [135] Patient information may take a variety of forms including written material, audio information, videos and the Internet. [50,63]

2.5.2 Patient interest in acquiring knowledge

Findings from the Quality Enhancing Interventions (QEI) review reveal that patients and the public would like more health information, the internet is used but mostly by younger, wealthier and more advantaged people, harm as a result of accessing unreliable websites may be under-reported, targeted mass media campaigns increase awareness but this may be short-lived, and written information together with consultations with HCPs results in an improvement in health knowledge and recall. [183] A pharmacist-led initiative into black and minority groups in the UK found that people do want to take an active role in their health care: they were interested in finding out more about medicines and medical conditions as well as healthy eating and exercise, and they appreciated having interactions with pharmacists in their communities as well as being spoken to in their own language. [184]

2.5.3 Barriers to patient communication and education

Many barriers have been identified in the provider-patient communication process. When educating patients, literacy and cultural and language barriers need to be considered. In developing countries, provider-patient communication presents many challenges as there

are often linguistic, socioeconomic, educational and cultural differences. [177,184,185] If the patient's primary language is different to that of the HCP and/or if the patient has low literacy skills, patients may be hesitant or embarrassed to tell HCPs that they do not understand instructions. [58,186] In a South African study on asthma, it was found that culture and language barriers negatively affected health care of Xhosa-speaking adults and children. They were unable to understand questions posed by HCPs and felt that they could not ask questions. This resulted in HCPs obtaining unreliable patient histories, and having difficulty in explaining what asthma is and counselling on correct use of medicines. The use of medical terminology by HCPs further compounded the communication barrier. Xhosa-speaking patients requested that interpreters be utilised during interviews but some HCPs expressed concern that interpreters may provide inaccurate histories and that HCPs would lose control of the interviews. [187] An intervention to teach isiXhosa language skills and cultural sensitivity to non-Xhosa-speaking health care workers in South Africa resulted in patients being better able to understand health care workers. Patients also found that health care workers were more respectful and concerned after the intervention. This led to increased patient satisfaction and decreased health care worker frustration. [188] An example of a culture-specific explanation of asthma in the Xhosa culture is "xakaxa" which refers to the thick mucus that is found in a child's lungs at birth. If "xakaxa" is not removed effectively it is thought to cause respiratory problems such as asthma. [187]

Reasons why patients do not understand the information given to them by HCPs include being older, waiting for a long time before being seen by a physician, the use of medical jargon, new patient/physician relationships, limited physician time, focusing on diagnosis-related information and not on instructions for treatment, and being tired, unwell and/or anxious. [58,68,189] A review of the literature by Kessels [190] on patient recall found that they often do not remember information given to them by HCPs and the information they do remember may be inaccurate. Between 40-80% is forgotten immediately and the more information that is given, the less will be correctly recalled. Recall of information is often worse by the person being diagnosed with a condition, possibly due to increased anxiety. [190] Good working partnerships between patients and HCPs are important for effective initiation and maintenance of therapy. [63]

Findings from the GAPP survey indicate that there are discrepancies between physician and patient perceptions on time spent on education, e.g., 23% of patients reported that physicians spent no time on education during consultations, whereas 87% of physicians stated that half the consultation time was spent educating patients. Just less than a third of

the patients stated that their physicians did not discuss correct inhaler technique, while most physicians (95%) stated that they did. [52]

2.5.3.1 Literacy

Literacy is no longer understood as only the ability to read, write and possess basic numeric skills. More complex definitions have been proposed, the bases of which are the ability to use the alphabet and numbers as well as media and electronic text for personal and community development. [191] According to a study in the USA, low literacy refers to reading at or below grade six level, marginal literacy refers to reading at grade seven or eight level and adequate literacy refers to reading at grade nine level or higher. [192]

According to the United Nations Children's Fund (UNICEF), the adult literacy rate in South Africa for 2005-2008 was 89%. Here literacy refers to the percentage of people 15 or more years old who can read and write. The literacy rate for male youths (15-24 years) was 96% which was slightly lower than that for females (98%). [193] However, these figures do not accurately represent the literacy-related skills of the South African population. Aitchison and Harley used education of less than grade 7 to indicate functional illiteracy, and according to statistics from the 2001 census, 32% of the adult population was functionally illiterate. This therefore suggests a functional rate of only 68%. Just over one in five (20%) adult black Africans had no schooling while just over one in a hundred (1%) whites had no schooling. A more recent census in South Africa was conducted in 2011, but these results are not yet available.

According to the Household Survey in 1995, the 1996 census and the 2001 census there has been no decrease in the percentage of functionally illiterate adults in South Africa. From the 2001 census, compared with other provinces in South Africa, the Eastern Cape had the third highest number of adults aged 20 years and older with no schooling. [194] Researchers have cautioned that the number of years of formal schooling is not necessarily an indicator of reading ability. [195]

2.5.3.2 Health literacy

The definition of health literacy according to the Institute of Medicine in America is: "the degree to which individuals can obtain, process, and understand basic health information and services they need to make appropriate health decisions. But health literacy goes beyond the individual. It also depends on the skills, preferences, and expectations of health information and care providers; our doctors; nurses; administrators; home health workers; the media; and many others." [196] Approximately 90 million American adults find it difficult

to understand and act upon available health information. [196] The European Health Forum defines health literacy as “the ability to make sound health decisions in the context of everyday life – at home, in the community, at the workplace, the health care system, the market place and the political arena. It is a critical empowerment strategy to increase people’s control over their health, their ability to seek out information and their ability to take responsibility.” [177] Although health literacy is closely associated with general literacy, being educated does not ensure adequate health literacy. [197-199]

Inadequate health literacy is more likely in people who are older, male, Hispanic, African American or Black, have a history of a “blue collar” (manual labour) occupation, live in poverty and/or with worse physical and mental health. [197-200] Besides education, factors that affect health literacy include cultural, social and other personal factors such as speaking, listening, and being proactive. [177,196] No reliable health literacy data are available for South Africa but it can be anticipated that health literacy would be inadequate as a result of poor education as less than a third of adults has a grade 12 or higher qualification. [98]. The many cultural groupings and 11 official languages could further compound the problem. Having sufficient background health information and being able to stand up for oneself in the health care system are also important. [196] To improve health literacy, HCPs need to be knowledgeable about, aware of and responsive to health literacy problems. [196,197] Various tests have been designed to assess health literacy, but these are time-consuming and it may be impractical to assess each patient. It has been suggested that HCPs assess health literacy for 100-200 patients consecutively at least once to determine the extent of poor health literacy as many HCPs underestimate the problem. [198] Before medicines are changed or doses increased when diseases are uncontrolled, an assessment should be done to determine if patients understood previous instructions. [201]

Those with low literacy are less likely to access preventative health care and are more likely to have worse health outcomes and to use expensive health services such as emergency departments. [196,202,203] Patients with poor reading ability find both oral and written communication difficult. Their problem-solving abilities may be limited and they are less likely to change behaviour when given new information. [204] People with limited or no literacy skills may not be able to comprehend and understand instructions on how to take their medicine(s), which could result in unintentional non-adherence leading to serious complications and increased health care costs. [122,205]

In a study in Georgia in the USA, although two-thirds of participants reported finishing high school, only 27% could read at high school level. Inadequate literacy was associated with

poorer knowledge of asthma and incorrect MDI technique. [195] Compared to children with parents with higher literacy, children with low-literate parents used salbutamol more often, missed more days of school and had more emergency department visits and hospital admissions. [206]

Patients with inadequate health literacy who have NCDs such as asthma are less likely to be knowledgeable about their condition and its management. [207] They will also have poorer HRQOL, poorer physical function and more visits to emergency departments. [208] Inadequate health literacy can increase health care costs and attempts must be made to address intervention strategies to address the problem. [197]

2.5.3.3 Quality of written patient information

Text used in health information is complex and even people with good literacy skills may find it difficult to obtain, understand and use. [122,196] Small font size is difficult for visually impaired and elderly people to read. [122,209] Package inserts accompanying medicines often do not meet patients' needs and are not viewed as important sources of information on medicines. They are often thrown away because there is too much to read, the appearance is dull and boring, the font is too small, they are folded and creased making them appear unimportant, information is not in the correct order and important information is not emphasised. [210] A Swedish study of medicine information leaflets showed that complex information was understood less well than simpler information, with drug-drug interactions and contra-indications being difficult to understand. Being older and having less education were both associated with reduced understanding. [211] A review of 168 leaflets on asthma in Britain showed that 97% of leaflets would need to be revised if they were to be understood by most people. It was also found that 99.4% were more than six years old and that 46.4% did not follow the British Thoracic Society guidelines. [212]

Patients with asthma stated that reading information on inhaler technique was insufficient and that they needed to be shown how to use an inhaler, and also that someone should check and correct their inhaler technique. [210] A study of consumer medicines information for 20 different inhalers used in America showed that in many cases it is not presented in a way that assists understanding by patients. [213] Tailored educational interventions have resulted in an improvement in knowledge of asthma, use of medicines and MDI technique. [207]

2.5.4 Implementation of patient education

There are many considerations when providing patients with information. It is important that the patient plays an active role and is not a passive recipient of health care. [1,18,183] Clear, accurate and simple information and instructions are likely to promote understanding and recall. [120,198,201] To achieve this, health-related information can be modified for particular target groups. This is known as 'information remodelling' and is defined by Aboyade [cited in 214] as "the collection and redesigning, remodelling, restructuring, reorganisation and dissemination of information to a peculiar group taking into cognisance the socio-economic, cultural and political backgrounds of the people."

Presenting the information in an organised way improves retention, e.g., telling the patient what is wrong, followed by tests required, what could happen after the tests, what treatment is necessary and what the patient can do to help himself. [190] When providing information, it is important that factual information be accompanied with 'know how' information, which includes practical ways for people to improve their health. [180] Information confirming existing beliefs is more likely to be remembered than information which contradicts these beliefs, and new information is remembered better than when existing knowledge is corrected. [190] A limited number (one to three) key points should be emphasised during encounters between HCPs and patients. [201,215]

Patient education can be individualised or conducted in groups. Education should start soon after diagnosis and be repeated as needed. The Internet can be used to reinforce or provide additional information, but it should not be relied on as the sole source as certain websites omit important information, e.g., websites on asthma may not include any information on asthma in pregnancy. [182]

Providing a patient with information and encouraging him/her to write down questions before the consultation with his/her HCP can result in the consultation time being used more effectively to ensure better understanding of the treatment regimen. Patients are often too embarrassed to admit that they do not understand certain information so open communication is recommended for all patients, [215] as is the reinforcement of the information by all members of the health care team. [216]

Speaking slowly, using simple non-medical language, limiting information, asking patients to repeat information given to them and encouraging questions are recommended, especially when communicating with patients with low health literacy. [198,201,215] Verbal information should always be reinforced with written or visual information, with visual communication

aids being particularly effective for low-literate patients. [21,190,201,210] Educational interventions for older patients and those with less education may need to be longer and of an improved quality. [70]

2.5.5 The quality and impact of educational interventions in asthma

Although many asthma studies have been reported in the literature, the lack of quality in various areas of the research process has compromised their potential impact on the field of educational interventions. A review of 94 studies found that most reports did not include the general and educational objectives of the study, the length of time of the study, the number of sessions spent with the patients, details of who conducted the intervention or whether patients were educated individually or in groups. It was evident that discrepancies existed in training methods and content, duration and number of the interventions and tools used (e.g., peak flow meters and asthma diaries). Because of this, asthma educational interventions are not easy to replicate and it is therefore difficult to determine which educational interventions are the most effective. [217]

Educational interventions delivered by a variety of HCPs have shown a positive impact on knowledge and asthma outcomes. An intervention by a trained nurse educator in Singapore for patients hospitalised for asthma resulted in a significant improvement in some aspects of knowledge, adherence and inhaler technique. [8] Regular nurse-administered education together with counselling from pharmacists in a Taiwanese study showed an improvement in knowledge of asthma and clinical symptoms of asthma. [218] In Australia, knowledge and adherence improved as a result of asthma education by community pharmacists [118,219] and in Brazil, a specially adapted educational intervention by pneumologists for a low-income population resulted in a significant improvement in asthma symptoms, knowledge of asthma and HRQOL. [220] In South Africa, studies in Coloured adults [156] and children [221] dependent on public sector health care facilities showed that an educational intervention by pharmacists resulted in a significant improvement in asthma knowledge, HRQOL, FVC, FEV1 and MDI technique and a reduction in asthma symptoms. Patient education emphasising the regular use of preventers in order to reduce the use of relievers resulted in improved adherence to preventers in a study conducted in Norway. [11]

2.5.6 Patient education for patients with asthma

Patients with asthma want to be kept up-to-date with information on asthma from professional and lay sources. Patient needs should be taken into account when designing medicine information materials. Patients with asthma should be involved in the design of written information as they have insight into what patients need to know and that this written

information should be tested on people with asthma. [210] They and their families would like information about asthma, what causes it, how they can manage the symptoms and problems associated with the disease, the medicines and other treatment, and when to seek professional help. [222,223] Patients with asthma believe that one-to-one verbal interactions with HCPs are important as the information is then tailored to their needs. [210]

An assessment of baseline knowledge of asthma is important before further education is offered. [201] Patients may benefit from regular contact with HCPs during their first few months of treatment so that information can be reinforced. Inhaler technique can also be assessed during these visits. Patients should not receive conflicting information from different HCPs. [68] In patients with asthma, cultural issues regarding asthma symptoms need to be considered as well as language differences in defining asthma symptoms. [46]

It is important that HCPs educate patients of all ages about asthma whenever they interact. [38,66] However, before they can educate patients effectively, HCPs need education regarding the management of asthma and correct MDI technique. [46,63,112,113] Education should take place over a few visits and nurses, doctors, pharmacists and other specially trained HCPs can be used for this. [63,68] Expert patients, i.e., patients with asthma can also be trained to provide education for other patients. [63] To maintain positive behavioural change, social and psychological support may be necessary and here, expert patients and support groups can play an important role. [38]

Time constraints are a limiting factor, but spending time educating patients, especially when asthma is first diagnosed, will save time later and reduce costs related to uncontrolled asthma. [63,133] Both the information and the education process should be personalised according to patient characteristics. [38,120] Core information and skills to focus on include [18,21,58,120]

- possible trigger factors and advice on how to avoid them
- importance of follow-up visits
- worsening signs of asthma
- detection of adverse effects of medicines
- explanation of what asthma is in early interventions
- explanation of the different medicines used
- benefits and use of inhaled corticosteroids
- adverse effects of medicines and how they can be minimised
- goals of treatment that must be agreed upon

- acknowledgement of the effort of patients when goals are attained.

Each admission to hospital for asthma exacerbation should be viewed as a failure of routine management. [21,35] Assessment and treatment while in hospital are usually adequate but the reasons for the exacerbation, establishment of adequate control before discharge and plans for follow-up are often lacking. To reduce further admissions, a suitably qualified HCP should discuss a personalised management plan, which includes adherence, with asthmatic patients. [21] Training on correct MDI technique should be done before patients are discharged from hospital. [63]

2.5.7 Patient education and use of inhalers

Patient education is critical for correct use and effectiveness of inhalers. [66,58] Many studies have shown that MDI technique is poor, indicating that new educational strategies are needed for both patients and professionals. [42] The different learning styles (visual, auditory and kinaesthetic) of people should be taken into account when devising training for inhaler technique. [63] Information alone is usually not enough to improve MDI technique, as users need to see and understand what they are doing incorrectly. [70,135] Educational programmes that include demonstration of correct technique have been found to be effective in improving MDI technique [62,67,70,139,173,224-226] which, in turn, is associated with improvements in peak flow results and asthma control. [70,224]

Prescribers often assume that patients will use inhalers correctly whereas patients often do not realise the importance of inhaler technique. [66] Patients get confused about the differences between inhalers used for prophylaxis (e.g., corticosteroids) and those used to relieve an asthma attack, resulting in the use of corticosteroids for an acute attack. [21,58] The use of two different types of inhalers may also cause confusion, e.g., MDIs require slow inspiration whereas dry powder inhalers require rapid inhalation. [58]

Patients should receive training on how to use inhalers, they should demonstrate satisfactory technique, and regular training is core to maintaining correct technique. [18,53,62,68,70,202,227] Practising MDI technique is associated with improved MDI technique and is more effective than either verbal instructions or leaflets. [70] Practical one-on-one training with an experienced ‘teacher’ proved successful in the UK, but was not compared to group training. [135] Group instruction proved more successful than personal instruction in a study in the Netherlands. [61] Patients must practise the correct method under supervision of a HCP until it becomes automatic. [18,135] The use of video cameras is a useful way of showing patients their incorrect technique. [61,135] Spending more time

instructing patients on how to use their MDIs and regular checking of MDI technique are associated with improved MDI technique. [70] The average time spent teaching MDI technique with verbal instruction together with demonstration in a study in Texas in the USA was just over eight minutes. [173]

Because instructions for MDI technique are complex, they should be broken down into easy-to-follow steps. [120] The following general principles are recommended for HCPs when explaining and demonstrating correct MDI technique: [63,58]

- Make time available to complete the instruction in a suitable environment.
- Have the necessary equipment and spares on hand.
- Engage the patient's attention.
- Verbally explain what you are going to do and the reasons for doing so.
- Demonstrate and explain each step.
- Repeat the MDI technique without talking so as to emphasise the co-ordination needed between actuation and inspiration.
- Repeat the demonstration and explanation again.
- Ask the patient to demonstrate MDI technique, identify different types of inhalers and assemble inhalers and spacers (if using).
- Point out problems and repeat the demonstration of MDI technique.
- Ask the patient to repeat the procedure.
- Ask the patient which steps are most important and which are difficult to implement.
- Explain that MDI technique may be lost over time but that this can be corrected.
- Arrange a follow-up visit and ask the patient to bring his/her inhalers and spacers with.
- Provide family and friends with instruction if required and then explain information leaflets or show videos if available.

2.5.8 Pictograms in health communication

Symbols have been used in many spheres of everyday life, from early cavemen up to and including modern man. They can be used to warn, encourage, instruct and educate and can be used as either a substitute or an adjunct to written or oral language. [205] According to the United States Pharmacopeia (USP) definition, pharmaceutical pictograms are: "Images representing proper ways to take or store medications, precautions, or other important information about a medication that a health care provider should provide to his or her patient." [228] International organisations have established standards for evaluating the comprehensibility of pictorial symbols. The criterion used by the International Standards

Organisation (ISO 3864) is that if a pictorial symbol is interpreted correctly by 67% of those evaluating it, then it is of acceptable comprehension. [229]

Pictograms have been used successfully to convey health-related information but can place extra demands on researchers and HCPs. [185] Pharmacists using pictograms spent more time counselling patients because they had to teach patients what each pictogram depicted. [122] Designing and evaluating pictograms is a complex process requiring input from the target population in all stages. [186] When pictograms are to be used to provide information on medicines, both HCPs and patients should be involved in all stages of the design and testing. [205] Graphic artists play an important role in the design of pictograms.

In a study on product safety pictograms, pictograms were noticed more easily when used with text and, conversely, the presence of a pictogram draws attention to text. Pictograms can be used to supplement the learning process as they can reinforce and remind people of specific information. [230] To investigate the effectiveness of pictograms in facilitating the communication of information, their testing should be done in a real context, i.e., if the intention is to incorporate pictograms into a PIL, then the PIL with pictograms must be tested and not the pictograms alone. [231,232]

2.5.8.1 Factors that influence interpretation of pictograms

A study on interpretation of safety pictograms on general products showed that most abstract symbols need to be learnt. [230] To facilitate correct interpretation of pictograms, training is required and this can be in the form of advertising campaigns in pharmacies, health systems and mass media as well as in schools.

Factors that may influence interpretation of pictograms include patient literacy levels, motivation levels and problem-solving abilities. [223,233] Lower levels of education had a significant negative effect on correct interpretation of USP and locally designed pictograms in South Africa. [234] Correct interpretation of pictograms decreased with increasing age and correct interpretation improved when patients were asked to recall the information illustrated by the pictograms. [235] If patients are presented with large amount of information, then pictograms and their meanings may have to be explained several times in order for patients to remember them. [223] Larger pictograms are more easily interpreted than smaller ones, which has implications for practice as larger ones are more difficult to incorporate into information leaflets and labels due to space restrictions. [235] Pharmacists in a US study of pictogram medicine labels stated that larger medicine containers needed to be used when incorporating pictograms and that this increased their costs. [122] Depicting the passage of

time pictorially is difficult and may not be understood well, [186,236] as is the instruction of what to do if a dose is missed. [233]

2.5.8.2 Acceptability of pictograms by patients

There is generally good acceptability of the use of pictograms in health information materials and an acknowledgement that the presence of pictograms enhances the attractiveness and readability of leaflets. Patients agreed that including pictograms in medicine information leaflets would assist them in locating the headings (dose, side effects, use in pregnancy etc). [237] They also felt that it was a good idea to have pictograms on medicine labels as they play an important role in facilitating the recall of directions for use. [186,209,238-240]

2.5.8.3 Pictograms for targeted populations

Although many pictograms may be understood by people in different countries, the design of pictograms for target populations with certain characteristics, e.g., low literacy is important. [185,186] A study in the UK compared 10 USP and 10 South African pictograms with the same meanings. A significant difference in understanding was found for only two of the 10 pictograms. Correct interpretation varied between the two countries, indicating that culture and place may influence interpretation. [235]

Interviews with black South African adults with <7 years of schooling showed that the participants understood pictograms that had been specially designed for the local population better than the standardised USP pictograms depicting the same information. Participants also preferred the local pictograms in 21 of the 23 cases. Although higher levels of education resulted in better interpretation, the overall influence of education on interpretation was not significant. [186] These USP and locally designed pictograms were then shown to low-literate people from eight different African language groups in South Africa. The local pictograms were preferred in all cases and were better interpreted. There was no significant difference in interpretation between the different language groups and 98% agreed that pictograms should be included on medicine labels. [234] A study in rural Cameroon concluded that “abstract, technical, or obscure visual aids have no meaning to the nonliterate and unsophisticated people with whom many health professionals work. The visuals must be simple, practical, and related to what the patients know and understand.” [185]

2.5.8.4 Evidence for best practice of pictograms

A review of the literature on the use of pictorial aids in medication instructions found that they improved patient recall, understanding of how medicines are used and adherence,

especially when used together with verbal instructions. [236] A study of junior college students in the USA showed that when pictograms were used together with verbal medical instructions, 85% of a maximum of 50 instructions were remembered a few minutes later. When only verbal instructions were given, later correct recall was only 14%, yielding a highly significant difference ($p<0.0001$). [223] In another study, patients with less than grade five reading skills were shown pictograms and had the associated medical instructions explained to them. On being shown the pictograms immediately thereafter, 85% of the 236 medical instructions were recalled correctly, with recall decreasing to 71% after four weeks. This study demonstrates that patients with minimal education are able to recall the correct meaning of pictograms even after a prolonged period of time. [241]
The use of pictograms on medicine labels for low-literate patients on short courses of antibiotics had a positive effect on understanding of instructions and adherence when compared to a control group. The explanation of pictograms on medicine labels did, however, take extra time. [238] A study investigating the influence of pictograms on medicine instructions in visually impaired and non-literate patients found that understanding of directions for use of medicines was better when pictograms were used. [122]

In a Canadian study, where 96% of participants had at least some high school education, five medication labels were tested with and without pictograms. The presence of pictograms did not improve comprehension of instructions on the label and the authors cautioned that physicians should not assume that pictograms improve recall and in fact may cause confusion. However, they also conceded that the pictograms used may have been ambiguous and possibly even misleading. [242]

Various South African studies have described the impact of incorporating pictograms into PILs. PILs with simple text and pictograms were more effective at conveying information to low-literate patients on long-term cotrimoxazole therapy than more complicated text-only PILs. [233] Tablet counts and self-reports showed that adherence improved in patients who were given PILs with simple text and pictograms. [9] In a study investigating the use of recorded audio media and brochures in health and HIV/AIDS communication, the inclusion of pictures in the brochures assisted people in understanding the text information, but limited reading skills severely impacted on the poor understanding of the text. [243]

A PIL that included pictograms designed to communicate information on antiretroviral medicines was tested in Tanzania and was found to be well understood and acceptance was high. [231] A study on illiterate patients in rural Cameroon showed that visual aids designed specifically for that population resulted in significant differences in comprehension and

adherence with antibiotic use when compared to those who received no intervention. Comprehension and adherence improved further in those who received an explanation, together with presentation of the visual aids, of why the antibiotic needed to be taken. [185]

Pictorial asthma plans were designed and tested among three different populations: adults attending a specialist asthma clinic in London, Somalis living in Manchester (UK) and Malaysians living in Malaysia. When asked to offer an interpretation of the pictograms depicted in the asthma plans, the majority of pictograms were interpreted correctly by all three groups. There was also agreement in all three groups for translucency testing, i.e., asking participants how well the pictogram represented an image. This study concluded that pictorial asthma plans are a reasonable alternative to written asthma plans. [244]

2.5.9 Written health information leaflets

The provision of written materials that can be read at home allows patients and their family members more time to assimilate and remember the information. [201,245]

2.5.9.1 Guidelines for developing print materials for low-literate readers

The US National Cancer Institute has developed guidelines for developing print materials for low-literate readers. Some common characteristics of how low-literate people interpret and process information include: [246]

- A tendency to think in concrete or immediate terms rather than in an abstract or futuristic manner
- Interpreting information literally
- An inability to comprehend and apply information from written materials due to insufficient language fluency
- Difficulty with information processing, such as reading a menu, interpreting a bus schedule, following medical instructions, or reading a prescription label.

Guidelines for developing print materials on health for low-literate readers are available from many sources and include the following: [186,230,231,239,245,246]

- Target audience research is required to determine the demographic and behavioural characteristics as well as current knowledge, attitudes, practices and cultural habits, preferences and sensitivities related to the research topic, as well as the most appropriate presentation method.
- Cultural differences must be taken into account. Written information should match the logic (the way the majority of the cultural group thinks), the language and the

experiences that the group can relate to. Images and examples of the cultural group must also be displayed in a positive way.

- Objectives should focus on concrete action, i.e., that the reader will be encouraged to take action and not simply be informed.
- Important points must appear first and last.
- Information must be presented in sections with a clear, ordered format.
- Font style must encourage easy reading and font size should be at least 12 point.
- Medical jargon must be avoided as well as long and complicated sentences.
- Sentences should be written in the active voice and should be simple, specific and direct.
- The reading level should be appropriate for the target population.
- Words used should be familiar to the reader and if new words are used, they must be explained.
- The amount of text should be limited, bullet points should be used where appropriate to make reading easier, and pictograms should be included.
- Text should include upper and lower case and capitalisation of words should be avoided.
- If emphasis is needed, then bolding or underlining should be used.
- Short, easy-to-read and highlighted headings make it easier for patients to navigate through print material.
- The presence of large spaces between paragraphs and important points make print material less intimidating.
- There should be a balance between white space, text and visuals.
- Visuals should relate to the text, be understood and accepted by the target population and placed appropriately.
- The material should be pretested and revised if necessary. Comprehension, attractiveness and acceptability of the material must be assessed.

There may be different minority groups in a country who do not understand the official language. These people are at increased risk of not being able to communicate with HCPs and will also have difficulty comprehending information in medicine information leaflets. [237] Language barriers require the assistance of interpreters, preferably those who have been trained and certified in the specific health care area. [245] Verbal counselling must always accompany the use of PILs that include pictograms and to be effective, the PILs must be memorable, understandable and acceptable. [205,233]

2.5.9.2 Readability testing of written information

The reading level of the text can be assessed using readability formulas. A Grade 3–5 reading level is usually appropriate for low-literate patients although some experts suggest a reading level that is 2–5 times lower than the average highest grade achieved by the target audience. [246]

A commonly used readability test is the SMOG test (Simple Measure of Gobbledegook). [247] SMOG levels are calculated by choosing 10 sentences in the text and then identifying the number of words that contain three or more syllables. According to the National Literacy Trust, “most people will understand a SMOG readability level of about under 10” but they do caution that SMOG levels are “far from an exact science and SMOG should only be taken as one indicator among many for the suitability of a text”. [248]

The Flesch Reading Ease Readability Formula is based on the premise that shorter sentences with fewer long words are easier to understand. A result of 90-100 (the highest possible score) indicate that the text is considered easily understandable by an average grade 5 reader, while a result of 80-90 indicates that it is easy to read by an average grade 6 reader. The lower the result, the more difficult the text is to understand, with scores between 0 and 30 being very confusing and understood only by university graduates. This formula also has its limitations. [249]

2.5.10 Accessibility of information about asthma

Information on asthma can be obtained from international organisations such as the GINA and the Global Alliance against Chronic Respiratory conditions (GARD). [6,250,251] Goals of GARD include collaboration between WHO and GARD organisations to set up programmes to raise awareness for the control, prevention and management of chronic respiratory conditions (including asthma) globally. According to GARD, preventable chronic respiratory conditions and their risk factors do not receive sufficient attention from the health care community, government officials and the media, as well as from patients and families. [251]

Various countries have national organisations that provide resources to asthma patients. The NAEPP in the USA and the British Thoracic Society are two such examples. [48,252] The National Asthma Education Program (NAEP) is a South African initiative that provides information on asthma to HCPs and the public. They also organise workshops and congresses, and take part in media interviews and other activities to improve awareness and management of asthma. [253] However, information from these sources relies mainly on

access to the Internet, which poses a problem for most patients in developing countries. There is therefore a need to design information that is more readily available to patients who are unable to access the Internet.

2.6 Research question, aim and objectives of this study Research question: Does a tailored educational intervention for low-literate asthma patients improve knowledge and management of asthma?

Aim: To investigate the impact of a tailored educational intervention on low-literate patients with asthma.

Objectives:

- to design PILs containing information on asthma, management of asthma and asthma therapy
- to use the PILs to educate low-literate asthma patients
- at baseline and post-intervention to evaluate:
    - self-reported selected HRQOL measures
    - self-reported self-efficacy
    - knowledge of asthma and asthma management
    - knowledge of the use of MDIs
    - MDI technique
- to investigate acceptability and understanding of the PILs.

CHAPTER THREE
METHOD: DESIGN AND EVALUATION OF PATIENT INFORMATION LEAFLETS

3.1 Background

In South Africa, according to the General Regulations of the Medicines and Related Substances Act, 1965 (Act no. 101 of 1965), as amended in 2003, “Each package of medicine shall have a patient information leaflet … in at least English and one other official language.” [254] Having these PILs available in each of the 11 official languages in South Africa would be ideal, but practical implications such as an increase in size of the PIL need to be considered. The beclomethasone and salbutamol MDI package inserts available for use at the study site at the time of the study were available in English and Afrikaans [57,59,255,256], two of the 11 official languages.

Companies that register medicines with the South African Medicines Control Council are required to include PILs with the product. Requirements for the content of PILs accompanying medicines are given in Regulation 10 of the Medicines and Related Substances Act, 1965 (Act no. 101 of 1965), as amended in 2003. [254] However, the PILs designed in this study do not comply with these requirements as they were developed for use by HCPs to assist in patient education.

3.2 Background to study setting and study population

3.2.1 Introduction

The estimated total population in South Africa in 2009 was just over 50 million people, with 61% living in an urban environment. Life expectancy at birth was estimated to be 52 years. [193] South Africa consists of nine provinces, one of which is the Eastern Cape (Figure 3.1). The study was conducted in Grahamstown and in Alexandria (Figure 3.1), both of which are situated in the Cacadu District in the Eastern Cape Province. [257]

According to Statistics South Africa, the Eastern Cape is home to 6.82 million people, constituting 14.4% of the total population (2001 Census). The majority (87.5%) of the population in the Eastern Cape are black Africans with 72.2% living in rural areas. [258] The estimated population in the Cacadu District in 2005 was 401 742 with an average of 6.8 people per square kilometre. [259] IsiXhosa is the most common language and is spoken by 83.4%. [258] The income per capita is low and it is the second poorest province in the country. The poverty rate in the Eastern Cape, at 68.7%, is the highest in the country. [257]

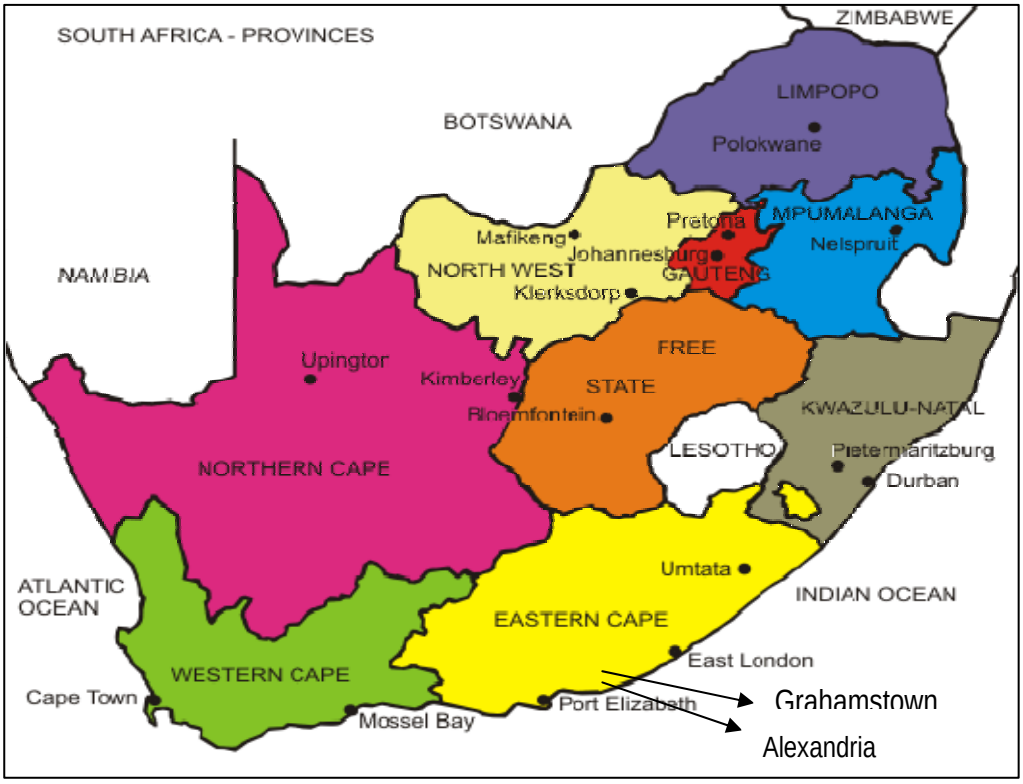


Figure 3.1 South Africa and its nine provinces

Approximately 60.1% of people in the Eastern Cape are functionally literate (defined as a person who is 15 years or older with at least seven years of schooling), with a slightly lower percentage of African blacks (55.9%) falling in this category. It is a matter of concern that 22.8% of people in the Eastern Cape have no schooling and 19.8% have only grade 1-6 education. [258] In South Africa, formal schooling usually occurs in primary schools (grades 1-7) and secondary schools (grades 8-12).

3.2.2 Health care in the Eastern Cape

According to the 2001 Census, there were 1 008 health facilities in the Eastern Cape, most of which are PHC clinics. In the General Household Survey of 2003, 85% of sick people in the Eastern Cape consulted health workers, predominantly doctors and nurses in public sector clinics and hospitals. Almost 91% of people did not have private medical aid but relied solely on public health facilities. Of the total deaths in South Africa in 2002, 14.6% were in the Eastern Cape, the third highest in the country. [258] The most recent figures available on the staff vacancy rate in the Cacadu District health services in 2005/6 was 43%, resulting in an under-resourced health system, which negatively affects service delivery. [259] In 2007/8, the per capita annual expenditure on PHC increased to R265 (approximately US$33), below the national average of R302 (US$37). Community health workers (CHWs) render certain basic health services in the communities in which they live. [260]

3.3 Brief overview of the study

Both Chapters 3 and 4 describe the methods used in the various stages of this project. This study consisted of 5 stages (see pg 67, Figure 3.10).

- Stage 1: Conceptualisation, first draft of PILs, output of modified first draft
- Stage 2: Qualitative evaluation of modified first draft PILs (nurses, PTC members), output of pre-test PILs
- Stage 3: Qualitative evaluation of pre-test PILs (patients, CHWs, PTC members, pharmacists), output of pilot PILs
- Stage 4: Questionnaire development, pilot study – testing of questionnaire, quantitative evaluation of pilot PILs (patients), output of modified questionnaire and PILs
- Stage 5: Quantitative evaluation of final PILs (patients)

This study took place in two public sector PHC clinics in the Cacadu District: the evaluation of the pre-test PILs (Stage 2) and pilot study (Stage 4) were conducted at Settlers Day Hospital in Grahamstown (Figure 3.1) and the main study (Stage 5) at the KwaNonqubela PHC clinic in Alexandria (Figure 3.1). No previous research on asthma had been conducted at the KwaNonqubela clinic, which is a rural clinic 2 km from the closest small town. None of the patients had medical aid and services are provided free of charge. Standard care for patients with chronic conditions such as asthma is that they are required to attend the PHC clinic every 28 days for a medical check-up and to collect a 28-day supply of medicines. Each visit is recorded in a 'health passport', a booklet containing details of medicines dispensed and medical history that the patient retains and which is presented when attending a health care facility.

3.4 Stage 1: Conceptualisation and design of the first draft PILs

The objectives for Stage 1 of this study were to design and evaluate PILs containing information on asthma, management of asthma and asthma therapy that would be suitable for a population with limited reading skills. A graphic designer from the Rhodes University Graphics Services Unit assisted with the design of the draft PILs. As the home language for the majority of patients in this study is isiXhosa, it was decided that the PILs for this study would be designed in English and then translated into isiXhosa.

Guidelines for designing written information, particularly medical information for low-literate individuals, were obtained from various sources [246,261-265] and were consulted in all stages of designing the PILs. Common themes identified were use of simple language (where possible), short sentences and the personalisation of information. As the investigator,

I drew on my previous research in this area, my own experiences of having asthma, as well as my experiences of working in both local public sector hospitals and in an academic environment. I looked at various MDI package inserts which were available in English and Afrikaans but not in isiXhosa. [57,59,255,256] Some contained pharmaceutical pictograms of inhaler technique but none contained pictograms to explain the anatomical changes in people with asthma or trigger factors of asthma.

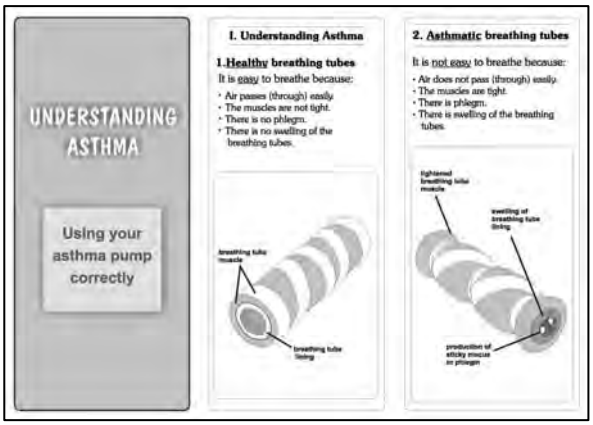
The following information areas were the focus when designing the PILs:

- A z-fold design using landscape A4 paper would be used to ensure easy printing.
- To reduce costs and to facilitate easy distribution, the PILs would be in black and white and saved as an Adobe pdf document for distribution via e-mail to HCPs, patients and asthma health care organisations.
- The low literacy level of the target population was considered. Limited simple text would be used and where possible, medical jargon would be avoided.
- To facilitate understanding by the proposed study participants, the PILs would be translated into isiXhosa by an African Languages expert at Rhodes University and back-translated to check for accuracy of translation by a Rhodes staff member.
- Pictograms relating to the text would be included to enhance understanding and recall. Images familiar to the target audience would be included. For example, many people in the Eastern Cape rely on paraffin stoves for cooking and a pictogram to depict a typical example of a paraffin stove was included in the trigger factors.
- Pictograms would be included to explain basic anatomy of the lungs as it was anticipated that the level of education of the target audience would be low.

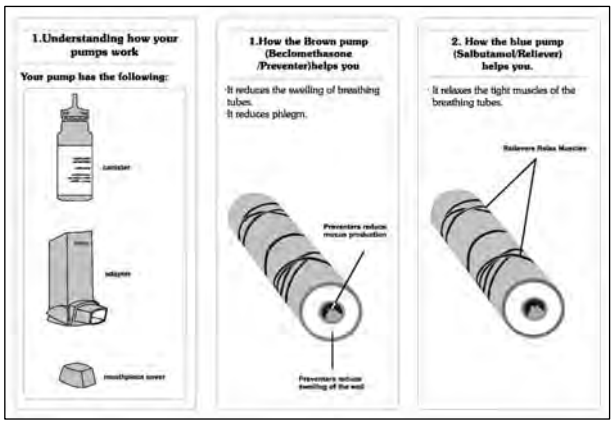
3.4.1 Design of PIL: ‘Understanding asthma’

The first draft of the PIL ‘Understanding asthma’ (Figure 3.2; Appendix A1) consisted of two pages with each page divided into three columns for the z-fold design. It included a simple explanation of the anatomy and physiology of people with and without asthma, an illustration of the components of a MDI, and the influence of the beclomethasone and salbutamol MDIs.

Changes to the first draft PIL were made following personal scrutiny of the PIL and discussions with academic pharmacy colleagues. The modified first draft can be seen in Figure 3.3 (Appendix A2).

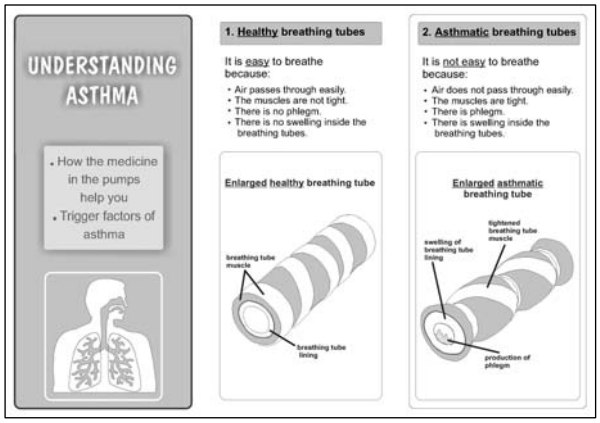


Pg 1

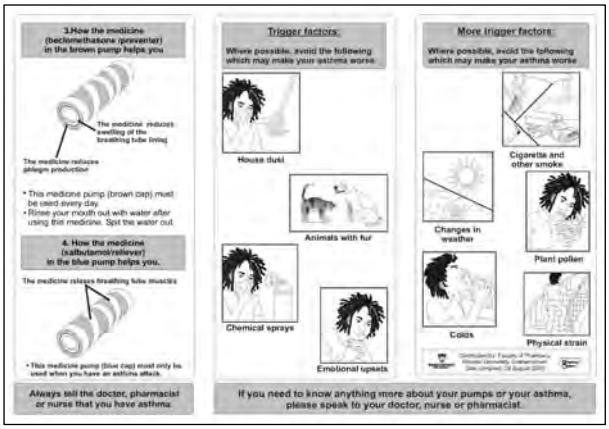


Pg 2

Figure 3.2 First draft: Understanding asthma



Pg 1



Pg 2

Figure 3.3 Modified first draft: Understanding asthma and trigger factors of asthma

The following changes were made:

Page 1:

- The subsection, ‘Using your asthma pump correctly’ below the heading ‘Understanding asthma’ was changed to ‘How the medicine in the pumps helps help you’ and ‘’Trigger factors of asthma’.
- A pictogram illustrating the anatomy of the respiratory system was included.
- The pictograms of the bronchi were labelled ‘Enlarged healthy breathing tube’ and ‘Enlarged asthmatic breathing tube’.
- The orientation of the bronchi pictograms was altered so that both were aligned in the same way.

Page 2:

- The pictograms of the MDI components were removed and replaced with modified pictograms of the influence of the MDIs.
- The text explaining the mechanism of action of beclomethasone and salbutamol was deleted as it was duplicated in the pictogram labels.
- Text explaining the use of beclomethasone was added, i.e., 'This medicine (brown cap) must be used every day' and 'Rinse your mouth out with water after using this medicine. Spit the water out.'
- Text explaining the use of salbutamol was included, i.e., 'This medicine (blue cap) must only be used when you have an asthma attack.'
- Pictograms and text of some of the trigger factors of asthma were included.
- A text box indicating the source of the PIL was included.
- A shaded text box was included at the bottom of the page to emphasize who to speak to for information.

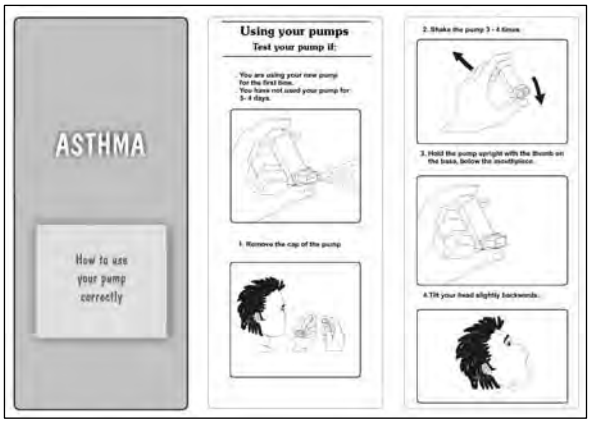
3.4.2 Design of PIL: 'How to use your pump correctly'

The first draft of the PIL 'How to use your pump correctly' (Figure 3.4; Appendix A3) provided an explanation of how to test an MDI and correct MDI technique. As for the previous PIL, it consisted of two pages with each page divided into three columns for the z-fold design. Changes were made to the first draft following personal observation and discussions with academic pharmacy colleagues and these are presented in Figure 3.5 (Appendix A4).

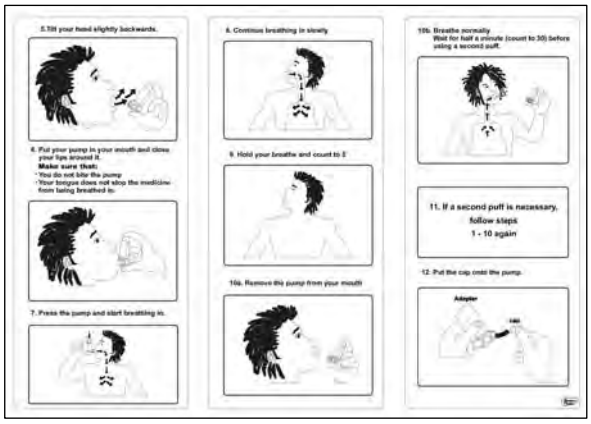
The following changes were made to the first draft:

Page 1:

- The MDI technique information boxes were numbered sequentially from 1 to 12.
- Headings were added: 'How to test your pump' and 'How to use your pump'.
- The components of the MDI were labelled and an arrow indicating the direction in which the canister should be actuated was added.
- Text explaining how to test MDI was included.
- The pictogram of a person's profile was deleted from box 1.
- The canister was shaded (pages 1 and 2).
- Pictogram changes included extending the lines of the body parts to the border of the box to make them appear more realistic (pages 1 and 2).

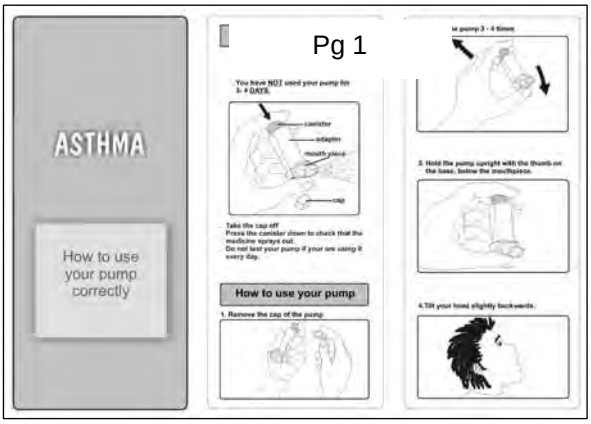


Pg 1

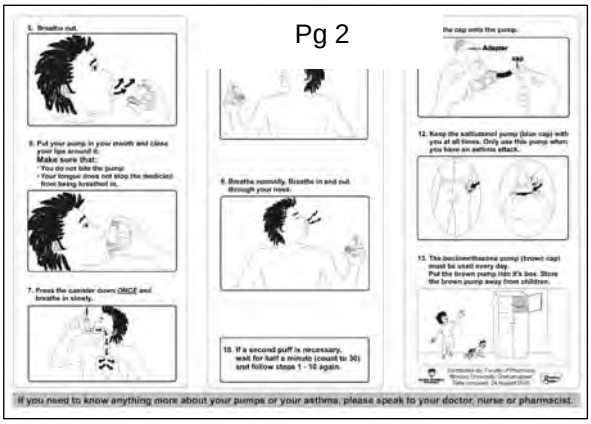


Pg 2

Figure 3.4 First draft: 'How to use your pump correctly'



Pg 1



Pg 2

Figure 3.5 Modified first draft: 'How to use your pump correctly'

Page 2:

- Pictogram changes included adding an outline of the lungs (box 7).
- For box 8, the lungs were deleted and a hand holding an MDI was included.
- Box 9 was deleted and the text for this was added to box 8.
- Boxes 10a, 10b and 11 were replaced with boxes 9 and 10.
- Arrows were added to box 9 to indicate breathing in and out of the nose.
- Additional pictograms were included to provide information pertaining to the use of salbutamol (box 12) and beclomethasone MDIs (box 13).
- A text box indicating the source of the PIL was included.
- A shaded text box was included at the bottom of the page to advise patients whom to speak to for information.

3.5 Stage 2: Evaluation of modified first draft PILs

The PILs were evaluated in two phases using different participants in the phases to assess participant opinion on both the concept of using the PILs and of PIL content, layout and format. [266] The home language of the majority of the participants was isiXhosa.

The first phase of evaluation consisted of:

- Individual interviews with 14 PHC nurses in the Grahamstown area.
- Group discussions, during two PTC meetings in Grahamstown. Various HCPs attend these regular meetings where pharmacy-related issues such as additions/deletions to the medicines formulary, medicine utilisation reviews and budgetary issues are discussed. The first took place at the Settlers Day Hospital PHC clinic and consisted of eight members: one doctor, one pharmacist and six nurses. The second formed part of the Grahamstown District PTC meeting and was attended by four pharmacists.

Participants in the individual interviews and group discussions were all asked the same questions. (Appendix A5)

3.5.1 Results of evaluation of the modified first draft PILs

3.5.1.1 Results: ‘Understanding asthma and trigger factors’

Feedback received from the interviews with nurses and group discussions with HCPs attending the PTC meetings was collated and is summarised in Table 3.1. Positive responses were received on the general appearance of both PILs and the use of pictograms to explain the text.

Table 3.1 Feedback from nurses and PTC HCPs on modified first draft: 'Understanding asthma and trigger factors'

Feedback: Nurses	Feedback: PTC HCPs
Pictograms • What if the patient is only using one type of inhaler e.g. salbutamol? • Everything makes sense • Good pictures • You are the first people showing interest in asthma • I can understand the pictures clearly • It should help the patients • I could use these to explain asthma to my patients • I think the patients will understand these **Text** • Language is simple and easy to understand • Clear, not loaded with information • Simple language and words • Must be in isiXhosa • Add more information on why beclomethasone should be used • Most patients do not use their beclomethasone properly so this will help them to understand why they should	**Pictograms** • I like the diagrams of the breathing tubes • Pictures are great – you need pictures that children will understand. • I like the pictures. • The pictures will help with understanding the information • Text 'air passes through easily' – should be added at the base of the healthy breathing tube as well as for the breathing tubes showing how salbutamol and beclomethasone work • Text – 'air does not pass through easily'- should be added at the base of the asthmatic breathing tube • The pictograms for emotional upsets and colds may be misinterpreted • The salbutamol MDI should be a blue colour and the beclomethasone MDI should be a brown colour **Text** • Instructions are clear and simple • There is a lot of information to read

3.5.1.2 Results: 'How to use your pump correctly'

Feedback from nurses and HCPs is summarised in Table 3.2. Positive responses were received on the general appearance of the PILs and the use of pictograms to explain the text.

Table 3.2 Feedback from nurses and PTC HCPs on modified first draft: 'How to use your pump correctly'

Feedback: Nurses	Feedback: PTC HCPs
Pictograms: • Very accurate and simple • It will help us • Patients will need to practice to do this properly • Patients will understand this when shown the pictures • I did not know that you must shake the pump and tilt the head back **Text:** • Patients will understand this • It will really help patients • Translation into patients' own language is needed • Some patients do not know how to count to five • Simple language	**Pictograms:** • PIL is excellent • PIL will improve adherence • Need a demonstration when explaining the PIL **Text:** • Need to mention side effects of overuse

3.5.2 Modification of PILs

Changes to the modified first draft PILs resulted in the development of the pre-test PILs.

3.5.2.1 Modification of PIL: 'Understanding asthma and trigger factors'

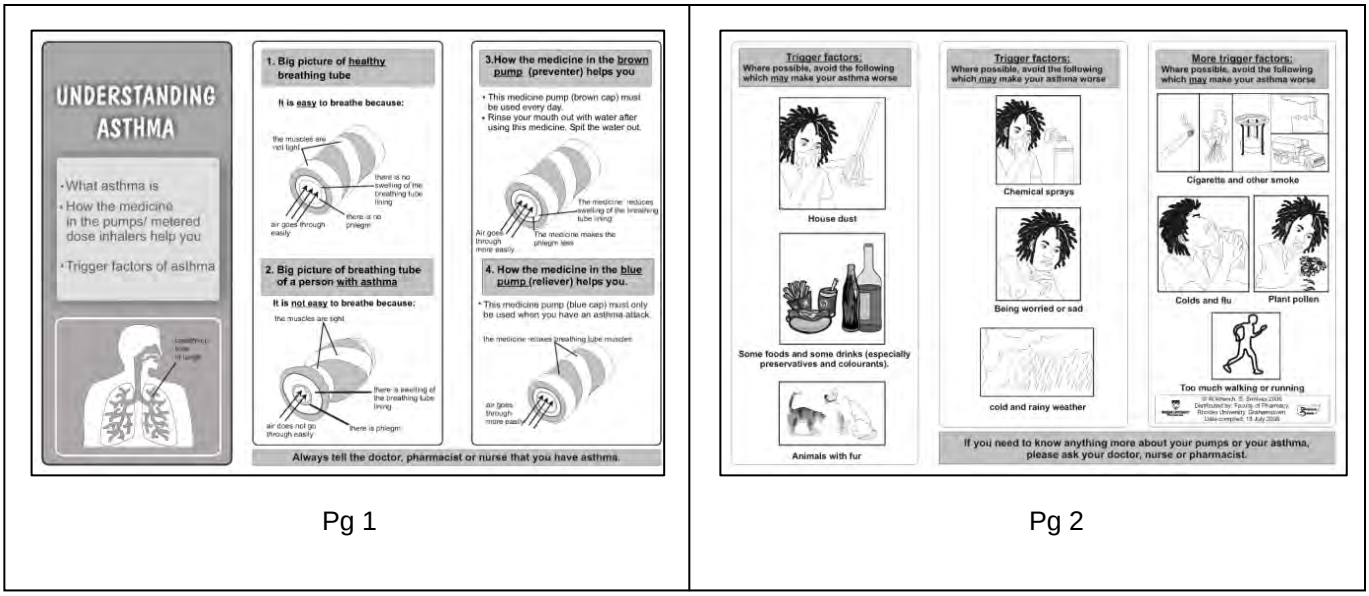
The PIL was modified based on feedback and personal input, resulting in the pre-test PIL shown in Figure 3.6 (Appendix A6).

Page 1:

- Three subheadings were included in column one.
- A label for the breathing tube was included in the pictogram of the respiratory system in column one.
- The pictograms of healthy and asthmatic breathing tubes were included in column two.
- The mechanism of action of beclomethasone and salbutamol were included in column three.
- The headings in columns two and three were simplified, e.g., 'enlarged' was replaced with 'big picture' and the words beclomethasone and salbutamol were deleted.
- The text below the healthy and asthmatic breathing tubes was incorporated as labels for the pictograms.
- Three arrows were used in each pictogram of a breathing tube to indicate easy flow of air while two were used to indicate that air flow through the tube was more difficult in people with asthma.

Page 2:

- All pictograms of trigger factors were included on this page.
- New pictograms were added, i.e., certain foods and drinks, and a paraffin stove.
- All pictograms depicting smoke were grouped together.
- Some text was changed, e.g., 'physical strain' was changed to 'too much walking or running', 'emotional upsets' was changed to 'being worried or sad' and 'colds' was changed to 'colds and flu'.
- Some pictograms were changed, e.g., 'physical strain' was changed to depict a person walking/running.



Pg 1 Pg 2

Figure 3.6 Pre-test PIL: 'Understanding asthma and trigger factors of asthma'

3.5.2.2 Modification of PIL: 'How to use your pump correctly'

Changes to the PIL (Figure 3.7; Appendix A7) based on the feedback obtained after the first evaluation together with personal input were:

- All the text and pictograms were incorporated into one page (A4 landscape) consisting of four columns and three rows as this appeared to be more user-friendly.
- The heading was changed to incorporate the words 'metered dose inhaler'.
- The text and information on testing the pump was deleted to avoid confusion regarding inhaler technique and to save space.
- The pictograms in box 1 were changed and the MDI was labelled and an arrow was included to indicate that the cap must be removed.
- Boxes 2 and 3 ('shake the pump 3-4 times' and 'hold the pump upright with the thumb on the base, below the mouthpiece') were combined into the revised box 2.
- The text 'as soon as you breathe out' was included in the revised box 5 to indicate that actuation takes place when inhalation occurs.
- The pictogram of the torso was removed from box 8 (box 7 in revised PIL).
- Some of the text in the revised boxes 11 and 12 was written in bold, italicised and/or underlined to provide emphasis, e.g., 'The *beclomethasone pump (brown cap) must* **be used every day**".
- Text and arrows to indicate where salbutamol MDIs (revised box 11) and beclomethasone MDIs (revised box 12) were added.

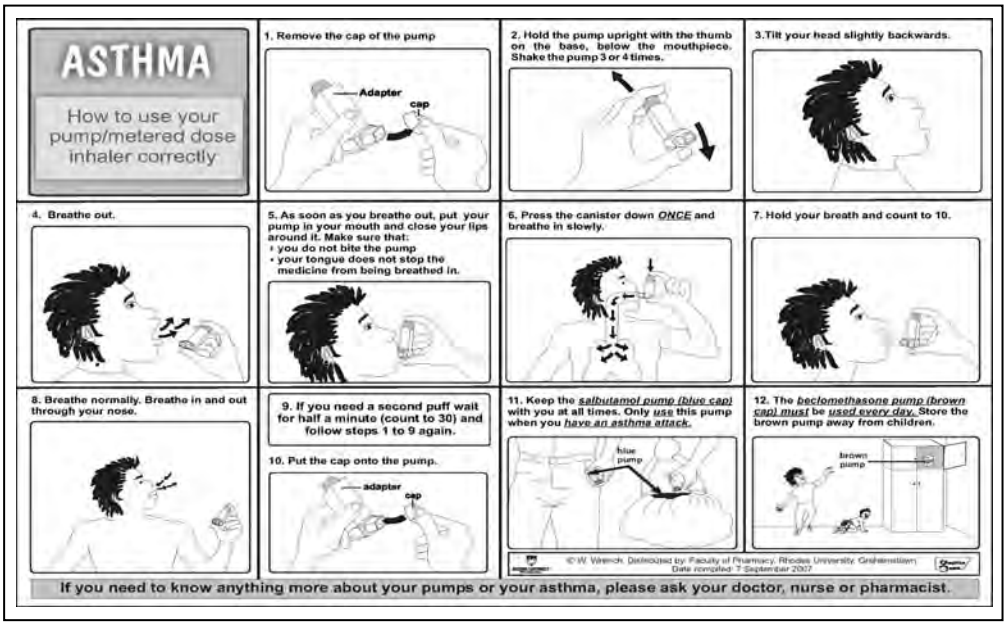


Figure 3.7 Pre-test PIL: 'How to use your pump correctly'

The revised PILs were translated into isiXhosa by an African language specialist. For both of the isiXhosa PILs, a sentence in isiXhosa was included, the English meaning of which is "Translated into isiXhosa by the African Language Studies Section (Rhodes University)" (Appendices A8 and A9).

3.6 Stage 3: Evaluation of pre-test PILs

This stage of the evaluation of the PILs included group discussions with patients, CHWs and members of a PTC. Selected public sector hospital pharmacists and selected members of the Faculty of Pharmacy were also approached to evaluate the PILs.

3.6.1 Patient criteria, recruitment and communication

3.6.1.1 Patient eligibility criteria

Inclusion criteria for patients were the following:

- 18 years or older
- dependant on public sector health care facilities in the Cacadu District Municipality
- diagnosed with asthma
- prescribed a MDI (beclomethasone and/or salbutamol) for at least one month
- English or isiXhosa-speaking

The exclusion criterion for patients in this study was:

- involvement in any other asthma educational intervention during the period of study.

3.6.1.2 Recruitment of patients

Ethical approval to conduct the study was obtained from the Rhodes University Faculty of Pharmacy Departmental Ethics Committee. Permission to conduct the study was obtained from the Eastern Cape Department of Health and the Cacadu District Municipality. Meetings were held with the HCPs responsible for the Settlers Day Hospital and KwaNonqubela PHC clinics during which the details of the study were explained. Questions relating to the study were answered and the HCPs signed an agreement letter. (Appendix A10) The HCPs assisted with identifying patients meeting the eligibility criteria. Patients were informed of the study and if they chose to participate, then informed consent was obtained either by signing their names or by putting a thumbprint on the consent form. (Appendix A11)

3.6.1.3 Communicating with patients

I am fluent in English and Afrikaans and can understand and speak limited isiXhosa. An interpreter, whose home language is isiXhosa, was used during all interactions with isiXhosa-speaking patients and other participants in this study. As a retired nursing sister, she was familiar with the medical terminology used in the study. During her training for her role in this study, I emphasized that simple, familiar words should be used whenever possible and complicated terminology should be simplified and explained to promote understanding. She was also asked to communicate only information that I had asked her to relay, and to avoid offering long explanations that could, inadvertently, prompt patients with clues to the answer.

3.6.1.4 Health-related terms commonly used by patients in the study setting

The correct isiXhosa word for asthma is 'sombefu'[2], but this is seldom used. The English translation of 'isifuba' is 'chest' which is the area of the body where patients experience asthma symptoms. A MDI is commonly known as 'impompo'[3] which translated into English is 'pump', the colloquial word used for a MDI. The word "inqawa"[4] is also used, the English translation of which is 'pipe', as patients relate the use of a MDI to the smoking of a pipe.

From my previous experience, I was aware that salbutamol MDIs were often referred to as 'blue pumps' as the cap and/or canister of these MDIs is blue. Salbutamol or trade names thereof were unlikely to be known by all patients. The same applied to beclomethasone MDIs which were referred to as 'brown pumps'.

[2] On authority of P. Maseko, Department of African Languages, Rhodes University
[3] On authority of J. White, pharmacist Settlers Day Hospital
[4] On authority of J. White, pharmacist Settlers Day Hospital

3.6.2 Evaluation method of pre-test PILs

Patients were recruited, the study was explained and participants were informed that the proceedings would be taped. I briefly explained the purpose of each PIL and stated that they were available in English and isiXhosa. Three group discussions were held at the Settlers Day Hospital PHC clinic in Grahamstown. The home language for all participants, except the doctor and pharmacist, was isiXhosa.

- **First group discussion:** Seven patients with asthma participated. A husband of one of the female patients requested that he be included as a participant in the group discussion as he wanted to learn more about asthma. Questions were asked (Appendix A12) and at the end of the discussion, each patient was given R30 (approximately US$4) to fund transport and acknowledge their time and contribution.
- **Second group discussion:** This formed part of the regular PTC meeting. A total of 13 people took part including one doctor, eight nurses, one enrolled nursing assistant, one pharmacist and three auxiliary workers from the pharmacy. (Appendix A13)
- **Third group discussion:** Nine CHWs signed consent to participate. The questions used for the second group discussion were asked. CHWs did not receive remuneration for their involvement.
- **Informal individual discussions with pharmacists:** The district pharmacist and the two pharmacists employed at the Settlers Day Hospital PHC clinic, as well as two academic pharmacists with previous practice experience in community, hospital and/or PHC pharmacies, were asked to provide feedback on the design and use of the PILs as in the second group discussion. Responses were recorded in writing.

3.6.3 Results of evaluation of pre-test PILs

3.6.3.1 Results: ‘Understanding asthma and trigger factors’

Feedback from patients and HCPs on the pre-test PIL (Figure 3.6) is summarised in Table 3.3. Feedback received from all the discussions was collated. Common themes were identified and are described below. The feedback informed subsequent modification of the PILs and provided support for the potential usefulness of such materials for both HCPs and patients.

Positive responses were received on the general appearance of the PILs. Feedback on the pictograms included having the healthy and asthmatic bronchi adjacent to each other as well as suggestions to make them look more authentic. Words that may be difficult for patients to understand were highlighted and it was suggested that the numbers be deleted from page

one as some readers may interpret them as steps. Inserting a contact number was recommended.

Table 3.3 Feedback from patients, HCPs (PTC members and CHWs) on pre-test PIL: 'Understanding asthma and trigger factors'

Feedback: Patients	Feedback: HCPs
General appearance of the PIL: • I am interested in reading this	**General appearance of the PIL:** • Second page – very nice pictures • Very clear and easy to see what is happening • Appealing to the eye • Drawings which show normal and abnormal airway: can see what is affected when you have asthma • Yes, I think that patients will want to read this but it will have to be explained first
Pictograms: • Understand all the pictures and it is also written in Xhosa • The size is just right	**Pictograms:** • Breathing tubes: lumen not clear, maybe shade; picture does not look like it relates to the body; I'd like to see something more realistic; these would have to be explained to CHWs; relate breathing tubes to lungs; move picture of lungs to top LHS corner • Put 1 and 2 (first page) next to each other. • Which drinks and which foods are you referring to? • Put more fur on animals • Put blocks around labels
Text: • Words are easy to understand • Writing on first page okay but writing on second page is a bit small (isiXhosa) • What are the bottles (trigger factors) • I need some explanation about this pipe that is swollen	**Text:** • Change subheadings to question format • The words preservatives and colourants may be difficult to understand • Sombefu (asthma): don't know this name. It should rather be isifuba or isifuba/sombefu. • List some foods • Zamachiza (chemical sprays) is more Zulu • Pollen: delete umungu then it will be clear. • Number 3: add morning, lunch, once or twice • Number 4: change asthma attack to difficulty in breathing and/or when your chest feels tight • Trigger factors: remove the word more from 3rd column • Add contact number • Maybe space should be left for each clinic to stamp their contact details • Picture of lungs: dark background makes writing difficult to read. • Take the numbers out as they may be interpreted as steps • Weather picture – maybe it should be coloured

3.6.3.2 Results: 'How to use your pump correctly'

Feedback from patients and HCPs on the pre-test PIL (Figure 3.7) is summarised in Table 3.4.

Table 3.4 Feedback from patients and HCPs (PTC members and CHWs) on pre-test PIL: 'How to use your pump correctly'

Feedback: Patients	Feedback: HCPs
General appearance of the PIL: • Yes, when I look at it I want to read it **Pictograms:** • Size is right • Everything is clear **Text:** • It's all written in our language, Xhosa • It's too small	**General appearance of the PIL:** • It's very busy but I think if you take the time to go through it with the patient it would be alright **Pictograms:** • Demonstration necessary • Box 3: mouth can be closed • Box 4: face is not tilting backwards • Box 7: use the same picture as in 6 but take the pump away from the mouth and close the mouth • Box11: may be interpreted as take the inhaler from the handbag and put it in your pocket; the handbag is not clear • Boxes 11 and 12: it says the blue one and the brown one but there is no difference in colour; will the pumps always be blue and brown? • I think that the person looks like a male **Text:** • The words are so small (isiXhosa) • Use left or right hand consistently to hold pump • Box 1: change adapter to pump; canister needs a label • Box 6: add 'at the same time' to the end of the sentence • Box 7: message is not clear; put hand in picture showing 5 fingers; change 'hold your breath' to 'close your mouth' or 'close your mouth, hold your breath and count to ten. • Box11: what is salbutamol? (CHW); change 'asthma attack' to 'difficulty in breathing' and/or 'when your chest feels tight' • Box 12: change store the brown pump away from children to store <u>all</u> medicine away from children; add twice a day to this • Need a pump for demonstration • The words work well with the pictures • Add contact numbers • Add toll-free helpline number

One HCP commented that "it's very busy but I think if you take the time to go through it with the patient it would be alright." Comments on the text below the pictograms included changing the text so that it relates more to the pictograms. The absence of colour to differentiate the 'blue' and 'brown' MDIs was also commented on. One participant also questioned if the salbutamol and beclomethasone adapters and/or mouthpieces would always include blue and brown colouring, respectively. The small font of the isiXhosa text was commented on and it was suggested that contact and toll-free helpline numbers be included.

3.6.3.3 Use of the PILs

The HCPs all agreed that the PILs would be useful as an aid for patient education. Comments included: "I won't forget to tell patient certain things"; "allows patient to engage with HCP and gives patients an opportunity to ask questions" and "support groups where

asthmatics get together could also use these." Time constraints and inability to speak the patient's language were mentioned as barriers. The CHWs agreed that the PILs would be useful but stated that they would need training before using them. Patients and HCPs agreed that the PILs would be of benefit to patients.

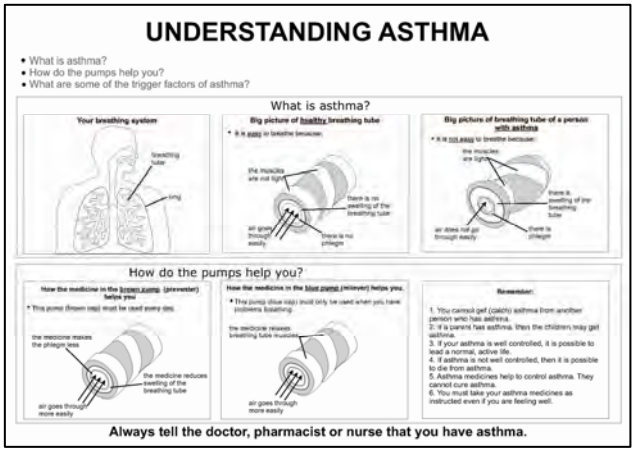
3.6.4 Modifications as a result of the PIL evaluations

Changes to the pre-test PILs resulted in the development of the pilot PILs. The following changes applied to both PILs:

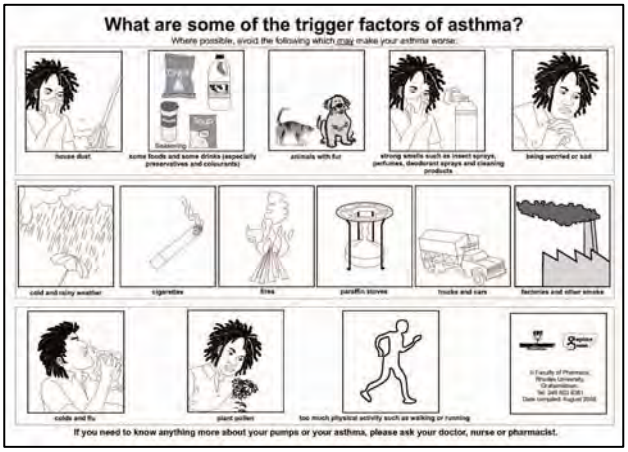
- To facilitate photocopying and use, each page would be printed in grayscale on one side of white A4-size pages.
- The PILs would not be folded as this would be time consuming and may discourage use.
- The PILs would be printed in black and white as colour would increase costs.
- The word 'sombefu' was changed to 'isifuba' (isiXhosa PILs).
- Changes in formatting were implemented, e.g., even spacing of bullet points and an increase in font size.
- The contact details of the Rhodes University Faculty of Pharmacy, the affiliation of the designers, were included.
- Unnecessary text was deleted.
- Frequencies of dosages of beclomethasone were not included as these may vary. [36,53]
- The sequencing of the words "….nurse, doctor or pharmacist" would stay as this is the order in which attendees at public sector PHC clinics come into contact with HCPs.
- Titles of each PIL were denoted in bold using capital letters, Arial font and a font size of 24 pt.
- Headings written in white on a black background were also written in capital letters using Arial font and a font size of 18 pt.
- Sub-headings were written in sentence case in bold using Arial font and a font size of 14 pt while Arial 12 pt was used for the labels for the pictograms which were written in either sentence or lower case.
- The advisory instructions written in white on a black background at the bottom of the PILs were in sentence case and varied in size depending on the space available.

3.6.4.1 Modification of PIL: 'Understanding asthma and trigger factors'

Changes to the pre-test PIL are described and the resulting pilot PIL is displayed in Figure 3.8 (Appendix A14).



Pg 1



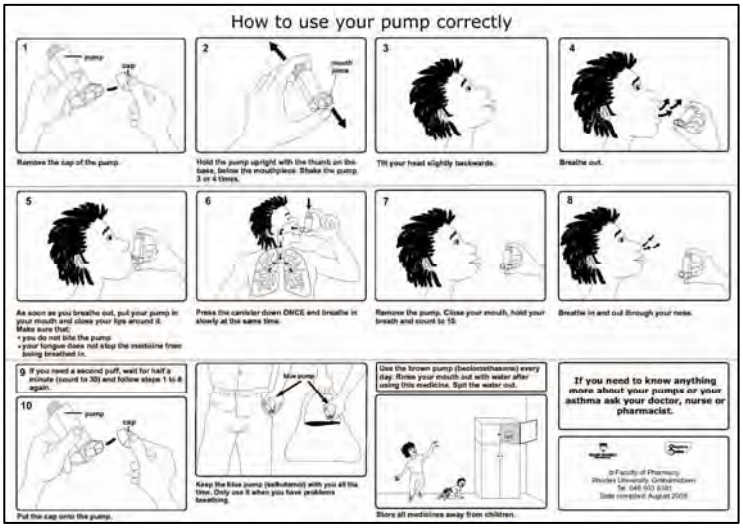
Pg 2

- Questions were included in some of the headings, e.g., ‘What is asthma?’, ‘How do the pumps help you?’ and ‘What are some of the trigger factors of asthma?’
- Numbers were deleted from page one (understanding asthma).
- The pictogram of the healthy breathing tube was placed next to that of an asthmatic’s breathing tube on page 1.
- A new section ‘Remember’ containing additional information about asthma was introduced on page 1.
- A single heading ‘What are the trigger factors of asthma?’ replaced the three trigger factor headings in the z-fold design.

Figure 3.8 Modifications to pre-test PIL and the resulting pilot PIL ‘Understanding asthma and trigger factors’

3.6.4.2 Modification of PIL: ‘How to use your pump correctly’

Changes to the pre-test PIL are described and the resulting pilot PIL is displayed in Figure 3.9 (Appendix A15).



- The word canister (step 1) was changed to pump and, the word mouthpiece (step 2) was added.
- The open mouth (step 3) was changed to a closed mouth and the lungs (step 6) were modified to make them look more realistic.
- 'Press the canister down once and breathe in slowly" (step 6) was changed to 'Press the canister down once and breathe in slowly at the same time'.
- '…count to 10' (step 7) was included.
- The broad shoulders and wide chest (step 8) were deleted.
- The text was changed from above the pictograms to below the pictograms to facilitate association of the text with the pictogram.
- 'Store the brown pump away from children' was changed to 'Store all medicines away from children'.

Figure 3.9 Modifications to pre-test PIL and the resulting pilot PIL "how to use your pump correctly'

These pilot PILs were evaluated in the pilot study to determine patient opinion on their use and acceptability. A brief overview of all stages of PIL development is presented in Figure 3.10.

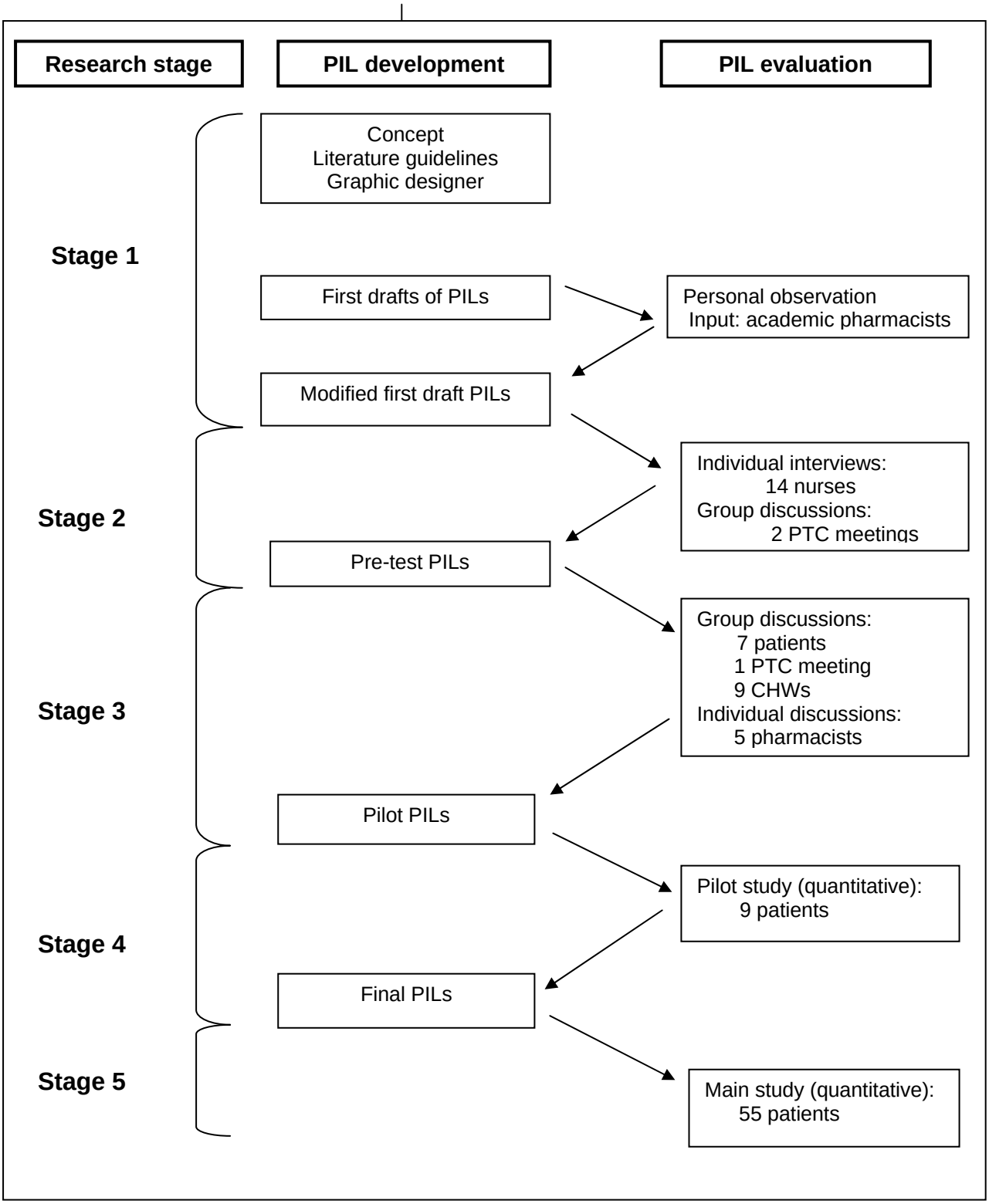


Figure 3.10 Overview of the design stages of the two PILs

CHAPTER FOUR
METHOD: PILOT AND MAIN STUDIES

4.1 Choice of study method

Randomised controlled trials (RCTs) are the 'gold standard' for studies in medical science as they provide more reliable evidence than other study methods when determining the effects of an intervention between control and experimental groups with similar variables. For RCTs, patients are randomly assigned to either a control or experimental group with neither the researchers nor the patients being aware of group allocation [267-269] thereby minimising potential bias and the placebo effect. [49]

Potential problems with having control and experimental groups include possible contamination of the control group, as well as the possibility that the experimental group will not fully utilise the intervention under investigation, referred to as the effect of compliance. [270,271] According to Corneya et al., [270] "contamination refers to the extent to which the control condition has adopted the intervention". If contamination occurs, statistically sound conclusions regarding interventions cannot be made. [272,273]

Ethical concerns to be considered when randomising include depriving patients in the control group of an intervention that is likely to be beneficial or, conversely, subjecting patients in the experimental group to an intervention that is likely to have adverse effects. [267,268] Although it is the patients' choice to become involved in the study, they may have an expectation of a positive outcome from being involved in the study. If the outcome is positive, those in the control group may feel disadvantaged. The converse would also apply, but if it is likely that the outcome will be positive and limited, or no adverse effects are anticipated, then assigning patients to a control group raises ethical concerns. [267,268,274]

The patients in this study were all part of the small rural community of Alexandria in the Eastern Cape, South Africa. A RCT method would require members of the experimental group to retain the information given to them during the educational baseline interviews. This was an unrealistic expectation as this was the first time that a study involving patients with asthma was conducted at the KwaNonqubela PHC clinic and news of this was likely to circulate rapidly throughout the local community. Some patients in the experimental group may also have felt a moral obligation to share the information with their acquaintances in the control group. The PILs therefore, represented a possible source of contamination if patients in the control group were able to access them. It was also possible that, during the baseline interview, patients in the control group identified deficiencies in their knowledge which could

stimulate them to actively seek information. This possible acquisition of ‘new information’ could then result in a change of knowledge and/or behaviour. [272] People in this community generally live and/or work in close proximity to each other, often share the same mode of public transport and attend common social gatherings, resulting in the control group being susceptible to contamination.

A before-and-after study design was adopted [275] in which each patient acts as his/her own control. [276] The impact of the educational intervention is assessed by comparing results pre- and post-intervention.

4.2 Development of the interview questionnaire

4.2.1 Design of the interview questionnaire

The design of the interview questionnaire (Appendix A16) formed part of Stage 4 in this study. The questionnaire consisted of 10 sections and was designed to collect the following data: demographic information; medical history; how asthma affects HRQOL; self-efficacy; knowledge of asthma, asthma management and use of MDIs; MDI technique; and acceptability and use of the PILs. [277-285] It was anticipated that participants in the study would have limited education and would be unlikely to be able to read a questionnaire. Therefore, an interviewer-administered questionnaire was developed.

4.2.2 Categorisation of interview questions

Section 1: Demographic characteristics

Data describing gender, age, race, home language, highest level of education as well as any additional or informal courses, and employment were captured.

Section 2: Medical history

This section documented patients’ self-reported asthma control in the previous two weeks. Here the patient’s opinion of their asthma control was sought and no specific criteria were used to classify asthma control. The medicines being taken for asthma according to both the patients and their health passports were also recorded. The following were enquired upon at baseline only: the time period of having asthma, the time period using MDIs, smoking history and if patients did smoke, what they smoked as well as the quantity smoked per day.

Section 3: Asthma and health-related quality of life measures

Ideas for questions in this section were extracted from HRQOL questionnaires [162,163] and adapted for use with this study population. Questions aimed to assess how signs and symptoms of asthma, activity limitation as a result of asthma and emotional functioning as a

result of asthma affect HRQOL. The first question in this section enquired about the general health of patients and was intended as an ice-breaker to create a rapport between the investigator, the interpreter and the patient. All except the first question in this section started with “During the last 2 weeks” in order for all responses to indicate the same limited time period. Examples were included to promote understanding of the questions. For example, when asking about social life, going to church, visiting friends and participation in family occasions were mentioned. For day-to-day activities, cooking, cleaning, sweeping, washing and working in the garden were given as examples.

Questions in this section and in Section 4 required patients to provide a rating in their responses. To assist patients in giving a response, a column graph visual analog scale was used to graphically depict responses measured on a scale of 0-5 or 0-10. The visual analog scale was printed on the questionnaire below specific questions in Sections 3 and 4. For example, for a question such as: “In general, would you say your health is: poor, fair, good, very good or excellent” (Figure 4.1), a column for each of the five options was depicted in ascending order.

Figure 4.1 Column graph visual analog scale used in pilot study

Section 4: Self-efficacy

The questions in this section aimed to establish the extent to which patients felt confident that they could manage their asthma and including enquiring about partaking in activities, using medicines to manage their asthma and whether they could avoid the trigger factors of asthma.

Section 5: Knowledge of asthma and asthma management

This section consisted of 10 questions. Correct answers are highlighted in Appendix A16 and the overall knowledge scores were expressed as a percentage. Patients’ asthma-related knowledge of the following was elicited:

- the organ involved
- simple pathophysiology of the bronchi

- importance of taking medicines for asthma
- consequences of discontinuing medicines
- if asthma can be cured by medicines
- if it is possible to live a normal, active life
- if there is a genetic component to asthma
- if asthma is infectious
- if asthma is a potentially fatal condition
- potential trigger factors of asthma.

When using the PIL to explain trigger factors to patients, it was emphasised that the trigger factors in the PIL did not apply to all patients with asthma and that patients should try to avoid only the trigger factors that exacerbated their asthma.

Section 6: Baseline knowledge of the use of MDIs

Patients were asked if they had seen, read and/or understood the written information and pictograms in the package inserts received with their MDIs. This section aimed to investigate how and from whom patients obtained information on the correct use of MDIs, and whether they had been shown how to use their MDIs.

Section 7: Use of salbutamol MDI

Questions elicited information on patient opinion of the effectiveness of salbutamol, the number of inhalations used at one time and frequency of use. Accepted correct responses for the how salbutamol ‘works’ were reduction of tightness or relaxation of the muscles in the lungs. The correct response for storage of salbutamol MDIs was having the MDI available for use at all times.

Section 8: Use of beclomethasone MDI

Similar questions were asked as for salbutamol. Of particular importance were the questions pertaining to dose and dosage interval, and adherence issues such as missed doses and daily use of beclomethasone to prevent asthma symptoms. A reduction in inflammation and mucus production in the lungs was accepted as the correct response to the question on the effect of beclomethasone. A correct response was recorded if patients responded that they rinsed their mouths to remove any medicine that was left in the mouth. Patients were asked about storage of their beclomethasone MDIs and the correct response included keeping it away from children and/or heat.

Section 9: MDI technique

The 12 step checklist to measure MDI technique was adapted from the Asthavent®, Venteze®, Ventolin® and Beclate® MDI package inserts. Information from the public sector PHC STGs [43] and assorted other sources were also consulted. [72,74,112,131,135,139,202,286-288] The closed-mouth MDI technique was advocated in all the product inserts and was therefore regarded as correct for this study. Asthavent® and Beclate® MDIs were the MDIs available at the PHC clinics at the time of the study. Questions regarding spacers were included at baseline only.

Section 10: Acceptability of PILs

This section was intended to elicit patients' opinions on the acceptability and use of the PILs. These questions were only asked at the follow-up interviews, at which stage patients had been able to refer to the PILS during the previous four weeks. Questions relating to the written text as well as the use of pictograms were included together with questions relating to the benefit of using the PILs.

4.3 Pilot study

The objective of the pilot study (Stage 4) was to pre-test the research instrument and to obtain feedback on the pilot PILs. Patients were recruited and the study was explained (Sections 3.6.1 and 3.6.2). One-on-one interviews were held with nine patients at the Settlers Day Hospital PHC Clinic in Grahamstown. The patients and the interpreter were encouraged to comment on confusing questions and to suggest any possible changes. The average time per interview was 59 minutes (range 50–65 minutes).

4.3.1 Modifications to the interview questionnaire as a result of the pilot study

The visual analog scale used to record responses to the HRQOL and self-efficacy questions took time to explain as initially patients appeared anxious and confused when shown the graphs. Having two different scales (1-5 and 1-10) added to the confusion. A single standardised visual scale on an A4 sheet of card was therefore devised with five blue ascending columns. The grey column shading used in the pilot study was not adequately bright so blue was chosen as the column colour to draw the attention of the viewer. A zero was also added to the graph to indicate either no or not at all (Figure 4.2).

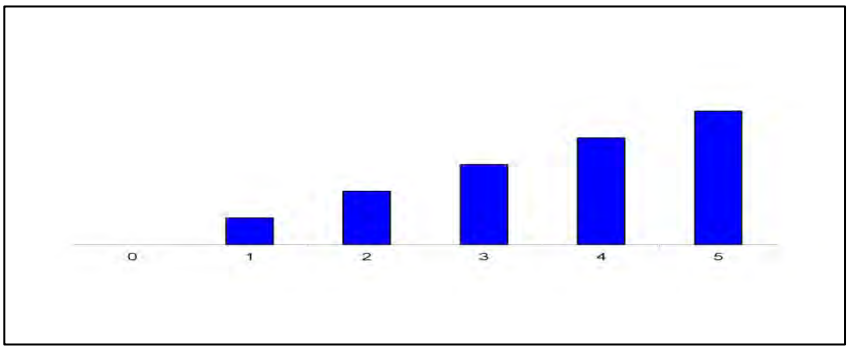


Figure 4.2 Modified column graph visual analog scale

The order of some questions in the acceptability of PILs section was changed to reflect the order in which the PILs were explained to patients. The following questions were modified to improve clarity or to allow for open answers:

- Many patients were unable to "measure" the period of time for various questions, e.g., for "How long have you had asthma?" responses included "a long time" or "can't remember". An option for open answers was added to accommodate such responses.
- "How confident are you that you can do things other than just taking medicines to reduce how much your asthma affects your everyday life?"
  Responses included "I was told to go to the clinic" and "I drink water", neither of which included the avoidance of trigger factors. The question was rephrased to be more direct and asked "Don't think about your asthma medicines for this question. How confident are you that you can avoid the things that make asthma worse?"
- "Do you think that it is possible to catch asthma from sitting in the same room as a person (not a family member) with asthma?"
  The word "catch" was misunderstood and was changed to "get".
- "Do you think that a person can die from having asthma that is not well controlled?", with an additional verbal intervention of: "Explain that it is possible to die from asthma."
  It was evident the information provided was inadequate. The intervention was changed to: "Explain that it is possible to die from asthma that is not well controlled".
- "Can you understand the **written information** in the pamphlet (package insert)?"
  This was changed to two questions: firstly, "Have you read the **written information?**" and secondly, "*If yes,* do you **understand** the written information in the pamphlet?" Only the salbutamol package insert was shown as it was anticipated that the majority of patients would have seen this.
- The two questions: "Have you been given a blue pump?" and "Have you been given a brown pump?" were deleted as this information had already been obtained in the medical history.

A section was added to record referral of patients back to the clinic HCPs if problems with asthma management were identified. Two questionnaires were developed for the main study, i.e., one for the baseline interviews (Appendix A17) and another for the follow-up interviews (Appendix A18).

4.4 The final study PILs

Although no feedback on the design of the PILs was received from patients during the pilot study, further changes were made based on my observations as the interviewer in the pilot study and from input from academic staff members.

4.4.1 Modifications to the layout, format, content and language of the final study PILs

Modifications were made to balance white space, text and pictograms. Headings were made more noticeable by capitalising them and by using white text on a black background to distinguish them from the main body of text, which was black on a white background. Bullet points were used to convey information where text only was used. Text was simplified further to render the PILs suitable for a low-literate population. The order of the pictograms explaining trigger factors was changed so that trigger factors associated with the home were grouped together in the top row, various sources of smoke were grouped in the second row and other unrelated trigger factors were grouped together in the third row. The revised English (Appendices A19 and A20) and isiXhosa (Appendix A21 and A22) PILs were used in the main study. Henceforth, the PIL, “Understanding asthma and trigger factors of asthma’ is referred to as PIL 1 and the PIL ‘How to use your pump correctly’ is referred to as PIL 2.

4.4.2 Readability tests: final PILs

The simplified version of the SMOG test [247] and the Flesch Reading Ease Readability Formula [249] were used to determine the readability level of the printed text in the English PILs. For PIL 1, the first test included the words in brackets and the second test excluded these words as it was anticipated that these technical words consisting of multiple syllables would be more difficult to understand, e.g., colourants and preservatives.

There was good agreement between the SMOG and Flesch results. The second page of PIL 1 was the most difficult to understand with a SMOG level of 14 and a Flesch RE result of 81.37 (text in brackets included), compared with a SMOG level of 13 and a Flesch result of 88.05 exclusive of text in brackets. Although these multisyllabic words increased the reading difficulty, they were included, as substitution with simpler explanations would have lengthened the sentences considerably. PIL 2 was the easiest to understand with a SMOG level of 10 and a Flesch result of 99.17.

According to the National Literacy Trust [248], “most people will understand a (SMOG) readability level of about under 10.” A SMOG readability level of 13 to 14 should be understood by an adult who “understands a range of texts of varying complexity accurately and independently and can obtain information of varying length and detail from different sources.” Flesch results between 90 and 100 (the highest possible score) indicate that the text is considered easily understandable by an average grade 5 reader and a result of between 80 and 90 indicates that it is easy to read by an average grade 6 reader. [249] Therefore, although it was anticipated that patients would find PIL 2 significantly easier to read than PIL 1, the PILs were intended for use together with verbal information, so the few potentially difficult words could be explained.

4.5 Main study

The objectives of Stage 5 of the study were:

- to determine self-reported asthma-related HRQOL measures at baseline and follow-up
- to determine self-efficacy related to asthma management at baseline and follow-up
- to evaluate, in a low-literate Xhosa patient population, the intervention effect of the PILs on knowledge of asthma and asthma management, and on MDI use
- to investigate acceptability of the PILs at follow-up.

The main study took place at the rural KwaNonqubela PHC clinic in Alexandria over the period September 2008 to November 2008. The sample size was determined using the Z-test for proportions power calculation. With a significance level of 5% and the power of the test = 0.80, the calculated sample size for a one-tailed test was 54. The sample size of 55 used in the analysis resulted in the power of the test to be 0.81. All consenting subjects satisfying the criteria were included in the study. The KwaNonqubela PHC clinic is in a rural area and the sample size was limited by the number of patients with asthma attending the clinic.

Recruitment, eligibility and communication with patients are described in Sections 3.6.1-3.6.3. The HCP in charge of the clinic arranged that five patients per day attend the interviews. In most instances, the interviews took place on the date when the patient was due to collect a refill of their prescription. Each interview took place after the patient had completed their consultation with the HCP and had received their repeat prescription. Baseline data were collected at the first interview and follow-up interviews took place approximately 28 days later.

4.5.1 The interview procedure

At the beginning of each one-on-one interview, the investigator introduced herself and the interpreter thanked the patient for attending. To explain the purpose of the study, each patient was given a copy of “Information for Patients in Masters Research: Wendy Wrench” (Appendix A23) and either read it or had the contents explained in detail. Thereafter, the contents of the consent form (Appendix A11) were explained in detail. Patients were encouraged to ask questions if they were unsure of the contents of these two documents. Patients were told that each interview would take approximately an hour to complete. Questions were asked in a non-threatening way and it was emphasised that the study was being conducted to assist patients with asthma. Patients were encouraged to ask questions at any stage of the interview and to give complete and honest responses to questions. When patient responses indicated a lack of knowledge, I explained the correct information.

I then proceeded with the interview as per the questionnaire. (Appendix A17). The relevant section numbers of the questionnaire appear in brackets in the description below. Demographic details (Section 1) and medical history (Section 2) were enquired about. I consulted the patients’ health passports to assess if the patient’s self-report of their current asthma medicines concurred with the chronic prescription in the health passport. The column graph visual analog scale was first explained before being used for the questions on HRQOL (Section 3) and self-efficacy (Section 4). Patients who were unemployed were not asked the question relating to the extent to which asthma interfered with their ability to work.

The first educational intervention took place when enquiring about knowledge of asthma and asthma management (Section 5). PIL 1 was used to explain the anatomy and physiology of the bronchi in the lungs and to explain trigger factors of asthma. When indicated, the text under the heading “Remember” in PIL 1 was also used to explain correct answers to other questions, e.g., that asthma is not infectious.

I then enquired about demonstration of MDI technique and reading of MDI package inserts prior to this study (Section 6). The patients were shown a salbutamol package insert [59], to clarify what was being referred to when asked if they had previously seen one, as I was concerned that they may not be familiar with terminology such as ‘pamphlet’ or ‘package insert’. These questions were only asked at baseline.

The educational intervention continued when enquiring about use of salbutamol (Section 7) and beclomethasone (Section 8). PIL 1 was used to explain the mechanism of action of salbutamol and beclomethasone which were referred to, respectively, as the “blue pump”

and the “brown pump”. If the responses given by the patient did not correspond with the directions for use written in the patient’s health passport, the directions for use according to the health passport were explained. If no directions for use of salbutamol appeared in the health passport, then one to two inhalations every four to six hours when necessary were advised and that inhalations be taken as soon as breathing becomes difficult. [43,53,55] It was explained to patients that in life-threatening situations only, up to 20-50 doses of salbutamol could be given over a few hours if severe difficulty in breathing was being experienced and that an ambulance be contacted if medical assistance was required. [53] I also emphasised that salbutamol should be kept on the person at all times in case of an asthma attack.

The information about beclomethasone explained to patients was as follows:

- The use of beclomethasone helps reduce the incidence and severity of future asthma attacks.
- It must be used continuously on a daily basis, unless otherwise indicated by a doctor. It was explained that daily use of beclomethasone reduced “xakaxa”. [187]
- It takes between one and four weeks of continuous use for a significant improvement in symptoms to become evident.
- It should be used even if the patient is feeling well. [53]
- If a dose of beclomethasone is missed and then remembered soon after, dose can be taken.
- If a missed dose is only remembered just before it is time for the next dose, then the next dose should be taken as usual and not doubled. [36]
- The mouth must be rinsed with water immediately after using beclomethasone to ensure that any medicine in the mouth is removed. The water must be spat out and not swallowed.
- The MDI must be stored away from children and heat.

A spacer was shown to patients when enquiring if they had received one and if they used it. (Section 9) These questions were asked at baseline only. Patients were requested to demonstrate their MDI technique (Section 9) by taking two inhalations from a placebo MDI. The placebo MDIs were obtained from GlaxoWellcome and contained norflurane, an inert propellant. It was explained to patients that the placebo was similar to their MDIs except that it did not contain any ‘medicine’ and that there was ‘air’ (propellant) in the MDI, which might cause a bitter taste on oral inhalation. The adaptor and mouth piece cap for each placebo MDI were sterilised using Milton® (active ingredients: sodium hypochlorite 1% and sodium

chloride 16.5%). Patients were then asked to demonstrate their MDI technique without any prior instructions or prompts. The 12 step checklist was used to confirm correct technique for each step.

The educational intervention was initiated after the patient had completed the demonstration. The investigator explained the correct technique by referring to each step in PIL 2 as well as demonstrating the correct technique. During the demonstration it was emphasised that the medicine (beclomethasone and/or salbutamol) must be inhaled deeply into the lungs as this is the site of action. The investigator pointed to her chest area when doing this. When explaining that it was necessary to hold one's breath for five to 10 seconds after inhalation, the investigator raised her hand and extended her fingers to indicate each number. This was done to assist those who were not familiar with counting and it was hoped that seeing the fingers move would promote memory recall. The same was done when counting to 30 between inhalations. The body language of patients was closely observed to guide the investigator in evaluating the level of understanding. Patients were then required to give a second demonstration and a second intervention was given if necessary.

Where indicated, the investigator wrote referral letters (Section 10) in the patients' health passports. Reasons for referral were documented in the questionnaire and explained to patients so that they were aware of the details of the referral. Any questions regarding these referrals were answered. At the end of each interview, each patient was thanked and received and signed for an honorarium of R30 (approximately US$4) in compensation for their time, transport and any other costs incurred in participating in the study. A return date for the follow-up phase interview was arranged and patients were given a written reminder. Patients took the PILs home with them as a reminder of what was discussed.

The follow-up interview was conducted in a similar manner. Acceptability of the PILs (Section 11) was assessed and pictograms that were not understood and details of misinterpretations were documented. To obtain this information, the investigator pointed at the pictograms in each PIL and asked the patient to explain what it depicted. The ISO criterion (3864) that if a pictorial symbol is interpreted correctly by 67% of patients, then it is of acceptable comprehension was applied in this study. [229] Details of the data collected at each interview are given in Table 4.1.

Table 4.1 Data collected at each interview

Variable	Baseline	Follow-up
Demographics	√	
Medical History	√	questions 2.1-2.3
Asthma and HRQOL measures	√	√
Self-efficacy	√	√
Knowledge of asthma and asthma management (intervention: PIL 1)	√	√
Knowledge of the use of MDIs	√	
Use of salbutamol MDI (intervention: PIL 1)	√	√
Use of beclomethasone MDI (intervention: PIL 1)	√	questions 8.1-8.11; 8.14
MDI technique (intervention: PIL 2)		
1st demonstration of MDI technique by patient	√	√
1st demonstration of MDI technique by investigator	√	√
2nd demonstration of MDI technique by patient	√	√
2nd demonstration of MDI technique by investigator	√	√
Referral	√	√
Acceptability of PILs		√

4.6 Data analysis

Chi-squared tests, using the McNemar-Bowker's test for dependent samples, were used to test for differences in observed frequencies between the baseline and follow-up phases. Pearson chi-squared tests using observed frequencies were conducted to investigate any gender, age and education effects. Bonferroni adjustment to the level of significance was used for multiple comparisons to ensure that the overall level of significance did not exceed 0.05.

Paired t-tests were used to test for differences in overall knowledge score between baseline and follow-up. T-tests for independent samples were conducted to investigate for any gender effect in both phases. One-way analysis of variance (ANOVA) tests were used to determine the effect of age and education. Tukey HSD post-hoc multiple comparison tests were used when the ANOVA results were significant.

It was anticipated that some patients had been given a demonstration of correct MDI technique prior to the study. T-tests for independent samples were used to investigate the pre-intervention effect of having had a demonstration on the mean number of correct steps in the first demonstration of MDI technique at baseline phase. The same tests were used to investigate the influence of pre-intervention understanding of the package inserts accompanying MDIs on the mean number of correct steps in the first MDI technique demonstration at baseline.

Pearson correlation analysis was conducted to determine if there was an association between the variables of length of time with asthma and length of time using MDIs, and the

mean number of correct steps in the baseline phase. For all results, the level of significance was set at a p-value < 0.05.

CHAPTER FIVE
RESULTS

5.1 Admissibility criteria

During the baseline phase, 57 patients were interviewed and 55 returned for the follow-up interview. One patient dropped out for personal reasons and the reason for non-attendance of the second patient is unknown. These two patients were excluded when comparing the findings of the baseline and follow-up phases. The remaining 55 patients all met the inclusion criteria.

5.2 Demographic characteristics

Demographic characteristics of the patients were collected during the baseline interviews and are presented in Table 5.1.

Table 5.1 Demographic characteristics (n=55)

Characteristics	Patients, n (%)
Gender	
Male	17 (30.9)
Female	38 (69.1)
Age (years)	
<50	12 (21.8)
50–59	17 (30.9)
60–69	12 (21.8)
≥70	13 (23.7)
Unable to remember	1 (1.8)
Race	
Black	54 (98.2)
White	1 (1.8)
Home language	
IsiXhosa	54 (98.2)
Afrikaans	1 (1.8)
Highest level of education	
No education	26 (47.3)
Grade 1–7	19 (34.5)
Grade 8–12	10 (18.2)
Additional /informal courses attended	10 (18.2)
Employment	
Unemployed	46 (83.6)
Part-time	5 (9.1)
Full-time	4 (7.3)

The majority (69.1%) of patients were female, and the age range was 18-86 years with a mean age of 58.9 ± 14.2 years. As over three-quarters of the asthma patients were 50 or more years old, the age groupings that were adopted focused on differentiating between higher age groups rather than including more traditional age groupings. One patient appeared to be slightly confused during the interviews, with some questions having to be

repeated, whereas other questions elicited no response at all (Tables 5.10, 5.11 and 5.20). The majority (98.2%) of patients were black and their first language was isiXhosa. One (1.8%) patient was white and spoke Afrikaans as her first language but was also fluent in English. Just under a half (47.3%) had no education, 34.5% had between 1–7 years of formal schooling and 18.2% had 8–12 years of formal schooling. The mean number of years of formal schooling was 3.0 ± 3.8 years. Additional courses such as sewing, beading, gardening and plumbing had been completed by 10 (18.2%) individuals, but none of these courses improved literacy skills. The majority (83.6%) were unemployed, while five (9.1%) worked part-time and four (7.3%) worked full-time.

5.2.1 Association of age, education and gender

Table 5.2 presents the association between age and level of education. One patient was excluded from these results as she could not remember her age and it was not recorded in her health records.

Table 5.2 Association of age and education (n=54, n (%))

Variable	Education			P- value*
	No education	Grade 1–7	Grade 8–12	
Age (years)				**0.001**
<50	0 (0.0)	4 (33.3)	8 (66.7)	
50–59	10 (58.8)	5 (29.4)	2 (11.8)	
60–69	6 (50.0)	6 (50.0)	0 (0.0)	
≥70	9 (69.2)	4 (30.8)	0 (0.0)	

* Significant if p<0.05

In this study the patients in the three older categories had significantly less education compared to the patients in the <50 year old group (Pearson test: p<0.001), a factor that should be taken into account when interpreting the results in this chapter. Patients with no formal education were all older than 50 years. There was no significant association between gender and age (Pearson test: p=0.562) or between gender and education with males and females having similar levels of education (Pearson test: p=0.775).

5.3 Medical history

5.3.1 Medicines prescribed for asthma

Prescriptions in patients' records (health passports) and patient self-reports of asthma medicine(s) used are presented in Table 5.3. Asthma medicines included inhaled beclomethasone, inhaled salbutamol, theophylline tablets and prednisone tablets. The most common self-reported medicine regimen was a combination of beclomethasone, salbutamol and theophylline which was reported by 15 (27.3%) patients at baseline and 18 (32.7%) at follow-up. When comparing the medicines according to patients' self-reports versus

prescriptions written in the patient records, a significant association was found for both baseline and follow-up (Pearson test: p<0.001 for both phases).

Table 5.3 Prescribed asthma medicines (n=55, n (%))

Asthma medicine(s)	Patient record		Patient self-report	
	Baseline	Follow-up	Baseline	Follow-up
Salbutamol	4 (7.3)	4 (7.3)	4 (7.3)	4 (7.3)
Beclomethasone and salbutamol	9 (16.4)	9 (16.3)	11 (20.0)	10 (18.2)
Salbutamol and theophylline	6 (10.9)	4 (7.3)	6 (10.9)	4 (7.3)
Beclomethasone, salbutamol and theophylline	15 (27.3)	18 (32.7)	15 (27.3)	18 (32.7)
Beclomethasone, salbutamol and prednisone	8 (14.5)	9 (16.4)	7 (12.7)	9 (16.3)
Other	13 (23.6)	11 (20.0)	12 (21.8)	10 (18.2)

Details of 'other' medicines in both phases were:

- beclomethasone, salbutamol, prednisone and theophylline
- salbutamol and prednisone
- salbutamol, prednisone and theophylline
- beclomethasone and prednisone

5.3.2 Medical history and asthma control

Table 5.4 presents medical history (baseline only) and patient self-reported asthma control (baseline and follow-up).

Table 5.4 Self-reported medical history and asthma control (n=55, n (%))

Question	Baseline	Follow-up	P-value*
How long have you had asthma? (years)			NC
<5	12 (21.8)	-	
5-20	18 (32.7)	-	
21-40	16 (29.1)	-	
>40	9 (16.4)	-	
How long have you been using asthma pumps? (years)			NC
<2.5	11 (20.0)	-	
2.5-5.0	15 (27.3)	-	
5.1-10	17 (30.9)	-	
>10	11 (20.0)	-	
Unable to remember	1 (1.8)	-	
If you smoke, how many do you smoke?			NC
Non-smoker	51 (92.7)	-	
<5 per day	4 (7.3)	-	
In the last 2 weeks, how has your asthma been?			**0.001**
Completely controlled	5 (9.1)	22 (40.0)	
Somewhat controlled	22 (40.0)	32 (58.2)	
Not controlled at all	28 (50.9)	1 (1.8)	

* Significant if p<0.05; NC = not calculated

The majority of patients (78.2%) reported having had asthma for five or more years with the mean being 21.8 ± 20.6 years (range 1-86 years). The 86-year-old patient reported having had asthma for the entire duration of his life. Most patients (78.2%) had been using MDIs for two and a half or more years with the mean being 7.6 ± 7.11 years (range 0.8-33.0 years). The majority (92.7%) reported that they were non-smokers. There was a significant improvement in asthma control from baseline to follow-up, with those responding that their asthma was completely controlled increasing from five (9.1%) at baseline to 22 (40.0%) at follow-up (McNemar-Bowker test: p<0.001). There was also a marked decrease in those stating that their asthma was not controlled at all, with 28 (50.9%) patients reporting this at baseline while only one (1.8%) reported this at follow-up (McNemar-Bowker test: p<0.001).

5.4 Asthma and selected health-related quality of life measures

Selected HRQOL measures are presented in Table 5.5.

Table 5.5 Selected asthma HRQOL measures (n=55)

Question	Baseline Mean±SD	Follow-up Mean±SD	P-value*
Scale 0 – 5; 0 (poor) to 5 (excellent)			
General health	2.8 ± 0.7	3.3 ± 0.9	**0.001**
Scale 0 – 5; 0 (not at all) to 5 (all the time)			
Effect of asthma on the following (previous 2 weeks):			
Ability to work	1.8 ± 2.1	0.5 ± 0.8	0.158
Social life	2.9 ± 1.7	1.3 ± 1.4	**0.001**
Day to day activities	2.8 ± 1.7	1.6 ± 1.6	**0.001**
Ability to do physical activity	3.2 ± 1.7	2.1 ± 1.7	**0.001**
Ability to sleep well at night	2.7 ± 1.8	1.3 ± 1.5	**0.001**
Scale 0 – 5; 0 (not at all) to 5 (all the time)			
Feeling worried about asthma	3.5 ± 1.3	2.3 ± 1.7	**0.001**

* Significant if p<0.05

The mean score for general health increased significantly from 2.8 ± 0.7 at baseline to 3.3 ± 0.9 at follow-up (Paired t-test: t=4.5, df=54, p<0.001). Generally, it is evident that asthma affected various activities to a lesser extent in the follow-up phase, with this effect being significant (p<0.001) in all cases except the ability to work. Patients were significantly less worried about their asthma, with the score decreasing from 3.5 ± 1.3 at baseline to 2.3 ± 1.7 at follow-up (Paired t-test: t=4.73, df=54, p<0.001).

5.5 Self-efficacy for asthma management

The mean scores for self-efficacy are presented in Table 5.6.

Table 5.6 Self-efficacy scores for managing asthma (n=55, n (%))

Question	Baseline Mean±SD	Follow-up Mean±SD	P-value*
Scale 0 – 5; 0 (not at all) to 5 (totally)			
Confidence regarding the following:			
Controlling asthma so that it does not stop you from doing the things you want to do	2.7 ± 2.1	2.9 ± 1.6	0.575
Using your medicines to manage your asthma	4.7 ± 1.0	4.8 ± 0.5	0.245
Avoiding the things that make your asthma worse	4.1 ± 1.8	4.8 ± 0.6	**0.008**

* Significant if p<0.05

Mixed results were obtained for self-efficacy at baseline and follow-up. Patients were not particularly confident that they could control their asthma in order to avoid it influencing desired activities and this did not improve significantly at follow-up. Patients were, however, more confident that the use of medicines helped manage their asthma, with the majority of patients, 46 (83.64%) at baseline and 47 (85.45%) at follow-up, reporting that they were totally confident about this. The score increased from 4.7 ± 1.0 at baseline to 4.8 ± 0.5 at follow-up, but this increase was not significant (Paired t-test: t=1.18, df=53, p=0.245). Patients were also more confident that they could avoid the trigger factors of asthma and this increased significantly after the intervention from 4.1 ± 1.8 at baseline to 4.8 ± 0.6 at follow-up (Paired t-test: t=2.77, df=53, p=0.008).

5.6 Knowledge of asthma and asthma management

Table 5.7 presents the correct responses for knowledge of asthma and asthma management. There was a significant improvement in the number of patients identifying that it was the lungs that do not function adequately in asthma (Question 1) with only two patients (3.6%) stating this at baseline compared with 34 (61.8%) at follow-up (Paired t-test: t=8.67, df=54, p<0.001). Incorrect responses included the chest, whole body, arms, shoulder blades, neck, waist, ribs, back, legs, lower body, the ears and the throat.

Because the chest is accepted as the area in the body where asthma occurs, those who responded with either chest or lungs for Question 1 were then asked if they were aware of what was occurring in the lungs or chest in people with asthma (Question 2). The response was regarded as correct if swelling, tightness and the presence of phlegm (mucus) in the lungs were all mentioned. The increase in the number of correct responses was not significant with no patients at baseline and only three (5.5%) at follow-up mentioning all three points (Paired t-test: t=1.76, df=54, p=0.083). There were however, significant increases in individual mention of swelling (Paired t-test: t=3.25, df=54, p=0.002), tightness (Paired t-test: t=4.54, df=54, p=0.001) and phlegm (Paired t-test: t=3.32, df=54, 0.002).

Table 5.7 Correct responses: knowledge of asthma and asthma management (n=55, n (%))

Question	Baseline	Follow-up	P-value*
1 Which part of your body is not working properly when you have asthma?	2 (3.6)	34 (61.8)	**0.001**
2 What happens in the lungs/chest when you have asthma?	0 (0.0)	3 (5.5)	0.083
- mentioned swelling	0 (0.0)	9 (16.4)	**0.002**
- mentioned tightness	1 (1.8)	18 (32.7)	**0.001**
- mentioned phlegm	1 (1.8)	12 (21.8)	**0.002**
3 Do you know what causes your asthma attacks?	22 (40.0)	54 (98.2)	**0.001**
4 Do you think that if parents have asthma then their children will have asthma?	37 (67.3)	42 (76.4)	0.279
5 Do you think it is possible to get asthma by being in the same room as another person with asthma?	26 (47.3)	43 (78.2)	**0.001**
6 Do you think it is possible to lead a normal, active life if you have asthma?	27 (49.1)	37 (67.3)	**0.032**
7 Do you think a person can die from having asthma that is not well controlled?	49 (89.1)	53 (96.4)	0.103
8 Do you think it is important to take your medicines for asthma?	53 (96.4)	55 (100.0)	0.159
9 Do you think that if you stop taking your medicines for asthma that your asthma will get worse?	51 (92.7)	54 (98.2)	0.322
10 Do you think that asthma can be cured by taking medicines for asthma?	23 (41.8)	40 (72.7)	**0.001**
Mean knowledge score ± SD	**52.7 ± 5.1**	**75.5 ± 15.1**	**0.001**

* Significant if p<0.05

The number of patients who knew some of the trigger factors of asthma (Question 3) increased significantly from 22 (40.0%) at baseline to 54 (98.2%) at follow-up (Paired t-test: t=8.67, df=54, p<0.001). In the follow-up phase, many more trigger factors from the PIL were mentioned. The majority of patients recognised that there is a genetic component to asthma (Question 4), but greater uncertainty was initially evident about the likelihood of asthma being infectious (Question 5) with 26 (47.3%) patients at baseline responding that it was not infectious. A significantly larger number of patients, 43 (78.2%), at follow-up knew that asthma is not infectious (Paired t-test: t=4.25, df=54, p<0.001). Those stating that it is possible to live a normal life with asthma (Question 6) increased significantly from 27 (49.1%) to 37 (67.3%) (Paired t-test: t=2.21, df=54, p=0.032).

The vast majority of patients answered Questions 7-9 correctly. These dealt with possible mortality associated with asthma and the importance of medicine in controlling the condition. Importantly, there was a significant increase in the number of patients who recognised that medicines could not cure asthma (23 (41.8%) at baseline versus 40 (72.7%) at follow-up) (Paired t-test: t=3.46, df=54, p=0.001).

The overall knowledge score for asthma and its management increased significantly from 52.7 ± 15.1% at baseline to 75.5 ± 15.1% at follow-up (Paired t-test: t=11.0, df=54, p<0.001). The effect of age, gender and level of education on the overall knowledge scores are listed in Table 5.8. The patient who did not know her age was excluded when determining the effect of age.

Table 5.8 Association between overall knowledge score of asthma and asthma management and selected variables (n=55, n (%))

Variable	Baseline		Follow-up	
	Knowledge score Mean±SD	**P-value***	**Knowledge score Mean±SD**	**P-value***
Gender		0.615	73.0 ± 18.3	0.415
Male	51.2 ± 18.0		76.6 ± 13.6	
Female	53.4 ± 13.8			
Age (years)		**0.001**		0.080
<50	63.3 ± 11.6		82.5 ± 7.5	
50-59	57.6 ± 16.4		78.8 ± 13.6	
60-69	44.2 ± 13.1		73.3 ± 20.2	
≥70	44.6 ± 9.7		68.5 ± 13.5	
Education		**0.031**		**0.015**
No education	48.5 ± 13.5		69.6 ± 16.9	
Grade 1-7	53.2 ± 16.7		79.0 ± 12.9	
Grade 8-12	63.0 ± 11.6		84.0 ± 7.0	

* Significant if p<0.05

Gender did not significantly affect the knowledge score at either baseline or follow-up. There was a significant age effect on the knowledge score at baseline, with the younger patients achieving better results. The score decreased from 63.3 ± 11.6% in the youngest age group to 44.6 ± 9.7% in the oldest age group (ANOVA: F=6.63, df=3,53, p=0.001). Tukey HSD post hoc tests indicated a significant difference between the <50 year group and both the 60–69 year group (p=0.005) and the ≥70 year group (p=0.005), as well as a significant difference between the 50-59 year group and both the 60–69 year group (p=0.045) and the ≥70 year group (p=0.049). No significant age effect was observed on the overall score in the follow-up phase (ANOVA: F=2.39, df=3,50, p=0.080).

As anticipated, there was a significant positive association between education and overall knowledge score in both phases. Mean baseline scores increased with higher education from 48.5 ± 13.5% to a high of 63.0 ± 11.6% (ANOVA: F=3.70, df=2,54, p=0.031). Higher scores were obtained in the follow-up phase ranging from 69.6 ± 16.9% to 84.0 ± 7.0% (ANOVA: F=4.57, df=2,52, p=0.015). Tukey HSD post hoc tests indicated that there was a significant difference between those who had no education and those with a grade 8–12 education (p=0.024 at baseline and at follow-up).

5.7 Baseline understanding of package inserts and previous demonstration of inhaler technique

Results for baseline understanding of commercial package inserts and previous demonstration of inhaler technique are presented in Table 5.9.

Table 5.9 Baseline understanding of commercial package inserts and previous demonstration of inhaler technique (n=55)

Question	Patients, n (%)
Have you been shown how to use your asthma pump?	
Yes	48 (87.3)
No	7 (12.7)
If yes, who showed you?	
Pharmacist or pharmacist's assistant	1 (1.8)
Nurse	11 (20.0)
Friends or family	1 (1.8)
Doctor	34 (61.8)
Did not know	1 (1.8)
Have you seen the package insert that came with your asthma pump?	
Yes	52 (94.6)
No	3 (5.4)
Have you read the information in the package insert?	
Yes	6 (10.9)
No	49 (89.1)
If yes, do you understand the written information?	
Yes	1 (1.8)
Partly understood	5 (9.1)
If no, why have you not read them?	
Can't read	32 (58.2)
Not in my language	8 (14.6)
Other reasons	7 (12.7)
Question not asked (investigator error)	2 (3.6)
Have you seen the pictures in the package insert?	
Did not see package insert	3 (5.5)
Yes	49 (89.1)
No	3 (5.4)
If yes, do you understand the pictures in the PIL	
Yes	31 (56.4)
No	17 (30.9)
Partly	1 (1.8)

The results presented in Table 5.9 indicate that the majority (87.3%) of patients responded that they had been shown how to use MDIs, with most (61.8%) having been shown by a doctor. A greater percentage of patients (94.6%) had seen the package insert accompanying their MDI but only five (9.1%) said that they had read it and of these, only one (1.7%) patient claimed to understand the written information. Illiteracy was offered by 32 (58.2%) patients as the main reason for not reading the package insert, with information not being in their home language reported by eight (14.6%) patients as a further reason. Other problems included small font size, poor eyesight and never having been encouraged to read it. Most patients (89.1%) claimed to have seen the pictograms in the package insert with just over half (56.4%) claiming that they could interpret them.

5.8 Use of salbutamol MDI

Table 5.10 represents the results regarding the use of salbutamol.

Table 5.10 Use of salbutamol MDI (n (%))

Question	Baseline (n=53)	Follow-up (n=55)	P-value*
Do you think that salbutamol helps your asthma?			0.625
Yes	48 (90.6)	52 (94.6)	
No	0 (0.0)	1 (1.8)	
Unsure	5 (9.4)	2 (3.6)	
How many puffs do you use each time?			0.117
1	7 (13.2)	3 (5.5)	
2	34 (64.2)	36 (65.5)	
3	9 (17.0)	7 (12.7)	
4	3 (5.6)	8 (14.5)	
No response	0 (0.0)	1 (1.8)	
Do you ever take more puffs than what you said earlier?			0.078
Yes	35 (66.0)	26 (47.3)	
No	18 (34.0)	27 (49.1)	
No response	0 (0.0)	1 (1.8)	
Question not asked (investigator error)	0 (0.0)	1 (1.8)	
If yes, how many?			0.999
2	1 (1.9)	2 (3.6)	
3	14 (26.4)	9 (16.4)	
4	13 (24.5)	12 (21.8)	
5	2 (3.8)	2 (3.6)	
6	2 (3.8)	0 (0.0)	
7	0 (0.0)	1 (1.8)	
8	1 (1.9)	0 (0.0)	
Other	2 (3.8)	0 (0.0)	
How many times a day do you use it?			0.070
Only when required	46 (86.8)	53 (96.4)	
2	4 (7.5)	0 (0.0)	
3	3 (5.7)	1 (1.8)	
No response	0 (0.0)	1 (1.8)	
Do you know how salbutamol works in your body?			**0.001**
Yes	11 (20.8)	27 (49.1)	
No	42 (79.2)	28 (50.9)	
If yes, give details			0.999
Correct	1 (1.9)	4 (7.3)	
Incorrect	10 (18.9)	23 (41.8)	
Where do you keep your salbutamol pump?			**0.001**
Correct	28 (52.8)	53 (96.4)	
Incorrect	25 (47.2)	2 (3.6)	

* Significant if $p<0.05$

The number of patients who had been prescribed salbutamol increased from 53 at baseline to all patients (55) at follow-up due to my recommendation after the baseline interview that salbutamol be prescribed for two patients for whom it had not previously been prescribed (Section 5.11). As would be expected, the majority of patients, 48 (90.6%) at baseline and 52 (94.6%) at follow-up, responded that salbutamol did help their asthma. Dosages ranged from one to four inhalations, with most patients in both phases using two inhalations. The mean number of inhalations at baseline and follow-up were 2.1 ± 0.7 and 2.4 ± 0.8,

respectively, a change which was not significant (Paired t-test: t=1.60, df=51, p=0.117). There was no significant change in the dosage frequency with the majority in both phases responding that they used salbutamol only when required (McNemar-Bowker test: p=0.070).

When asked if more inhalations of salbutamol were taken than initially stated, 35 (66.0%) at baseline and 26 (47.3%) at follow-up replied in the affirmative. The number of inhalations taken ranged from two to eight with the mean number of inhalations being 3.8 ± 1.1 at baseline and 3.7 ± 1.0 at follow-up, a change that was not significant (Paired t-test: t=0.01, df=16, p=0.999). Some patients either could not recall or merely responded with 'many inhalations'. In both the baseline and follow-up phases it was necessary to explain some or all of the directions for use. Directions for frequency of use were not written in the health passport by a HCP at the clinic for the majority of patients (69.1%) at baseline and this did not change at follow-up. I did not refer these patients at baseline and did not write the suggested dose in each patient's health passport. However, I did bring this to the attention of the HCPs at the clinic as general feedback.

Most patients did not know how salbutamol worked in their bodies and had difficulty in expressing themselves when asked this question. However, of the 11 (20.8%) patients at baseline who responded that they did know, only one (1.9%) gave a correct response. Similarly, at follow-up, of the 27 (49.1%) patients who responded that they did know, only four (7.3%) gave a correct response. This change from one to four correct responses was not significant (McNemar-Bowker test: p=0.999). In the baseline phase, only 28 (52.8%) patients reported that they had their salbutamol accessible at all times and this increased significantly to 53 (96.4%) in the follow-up phase (McNemar-Bowker test: p=0.001).

5.9 Use of beclomethasone MDI

Table 5.11 presents the results on the use of beclomethasone. From this table, it can be seen that, at baseline, 42 patients had been prescribed beclomethasone and this increased to 44 at follow-up. A possible explanation is my recommendation following the baseline interview that beclomethasone be prescribed for two patients whose asthma was not well managed on salbutamol only.

Table 5.11 Use of beclomethasone MDI (n (%))

Question	Baseline (n=42)	Follow-up (n=44)	P-value*
Do you think that beclomethasone helps your asthma?			**0.001**
Yes	15 (35.7)	39 (88.6)	
No	15 (35.7)	2 (4.6)	
Unsure	12 (28.6)	0 (0.0)	
Missing	0 (0.0)	3 (6.8)	
How many puffs do you use each time?			**0.001**
1	11 (26.2)	3 (6.8)	
2	20 (47.6)	19 (43.2)	
3	10 (23.8)	3 (6.8)	
4	1 (2.4)	17 (38.6)	
Missing	0 (0.0)	2 (4.6)	
How many times a day do you use it?			0.406
1	13 (30.9)	7 (15.9)	
2	18 (42.9)	24 (54.5)	
3	6 (14.3)	6 (13.6)	
4	2 (4.8)	2 (4.6)	
Missing	3 (7.1)	5 (11.4)	
Do you use it every day?			**0.004**
Yes	14 (33.3)	27 (61.3)	
No	28 (66.7)	15 (34.1)	
Missing	0 (0.0)	2 (4.6)	
If yes, do you know why you need to use it every day?			0.343
Don't know	6 (14.3)	6 (13.6)	
Correct	1 (2.4)	7 (15.9)	
Other	6 (14.3)	14 (31.8)	
No response	1 (2.4)	0 (0.0)	
What do you do if you miss a dose?			NC
Double the next dose	2 (4.8)	4 (9.1)	
Wait until it is time for the next dose	5 (11.9)	17 (38.6)	
Other	2 (4.8)	6 (13.7)	
Missing	33 (78.5)	17 (38.6)	
Do you know how beclomethasone works?			**0.001**
Yes	3 (7.1)	22 (50.0)	
No	39 (92.9)	21 (47.7)	
Missing	0 (0.0)	1 (2.3)	
If yes, explain.			0.317
Correct	0 (0.0)	2 (4.5)	
Incorrect	2 (4.8)	11 (25.0)	
Partially correct	1 (2.4)	9 (20.5)	
Do you rinse your mouth out after using the pump?			**0.001**
Yes	15 (35.7)	36 (81.8)	
No	26 (61.9)	5 (11.4)	
Sometimes	1 (2.4)	2 (4.5)	
Missing	0 (0.0)	1 (2.3)	
If yes or sometimes, why do you rinse your mouth out?			NC
Correct	0 (0.0)	13 (29.5)	
Incorrect	15 (35.7)	24 (54.5)	
Missing	1 (2.4)	1 (2.3)	
Who told you to rinse your mouth out?			NC
Nurse	2 (4.8)	-	
Doctor	2 (4.8)	-	
Not told	38 (90.4)	-	
Where do you keep your beclomethasone?			**0.001**
Correct	28 (66.7)	41 (93.2)	
Incorrect	13 (30.9)	1 (2.3)	
Missing	1 (2.4)	2 (4.5)	

* Significant if $p<0.05$; NC = not calculated

Reasons for ‘missing’ data reported in Table 5.11 included: refusing to respond to the question; some questions not being asked as one patient thought that the beclomethasone was for diabetes; all questions at follow-up not being asked of one patient as beclomethasone had been issued for the first time on the day of the interview; not taking beclomethasone daily; and never missing a dose.

There was a fair amount of ambivalence about patient opinion of the effectiveness of beclomethasone, with only 15 (35.7%) patients at baseline responding that it was effective, whereas this increased significantly at follow-up to 39 (88.6%) (McNemar-Bowker test: $p<0.001$). Just under half (47.6%) at baseline and 43.2% at follow-up responded that they were taking two inhalations (100 mcg) of beclomethasone. There was a marked decrease in the number of patients taking only one inhalation (26.2% at baseline and 6.8% at follow-up) and it was encouraging to note that the percentage of patients taking four inhalations increased from 2.4% to 38.6%. The mean number of inhalations at baseline and follow-up was 2.0 ± 0.7 and 2.8 ± 1.1 respectively, a significant increase (Paired t-test: $t=4.03$, $df=40$, $p<0.001$).

Dosage frequency ranged from one to four times a day with most using beclomethasone twice a day. There was no significant difference in the mean number of times a day that beclomethasone was used, which was 1.9 ± 0.9 at baseline and 2.1 ± 0.7 for the follow-up phase (Paired t-test: $t=0.84$, $df=35$, $p= 0.406$). At baseline, only 14 (33.3%) patients reported using beclomethasone every day and this almost doubled to 27 (61.4%) at follow-up, a significant increase (McNemar-Bowker test: $p=0.004$).

Those who were using beclomethasone every day were asked if they knew why daily use was necessary and correct responses of one (2.4%) at baseline increased non-significantly to seven (15.9%) at follow-up (McNemar-Bowker test: $p=0.343$). Responses provided in both phases that were recorded as “other” included:

- being told to do so by a doctor, clinic staff or myself
- being afraid of night-time asthma attacks
- “making air passages free”
- a reduction in sputum production
- a reduction in swelling
- to “get better”.

At baseline, the directions for use were not written in the health passports for 29 (52.7%) patients, all of whom were then referred with a written suggested dose in each health passport. This was done because as the investigator, I could not make changes to the chronic medication list as this could only be done by an HCP employed at the clinic. However, at follow-up, no changes to the dose on the chronic medication list had been made by the HCPs at the clinic. Some patients in both phases reported that they only used beclomethasone when required for treating the symptoms of asthma. When asked what they would do if they missed a dose, five (11.9%) patients at baseline responded correctly and this increased to 17 (38.6%) at follow-up. Only three (7.1%) patients at baseline reported knowing how beclomethasone worked in their bodies and this increased significantly to 22 (50.0%) at follow-up (McNemar-Bowker test: $p<0.001$). However, when asked to give an explanation, none at baseline and only two at follow-up gave a correct response. Difficulty in articulating the correct response was similar to that found with salbutamol.

At baseline, 15 (35.7%) patients reported rinsing their mouths out with water after using beclomethasone and this increased significantly to 36 (81.8%) in the follow-up phase (McNemar-Bowker test: $p<0.001$). When asked why they did so, none responded correctly at baseline whereas 13 gave the correct response at follow-up. Only four stated that they had been told to rinse their mouths out by either a doctor or a nurse. Correct storage of beclomethasone increased significantly from 28 (66.7%) at baseline to 41 (93.2%) at follow up (McNemar-Bowker test: $p<0.001$).

5.10 MDI technique

Questions regarding spacer devices were asked only at baseline. Only four patients had been issued a spacer device but these were not being used.

5.10.1 Demonstration of MDI technique

The results of the first and second demonstrations of MDI technique at baseline and follow-up are presented in Table 5.12. There was an improvement in all steps except for steps 1 and 12 (remove and replace the mouthpiece cap), as these had been demonstrated correctly by most patients in both phases. It was interesting to note that despite an improvement after the interventions at baseline, this was not retained at follow-up as there was an increase in the incorrect performance of steps 2, 3, 4, 5, 6, 7, 9, 10 and 11 during the first follow-up demonstration. After the second demonstration by patients in both phases, it was necessary for the investigator to provide a third explanation and demonstration of MDI technique to 48 (87.3%) patients at baseline and to 38 (69.1%) patients at follow-up, a decrease that was significant (McNemar-Bowker test: $p=0.013$).

Table 5.12 Incorrect MDI technique results for the two demonstrations at baseline and follow-up (n=55, n (%))

MDI Checklist Step	Baseline		Follow-up	
	1st demo	2nd demo	1st demo	2nd demo
1: Did not remove mouthpiece cap	4 (7.3)	1 (1.8)	1 (1.8)	0 (0.0)
2: Did not hold pump correctly	35 (63.6)	4 (7.3)	12 (21.8)	1 (1.8)
3: Did not shake pump	34 (61.8)	12 (21.8)	21 (38.2)	4 (7.3)
4: Did not tilt head slightly backwards	41 (74.5)	4 (7.3)	8 (14.5)	1 (1.8)
5: Did not breathe out through mouth	52 (94.5)	32 (58.2)	43 (78.2)	19 (34.6)
6: Did not put MDI in mouth correctly	27 (49.1)	10 (18.2)	14 (25.5)	7 (12.7)
7: Did not actuate pump once during inspiration	45 (81.8)	13 (23.6)	30 (54.5)	12 (21.8)
8: Did not remove pump from mouth	15 (27.3)	5 (9.1)	5 (9.1)	3 (5.5)
9: Did not hold breath for 5-10 seconds	47 (85.5)	12 (21.8)	21 (38.2)	8 (14.6)
10: Did not breathe normally through the nose	47 (85.5)	9 (16.4)	21 (38.2)	8 (14.6)
11: Did not wait 30-60 seconds	54 (98.2)	19 (34.5)	47 (85.5)	27 (49.1)
12: Did not replace the cap	6 (10.9)	4 (7.3)	2 (3.6)	1 (1.8)

Table 5.13 presents information on the number of steps demonstrated correctly as well as the mean number of steps correct during the first and second demonstrations at baseline and at follow-up. Before the educational intervention, no patients managed to demonstrate all the steps correctly and this was not much different at follow-up, with only one patient getting all the steps correct. Therefore, all 55 (100.0%) patients at baseline phase and 54 (98.2%) at follow-up, were required to give a second demonstration of MDI technique. Although there was an overall increase (4.6 ± 2.2 to 10.2 ± 1.9) in the mean number of correct steps, it was concerning to note the decline from the second demonstration at baseline (9.7 ± 2.3) to the first demonstration at follow-up (7.9 ± 2.7).

Table 5.13 Steps correct in the two demonstrations of MDI technique at both baseline and follow-up (n=55, n (%))

MDI Checklist Step	Baseline		Follow-up	
	1st demo	2nd demo	1st demo	2nd demo
Zero steps correct	2 (3.6)	1 (1.8)	0 (0.0)	0 (0.0)
All 12 steps correct	0 (0.0)	7 (12.7)	1 (1.8)	15 (27.3)
Mean number of correct steps ± SD	**4.6 ± 2.2**	**9.7 ± 2.3**	**7.9 ± 2.7**	**10.2 ± 1.9**

5.10.2 Effect of selected variables on first demonstrations

Demonstration of MDI technique prior to the intervention was done mostly by either a doctor, 34 (61.8%) or a nurse, 11 (20.0%). Therefore, only these two HCPs were taken into consideration when deciding if previous demonstration by either would have an effect on correct MDI technique. The mean number of correct steps revealed no significant effect (Independent t-test: t=1.55, df=53, p=0.128), with the mean being 4.8 ± 2.2 (had MDI technique demonstrated) versus 3.4 ± 1.5 (no demonstration of MDI technique). Having read the package inserts received with their MDIs prior to the intervention was also not

significantly advantageous with the mean number of correct steps for those who had read them being 5.7 ± 1.6 versus 4.5 ± 2.2 for those who had not (Independent t-test: t=1.24, df=53, p=0.221). There was a weak positive correlation between the number of years of using MDIs and the mean number of correct steps at baseline (r=0.28; n=54; p=0.039).

5.10.3 Comparison of MDI technique to evaluate the effect of the intervention

The influence of the educational intervention was determined by comparing the first and last patient demonstrations of MDI technique. The first demonstration at baseline (pre-intervention MDI demonstration) was compared with the second demonstration at follow-up (post-intervention MDI demonstration). Figure 5.1 illustrates, for each step, the percentage of patients who performed it correctly.

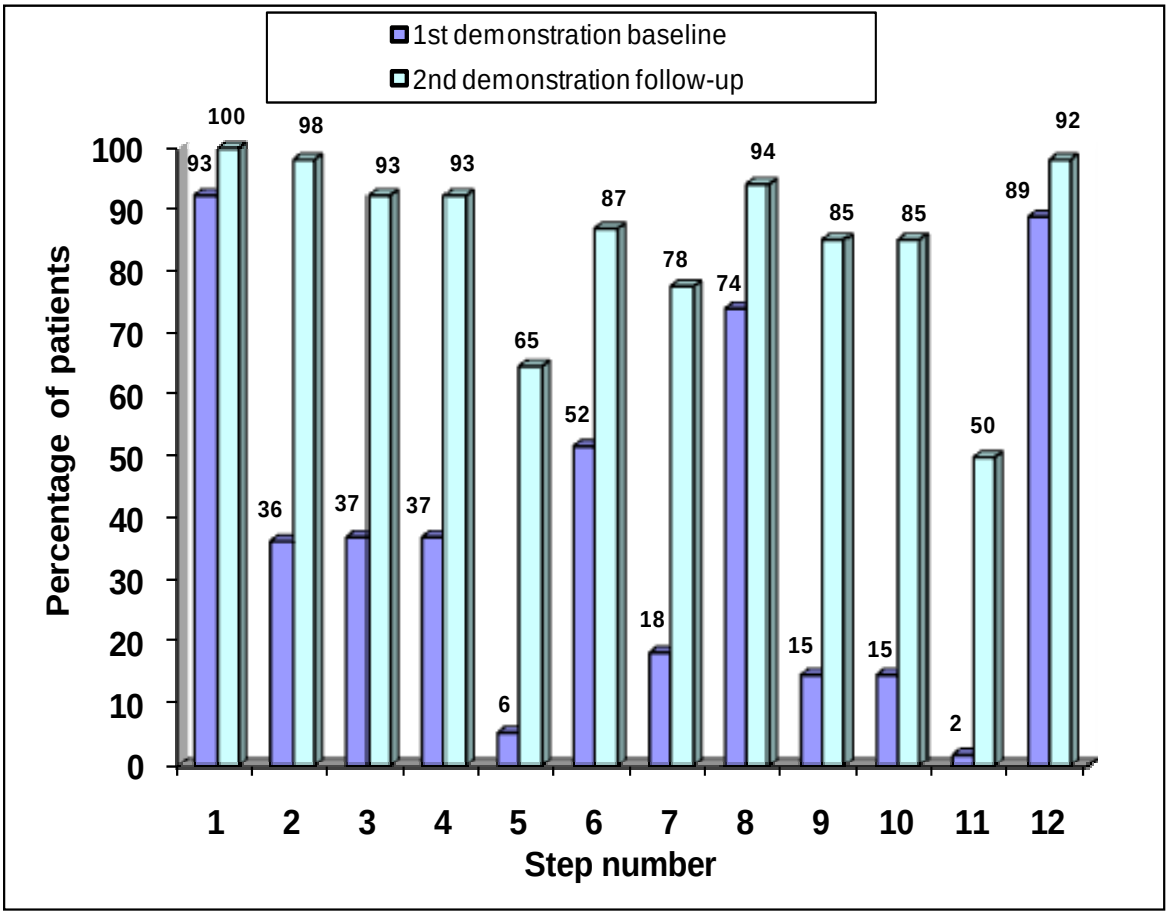


Figure 5.1: Percentage of patients performing each individual MDI step correctly during the 1st demonstration at baseline and 2nd demonstration at follow-up

The only steps showing no significant improvement were the first and last steps (remove and replace the cap) as the majority of patients demonstrated these correctly in both phases. There was a significant improvement in all the other steps. The mean number of correct

steps at baseline increased significantly from 4.5 ± 2.0 to 10.2 ± 1.9 at follow-up (Paired t-test: t=20.32; df=53; p<0.001). Further confirmation of the positive effect of the intervention is illustrated by the number of patients with all steps correct. This increased significantly from zero in the first demonstration at baseline (pre-intervention MDI demonstration) to 15 (27.8%) in the second demonstration at follow-up (post-intervention MDI demonstration) (McNemar-Bowker test: p<0.05).

5.10.4 Identification of common errors in MDI technique

The six steps which incurred the highest number of incorrect responses in the first and second demonstrations in both phases are listed in descending order in Table 5.14. Not exhaling before placing the MDI in the mouth and not waiting for 30-60 seconds between inhalations were the most common errors in all the demonstrations.

Table 5.14 MDI technique steps incurring the highest number of incorrect responses (n=55)

MDI step	Patients, n (%)
1st Demonstration: baseline phase	
Step 11: Did not wait 30-60 seconds before next inhalation	54 (98.2)
Step 5: Did not breathe out through mouth	52 (94.6)
Step 9: Did not hold breath for 5-10 seconds	47 (85.5)
Step 10: Did not breathe normally through the nose	47 (85.5)
Step 7: Did not actuate pump once during inspiration	45 (81.8)
Step 4: Did not tilt head slightly backwards	41 (74.6)
2nd Demonstration: baseline phase	
Step 5: Did not breathe out through mouth	32 (58.2)
Step 11: Did not wait 30-60 seconds before next inhalation	19 (34.6)
Step 7: Did not actuate pump once during inspiration	13 (23.7)
Step 3: Did not shake pump	12 (21.8)
Step 9: Did not hold breath for 5-10 seconds	12 (21.8)
Step 6: Did not put mouthpiece in mouth correctly	10 (18.2)
1st Demonstration: follow-up phase	
Step 11: Did not wait 30-60 seconds before next inhalation	47 (85.5)
Step 5: Did not breathe out through mouth	43 (78.2)
Step 7: Did not actuate pump once during inspiration	30 (54.6)
Step 3: Did not shake pump	21 (38.2)
Step 9: Did not hold breath for 5-10 seconds	21 (38.2)
Step 10: Did not breathe normally through the nose	21 (38.2)
2nd Demonstration: follow-up phase	
Step 11: Did not wait 30-60 seconds before next inhalation	27 (49.1)
Step 5: Did not breathe out through mouth	19 (34.6)
Step 7: Did not actuate pump once during inspiration	12 (21.8)
Step 9: Did not hold breath for 5-10 seconds	8 (14.6)
Step 10: Did not breathe normally through the nose	8 (14.6)
Step 6: Did not put mouthpiece in mouth correctly	7 (12.7)

5.10.5 Effect of age, education and gender on MDI technique

Age had a significant effect with patients ≥50 years old making more errors in certain steps than those <50 years old (Table 5.15). However, there was no significant age effect on the total number of correct steps in both phases.

Table 5.15 Effect of age on MDI technique (n (%))

Incorrect MDI Technique	Age group				P-value*
	<50 years	50-59 years	60-69 years	≥70 years	
1st Demonstration (baseline)					
Did not tilt head back (n=40)	5 (12.5)	14 (35.0)	10 (25.0)	11 (27.5)	**0.037**
1st Demonstration (follow-up)					
Did not shake MDI (n=20)	2 (10.0)	7 (35.0)	8 (40.0)	3 (15.0)	**0.049**
Did not exhale before inspiration (n=42)	5 (11.9)	14 (33.3)	11 (26.2)	12 (28.6)	**0.007**

* Only significant results shown, p<0.05

Significant results for the effect of education on MDI technique are presented in Table 5.16. As anticipated, education had a significant effect with more errors associated with lower educational status. Forty-eight (87.3%) patients did not get all the steps correct in the second demonstration at baseline and therefore required a second demonstration and explanation of correct MDI technique by the investigator, with just over half of these patients having no education.

Table 5.16 Effect of education on MDI technique (n (%))

Incorrect MDI Technique	Education			P-value*
	No education	Grade 1-7	Grade 8-12	
1st Demonstration (baseline)				
Did not tilt head back (n=41)	23 (56.1)	13 (31.7)	5 (12.2)	**0.032**
2nd Demonstration (baseline)				
Did not hold breath for 5-10 seconds after actuation (n=12)	10 (83.4)	1 (8.3)	1 (8.3)	**0.017**
Did not get all steps correct (n=48)	26 (54.2)	14 (29.2)	8 (16.6)	**0.024**
Required a second demonstration by investigator (n=48)	26 (54.2)	14 (29.2)	8 (16.6)	**0.024**
1st Demonstration (follow-up)				
Did not hold MDI correctly (n=12)	10 (83.4)	2 (16.6)	0 (0.0)	**0.015**
Did not tilt head back (n=8)	7 (87.5)	1 (12.5)	0 (0.0)	**0.045**
Did not exhale before actuation (n=43)	25 (58.1)	14 (32.6)	4 (9.3)	**0.001**

* Only significant results shown, p<0.05

Significant gender effects were noted in three steps with females making more errors than males in two of these steps (Table 5.17). There was no significant gender effect on the total number of correct steps in both phases.

Table 5.17 Effect of gender on MDI technique (n (%))

Incorrect MDI Technique	Gender		P-value*
	Male	Female	
2nd Demonstration (baseline)			
Did not hold pump correctly (n=4)	3 (75.0)	1 (25.0)	**0.048**
Did not exhale before actuation (n=32)	6 (18.7)	26 (81.3)	**0.021**
1st Demonstration (follow-up)			
Did not put pump in mouth with lips tightly closed around it (n=14)	1 (7.1)	13 (92.9)	**0.026**

* Only significant results shown, p<0.05

5.11 Referral of patients to the health care system

During the baseline phase, I referred 47 (85.5%) patients to the health care system for further follow-up and/or investigation compared with 37 (67.3%) during the follow-up phase, a significant decrease (McNemar-Bowker test: p=0.021). The following pharmaceutical care recommendations were made:

- For the majority, beclomethasone 200 mcg 12 hourly daily was suggested due to the following inappropriate usage:
    - it was being used when necessary instead of daily,
    - dosages were below those recommended in the PHC STGs, [43]
    - dosage intervals were incorrect (used either once daily or on alternate days) and/or
    - it had been prescribed and patients were either not using it or it had not been dispensed by the PHC clinic.
- Addition of beclomethasone was recommended for two patients whose asthma was not well controlled on salbutamol only.
- Salbutamol was suggested for two patients for whom it had not been prescribed.
- Refills of salbutamol and/or beclomethasone were recommended as patients said that they were “empty”.
- Discontinuation of theophylline was suggested for a patient with a history of gastric ulcers, but continuing with beclomethasone and salbutamol.
- As beta-blockers are not advised in asthma [53,289], discontinuation of atenolol for two patients at baseline was discussed immediately with a HCP at the PHC clinic.
- For those for whom ibuprofen had been prescribed, it was suggested that this be used with caution [290] in future. This was brought to the attention of the HCPs at the clinic.
- Although I explained to one patient that prednisone tablets were not for hypertension, I requested that the HCPs educate the patient at future visits to the clinic.
- Further education by the HCPs to reinforce education given by me during the interview was suggested for a patient who thought that beclomethasone was for diabetes. Further

investigation was requested for various patients reporting pain on the left-hand side of the body, elevated blood pressure, hot flushes, being tearful throughout the interview, poor vision, hyperglycaemia and/or arthritis.

5.12 Acceptability of PILs

Acceptability of the PILs was quantitatively evaluated in the follow-up phase and these results are presented in Table 5.18. Note that patients who were unable to read at all were not asked questions relating to the text, i.e., n= 26 in the first three questions in Table 5.18.

Table 5.18 Acceptability of patient information leaflets (n=55)

Question	Patients, n (%)
Do you think it was easy to read these PILs?	
Yes	26 (47.3)
No	0 (0.0)
Is the writing big enough?	
Yes	25 (45.5)
No	1 (1.8)
Are there any words that you don't understand?	
Yes	2 (3.6)
No	24 (43.6)
Do you like having pictures in the PILs?	
Yes	54 (98.2)
No	1 (1.8)
Are there any pictures you don't understand?	
Yes	46 (83.6)
No	9 (16.4)
Did the PIL help you understand what asthma is?	
Yes	55 (100.0)
No	0 (0.0)
Did the PIL help to remind you about trigger factors?	
Yes	54 (98.2)
No response	1 (1.8)
Did the PIL help you to use your pump correctly?	
Yes	53 (96.4)
No response	2 (3.6)
Did any of your family members read this PIL?	
Yes	45 (81.8)
No	10 (18.2)
Did the PILs help you in any other way?	
Yes	54 (98.2)
No response	1 (1.8)

The 26 (47.3%) literate patients all responded that the text was easy to read, mainly because it was in their home language (isiXhosa). Other reasons included being interested in learning more about asthma, having typed text instead of cursive, having pictures and words on each page, having family members to help them, and being educated and therefore able to read. One patient whose home language was Afrikaans said that the language used in the English PILs was "easy, plain English". Generally, the font size was

adequate and only two of the literate patients reported not understanding certain words such as ‘beclomethasone’ and ‘sebenzisa’ (isiXhosa word meaning ‘work’).

All 55 of the patients felt that the PILs had helped them gain an understanding of asthma. This was a particularly important result as before the intervention many did not understand basic anatomy and physiology of the lungs and the changes that occur in the lungs as a result of asthma. Most patients (98.2%) reported that the PILs helped to remind them about the trigger factors of asthma, with many commenting that the pictograms were helpful. Some also mentioned that before being given the PILs they were unaware of some of the trigger factors of asthma and that they were now trying to avoid those that exacerbated their asthma. Almost all patients (96.4%) reported that the PIL helped with MDI technique and some added that the demonstration of MDI technique by the investigator had also been beneficial. Forty-five (81.8%) said that family members had read the PILs and had also learnt more about asthma.

When asked if the PILs had helped them in other ways, 54 (98.2%) offered responses and these included:

- “Yes, a lot. I’ve never been told about these things before. You’re the first person to help me.”
- “Yes, it’s shown me all the important things.”
- “Yes, I know how to look after myself.”
- “Yes. They helped me a lot. My asthma is not so much.”
- “Yes. I did not know a thing about asthma. I now know what causes asthma.”
- “Yes. I want to know everything about asthma.”
- “They helped a lot because I sometimes forget things. These will help me to remember things about asthma.”
- “Yes, I know more. When I got admitted to hospital nobody told me these things.”
- “Yes a lot. I can see what’s wrong and what’s right.”
- “Yes. I read them. They were interesting.”
- “Yes, before you came, I used to be sick every week. Now I don’t get asthma that much.”
- “Yes. I need to learn more especially about how to use my pump.”
- “Please don’t get tired of teaching.”

5.12.1 Interpretation of pictograms

All but one patient commented favourably on the inclusion of pictograms in the PILs and this patient stated “No, because they showed me what is wrong with me.” Patients were asked to

explain each pictogram with nine (16.4%) offering the correct interpretation for all the pictograms. Table 5.19 lists those pictograms that were incorrectly interpreted.

Table 5.19 Problems with interpretation of pictograms in the PILs (n=55)

Pictogram	Patients, n (%)
Understanding asthma (PIL 1: pg 1)	
Could not differentiate between healthy and asthmatic breathing tubes	6 (10.9)
Could not explain how salbutamol and beclomethasone worked in the body	18 (32.7)
Could explain how salbutamol worked but could not explain how beclomethasone worked in the body	1 (1.8)
Could not explain how salbutamol worked in the body	7 (12.7)
Could partially explain how beclomethasone worked in the body	3 (5.5)
Trigger factors (PIL 1: pg 2)	
Dust	20 (36.4)
Packet of soup (representing food with preservatives and/or colourants)	23 (41.8)
Milk	3 (5.5)
Seasoning (representing food with preservatives and/or colourants)	17 (30.9)
Chips (potato crisps; representing food with preservatives and/or colourants)	16 (29.1)
Fur of animals (dog)	2 (3.6)
Fur of animals (cat)	3 (5.5)
Strong smells	23 (41.8)
Plant pollen	10 (10.9)
Smoke from cigarettes	7 (12.7)
Smoke from fires	8 (14.6)
Smoke from paraffin stoves	2 (3.6)
Smoke from trucks and cars	1 (1.8)
Smoke from factories	31 (56.4)
Cold and rainy weather	26 (47.3)
Colds and flu	29 (52.7)
Being worried or sad	17 (30.9)
Too much physical activity	1 (1.8)
MDI Technique (PIL 2)*	
Step 1	11 (20.0)
Step 2	22 (40.0)
Step 3	12 (21.8)
Step 4	13 (23.6)
Step 5	1 (1.8)
Step 6	6 (10.9)
Step 7	23 (41.8)
Step 8	6 (10.9)
Step 10	13 (23.6)
Keep medicines out of the reach of children	13 (23.6)

* Step 9 information box contained only text and no pictograms

Pictograms on page 1 of PIL 1 (Appendix A19) which did not comply with the ISO 3864 criterion [229] that 67% of pictograms should be interpreted correctly, were the pictograms depicting how salbutamol and beclomethasone worked in the body. On page 2 of PIL 1, the following pictograms did not comply: dust, packet of soup powder, seasoning, chips (potato crisps), strong smells, smoke from factories, cold and rainy weather, colds and flu and being

worried or sad. In PIL 2, the pictograms illustrating steps 2 and 7 did not comply with the ISO criterion rating. Overall, a total of 13 of the 34 pictograms did not meet the ISO criterion.

5.12.2 Effect of age, education and gender on acceptability of the PILs

Age had a significant effect, with patients ≥50 years old having greater difficulty in reading and understanding the PILs when compared to those <50 years old. More patients >50 years old also found that the text was not large enough and in this age group more family members read the PILs. As anticipated, education had a significant effect, with those who had been educated finding it easier to read and understand the PILs. It was interesting to note that the majority of patients whose family members had read the PILs and those who did not understand one or more of the pictograms, had no education. The only significant gender effect was that more females than males had difficulty understanding some of the pictograms.

5.13 Conclusion

There was a significant improvement at follow-up in asthma control, selected HRQOL measures, self-efficacy (ability to avoid trigger factors), overall mean percentage knowledge scores, some aspects relating to the use of salbutamol and beclomethasone MDIs as well as in most steps of MDI technique. The PILs were mostly well understood with 13 (38.2%) of the 34 pictograms not complying with the ISO criterion of 67%. Further modifications to improve understanding will be required, especially for patients with limited or no education.

CHAPTER SIX
DISCUSSION

6.1 Asthma medicines history and asthma control

The intervention described in this thesis resulted in a significant improvement in asthma control and general health with the results concurring with other educational intervention studies on asthma control. [128,291] Despite this finding, only six of the 55 study patients stated at follow-up that their health was excellent. This may have been due to the advanced age of many of the participants as well as co-morbid conditions. Fear of losing a disability grant may also have prompted this response. These grants are often the only regular source of income for patients who rely heavily on them to provide support, often for an extended family. Although confidentiality agreements were signed, some patients may have been concerned that this information would be made available to government authorities administering the disability grants. Reporting good health could possibly result in suspension of the grant, which has been reported in HIV positive people on antiretroviral treatment (ART). [292] Sometimes HIV positive patients who live in dire situations dominated by poverty, unemployment and illiteracy choose to discontinue their ART so that they can maintain low CD4 count levels and continue to qualify for their disability grants. This encourages individuals to maintain a 'sick' role, as they are financially dependent on the disability grants.

A significant positive association was found between patients' self-reported asthma medicines use and the prescription records at both baseline and follow-up, indicating good awareness of their current prescriptions. This association was anticipated because patients were not required to identify medicines by their generic or trade name but rather identified the MDIs by colour and the tablets by colour and size. Medicines were available at no cost to the patients which is in accordance with one of the goals of GARD, i.e., to make medicines available and affordable to all patients with chronic respiratory disease. [251,293]

6.2 Health related quality of life (HRQOL)

Significant improvements in HRQOL were evident in this study and concurred with other studies in which educational interventions resulted in improved HRQOL. [119,123,129,291]. When asked about ability to exercise, patients tended to focus on ability to walk long distances, possibly because asthma impacting negatively on their ability to walk would have a significant impact on their daily lives as most were unemployed and would walk where possible due to lack of income to pay for transport costs. During follow-up, one patient commented that she did not understand the graphically depicted scales used in this and the

self-efficacy section and on observation it was apparent that another patient also had difficulty understanding them. The most likely explanation is lack of education and not having previous exposure to numerically based scales.

6.3 Self-efficacy

The only significant improvement in self-efficacy was avoidance of trigger factors, which may be due to the detailed textual explanation illustrated by pictograms in the "Understanding asthma and trigger factors of asthma" PIL (Appendix A20) designed in this study. Actual avoidance of trigger factors was not measured in this study. Self-efficacy in using medicines to control asthma was high at both baseline and follow-up. Experiences (either of self or of observing others) determine self-efficacy, e.g., if success is experienced, then this improves self-efficacy. [169] Patients reported a significant improvement in asthma control at follow-up and it is anticipated that if they maintain or continue to experience an improvement in asthma control that their self-efficacy is likely to improve.

6.4 Knowledge of asthma and asthma management

After the intervention, knowledge of asthma and its management increased significantly from 53% to 76%. This supports results reported in similar HCP driven educational interventions. [118,220,291,294] Caution is advised in interpreting the study results because of the relatively short time between the educational intervention and follow-up. Moldofsky et al. reported that although knowledge of asthma increased significantly in the experimental group immediately after an educational intervention, it decreased to the level of the control group after 16 months. [295] However, Allen et al. found that a significant improvement in patient knowledge of asthma was maintained for 12 months after the intervention. [219] Ideally, in order to reinforce and clarify information, patient education should be ongoing over a prolonged period of time to reduce the possibility of patients forgetting what they have learnt.

There was a significant improvement in five of the ten knowledge questions in this study. Knowledge of what occurs in the lungs in asthma was poor in both phases with no patients mentioning tightness, swelling and the presence of sputum at baseline and only three of the 55 mentioning all three of these at follow-up. However, it was encouraging that there was a significant increase in the number of patients who mentioned one or two of the aforementioned after the intervention. As the majority of patients in this study had limited or no education, it can be expected that they would have difficulty understanding and recalling the anatomy of the lungs and pathophysiology of asthma. Not having been exposed to biomedical information in the health care or other informal setting could also play a role. In

addition, a considerable amount of information was given to patients at baseline which may have resulted in difficulty in recalling all the information, especially for the older patients. Moreover, since each interview took approximately one hour, some patients got tired and restless, which possibly reduced their ability to retain information.

The vast majority of patients got four of the ten knowledge questions correct in both phases. Additional information volunteered by patients indicated that their responses were based on their own life experiences. For example, nine patients at baseline and 28 at follow-up stated that a family member had asthma and when asked if asthma is contagious one patient stated “No, for years I have been sleeping in the same bed as my cousins and I haven’t given them asthma.” Others responded that their husbands had not acquired asthma from them and one said “No, it’s not like TB.”

At baseline, the majority of patients were unable to identify the cause of their asthma symptoms whereas at follow-up this improved significantly with only one patient unable to do so. These results concurred with studies by Prabhakaran et al. [8] and Janson et al. [128] My study patients were also very interested to know what caused their asthma symptoms. After the trigger factors had been explained with the aid of the PIL at the baseline interview, comments included: “Yoh, I did not know this”, “I will avoid them”, “I’m very happy to get this advice” and “Thank you, I wasn’t sure but now I know that Doom® (insecticide spray) doesn’t agree with me.”

At follow-up it was evident from their responses that many patients had referred to and learnt from the information in the PILs. They were able to identify a number of the trigger factors and the majority knew that it is possible to die from asthma that is not well controlled. Similar increases in knowledge were obtained in a study in patients in a London hospital where 82% were able to recall key information. [222]

A significant age effect on knowledge was found at baseline only with the younger patients achieving better results. The younger patients were more educated than the older patients in this study, which may account for this result. It was encouraging to note that at follow-up, age did not significantly affect the knowledge scores, evidence that older patients can benefit from an educational intervention. There was a significant positive association between education and overall percentage score in both phases with higher scores being obtained by those with more education. A possible explanation for this is that during the apartheid years, i.e., the time when the older patients in this study were of school-going age, there were marked inequities in the quality of education for black Africans. Access to education was

also difficult, especially in rural areas, which may explain why all patients with no education were more than 50 years old. Similar results were found in a study pertaining to cotrimoxazole knowledge by Mansoor and Dowse. [233]

6.5 Baseline knowledge of the use of MDIs

Although the majority of patients stated at baseline that they had been shown how to use MDIs, technique was poor with not a single patient performing all the steps correctly. The date of the most recent pre-study demonstration of MDI technique at the clinic by a HCP could not be established, but if an extended period of time had elapsed between the pre-study demonstration and this study, MDI technique may have been negatively affected. Also, it is not clear if HCPs used a placebo MDI for demonstration purposes or if each step was demonstrated correctly. In my experience as a practising pharmacist, HCPs sometimes use a salbutamol or beclomethasone MDI to demonstrate technique and because they do not want to inhale the active ingredient, they do not put the mouthpiece in their mouths, do not actuate and/or do not inhale. The patient may then repeat what they have seen when at home, even if the HCP gives verbal instructions that the MDI put the mouthpiece should be put in the mouth and that patients must actuate while inhaling.

Four (7.3%) patients had been issued a spacer device but these were not being used. Similar results were found in a study in the UK where 93% of patients were using an MDI without a spacer. [296] Spacers are particularly useful when patients have difficulty co-ordinating actuation and inhalation when using their MDIs. [21,58,67] In this study, patients found co-ordination difficult, and therefore the use of spacers may need to be considered by this and other public sector PHC clinics.

An Italian study identified that reading of the package insert was significantly associated with both higher education and correct MDI technique. [70] Only six patients in my study stated that they had read the package insert accompanying their MDI and of these, only one claimed to have understood the written information. This finding is not an unexpected one given the low average level of education of the patients and their poor literacy skills. It was interesting to note that the six patients who had read the package inserts had an average education of grade 9, markedly higher than the study average of grade 3. As patients often use the package insert to recall and reinforce information that is verbally communicated by HCPs, their inability to read the MDI insert possibly explains why their MDI technique was poor.

6.6 Knowledge of salbutamol use and how it works in asthma

Significantly more patients stated that they knew how salbutamol relieved their asthma after receiving the intervention, although only four patients were able to actually offer a simple explanation. Limited education is the most likely explanation for this but the length of the interview and amount of information given as discussed in Section 6.4 may also have played a role. Although this means that only 7% of the study population had this kind of insight, it is unclear whether this type of knowledge presents any barrier to optimal usage. It is possible that patients are more concerned about the dose that needs to be taken to relieve asthma symptoms than the mechanism of action of salbutamol.

In both the baseline and follow-up phases it was necessary to explain some or all of the directions for use to the majority of patients. At follow-up, an increase in the correct responses to the two questions investigating dose and frequency of use of salbutamol inhaler was noted. This indicates the potential of effective educational interventions to decrease indiscriminate use of beta-agonist inhalers.

The importance of keeping salbutamol on hand so that it could be used for early treatment of asthma symptoms is important because this is the best strategy for minimising exacerbations. [35] In my study there was a significant increase in patients reporting that they had their salbutamol MDIs accessible at all times. In a study by Prabhakaran et al. [8], an educational intervention resulted in an insignificant increase in having salbutamol MDIs available as the majority already did so at baseline. It was interesting to note that at baseline in my study, 22 patients stated that they left their salbutamol MDIs in various places in the home, responses that were recorded as incorrect. The question was phrased as “Where do you keep your blue pump?” which may have been misleading for some patients. Perhaps if the question had been phrased as “Do you take your blue pump with you wherever you go?”, the responses may have been different. However, during the design of the research instrument, I believed that this could be a leading question which would prompt an automatic positive response and thus generate a misleading result. It was encouraging to note that after the intervention the vast majority stated that they kept their salbutamol MDIs with them at all times.

6.7 Knowledge of beclomethasone use and how it works in asthma

There was a significant increase in correct responses in six of the 12 questions relating to beclomethasone after the intervention. Similarly to findings on salbutamol, only two patients were able to offer a simple explanation of the mechanism of action of beclomethasone at follow-up.

The number of patients who knew that beclomethasone was used to prevent future asthma attacks did increase post-intervention, albeit not significantly. However, it is a matter of concern that only 2% at baseline and 16% at follow-up were aware of beclomethasone's preventative role. These results did not concur with a study in the UK where, after being shown a video on asthma and having prior access to written information on asthma, 86% of patients knew that inhaled corticosteroids were preventative therapy, [222] or with a study in Singapore [8] where there was a significant improvement in this knowledge after an educational intervention (52% vs 92%). The limited education of the participants in this study as well as their limited access to asthma information could account for this.

In my study, approximately one third of patients at baseline stated that they were using beclomethasone daily and this may account for the mixed responses obtained regarding its effectiveness. After the intervention there was a significant increase in those stating that beclomethasone was effective. Either appropriate daily use or the increased dosages suggested in the referrals may have resulted in a decrease in asthma symptoms. Patients may also have become more aware of the trigger factors of asthma.

According to the 2001 WHO report: Adherence to Long-term Therapies: Policy for Action, adherence to long-term therapy for chronic conditions in developed countries averages 50% and is less in developing countries. [138] Adherence to beclomethasone is vitally important to reduce the incidence and severity of asthma exacerbations. In this study, self-reported daily use of beclomethasone increased significantly to 61% at follow-up with similar results being found in other studies where adherence to inhaled corticosteroids improved after an educational intervention. [128,219,291,294] The fact that asthma symptoms are not always present may explain why some patients were not taking beclomethasone daily. Convincing people with chronic NCDs such as asthma and hypertension to take their medication daily when they are not experiencing symptoms is a challenge, but patient education could make patients aware of the negative effect on health outcomes if not taken daily.

According to the PHC STGs, the minimum adult dosage for beclomethasone is 200 mcg 12 hourly. [43] The study site beclomethasone MDIs delivered 50 mcg per dose with a minimum of four inhalations required 12 hourly to comply with local guidelines. It was encouraging to note at follow-up that the self-reported mean number of doses taken at one time increased significantly from 2.0 ± 0.7 to 2.8 ± 1.1 and that the number of patients taking four inhalations increased significantly to almost 40% and that 55% were taking beclomethasone 12 hourly daily. It is however, a matter of concern that the mean number of inhalations used at one

time at follow-up was 2.8 ± 1.1, which is lower than the 4 inhalations recommended as the minimum adult dose of beclomethasone. [43]

Actual adherence could not be assessed in this study but self-reported adherence at baseline (33%) and follow-up (61%) was still below the average range of adherence (63-92%) reported in a literature review by Cochrane et al. [72] Thus, despite the referrals to the health care system regarding dosage of beclomethasone, patients were not taking beclomethasone as recommended in the PHC STGs. This indicates that more patient education, and possibly also HCP education is required. Taking four doses at one time could also be inconvenient for patients. [53] The significant increase in self-reported adherence was encouraging and may be due to patients being told during the intervention at the baseline interviews that daily use of beclomethasone reduces “xakaxa”.[187] This culture-specific reason could possibly be more effective at ensuring sustained long term daily use of beclomethasone than the biomedical model explanation of pathophysiology.

The majority of patients in my study did not know why beclomethasone should be used daily. Responses recorded as “other” suggest that patients are reliant on HCPs for instructions, e.g., “It loosens up sputum. Doctor told me.” Information given during the intervention had caused some confusion, e.g., “The brown pump is doing the same as the blue one.” It was evident that patients also found the medical terminology difficult, e.g., stating that beclomethasone “makes the air passages free”.

According to Horne [297], although patient self-reports are cheap and easy, they are often inaccurate. Responses may depend on the relationship between the HCP and the patient as well as the way in which questions are asked. Information volunteered by patients in this study that suggests that they did not know that beclomethasone should be used daily, the clinic staff had told them not to waste their beclomethasone MDIs and that they should only be used for asthma attacks. Thus, although forgetfulness is a common reason for non-adherence [142,298], lack of patient education before the intervention could also have played a role. Janson et al. [128] found that, although a self-management intervention resulted in improved adherence with inhaled corticosteroid, adherence decreased over time in both intervention and control groups but the decrease was less in the intervention group. This emphasises the need for continuous education and monitoring of adherence.

Because beclomethasone should be taken daily, it was important to ask patients what they would do if they missed a dose. Although there was an improvement in correct responses, it is a matter of concern that the majority of patients gave an incorrect answer. I found it

difficult to explain what patients should do and although I gave examples, it appeared that patients had difficulty grasping this concept, which may have contributed to the poor results.

It was pleasing to note that the number of patients rinsing their mouths out after using beclomethasone increased significantly. Incorrect responses when enquiring why the mouth should be rinsed out included “To get rid of the bitter taste” and “My doctor told me. I follow orders.” It is noteworthy that being given instructions by an HCP was repeated as a reason for following instructions.

6.8 MDI technique

Incorrect MDI technique appears to be a universal problem. For example, studies on MDI technique in Italy [70], Iran [225,299], USA [139,173], Saudi Arabia [224,286], Trinidad [144], Spain [42], France [202] and the Netherlands [300] all showed that patients had difficulty executing correct MDI technique. Giraud and Roche [202] found that 71% of MDI users had co-ordination errors, but only 15% rated themselves as poor or very poor users. Assessing technique is therefore important so that patients can be made aware of their errors. With respect to clinical response, some steps are more important than others. For example, if the mouthpiece cap is not removed, this leads to complete failure, whereas not shaking the MDI before use results in only partial failure. [56,66] Other steps that have an important negative clinical effect (in order of significance) if not carried out correctly are: not actuating the inhaler during the first half of inspiration, not putting the inhaler in the mouth with the lips tightly closed around it and obstructing the mouthpiece with the tongue, not inhaling slowly while activating the inhaler, not continuing to fill the lungs completely after actuation, and not holding breath for at least 8-10 seconds or as long as possible after inhalation is complete. [66]

6.8.1 The 12 MDI steps

The percentage of incorrect action for each step before the intervention compared with the first demonstration of MDI technique at follow-up are an indicator of the effectiveness of the educational intervention. Results from this study are noted in brackets as (baseline % vs follow-up %) to allow for easy, direct comparison with other studies. Many of the errors in technique can be attributed to factors such as poor education and low-literacy, and these have been discussed in Section 6.4.

Step 1: Remove mouthpiece cap (7% vs 2%)

It was encouraging that there was a decrease in the number of patients not completing this critical step. Results from other studies for not completing this action ranged from 0-

8% at baseline [70,139,173,202,224] with all results post-intervention being 0%. In a study by Plaza and Sanchis, 20% of patients did not remove the cap and shake the inhaler. [42] It is unclear which of these did not remove the cap, did not shake the inhaler or did not do both of these.

Step 2: Hold pump upright with thumb on base (64% vs 22%)

In this study, the step was only recorded as correct if the MDI was held upright and the thumb was on the base of the MDI as this is what is advised in four of the package inserts consulted. [57,59,238,239] Not holding the MDI upright was observed by Alamoudi [224] who found that an educational intervention resulted in a reduction from 6% to just under 2%, while Sestini et al. [70] and Shrestha et al. [173] observed that 8% and 0%, respectively, did not do so. In these studies, placing the thumb on the base was not specified in assessment of this step. Giraud and Roche [202] observed that 7% held the pump 'incorrectly', the exact interpretation of which is unclear. These differences in assessment may account for the poor performance of this step in my study.

Step 3: Shake pump (62% vs 39%)

In other studies, this step was executed incorrectly by fewer patients: 27% at baseline, 4% after intervention [139], while studies where no intervention took place, recorded that 8-22% failed to do so. [70,144,173,225,300]. In a study by Plaza and Sanchis [42], 20% did not remove the cap and shake the inhaler. It is unclear which of these 20% did not remove the cap, did not shake the inhaler or did not do both of these.

Step 4: Tilt head slightly backwards (75% vs 15%)

This step was difficult step to assess because the action "tilt head slightly backwards" is subjective and open to varying interpretation. My study results were similar to those in a study by Al-Wasil and Al-Mahaimeed [286] where 78% of patients did not do so but improved results were found by Alamoudi [224] where 10% did not do this before intervention compared with no patients post-intervention**.** A number of other studies did not include this step for assessment. This step was however, included in the package inserts [57,59,255,256] consulted when designing the checklist and is recommended by the NAEP. [301]

Step 5: Breathe out through mouth (95% vs 79%)

Hindle et al. found that exhaling gently to residual volume resulted in greater bioavailability in the lungs. [302] It was a matter of concern therefore, that the majority of patients did not perform this step correctly. This step was also not performed well in other

studies (31-52%). [42,144,173,225] Results from other intervention studies were mixed: for example, 73% at baseline and 35% after intervention [139] and 39% at baseline and 13% after intervention. [224]

Step 6: Put MDI in mouth with lips tightly closed round mouthpiece (49% vs 26%)

These results are poor when compared to other educational intervention studies, with results ranging from 10% at baseline, 4% after intervention [224] and 12% at baseline, 0% after intervention. [139] I was unable to assess if patients in this study obstructed the mouthpiece with the tongue [66] but this important information was given to patients verbally and is included in the text of the PIL 'How to use your pump correctly'. (Appendix A20)

Step 7: Actuate pump once during inspiration (82% vs 55%)

Incorrect responses for this clinically important step [66] were recorded if patients did not actuate, actuated more than once and/or did not inhale adequately. In the majority of cases, actuating more than once was the error, possibly due to the standard prescribed dose of two inhalations. Established behaviour patterns are difficult to change, and it is possible that patients who had been taking two or more inhalations may have found it difficult to break old habits. Comparisons with other studies were difficult as assessment was based on either one or more of the criteria used in this study. The incidence of taking more than one inhalation ranged from 16-27% [42,70,144,173,202,224]; not inhaling slowly ranged from 10-34% [42,144,202,300] and not actuating while inhaling was the most problematic and ranged from 10-65% [42,139,144,225,300]. It is a matter of concern that even after intervention, more than half the patients in this study did not co-ordinate actuation and inhalation, which could negatively affect asthma control.

Step 8: Remove pump from mouth (27% vs 9%)

Although this step was not included in other studies, it was seen to be important in this study because it formed part of the instructions for use of MDIs in the package inserts. [57,59,255,256] The majority of patients did not remove the MDI from their mouths and from my observations, I found that patients are more likely to be able to hold their breath for 5-10 seconds when their mouth is closed and they do not need to think about the imminent removal of the MDI.

Step 9: Hold breath for 5-10 seconds (86% vs 38%)

The significant improvement in this step is important as it is one of the steps that has a negative clinical effect if not carried out correctly. [66] Improved results in pre- and post-intervention studies were found by Foland et al (54% vs 8%) while mixed results were found in other studies with results ranging from 19-77%. [70,139,144,173,202,225]

Step 10: Breathe normally through the nose (85% vs 38%)

This step was included to ascertain if patients were breathing through their nostrils or their mouths but proved difficult to assess as the majority of patients did not wait for 30-50 seconds between inhalations (Section 7.10.11). Breathing in and out through the nose at all times is advised for asthmatics [28] but is not specifically stated in package inserts that I consulted. [57,59,255,256] As this is not important to MDI technique, it is suggested that this step be removed and added to general advice given to patients.

Step 11: Wait 30–60 seconds before next inhalation (98% vs 85%)

The majority of patients did not wait approximately 30–60 seconds before the next inhalation. One patient in the follow-up phase stated that she could only count to 10. She was thus advised to count to 10 three times between inhalations. Similar results were found by Foland [139] with 73% before and 31% after intervention not waiting the recommended time. Improved results were achieved in an intervention study with 28% before and 12% after failing to wait [224] and in studies where no intervention took place, results ranged from 37.0% to 49%. [42,144,173]

Step 12: Replace the cap (11% vs 4%)

Results of this step were not recorded in other studies consulted. Although this is not a critical step in MDI technique, it is advocated in package inserts. [57,59,255,256].

All steps correct (0% vs 2%)

The poor results in this study are supported by previous findings ranging from 0%-33%. [144,220,225,286] In an intervention study, an increase from 12% to 31% was found. [139] Sestini et al. [70] observed that inhalation technique was better when inhalers were used daily and when patients were confident that they could use inhalers. Therefore, the fact that only a third of patients at baseline were using their MDIs daily, could explain the poor inhaler technique in this study. It was also interesting to note that although the majority of patients at baseline were confident that they could use medicines to manage their asthma, no patients got all steps of the MDI technique correct.

6.8.2 Common errors in MDI technique

In a systematic literature review of articles from January 1966 to 1997 on inhaled corticosteroids by Cochrane et al. [72], it was found that common errors in MDI technique were lack of co-ordination of MDI actuation and deep inspiration, not breathing out before actuation, and not holding the breath at the end of inspiration. These errors were also common in this and other studies. [42,66,70,173,202,224,286,300]

6.8.3 Effect of age, gender and education on MDI technique

Age had a significant effect in this study, with older patients making more errors in some of the steps. These results are supported by some studies [21,70,73,74,202] but not by the study by Al-Wassid and Al-Mahaimeed. [286] Limited education had a negative effect on some of the steps and similar results were found in other studies [70,286] There was no significant gender effect on the total number of correct steps attained during either of the phases. Significantly more females made errors than men in one study [286], whereas gender was found to play no significant role in two other studies. [70,202]

6.9 Referral of patients to the health care system

One of the main reasons for the many referrals in this study was that patients were not taking at least the minimum adult dose of beclomethasone and if they were, they were not taking it daily. These results concur with Allen et al. [219] who found that surprisingly few patients had adequate treatment to manage their asthma. Although patients should be referred to specialists if asthma is not well controlled [137], this may be problematic in South Africa due to the limited number of pulmonologists, especially in the public sector health care system.

6.10 Acceptability of the PILs

Although favourable responses were received for most questions, the results should be interpreted with a degree of caution as patients may have felt reluctant to criticize the intervention. It was pleasing to note that all the literate patients reported that the PILs were easy to read. All patients reported that the PIL ‘Understanding asthma and trigger factors of asthma’ (Appendix A19) helped them to understand what asthma is. However, when patients were asked to explain each of the pictograms in this PIL to me at follow-up, some did not provide the correct explanation. Therefore, although this PIL improved understanding, not all patients had a complete understanding of asthma after the intervention, which was expected due to limited education. Positive responses were received about the page on trigger factors and the PIL illustrating MDI technique (Appendix 20) was regarded as being very useful. Patients did not always interpret the pictograms correctly when asked at follow-up, indicating

that further education to reinforce information is important. Patients commented that they found the demonstration of correct MDI technique beneficial and having the PILs in their home language was reported as assisting with understanding of the information.

The majority of patients returned for the follow-up interviews and many stated that they were interested in learning more about asthma. These findings concur with the QEI review which concluded that patients and the general public would like more health information [183] and that people appreciated education on health-related matters from pharmacists. [184] It was interesting that 82% of patients reported that their family members had read the PILs.

Common themes that arose from responses to the question ‘Did the PILs help you in any other way?’ were that some patients had not received information about asthma before the study commenced, that the PILs would help with self-management of asthma, that patients were keen to learn more about asthma, and that their asthma symptoms had reduced as a result of the intervention.

The majority of patients commented positively on the inclusion of pictograms in the PILs. Comments received included: ‘Yes, They remind me’, ‘Yes, they showed me what to do’ and ‘Yes a lot. I didn’t know much about asthma.’ The results of this study concur with other studies in low-literate populations in which PILs containing pictograms resulted in improved patient recall, understanding of information and adherence. [9,233,239,241] One patient did not comment favourably on the inclusion of pictograms and stated that the pictograms “showed me what is wrong with me.” It is possible that this patient had difficulty accepting that she had a chronic condition and that the pictograms and information in the PIL made her face this reality.

Although it was time-consuming, asking each patient at follow-up for their interpretation of each pictogram proved useful as this allowed me to gain valuable insight into misinterpretations. For example, many patients did not know that the lungs do not function adequately in asthma and when shown the pictogram of the respiratory system, one patient said “I did not know that my lungs are not working well. I thought it was my heart or my liver.” and another stated that “I’ve seen cow and sheep’s lungs but I didn’t know I had lungs.” Interpretation of certain pictograms highlighted the role that culture plays in interpretation of visual images. For example, the person in the ‘keep medicines away from children’ pictogram was often interpreted as being male, as it is the males who wear long pants, with the more traditional isiXhosa women usually wearing dresses.

Although the majority of patients commented favourably on the inclusion of pictograms, it was of concern to note that when asked to explain each of the pictograms, the majority misinterpreted at least one pictogram incorrectly. Thirteen of the 34 pictograms did not comply with the ISO criterion [229] that 67% of patients should understand the pictogram. Given the low educational levels of my study participants, poor visual literacy skills were predicted. Dowse and Ehlers [303] reported that interpretation of pharmaceutical pictograms was dependent on education. However, they also commented that the potential for misinterpretation occurs throughout all educational levels. This will be taken into account when making changes to the PILs before they are made available for intended general use in the PHC clinics. HCPs will also be advised of the possibility of misinterpretation and clear explanation of the PILs will be emphasised, especially for illiterate and low-literate patients.

Education had a significant effect on the effectiveness of the PILs, with the more highly educated patients finding it easier to read and understand the PILs. Even minimal literacy skills would have assisted patients in interpreting the pictograms if they were able to read a few of the associated words. Low visual literacy is particularly important when trying to interpret pictograms depicting unfamiliar concepts and settings. For example, Alexandria is a small rural town with one factory. Many patients, who live some distance away, had probably never seen this factory and would then have had difficulty in interpreting the unfamiliar image. If educated, they may have read about factories or seen pictures of them.

Age also had a significant effect with older patients (>50 years) having more difficulty understanding the PILs. Age-related deterioration in eyesight must be taken into consideration for those who responded that the writing was not big enough. The older patients most commonly reported that the PILs were read by other family members, possibly because the older patients were less educated. There were significant gender effects in this study, with more females than males having difficulty understanding some of the pictograms. These results concurred with the study by Al-Wassid and Al-Mahaimeed [286] but were not supported by a study by Chafin et al. [304]

6.11 Suggested modifications to the PILs

Changes based on the feedback received during the study will be made before they are made available for general use. The pictograms that did not achieve the ISO criterion of 67% need to be redesigned and tested. Further suggested changes for inclusion in the ‘How to use your pump’ PIL are that MDIs should be kept away from heat and that for acute asthma in adults, 10-20 inhalations of salbutamol be administered immediately via a large volume spacer. In very severe cases, the salbutamol inhalations can be given at these higher

dosages every 20 minutes for an hour or continuously. [54] A modified recommendation from a local paediatrician for severe asthma attacks is to administer 6-10 inhalations of a MDI at one minute intervals through a spacer and this can then be repeated if necessary (personal communication, Dr M Levin, Head of Division of Asthma and Allergy at the University of Cape Town in South Africa). Further clarification on the number of inhalations to be taken is required. The words 'Remove the pump' should be reconsidered and possibly be deleted in Step 7 and Step 8, 'Breathe normally through your nose' should be deleted and this information should be added to the bullet points in the 'Remember' box on page 1 of the PIL 'Understanding asthma and trigger factors of asthma.' The following should also be included in the 'Remember' box: If you are using your pump/inhaler for the first time or if you have not used it for more than seven days, you must spray one puff into the air to check that the pump/inhaler is working properly. [57,59] For the pictogram depicting correct storage of medicines, it would be important to add a pictogram of an adult female wearing a dress as this is traditionally more acceptable amongst the isiXhosa community.

6.12 Feedback to HCPs at the study site

An important component of this educational study was to feed the results back into the health care system. After the study was completed, a meeting was arranged with the HCPs at the KwaNonqubela PHC Clinic to thank the HCPs for their assistance with the study and to provide them with feedback of the study findings. The HCPs were encouraged to provide education to their patients with asthma to improve patient self-efficacy and self-management, especially for those with limited or no literacy skills. I responded to questions asked by the HCPs and informed them that one of the conditions of being granted permission to conduct research by the Department of Health: Eastern Cape Provincial Government was that I was required to submit the findings to them once the study was completed.

6.13 Shortage of health care facilities and HCPs in this study

At the time of the study, a public sector doctor visited the KwaNonqubela PHC clinic approximately once a week. There was no private medical doctor in nearby Alexandria. Patients stated that they had consulted a doctor in Alexandria but further investigation showed that they were referring to a phytotherapist, not a medical doctor. It is unclear if the patients were aware of this difference as the phytotherapist was referred to as "Doctor". Patients were required to pay for these consultations and, on occasion, purchased MDIs from the local pharmacy, an additional financial burden for this low-income group. There is no hospital in Alexandria, the nearest one being approximately 40 km away. Transport to the clinic would be difficult for patients as most would rely on taxis for which they would need to

pay. Ambulances could be used in emergencies. There are limited health care facilities and HCPs for the patients in Alexandria, a situation which is common for patients dependent on the public sector health care services in South Africa. [98,99]

6.14 Implications for future practice

This study was a valuable opportunity for translational research. It is anticipated that after changes are made to the PILs, they will be made available to HCPs and CHWs in both the public and private sectors. The use and dissemination of the PILs will also be discussed with the NAEP in South Africa. It has been suggested that information be made available online. [63] The establishment of an online repository for PILs which could be used internationally by HCPs and patients is currently being investigated, and the inclusion of these study PILs could be considered, especially as the establishment of instructions for correct inhaler technique is one of the recommendations of the Aerosol Drug Management Improvement Team (ADMIT). [62] To achieve this, specific guidelines on how HCPs should use the PILs developed in this study need to be devised.

The following guidelines for using the study PILs as an educational tool are suggested, but will need continuous revision:

- When giving PILs to patients/members of the community, clear, verbal explanations must also be offered, preferably in the patients' home language. If this is not possible, then an interpreter who is familiar with the contents of the PILs should be used.

- A physical demonstration of placebo MDI technique by the HCP must always accompany the issuing of the MDI technique PIL.

- Patients should demonstrate their technique with the aid of a placebo MDI. A standardised checklist should be used to identify any errors which should be explained to the patient. The PIL and a physical demonstration can be used to achieve this. It is advisable that this be done at least once a month until the patient displays correct technique and a record of the results should be kept. Thereafter, once every 3-6 months should suffice.Patients must always be given an opportunity to ask HCPs questions to clarify any uncertainties.

- Feedback on the use of the PILs by HCPs and patients is encouraged so that further modification of the PILs can be undertaken.

Because there is a serious shortage of HCPs in South Africa [13,98,99,111], regular reviewing and implementation of personalised asthma management plans is unlikely for all

patients. The PILs used in this study may serve as a tool to reduce the time needed to write individual management plans, as specific problem areas could be circled or highlighted using a coloured or highlighter pen. [130] Once at home, the circled/highlighted area would serve as a reminder for the patient and other family members or supporters. Nurses who have a good knowledge of asthma can play an important role in asthma, particularly for evaluating patients as well as in patient education. [6,21,294] PHC clinics in South Africa are staffed mainly by nurses and are assisted by CHWs, both of whom could be trained to educate patients about asthma.

Comprehensive and motivational programmes allow patients to make and adhere to informed decisions. [305] In this study, information was given to patients that would allow them to make informed decisions with each one-on-one interview taking approximately one hour. If interpreters are not required, this would speed up the process. However, the one-on-one interviews using the questionnaires which included the educational intervention allowed both the interpreter and me to create a rapport with each patient. This probably had a positive effect on the results as during the interviews, patients were actively involved and they were also treated with dignity and care throughout the process. In future, to encourage active patient involvement, group educational interventions and role plays using the study PILs and demonstration of MDI technique could be considered in patients with asthma. Information volunteered by patients in this study indicates that patients may find the change from being passive to active recipients of health care difficult as they are accustomed to adopting a passive role. This change requires thought and planning and existing programmes should be investigated and adapted for South Africans in different health care settings. Peer support groups should also be considered as an advantage of these is that patient adherence improves. [14]

Pharmacists can play an active role in monitoring patients with asthma. They may require training to identify, educate and supervise patients who need monitoring. [306] The results of this study show that an educational intervention by a pharmacist was effective in significantly improving asthma control, with similar results reported in other studies. [8,118,119,125-128] Pharmacists should be consulted when educational interventions for pharmacists involved in the implementation of such interventions are designed. [307] In this study, pharmacists working in the public sector and in academia were consulted and they provided valuable input particularly with the design and use of the PILs. My previous experience of practising pharmacy in a public sector environment provided me with some insight into the issues facing patients with asthma and this was further enhanced by undertaking this study.

Pharmacists reported that by demonstrating inhaler technique in one-on-one encounters, the relationship between pharmacist and patient improved. [130] In this study, I found that patients volunteered more information at follow-up and also appeared more relaxed. However, because there were only two interviews, an improvement in relationship could not be reported; however based on my previous experience as a practising pharmacist, this would certainly be possible if regular, ongoing positive interactions took place. Patients in self-controlled studies change their behaviour and sometimes improve simply because of the special attention received, a phenomenon known as the Hawthorne effect. [276] Patients often appreciate the extra attention, care and feedback related to their condition, [298] so the Hawthorne effect may have played a role in the positive results achieved in this study.

6.15 Strengths and limitations

A strength of this study is that it was conducted in a standard primary care practice setting in a rural environment in which no previous research study had been implemented. The setting is typical of the majority of rural primary care clinics in South Africa and it is in settings such as these that patients often receive no information, or very little information, to support any self-management of their conditions. As no previous research on asthma had been conducted at the clinic, the results are likely to be attributable only to the educational intervention described in this study. The same interpreter assisted during all the interviews, a key factor in ensuring consistency in the interview and data collection process. Each interview took approximately one hour and the interventions were explained in detail to each patient.

Limitations include the relatively small sample of 55 patients who completed the study. A larger sample size with a control group would provide more robust evidence. The research was conducted at only one clinic and many of the patients were > 50 years old. The findings may be generalisable only to other clinics with similar patient demographics. Extrapolation of the study findings to patients in other parts of the country or in different health care settings should be done with caution. The interview time of approximately one hour may also be viewed as a limitation as some patients got tired and restless, which possibly reduced their ability to retain information.

The time period between the intervention and follow-up interviews was approximately one month. A longer interval would possibly have given a better indication of the long-term effectiveness of the intervention. Time intervals in other asthma intervention studies range from one week to two years. [131,134,224,225,287,296,304,308,309] Further follow-up interviews would have enabled testing of long-term recall of contents of the PILs as well as

investigation into the effects of knowledge on the self-management of asthma and MDI technique.

The graphically depicted scales were not well understood by some patients, and their design should be modified and tested prior to future use in similar studies. Due to the lack of peak flow and spirometry tests, I had to rely on subjective patient self-reports to evaluate severity of asthma. These subjective reports may not have been a true reflection of asthma control and patient opinions on the severity of asthma may vary, e.g., if conducted, spirometry test results for a patient stating that their asthma control was poor may have been markedly different to those of other patients reporting the same, but in this study they would both have been recorded as having poor control. I demonstrated MDI technique for all patients interviewed. This had the potential to result in observer bias, but the use of a checklist should have reduced this.

Patients were paid R30 for each interview to cover transport costs to and from the clinic and for the time that may have been lost if they were employed. Although this is a nominal amount, motivation (financial gain as opposed to a desire to improve asthma) to be included in the study could be questioned. When providing self-reports of their asthma control, some patients may have felt obliged to state an improvement. Actual adherence was also not measured and was based on patients' self-reports which may not be indicative of actual adherence.

CHAPTER SEVEN
CONCLUSIONS AND RECOMMENDATIONS

The aim of this study was to determine the effect of a tailored educational intervention using specially designed illustrated PILs in low-literate, mostly Xhosa asthma patients at a rural PHC clinic. The educational intervention resulted in a significant increase in mean knowledge of asthma and asthma management, as well as knowledge of MDI usage and storage. Self-reported management and control of asthma improved and this was reflected by the enhanced HRQOL results. MDI technique also improved significantly at follow-up with an increase in the mean number of correct steps.

Lack of education was a key contributing factor to poor patient knowledge of asthma and asthma management measured prior to the intervention and also contributed to patient inability to benefit from some aspects of the intervention, e.g., not being able to read the text in the PILs. Lack of prior exposure to biomedical information also played a role as did cultural differences and different models of disease. The inclusion of pictograms in the PILs facilitated understanding of the information given during the interviews but not all of the pictograms were interpreted correctly. Despite being designed for a particular target population, there is no guarantee of correct interpretation of pictograms by the target population. It is essential, therefore, that pictograms that are designed to be used alone or in information leaflets must be pre-tested in the target population.

PILs including pictograms were received favourably by low-literate public sector patients with asthma. This cost-effective and simple educational intervention improved knowledge of asthma and asthma management which, according to the literature, has the potential to reduce exacerbations of asthma, reduce costs related to hospital admissions and emergency departments and to improve health outcomes and HRQOL. [231,236,241] The results of this study show that specially designed illustrated PILs are an effective tool for educating low-literate patients with asthma. Well-designed PILs could be part of an intervention to facilitate management of asthma and this could be extended to other low-literate populations in all countries.

7.1 Recommendations for ongoing care of patients with asthma

Once modifications have been made to the PILs designed for use in this study, they could be used as a tool for asthma patient education at South African public sector health care facilities. The education process could take place when patients return to the clinic to collect their monthly supply of medication. If nurses are unable to do this due to patient overload,

then individual or group education by CHWs, who have received basic training on asthma and the management thereof, could educate patients. The study PILs could be used as a tool to facilitate this process. MDI technique must be evaluated individually and the CHW could use the modified checklist used in this study to do so. Any errors in technique could be highlighted on the 'How to use your pump correctly' PIL which the patient could refer to at home. Ideally, the MDI checklist completed by the CHW should be kept in the patient's file at the clinic and the effects of the training should be monitored. Asthma education should be ongoing and should not be restricted to health care facilities.

Given the interest shown by family and community members in the materials developed for this research, and the potentially serious outcomes of asthma, members of the community should also be educated about asthma. The PILs used in this study could be used to assist with this.

To minimise the number of inhalations of beclomethasone taken per dose, beclomethasone MDIs containing 100 and 200 mcg per dose should be made available to patients. If MDI technique remains problematic despite continuous education, then the use of large volume spacer devices or other delivery devices such as dry powder inhalers should be considered for inclusion in the STGs used in the public sector.

Collaboration between researchers and asthma organisations should be established in an effort to identify which educational interventions are most effective for particular target groups and to work together on developing new education strategies. Researchers in patient education should be encouraged to share their findings and their materials with health organisations.

7.2 Recommendations for future research

Future studies should investigate the impact of similar educational interventions over a longer period of time to evaluate long-term retention of knowledge acquired from the intervention and to determine if behaviour changes, such as improved self-management and inhaler usage, are sustained. As the incidence of asthma is higher in children, it is particularly important to address this population in future patient education studies.

Further research could include conducting comparative studies in populations with different characteristics to compare the success of this type of educational intervention, e.g., in rural patients and in urban patients who may live in a more industrial environment. This could inform the development of different targeted educational strategies and patient education

materials for various groups. With the high incidence of poor reading skills in South Africa, the use of audiovisual materials in patient education on asthma should be investigated and compared with the use of written materials, e.g., the PILs developed in this study.

Another suggestion for future research would be to determine the effectiveness of using expert patients to educate other patients with asthma. Patients who are identified by nurses or CHWs as having a good understanding of asthma and asthma management (particularly the avoidance of trigger factors and correct MDI technique) could be approached to be the expert patients. These expert patients could share their knowledge with other asthma patients in an informal, supportive setting or possibly establish and facilitate more formal support groups. These could take place at the health care facility or at venues such as a community hall or in the homes of patients.

The use of spacers in the South African public health sector should be investigated both at health systems level and for individual patients. Such a study should address issues such as economic factors related to the use of spacers, reasons for their low usage, nurse knowledge, attitudes and practice surrounding spacers, and individual patient acceptability of the use of spacers. There is a need for a simple, illustrated PIL describing the use of spacers and this should be tested for understanding and evaluated for its potential as an educational tool.

With the high penetration of cellphones in South Africa, there is a need to investigate the application of mobile phone technology to promote adherence. Research should investigate the percentage of public sector patients who own cellphones, ‘cellphone literacy’ including the ability to set reminders, and to receive and read text messages, and the attitude of patients to the use of cellphones as a health-related tool.

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APPENDIX A1

First draft PIL 'Understanding asthma' (pg 1)

UNDERSTANDING ASTHMA

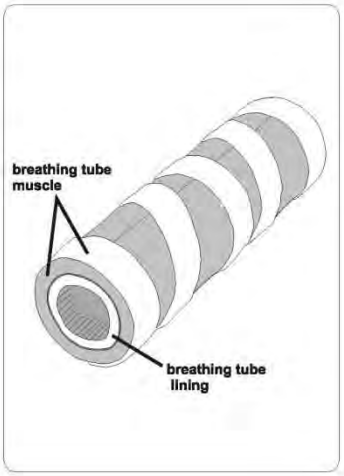
Using your asthma pump correctly

I. Understanding Asthma

1.Healthy breathing tubes

It is easy to breathe because:

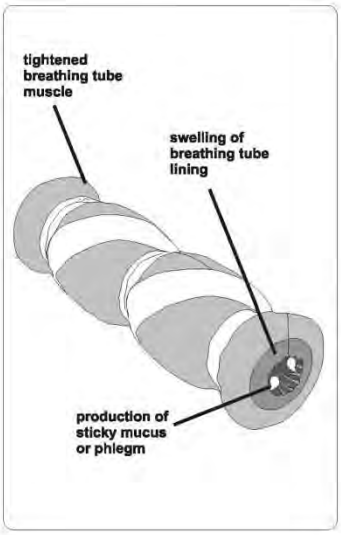
- Air passes (through) easily.
- The muscles are not tight.
- There is no phlegm.
- There is no swelling of the breathing tubes.



2. Asthmatic breathing tubes

It is not easy to breathe because:

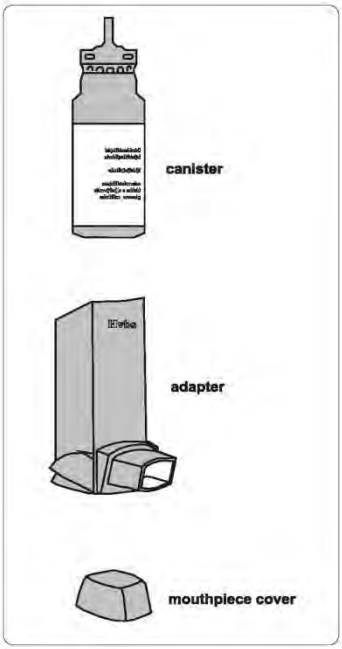
- Air does not pass (through) easily.
- The muscles are tight.
- There is phlegm.
- There is swelling of the breathing tubes.



First draft PIL ‘Understanding asthma’ (pg2)

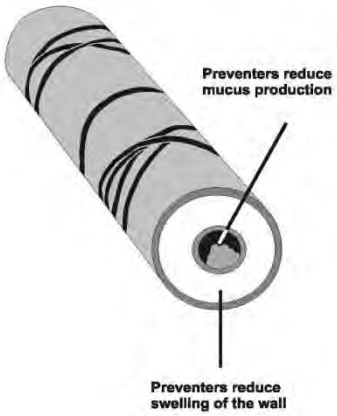
1.Understanding how your pumps work

Your pump has the following:



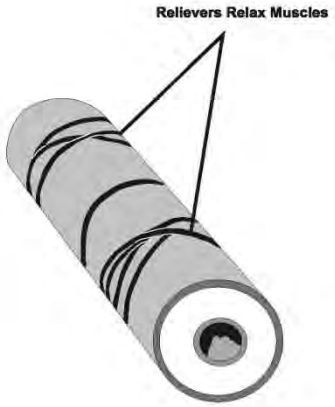
1.How the Brown pump (Beclomethasone /Preventer)helps you

·It reduces the swelling of breathing tubes.
·It reduces phlegm.



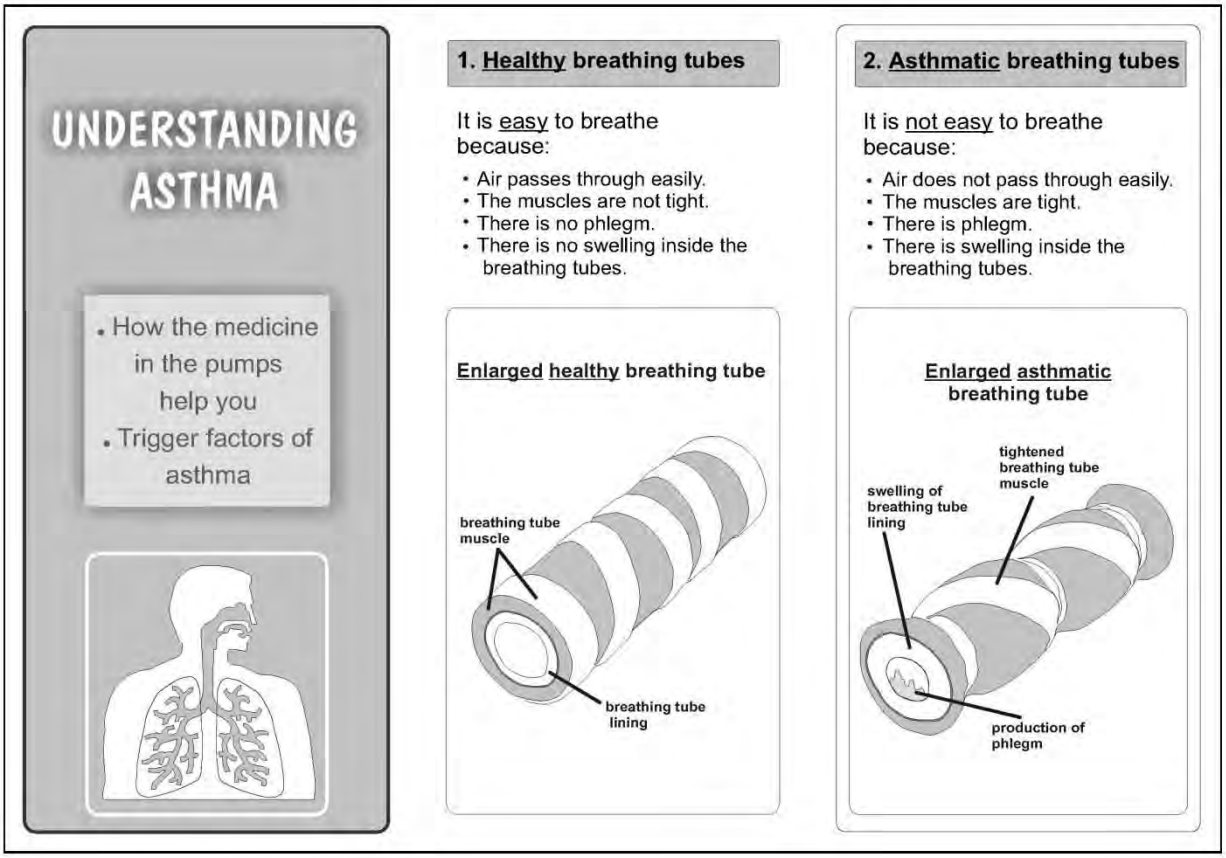
2. How the blue pump (Salbutamol/Reliever) helps you.

· It relaxes the tight muscles of the breathing tubes.

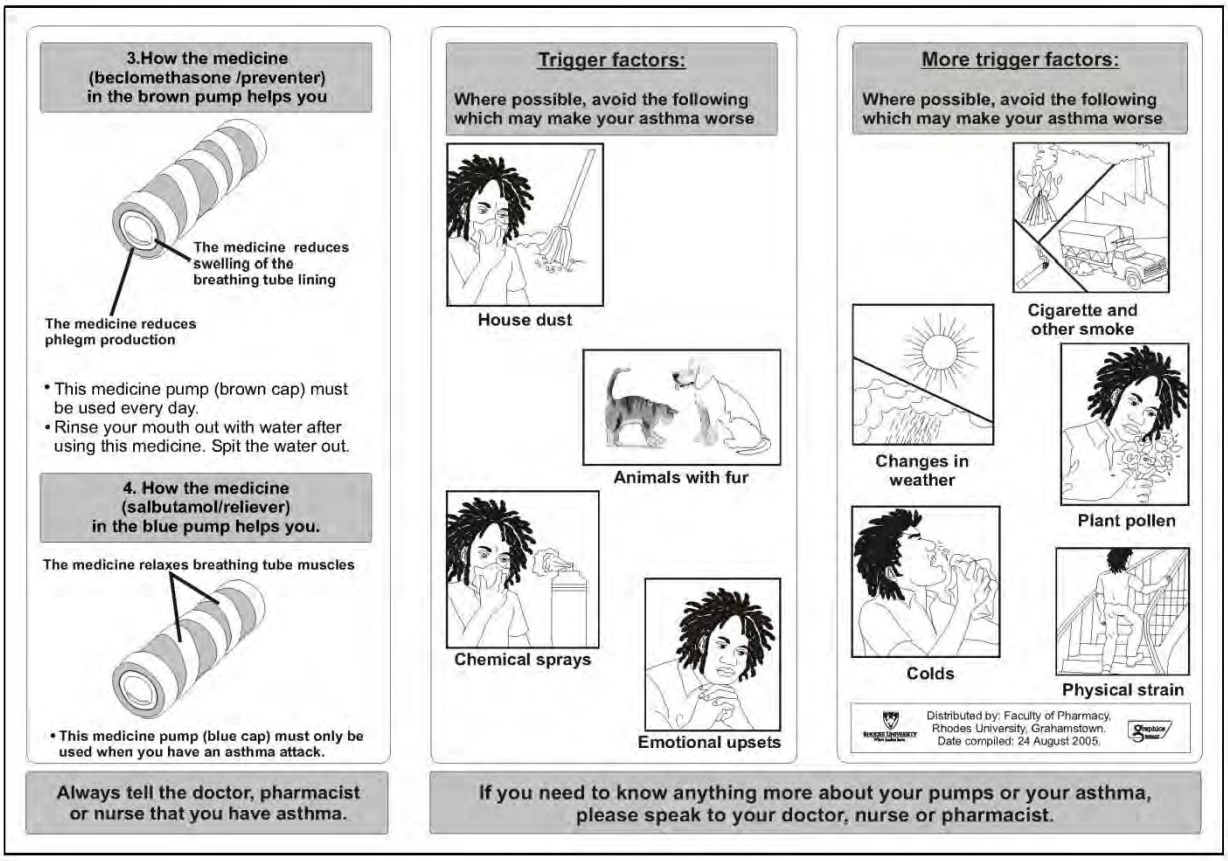


Appendix A2

Modified first draft PIL: 'Understanding asthma' (pg 1)

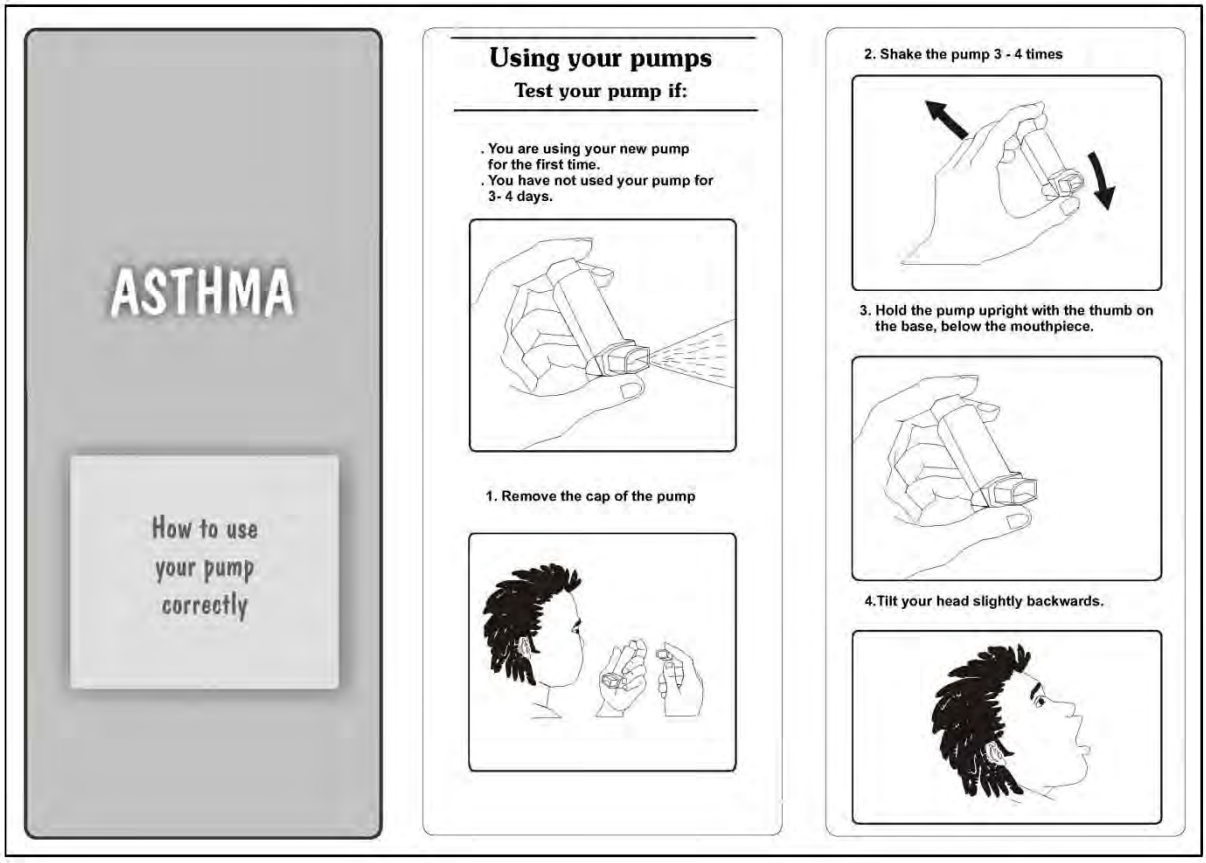


Modified first draft PIL: 'Understanding asthma' (pg 2)

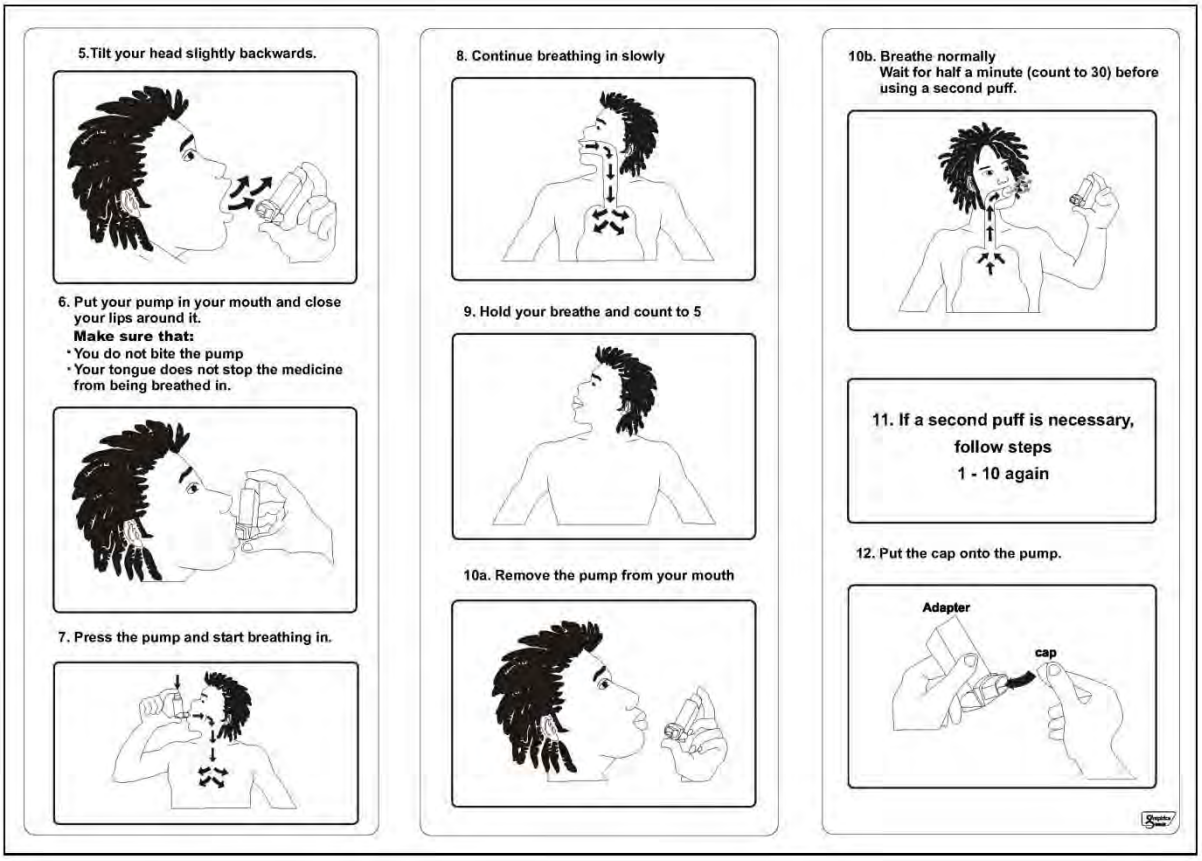


Appendix A3

First draft PIL: ‘How to use your pump correctly’ (pg 1)

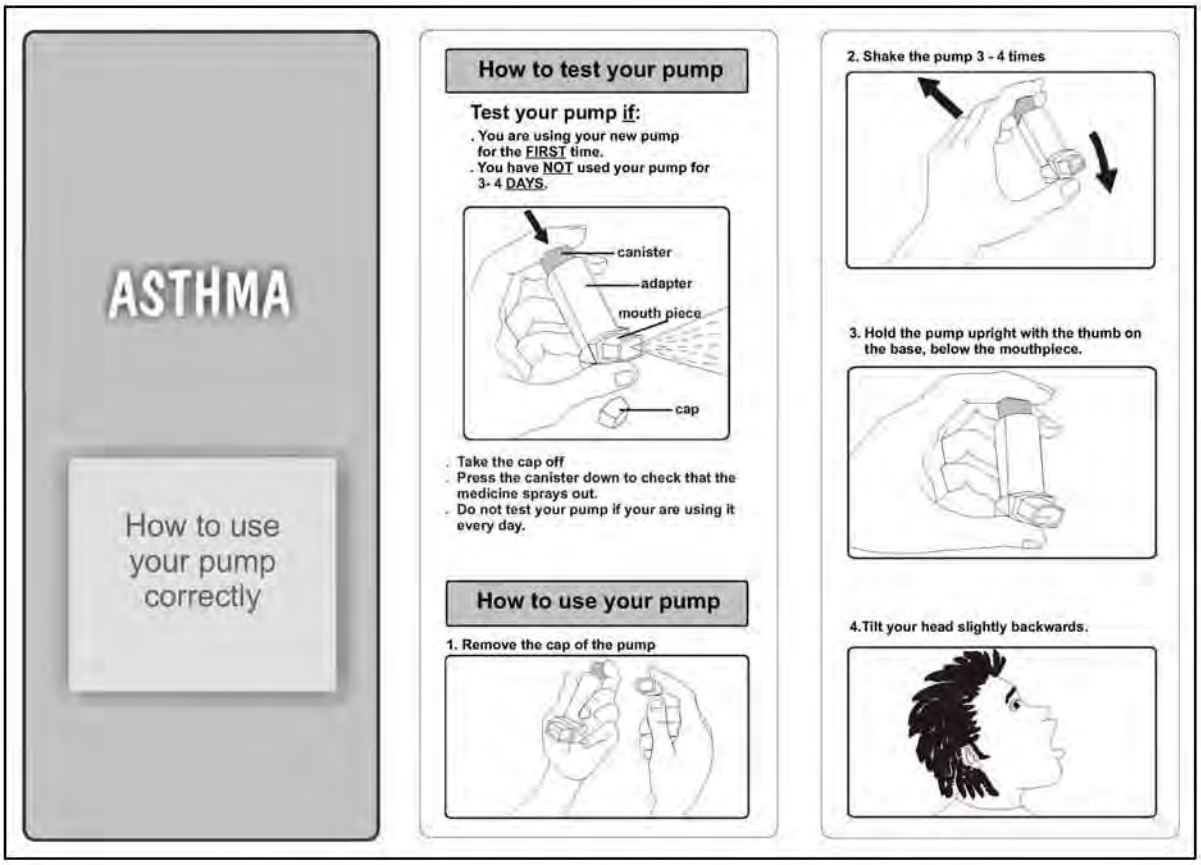


First draft PIL: ‘How to use your pump correctly’ (pg 2)



Appendix A4

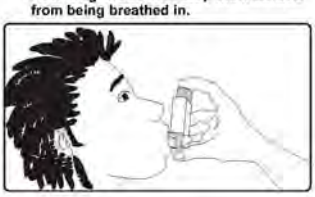
Modified first draft PIL: 'How to use your pump correctly' (pg 1)



Modified first draft PIL: 'How to use your pump correctly' (pg 2)

5. Breathe out.

6. Put your pump in your mouth and close your lips around it.
Make sure that:
- You do not bite the pump
- Your tongue does not stop the medicine from being breathed in.



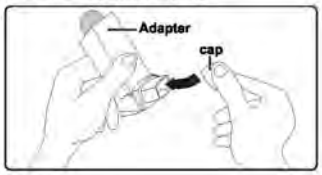
7. Press the canister down *ONCE* and breathe in slowly.

8. Remove the pump from your mouth. Hold your breath and count to 5.

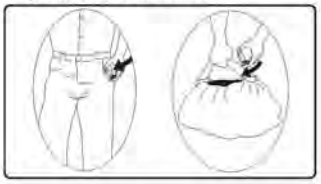
9. Breathe normally. Breathe in and out through your nose.

10. If a second puff is necessary, wait for half a minute (count to 30) and follow steps 1 - 10 again.

11. Put the cap onto the pump.



12. Keep the salbutamol pump (blue cap) with you at all times. Only use this pump when you have an asthma attack.



13. The beclomethasone pump (brown cap) must be used every day.
Put the brown pump into it's box. Store the brown pump away from children.

Distributed by: Faculty of Pharmacy, Rhodes University, Grahamstown
Date compiled: 24 August 2005

If you need to know anything more about your pumps or your asthma, please speak to your doctor, nurse or pharmacist.

Appendix A5

Questionnaire: Evaluation of Modified PILs (HCPs)

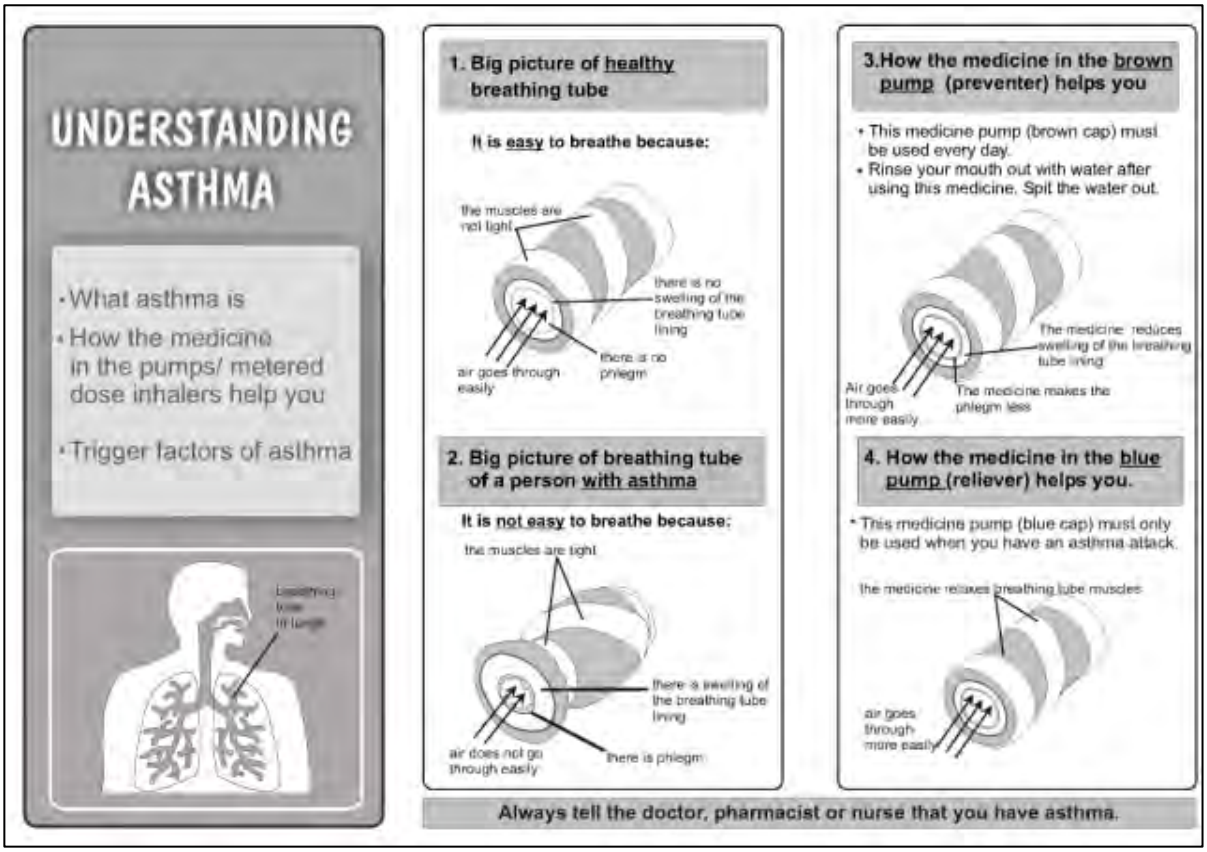
ACCEPTABILITY OF PATIENT INFORMATION LEAFLETS (PILs) FOR ASTHMATIC PATIENTS
INPUT FROM HCPs

	In your opinion:				PIL 1	PIL 2
1	Was the PIL easy to read?	V. Easy[1]	Average[2]	V. Difficult[3]		
2	Did you like having pictures in the PIL?	Yes[1]	No[2]			
3	Do you think that the pictures would help patients understand the information better?	Yes[1]	No[2]			
4	Is the writing big enough?	Yes[1]	No[2]			
5	Would patients find it helpful getting a PIL with their inhalers?	Yes[1]	No[2]			
6	Would the PIL help patients understand how to use their inhalers correctly?	Yes[1]	No[2]			
7	With the help of the PIL and an explanation from a health care professional, do you think that patients will be able to use their inhalers more confidently?	Yes[1]	No[2]			
8	Did you like anything in particular about the PIL?	Yes[1]	No[2]			
9	If yes, please state PIL number(s) and explain what you liked.					
10	Are there any words in the PIL that you did not understand?	Yes[1]	No[2]			
11	If yes, please state PIL number(s), step number(s) and word(s) you did not understand. Use back of this page if you need more space.					
12	Are there any pictures that you did not understand?	Yes[1]	No[2]			
13	If yes, please state PIL number(s), step number(s) and picture(s) you did not understand. Use back of this page if you need more space.					

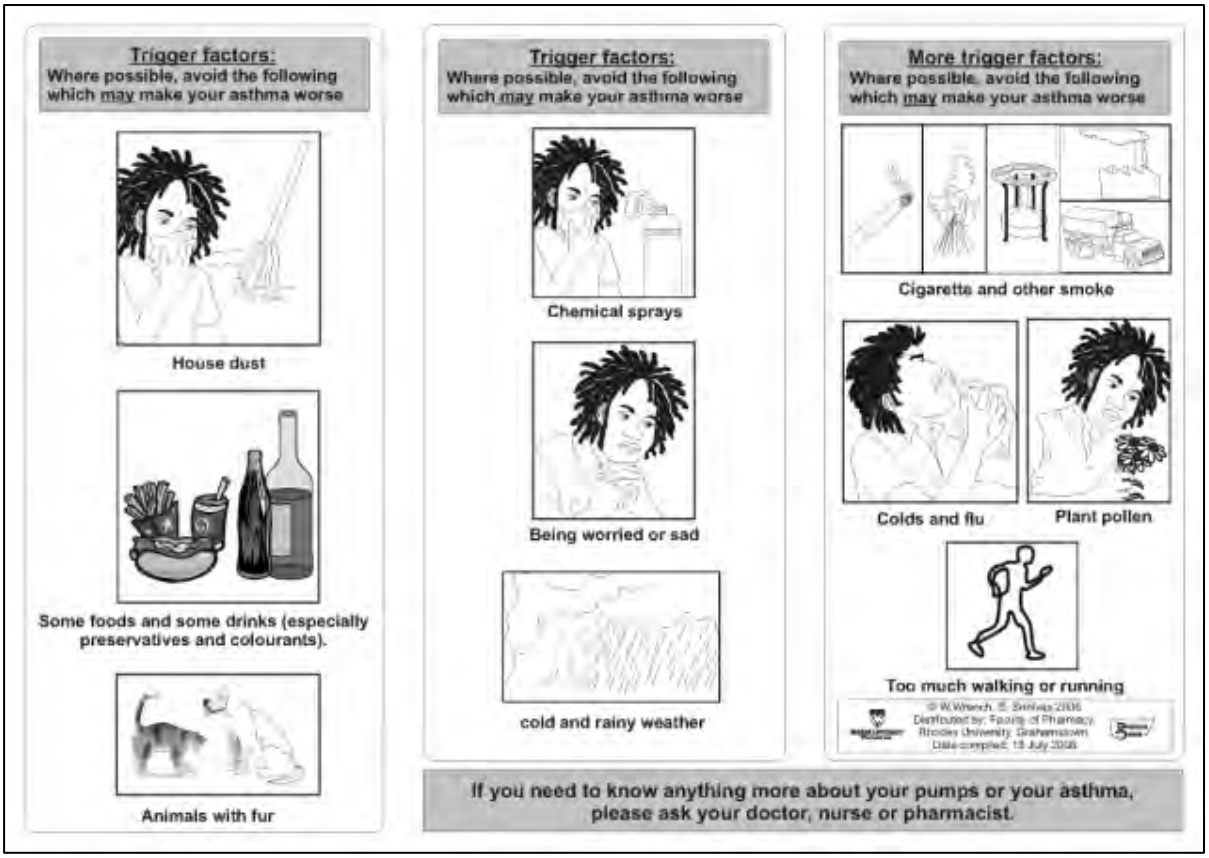
Thank you for your input!

Appendix A6

Pre-test PIL: 'Understanding asthma and trigger factors of asthma' (pg 1)

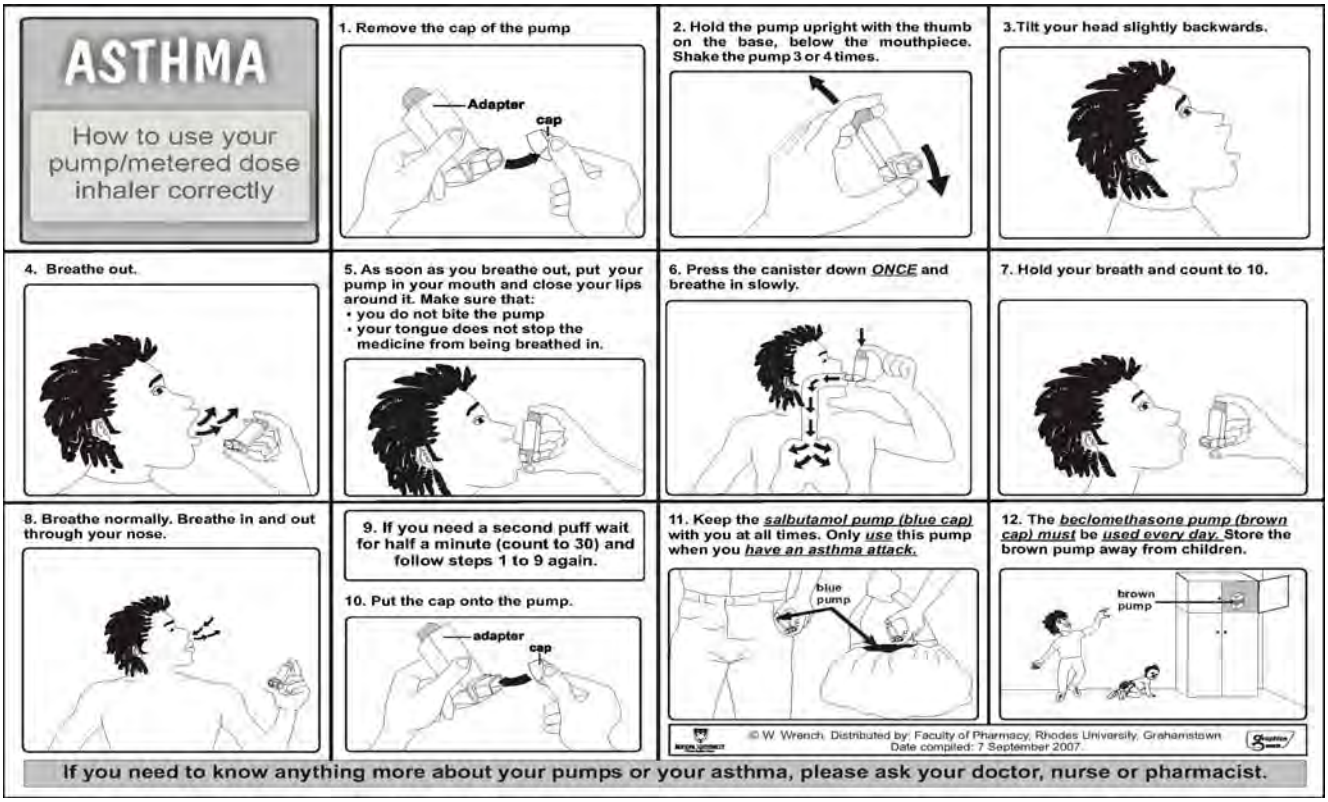


Pre-test PIL: 'Understanding asthma and trigger factors of asthma' (pg 2)



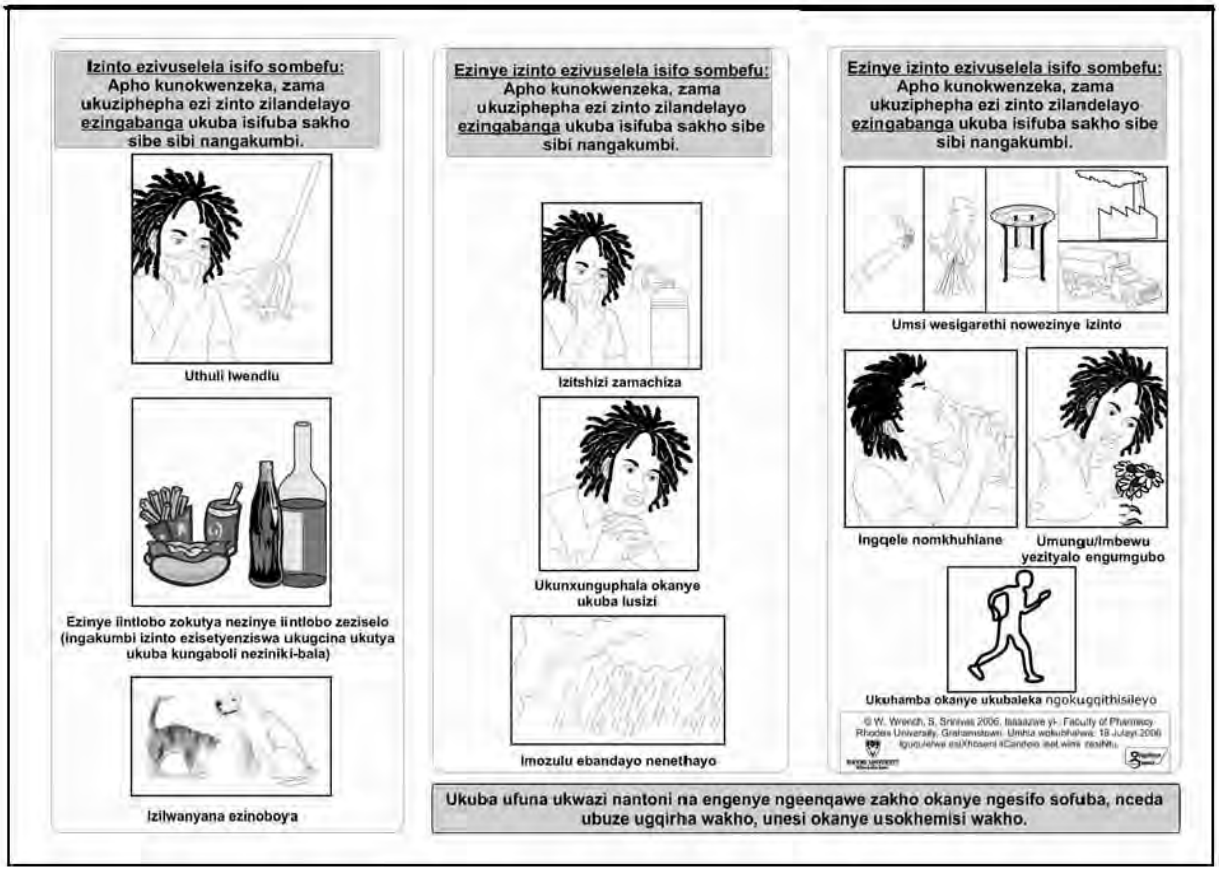
Appendix A7

Pre-test PIL: 'How to use your pump correctly'



Appendix A8

Pre-test PIL: ‘Understanding asthma and trigger factors of asthma’ (isiXhosa) (pg 1)



Pre-test PIL: 'Understanding asthma and trigger factors of asthma' (isiXhosa) (pg 2)

Appendix A9

Pre-test PIL: ‘How to use your pump correctly’ (isiXhosa)

Appendix A10

Agreement letter: HCPs at Settlers Day Hospital and KwaNonqubela clinics

To: Sisters in charge
Makana Primary Health Care clinics

From: Wendy Wrench (046 6038395 or 082 365 4444)
Faculty of Pharmacy
Rhodes University
PO Box 94
Grahamstown
6140

Agreement for Research in Asthma Patients

My name is Wendy Wrench and I am a lecturer at the Faculty of Pharmacy at Rhodes University in Grahamstown. I am also registered for a postgraduate degree at Rhodes University and my supervisors are Prof S. Srinivas and Prof R. Dowse. My area of research is asthma and I would therefore request your permission to interview people with asthma who attend your clinic. I would like to interview people who are 18 years or older who have been diagnosed with asthma and who have been prescribed a metered dose inhaler (either salbutamol or salbutamol and beclomethasone). People can either be English or Xhosa speaking. I will make use of an interpreter where necessary. All people interviewed must not be involved in any other asthma educational intervention while I am doing my research. I will not be interviewing anyone with 10 or more years of formal schooling. The interviews will take place from July to December 2008 and each person will be interviewed twice in that period. I will contact you before the interviews take place. The details of the patients' name and condition will only be available to Ms Wendy Wrench, Prof S Srinivas and Prof R Dowse.

I will require your assistance in identifying people with asthma. The research will not disrupt the working procedures of the clinic. Patients will be required to sign an informed consent form. Permission to conduct this research will be obtained from the Rhodes University Ethical Standards Committee as well the Eastern Cape Department of Health. Key findings of the research will be shared with you after the research is completed. It is anticipated that this research will assist with self-management for people with asthma. It will also assist health care providers in educating people with asthma.

……..

Name of clinic:…….. Tel number:……

Name of sister in charge of clinic:……. (Please print)

Signature of sister in charge of Clinic:……Today's date:…….

Appendix A11 Informed consent forms

JRC project - Asthma Consent form

Title of Research Project: Patient Information Leaflets (PILs): do they influence Metered Dose Inhaler (MDI) technique and understanding of asthma?
Principal Investigator: Ms. Wendy Wrench
Co Investigator: Prof. Sunitha Srinivas and Prof Ros Dowse

Introduction

We are from Rhodes University and are conducting research on the use of inhalers by patients in the public sector. If you are an asthma patient who is 18 years old or older and have been using a Metered Dose Inhaler (MDI) for at least one month, it would be highly appreciated if you would participate in our research. Please ask any questions about this study before you agree to join. You may also ask questions at any time after joining the study.
Purpose - To investigate the impact of PILs containing information on asthma, correct MDI technique and lifestyle changes on self-management and health-related quality of life (HRQOL).
Procedures - Questionnaires and checklists will be used. A placebo inhaler will be used for patients to demonstrate their inhaler technique.
Risks/Discomfort - None
Confidentiality -You will remain anonymous in this study. The details of your name and condition will only be available to Ms Wendy Wrench, Prof Sunitha Srinivas and Prof Ros Dowse.
Compensation -You will be paid R30 per interview to participate in this study.

Consent

I am 18 years or older and have read and/or understood the conditions above and I consent to voluntarily participate in this research study. I realize I am free to withdraw my consent and to withdraw from this study at any time without negative consequences. I consent to the principal investigator having access to my health passport. I consent to the use of visual images (photos, videos, etc.) involving my participation in this research.

Name of Subject (Please print) ……

Signature of Subject ……

Date ……..

Name of witness to consent ……

Signature of witness……

Date ……..

Name of person obtaining consent ……..

Signature of person obtaining consent ……

Date ……

Name of the clinic ……

Appendix A12

Group discussion questions: patients

Group Discussion – Asthmatic Patients at Settlers Day Hospital

General questions regarding the PILs:

1. Would you like to the staff at the clinic to give you information about asthma to take home with you?
If yes, why?
If no, why not?

2. Please look at the **design** of **each** PIL (English and isiXhosa version of each PIL.) What is your opinion on?

- the **general appearance** of the PIL
- the **pictures (pictograms)**:
    - Are there any pictures that you do not understand? If yes, please explain which ones.
    - What is your opinion about the size of the pictograms?
    - Any other comments?

- The **writing** (**text)**:
    - Is the writing easy to understand?
    - Are there any words that are confusing for you? If yes, please explain which words and why.
    - What do you think about the size of the writing?
    - Any other comments?

- Is there anything that you **like** about this PIL?

- Is there anything that you **don't like** about this PIL?

- What other **suggestions for improvement** to the PIL do you have?

3. Would you like the staff at the clinic to give you these PILs when you go to the clinic?

4. Do you think that patients with asthma would benefit from using these PILs?

Appendix A13

Group Discussion – Health Care Providers (HCPs)

Questions regarding the *design* of the PILs:

1. Please look at the **design** of **each** PIL.

Give each participant an English and isiXhosa version of each PIL. Give a few minutes to look at.

What is **your opinion** on?

- the **general appearance** of the PIL?
- the **pictograms**:
  - Are there any pictograms that may be ambiguous or **misinterpreted**? If yes, please **explain which ones and why.**
    - What is your opinion about the **size** of the pictograms?
    - Any **other** comments?
- the **text (writing)**:
  - Is the text **easy to understand** (both English and isiXhosa)? Please explain your answer.
  - Is there any text which may be ambiguous or **misinterpreted**? If yes, please **explain which words and why**.
  - What is your opinion on the **size** of the font?
    - Any **other** comments?

What other **suggestions for improvement** to the PIL do you have?

General questions regarding the *use* of the PILs:

2. Do you think that **Health Care Professionals** (e.g. nurses, doctors, pharmacists) will find the PILs useful as an aid for patient education?
If yes, which HCPs and why?
If no, why not?

2.1 Would **Community Health Workers or other staff** at Primary Health Care clinics find the PILs useful as an aid for patient education?
If yes, who and why?

3. Do you think that **HCPs** will have the time to explain the PILs to patients?
If yes, why?
If no, why not?

4. Do you think that **patients** will benefit from having the PILs **given to them to take home?**
If yes, why?
If no, why not?

Appendix A14

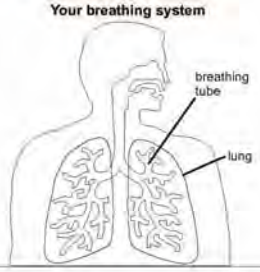
Pilot study PIL: 'Understanding asthma and trigger factors of asthma' (pg 1)

UNDERSTANDING ASTHMA

- What is asthma?
- How do the pumps help you?
- What are some of the trigger factors of asthma?

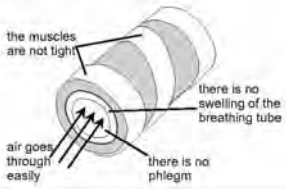
What is asthma?

Your breathing system



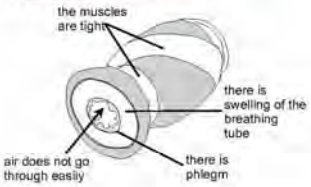
Big picture of healthy breathing tube

- It is easy to breathe because:



Big picture of breathing tube of a person with asthma

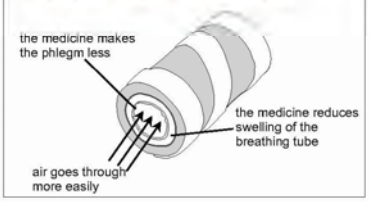
- It is not easy to breathe because:



How do the pumps help you?

How the medicine in the brown pump (preventer) helps you

- This pump (brown cap) must be used every day.



How the medicine in the blue pump (reliever) helps you.

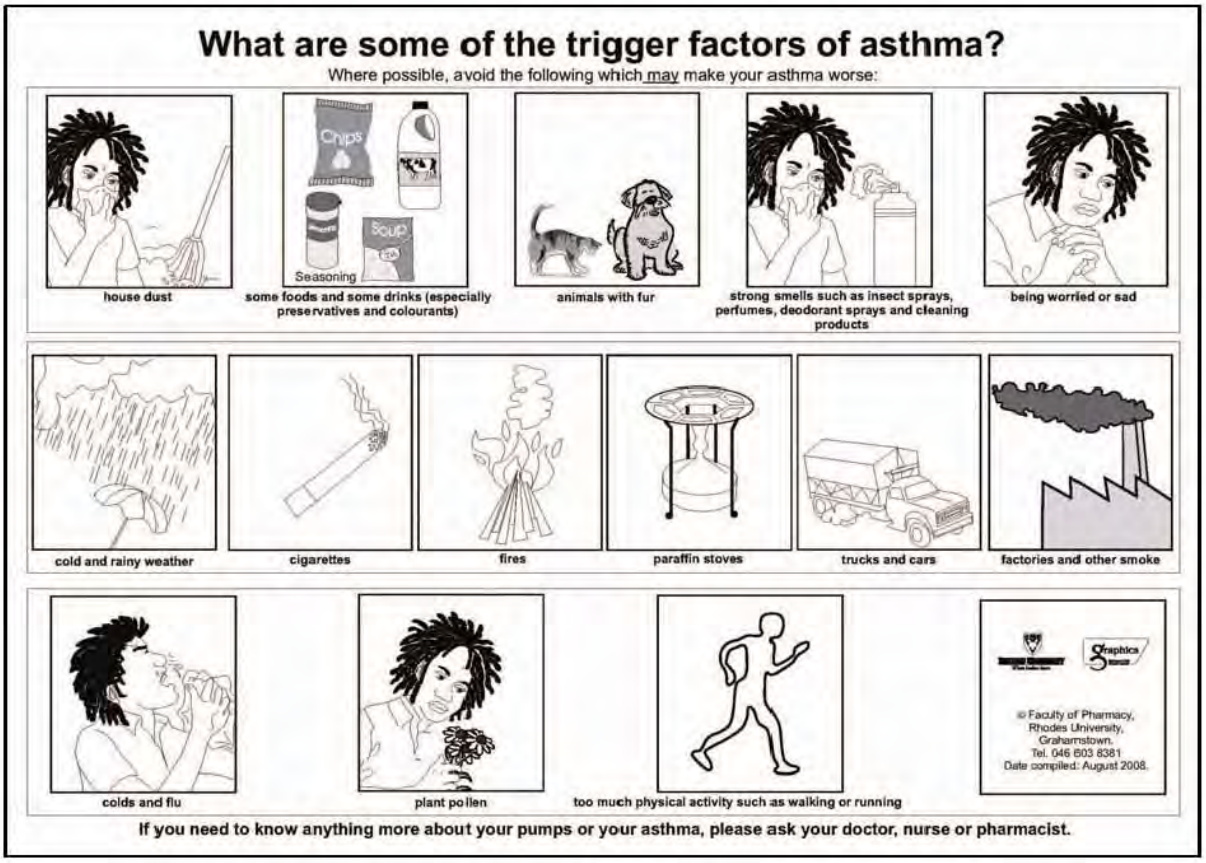
- This pump (blue cap) must only be used when you have problems breathing.

Remember:

1. You cannot get (catch) asthma from another person who has asthma.
2. If a parent has asthma, then the children may get asthma.
3. If your asthma is well controlled, it is possible to lead a normal, active life.
4. If asthma is not well controlled, then it is possible to die from asthma.
5. Asthma medicines help to control asthma. They cannot cure asthma.
6. You must take your asthma medicines as instructed even if you are feeling well.

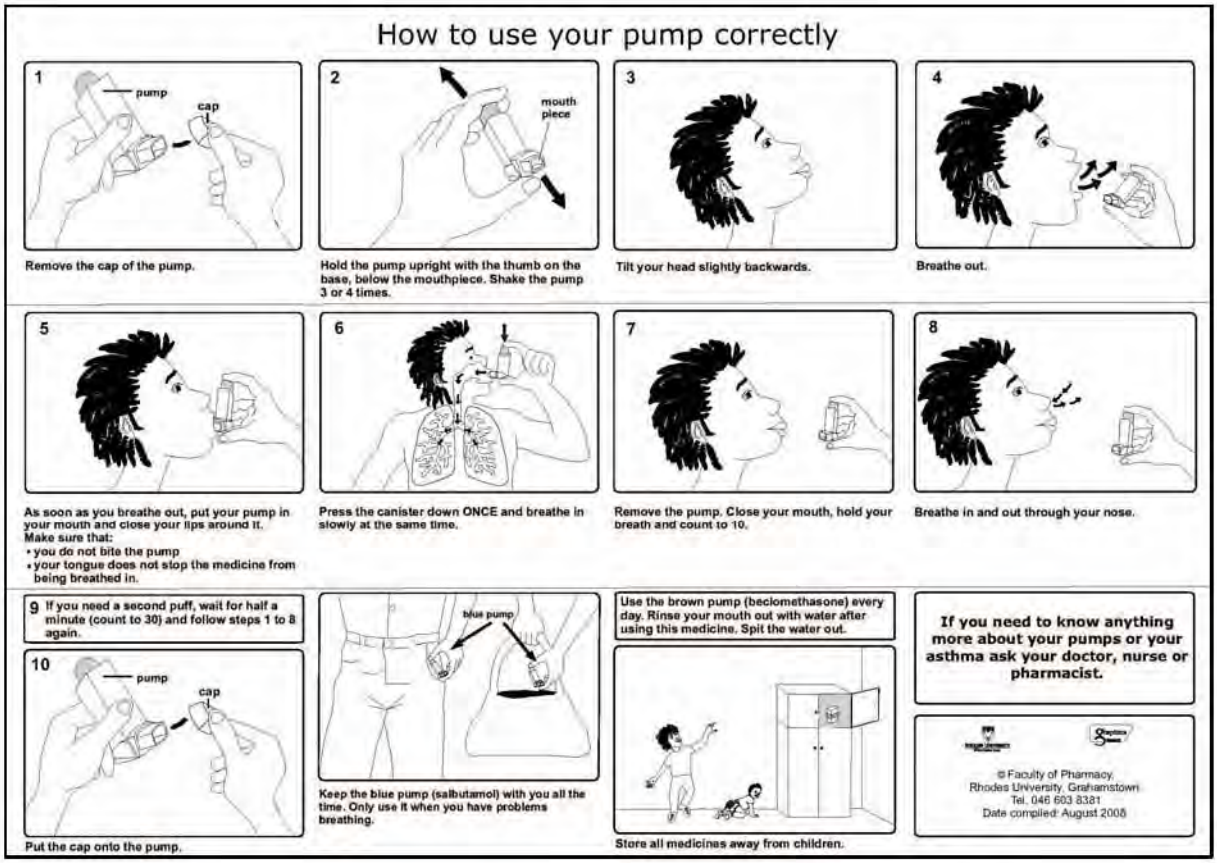
Always tell the doctor, pharmacist or nurse that you have asthma.

Pilot study PIL: 'Understanding asthma and trigger factors of asthma' (pg 2)



Appendix A15

Pilot study PIL: ‘How to use your pump correctly’



Appendix A16: Pilot study questionnaire

QUESTIONNAIRE - PILs FOR ASTHMATICS - 2008

Researcher: W. Wrench_____

Name of the clinic _____ Date _____

Respondent number [ ]

Respondent name _____

First or second interview? [First 1] [Second 2]

Has the consent form been explained and signed?

Contact number? _____

1. DEMOGRAPHICS

1.1 Gender [Male 1] [Female 2]

1.2. Age in years *(or date of birth)* [yrs]

1.3 Race [Black 1] [White 2] [Coloured 3] [Asian 4]

1.4 Home language [Xhosa 1] [English 2] [Afrikaans 3] [Other 4]

If other, please specify _____

1.5 Highest level of school education? [Grade]

1.6 If any, specify additional or informal courses _____

1.7 Are you employed? [Not employed 0] [Part-time 1] [Full-time 2]

1.8 If employed, what type of work do you do? _____

2. MEDICAL HISTORY

2.1 In the last 2 weeks, how has your asthma been? [Completely controlled 1] [Somewhat controlled 2] [Not controlled at all 3]

2.2 What medicines are you taking for asthma? *(patient self-report)*

[Bec 1] [Sal 2] [Bec & Sal 3]
[Sal & Theo 4] [Bec & Theo 5]
[Bec, Sal & Theo 6]

2.3 Prescribed asthma medicines *(according to health passport)*

[Bec 1] [Sal 2] [Bec & Sal 3]
[Sal & Theo 4] [Bec & Theo 5]
[Bec, Sal & Theo 6]

2.4 How long have you had asthma? *(patient self-report)* [mths]

2.5 How long have you been using asthma pumps? *(patient self-report)* [mths]

2.6 If you smoke, what do you smoke?

Non-smoker[0]	cigarettes[1]	pipe[2]	rolled cigarettes[3]
Other[3]			

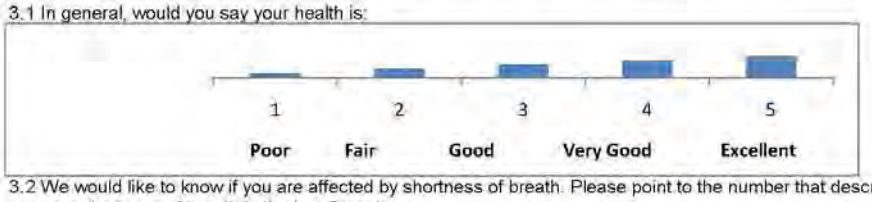
If other, please specify. _____

2.7 If you smoke, how many do you smoke per day?

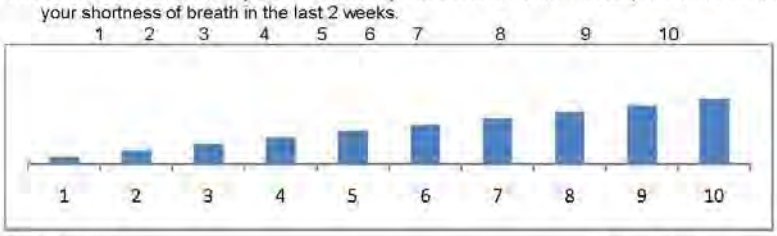
Non-smoker[0]	< 5 /day[1]	5-10/day[2]	11-20/day[3]	>20 /day[4]

3. ASTHMA AND Seleced HEALTH-RELATED QUALITY OF LIFE measures.

3.1 In general, would you say your health is:



3.2 We would like to know if you are affected by shortness of breath. Please point to the number that describes your shortness of breath in the last 2 weeks.

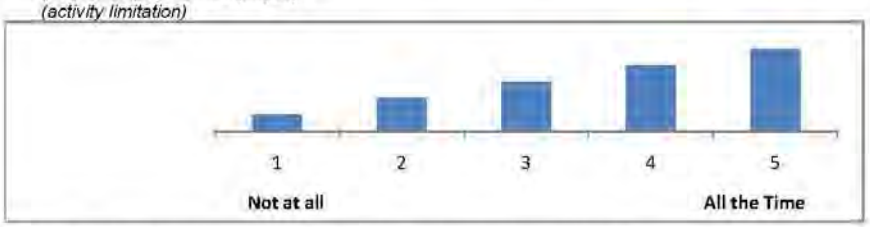


No shortness of breath

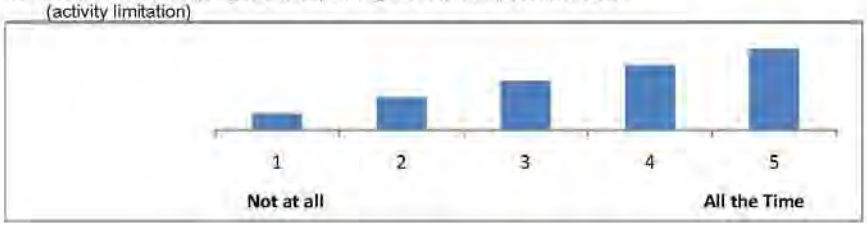
Severe shortness of breath

During the last 2 weeks, how much has asthma interfered with your:

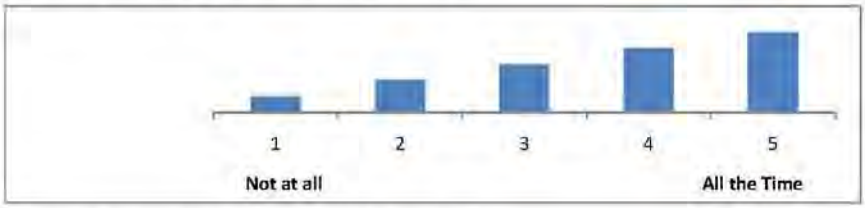
3.3 Ability to work?
(only ask if person is employed)
(activity limitation)



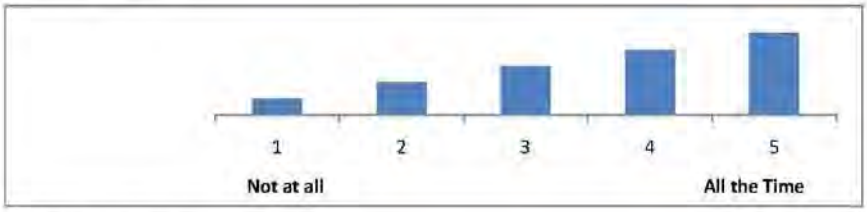
3.4 Social life such as going to church, visiting friends, family occasions etc?
(activity limitation)



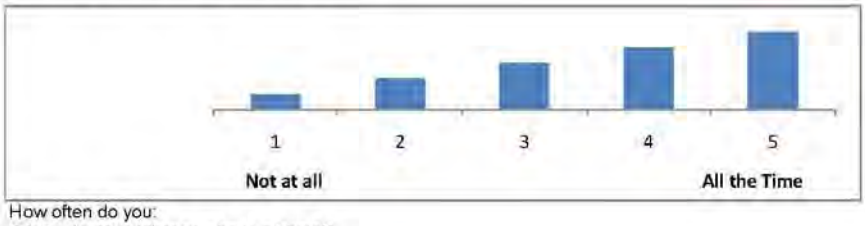
3.5 Day to day activities in home such as cooking, cleaning, sweeping, washing, working in garden etc? (activity limitation)



3.6 Ability to exercise, or walk long distances, garden etc? (activity limtation)

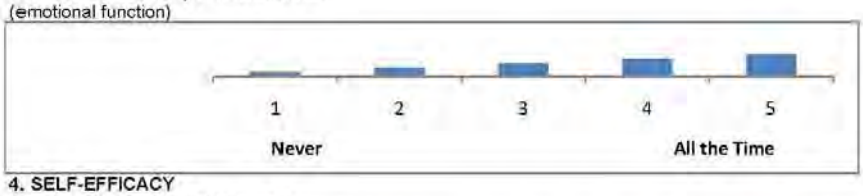


3.7 Ability to sleep well at night? (symptoms)



How often do you:

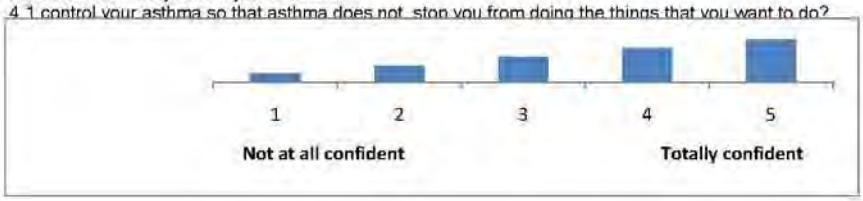
3.8 Feel worried that you have asthma? (emotional function)



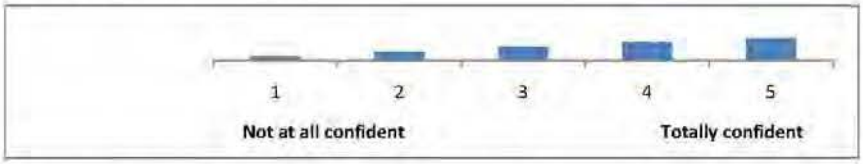
4. SELF-EFFICACY

How confident are you that you can.....

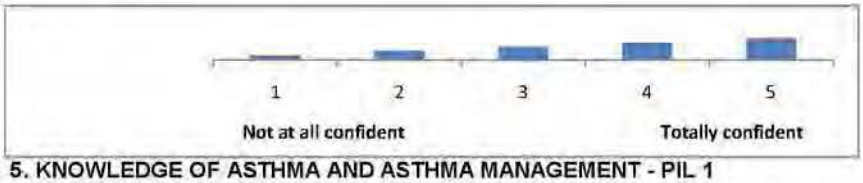
4.1 control your asthma so that asthma does not stop you from doing the things that you want to do?



4.2 use your medicines to manage your asthma?



4.3 do things other than just taking medicines to reduce how much your asthma affects your everyday life? *(avoiding trigger factors)*



5. KNOWLEDGE OF ASTHMA AND ASTHMA MANAGEMENT - PIL 1

5.1 Which part of your body is not working properly when you have asthma? Don't Know[1] | Lungs[2] | Chest[3] | Other[4]

Details of other _____

5.2 (*If answered lungs or chest for 3.1*) What happens in the lungs when you have asthma? N/A[0] | Don't Know[1] | Correct[2] | Incorrect[3] | Partially correct[4]

_____

(Correct = swelling, muscles tight & phlegm; Partially correct = mentioned 2 of previously mentioned)

5.2.a Mentioned swelling? Swelling[1]

5.2.b Mentioned muscles tight? Muscles tight[1]

5.2.c Mentioned phlegm? Phlegm[1]

(Show PIL 1 and explain what asthma is.)

5.3 Do you think it is important to take your medicines for asthma? Yes[1] | No[2] | Unsure[3]

If yes, explain why. _____

If no, explain why not. _____

Explain that it is important to take your medicines.

5.4 Do you think that if you stop taking your asthma medicines that your asthma will get worse? Yes[1] | No[2] | Unsure[3]

If yes, explain why. _____

If no, explain why not. _____

Explain that it is possible for asthma to get worse if medicines are stopped.

5.5 Do you think that if parents have asthma, then their children may also have asthma? | Yes[1] | No[2] | Unsure[3]

Explain that children may get asthma if their parents had asthma.

5.6 Do you think it is possible to get ("catch") asthma by being in the same room as another person with asthma? | Yes[1] | No[2] | Unsure[3]

Explain that a person cannot get asthma from being in contact with people with asthma.

5.7 Do you think that it is possible to live a normal, active life if you have asthma? | Yes[1] | No[2] | Unsure[3]

Explain that it is possible to lead a normal, active life if asthma is controlled.

5.8 Do you think that a person can die from having asthma that is not well controlled? | Yes[1] | No[2] | Unsure[3]

Explain that it is possible to die from asthma.

5.9 Do you think that asthma can be cured by taking medicines for asthma? | Yes[1] | No[2] | Unsure[3]

Explain that asthma cannot be cured but that medicines can reduce the number and severity of asthma attacks.

5.10 Do you know what causes your asthma? | N/A[0] | Yes[1] | No[2]

If yes, can you tell me what causes your asthma? _____

_____

(Show PIL 1 and explain trigger factors. Emphasise that the triggers do not affect everyone and that where possible, they should be avoided.)

6. KNOWLEDGE W.R.T. THE USE OF MDIs

6.1 Have you been shown how to use your asthma pump? | Yes[1] | No[2]

6.2 If yes, who first showed you? | N/A[0] | Pharmacist or pharm assistant[1] | Nurse[2] | Friends or family[3] | Doctor[4] | Other[5]

If other, please specify. _____

6.3 Have you seen the pamphlet that comes with your asthma pump? | Yes[1] | No[2]
(Show salbutamol and beclomethasone package inserts.)

6.4 Can you understand the **written information** in the pamphlet? | N/A[0] | Yes[1] | No[2]
(patient self-report)

6.5 Can you understand the **pictures** in the pamphlet? | N/A[0] | Yes[1] | No[2]
(patient self-report)

7. USE OF SALBUTAMOL MDI (BLUE PUMP)

(N/A = not using salbutamol MDI)

7.1 Have you been given a blue pump? *(Show salbutamol MDI.)*			Yes[1]	No[2]
7.2 Do you think that the blue pump helps your asthma?	N/A[0]	Yes[1]	No[2]	Don't know[3]
7.3 How many puffs do you use each time you use it?				
7.4 How many times a day do you use it?		N/A[0]	p r n[1]	
7.5 Does patient's response correspond to health passport?		N/A[0]	Yes[1]	No[2]
7.6 Are there times when you use your blue pump more often?		N/A[0]	Yes[1]	No[2]
7.7 If yes, how many puffs would you take?			N/A[0]	

** Explanation given: correct dose according to health passport*
** Explanation given: how blue pump works in the body (PIL 1)*

8. USE OF BECLOMETHASONE (BROWN PUMP)

8.1 Have you been given a brown pump? *(Show beclomethasone MDI)*			Yes[1]	No[2]
8.2 Do you think that the brown pump helps your asthma?		N/A[0]	Yes[1]	No[2]
8.3 How many puffs do you use each time you use it?			N/A[0]	
8.4 How many times a day do you use it?			N/A[0]	
8.5 Do you use it every day?		N/A[0]	Yes[1]	No[2]
8.6 If yes, do you know why you need to use it every day? *(Correct = to prevent asthma attacks)*	N/A[0]	Don't know[1]	Correct[2]	Other[3]

If other, fill in details here. _____

8.7 Does patient's response regarding dose correspond to health passport?	N/A[0]	Yes[1]	No[2]

** Explanation given regarding correct dose.*
** Explanation given: how brown pump works in the body (PIL 1)*
** It stops you getting lots of bad asthma attacks.*
** It takes between 1-4 weeks after starting the brown pump for it to work.*

8.8 Do you ever miss a dose?	N/A[0]	Yes[1]	No[2]	Sometimes[3]

8.9 What do you do if you miss a dose?	N/A[0]	Double the next dose[1]	Wait until it is time for the next dose[2]	Other[3]

If other, please explain. _____

** Explanation: If it is almost time for your next dose, wait until then to use the medicine.*
** Do not use extra medicine because it is not good to have too much medicine in your body.*
** The brown pump must be used every day even if you are feeling well.*

8.10 Do you rinse your mouth out after using the brown pump?	N/A [0]	Yes [1]	No [2]		
8.11 If yes, why do you rinse your mouth out?	N/A [0]	Correct [1]	Incorrect [2]	Not rinsing [3]	
8.12 Have you been told to rinse your mouth out after using the brown pump?	N/A [0]	Yes [1]	No [2]		
8.13 If yes, who told you to do this?	N/A [0]	Pharmacist or pharm assistant [1]	Nurse [2]	Friends or Family [3]	Doctor [4]	Other [5]

If other, please specify. _____

* *Explanation: You must rinse your mouth out to remove any medicine left in your mouth.*

9. MDI TECHNIQUE - PIL 2.

(Placebo to be cleaned between patients, using alcohol swab).

9.1 Have you been given a spacer? *(show spacer)*	Yes [1]	No [2]	
9.2 Do you use a spacer?	N/A [0]	Yes [1]	No [2]

Using the placebo pump ask the respondent to inhale 2 puffs.
Explain that the placebo does not contain any medicine. Patient may taste the "air" in the inhaler.

			Correct [1]	Incorrect [2]
9.3	step 1	Remove mouth piece cap		
9.4	step 2	Hold pump upright with thumb on base, below mouthpiece		
9.5	step 3	Shake pump		
9.6	step 4	Tilt head slightly backwards		
9.7	step 5	Breathe out through the mouth		
9.8	step 6	Put mouthpiece in mouth		
9.9	step 7	Actuate pump once during inspiration		
9.10	step 8	Remove pump from mouth		
9.11	step 9	Hold breath for 5-10 seconds		
9.12	step 10	Breathe in and out through the nose		
9.13	step 11	Wait approx 30 seconds before next inhalation		
9.14	step 12	Replace the cap		

9.15 All steps correct	Yes [1]	No [2]
9.16 Number of steps correct		

If necessary, demonstrate correct procedure - PIL 2 and placebo.

If necessary, ask respondent to repeat the procedure.

			Correct [1]	Incorrect [2]
9.17	step 1	Remove mouth piece cap		
9.18	step 2	Hold pump upright with thumb on base, below mouthpiece		
9.19	step 3	Shake pump		
9.20	step 4	Tilt head slightly backwards		
9.21	step 5	Breathe out through the mouth		
9.22	step 6	Put mouthpiece in mouth		
9.23	step 7	Actuate pump once during inspiration		
9.24	step 8	Remove pump from mouth		
9.25	step 9	Hold breath for 5-10 seconds		
9.26	step 10	Breathe in and out through the nose		
9.27	step 11	Wait approx 30 seconds before next inhalation		
9.28	step 12	Replace the cap		

9.29 All steps correct	Yes[1]	No[2]
9.30 Number of steps correct		
If necessary, demonstrate correct procedure a second time - PIL 2	N/A[0]	Done[1]

10. ACCEPTABILITY & USE OF PILs 1 & 2. (2nd interview only)

10.1	Do you think it was easy to read this pamphlet?	Easy[1]	Not that difficult[2]	Difficult[3]
10.2	Is the writing big enough?	Yes[1]	No[2]	
10.3	Are there any words in the pamphlet that you did not understand?	Yes[1]	No[2]	
	If yes, please point out _____			
	_____			
10.4	*Number of words not understood?*			
10.5	Do you like having pictures in the pamphlet ?	Yes[1]	No[2]	
10.6	Are there any pictures that you did not understand?	Yes[1]	No[2]	
	If yes, please point out. _____			
	_____			
10.7	Did the pamphlet help you to use your asthma pump correctly?	Yes[1]	No[2]	
	If yes, how did the pamphlet help you? _____			
10.8	Did the pamphlet help you to understand what asthma is?	Yes[1]	No[2]	
	If yes, how did the pamphlet help you? _____			
10.9	Did the pamphlet help to remind you about what can start an asthma attack?	Yes[1]	No[2]	
	If yes, how did the pamphlet help you? _____			
10.10	Did any of your family members read this pamphlet?	Yes[1]	No[2]	
	If yes, why did they read it? _____			
	_____			
10.11	Did the pamphlets help you in any other way?	Yes[1]	No[2]	
	If yes, give details. _____			
	_____			

Appendix A17

Main study questionnaire: baseline interviews

QUESTIONNAIRE - PILs FOR ASTHMATICS - 2008

Researcher: W. Wrench_____

Name of the clinic _____ Date _____

Respondent number [ ]

Respondent name _____

First or second interview? [First 1] [Second 2]

Has the consent form been explained and signed?

Contact number? _____

1. DEMOGRAPHICS

1.1 Gender [Male 1] [Female 2]

1.2. Age in years *(or date of birth)* [ ] yrs

1.3 Race [Black 1] [White 2] [Coloured 3] [Asian 4]

1.4 Home language [Xhosa 1] [English 2] [Afrikaans 3] [Other 4]

If other, please specify. _____

1.5 Highest level of school education? [Grade]

1.6 If any, specify additional or informal courses. _____

1.7 Are you employed? [Not employed 0] [Part-time 1] [Full-time 2]

1.8 If employed, what type of work do you do? _____

2. MEDICAL HISTORY

2.1 In the last 2 weeks, how has your asthma been? [Completely controlled 1] [Somewhat controlled 2] [Not controlled at all 3]

2.2 What medicines are you taking for asthma? *(patient self-report)*

[Bec 1] [Sal 2] [Bec & Sal 3]
[Sal & Theo 4] [Bec & Theo 5]
[Other 6] [Bec, Sal & Theo 6] [Bec, Sal & Pred 7]

If other, give details._____

2.3 Prescribed asthma medicines *(according to health passport)*

[Bec 1] [Sal 2] [Bec & Sal 3]
[Sal & Theo 4] [Bec & Theo 5]
[Other 6] [Bec, Sal & Theo 6] [Bec, Sal & Pred 7]

If other, give details._____

2.4 How long have you had asthma? _____ [ ] mths
(patient self-report)

2.5 How long have you been using asthma pumps? _____ [ ] mths
(patient self-report)

2.6 If you smoke, what do you smoke?

Non-smoker[0]	cigarettes[1]	pipe[2]	rolled cigarettes[3]
Other[4]			

If other, please specify. _____

2.7 If you smoke, how many do you smoke per day?

Non-smoker[0]	< 5 /day [1]	5-10/day [2]	11-20/day [3]	>20 /day[4]

3. ASTHMA AND SELECTED HEALTH-RELATED QUALITY OF LIFE MEASURES

(show graphs on separate sheet of paper)

3.1 In general, would you say your health is:

0	1	2	3	4	5
poor					excellent

3.2 In the last 2 weeks, have you been affected by shortness of breath? Please point to the number that describes your shortness of breath in the last 2 weeks.

0	1	2	3	4	5
no shortness of breath					severe shortness of breath

During the last 2 weeks, how much has asthma interfered with your:

3.3 Ability to work?
(only ask if person is employed)
(activity limitation)

N/A[6]	0	1	2	3	4	5
	not at all					all the time

3.4 Social life such as going to church, visiting friends, family occasions etc?
(activity limitation)

0	1	2	3	4	5
not at all					all the time

3.5 Day to day activities at home such as cooking, cleaning, sweeping, washing, working in garden etc?
(activity limitation)

QN/A	0	1	2	3	4	5
	not at all					all the time

3.6 Ability to exercise, walk long distances etc?
(activity limtation - aerobic exercise)

QN/A	0	1	2	3	4	5
	not at all					all the time

3.7 Ability to sleep well at night?
(symptoms)

0	1	2	3	4	5
not at all					all the time

3.8 In general, how often do you feel worried that you have asthma?
(emotional function)

0	1	2	3	4	5
never					all the time

4. SELF-EFFICACY

How confident are you that you can.....

4.1 control your asthma so that asthma does not stop you from doing the things that you want to do?

0	1	2	3	4	5
not at all confident					totally confident

_____

_____

4.2 use your medicines to manage your asthma?

0	1	2	3	4	5

not at all confident — totally confident

4.3 Don't think about your asthma medicines for this question.
How confident are you that you can avoid the things that make asthma worse?
(avoiding trigger factors)

0	1	2	3	4	5

not at all confident — totally confident

5. KNOWLEDGE OF ASTHMA AND ASTHMA MANAGEMENT - PIL 1

5.1 Which part of your body is not working properly when you have asthma?

Don't Know[1] | [redacted] | Chest[3]
Other[4]

*Details of other*_____

5.2 *If answered lungs or chest for 3.1,* What happens in the lungs/chest when you have asthma?

N/A[0] | Don't Know[1] | [redacted] | Incorrect[3]
Partially correct[4]

(Correct = swelling, tightness & phlegm. Partially correct = mentioned 2 of previously mentioned)

5.2.1 Mentioned swelling? N/A[0] | Yes[1] | No[2]

5.2.2 Mentioned tightness? N/A[0] | Yes[1] | No[2]

5.2.3 Mentioned phlegm? N/A[0] | Yes[1] | No[2]

Show PIL 1 and explain what asthma is.

5.3 Do you think it is important to take your medicines for asthma? [redacted] | No[2] | Unsure[3]

If yes, explain why. _____

If no, explain why not. _____

Explain that it is important to take your medicines.

5.4 Do you think that if you stop taking your asthma medicines that your asthma will get worse? [redacted] | No[2] | Unsure[3]

If yes, explain why. _____

If no, explain why not. _____

Explain that it is possible for asthma to get worse if medicines are stopped.

5.5 Do you think that if parents have asthma, then their children may also have asthma? | Yes[1] | No[2] | Unsure[3]

Explain that children may get asthma if their parents had asthma.

5.6 Do you think it is possible to get asthma by being in the same room as another person (not a family member) with asthma? | Yes[1] | No[2] | Unsure[3]

Explain that a person cannot get asthma from being in contact with people with asthma. Asthma is not infectious.

5.7 Do you think that it is possible to live a normal, active life if you have asthma? | Yes[1] | No[2] | Unsure[3]

Explain that it is possible to lead a normal, active life if asthma is controlled.

5.8 Do you think that a person can die from having asthma that is not well controlled? | Yes[1] | No[2] | Unsure[3]

Explain that it is possible to die from asthma that is not well controlled.

5.9 Do you think that asthma can be cured by taking medicines for asthma? | Yes[1] | No[2] | Unsure[3]

Explain that asthma cannot be cured but that medicines can reduce the number and severity of asthma attacks.

5.10 Do you know what causes your asthma attacks? | N/A[0] | Yes[1] | No[2] | Unsure[3]

If yes, can you tell me what causes your asthma? _____

_____

Show PIL 1 and explain trigger factors. Emphasise that the triggers do not affect everyone and that where possible, they should be avoided.

6. KNOWLEDGE OF ASTHMA AND ASTHMA MANAGEMENT - PIL 1

6.1 Have you been shown how to use your asthma pump? | Yes[1] | No[2]

6.2 If yes, who first showed you? | N/A[0] | Pharmacist or Pharm assist[1] | Nurse[2] | Friends or family[3] | Doctor[4] | Other[5] | Don't know[6]

If other, please specify. _____

6.3 Have you seen the pamphlet that comes with your asthma pump? | Yes[1] | No[2]
Show salbutamol package insert.

6.4 Have you read the **written information**? | Yes[1] | No[2]

6.5 *If yes for 6.4,* do you **understand** the **written information** in the pamphlet? *(patient self-report)* | N/A[0] | Yes[1] | No[2] | Partly[3] | Other[4]

If other, give details_____

6.7 *If no for 6.4,* why have you not read them? | N/A 0 | Can't read 1 | Not in my language 2 | Other 3

If other, give details_____

6.8 Have you seen the **pictures** in the pamphlet? | Yes 1 | No 2

6.9 If yes, do you **understand** the **pictures** in the pamphlet? *(patient self-report)* | N/A 0 | Yes 1 | No 2 | Partly 3

7. USE OF SALBUTAMOL MDI (BLUE PUMP)

(N/A = not using salbutamol MDI)

7.1 Do you think that the blue pump helps your asthma? | N/A 0 | Yes 1 | No 2 | Unsure 3

7.2 How many puffs do you use each time you use it? | |

7.3 How many times a day do you use it? | N/A 0 | p r n 1 | |

7.4 Does patient's response correspond to health passport?

| N/A 0 | Yes 1 | No 2 | Dose not in passport 3 |

7.5 Do you ever take more puffs than what you told me just now? You said that you take . . puffs. | N/A 0 | Yes 1 | No 2

7.6 If yes, how many puffs would you take? | N/A 0 | |

7.7 If incorrect, explanation given:

N/A 0	dose according to health passport explained. 1
	no dose in passport, advised 2 puffs every 4-6 hours prn 2
	advised 2 puffs every 4-6 hours prn 3

7.8 Do you know how the blue pump works in your body? | N/A 0 | Yes 1 | No 2

7.9 If yes, give details._____ | N/A 0 | Correct 1 | Incorrect 2

_____

Explanation given: how blue pump works in the body (PIL 1)

7.10 Where do you keep your blue pump?_____ | N/A 0 | Correct 1 | Incorrect 2

If incorrect, explanation given: Keep the blue pump with you at all times in case you need it for an asthma attack.

8. USE OF BECLOMETHASONE (BROWN PUMP)

N/A answers = patient not using belomethasone

8.1 Do you think that the brown pump helps your asthma? | N/A 0 | Yes 1 | No 2 | Unsure 3

8.2 How many puffs do you use each time you use it? | N/A 0 | |

8.3 How many times a day do you use it? | N/A 0 | |

8.4 Do you use it every day? | N/A 0 | Yes 1 | No 2

8.5 If yes, do you know why you need to use it every day? | N/A 0 | Don't know 1 | Correct 2 | Other 3
(Correct = to prevent asthma attacks)

Details of other: _____

8.6 Does patient's response regarding dose correspond to health passport?
N/A 0 | Yes 1 | No 2 | Dose not in passport 3

If no, correct dose explained to patient according to health passport
If dose not in passport, referred to sister. _____

8.7 Do you know how your brown pump works in your body? | N/A 0 | Yes 1 | No 2

8.7.1. If yes, explain. _____ | N/A 0 | Correct 1 | Incorrect 2 | Partially correct 3
(correct = reduces swelling and phlegm)
If incorrect or partially incorrect, explanation given: how brown pump works in the body (PIL 1)
It stops you getting lots of bad asthma attacks.
It takes between 1-4 weeks after starting the brown pump for it to work.

8.8 Do you ever miss a dose? | N/A 0 | Yes 1 | No 2 | Sometimes 3 | Not taking daily 4

8.9 What do you do if you miss a dose? | N/A 0 | Double the next dose 1 | Wait until it is time for the next dose 2 | Other 3
(If yes or sometimes TO 8.8)

_____

Explanation: If it is almost time for your next dose, wait until then to use the medicine.
Do not use extra medicine because it is not good to have too much medicine in your body.
The brown pump must be used every day even if you are feeling well.

8.10 Do you rinse your mouth out after using the brown pump? | N/A 0 | Yes 1 | No 2 | Sometimes 3

8.11 If yes or sometimes, why do you rinse your mouth out? | N/A 0 | Correct 1 | Incorrect 2

_____

8.12 Have you been told to rinse your mouth out after using the brown pump? | N/A 0 | Yes 1 | No 2

8.13 If yes, who told you to do this? | N/A 0 | Pharmacist or pharm assistant 1 | Nurse 2 | Friends or Family 3 | Doctor 4 | Other 5

If other, please specify: _____

Explanation: You must rinse your mouth out to remove any medicine left in your mouth. Spit the water out.

8.14 Where do you keep your brown pump? _____ | N/A 0 | Correct 1 | Incorrect 2
(correct = away from children)
If incorrect, explanation given

9. MDI TECHNIQUE - PIL 2.

(Placebo to be used).

9.1 Have you been given a spacer? | Yes 1 | No 2
(show spacer)

9.2 Do you use a spacer?	N/A [9]	Yes [1]	No [2]

Using the placebo pump ask the respondent to inhale 2 puffs.
Explain that the placebo does not contain any medicine. Patient may taste the "air" in the inhaler.

			Correct [1]	Incorrect [2]
9.3	step 1	Remove mouth piece cap		
9.4	step 2	Hold pump upright with thumb on base, below mouthpiece		
9.5	step 3	Shake pump		
9.6	step 4	Tilt head slightly backwards		
9.7	step 5	Breathe out through the mouth		
9.8	step 6	Put mouthpiece in mouth with lips closed tightly round it		
9.9	step 7	Actuate pump once during inspiration		
9.10	step 8	Remove pump from mouth		
9.11	step 9	Hold breath for 5-10 seconds		
9.12	step 10	Breathe normally through the nose		
9.13	step 11	Wait approx 30-60 seconds before next inhalation		
9.14	step 12	Replace the cap		

9.15 All steps correct	Yes [1]	No [2]

9.16 Number of steps correct	

If necessary, demonstrate correct procedure - PIL 2 and placebo.

If necessary, ask respondent to repeat the procedure.

			Correct [1]	Incorrect [2]
9.17	step 1	Remove mouth piece cap		
9.18	step 2	Hold pump upright with thumb on base, below mouthpiece		
9.19	step 3	Shake pump		
9.20	step 4	Tilt head slightly backwards		
9.21	step 5	Breathe out through the mouth		
9.22	step 6	Put mouthpiece in mouth with lips closed tightly round it		
9.23	step 7	Actuate pump once during inspiration		
9.24	step 8	Remove pump from mouth		
9.25	step 9	Hold breath for 5-10 seconds		
9.26	step 10	Breathe normally through the nose		
9.27	step 11	Wait approx 30-60 seconds before next inhalation		
9.28	step 12	Replace the cap		

9.29 All steps correct	Yes [1]	No [2]

9.30 Number of steps correct	

9.3.1 If necessary, demonstrate correct procedure a second time - PIL 2.	N/A [9]	Done [1]

1st interview:patient to sign for R30
date and time for next interview arranged. *Date:* *Time:*

10. REFERRAL

10.1 Referral to health care system:	Yes [1]	No [2]

*If yes, reason(s) for referral*_____

Thank you for agreeing to meet me to discuss your asthma.

Please be at the clinic on ..... at.....

As mentioned in the information given to you, you will be paid R30 for the interview.
Wendy Wrench

QNA = QUESTION NOT ASKED. added for patient in wheelchair

Appendix A18

Main study questionnaire: follow-up interviews

QUESTIONNAIRE - PILs FOR ASTHMATICS - 2008

Researcher: W. Wrench_____

Name of the clinic _____ Date _____

Respondent number [ ]

Respondent name _____

First or second interview? [1] First [2] Second

Contact number? _____

2. MEDICAL HISTORY

2.1 In the last 2 weeks, how has your asthma been?

[1] Completely controlled	[2] Somewhat controlled	[3] Not controlled at all

2.2 What medicines are you taking for asthma?
(patient self-report)
If other, give details _____

[1] Bec	[2] Sal	[3] Bec & Sal
	[4] Sal & Theo	[5] Bec & Theo
[6] Other	[8] Bec, Sal & Theo	[7] Bec, Sal & Pred

2.3 Prescribed asthma medicines
(according to health passport)
If other, give details _____

[1] Bec	[2] Sal	[3] Bec & Sal
	[4] Sal & Theo	[5] Bec & Theo
[6] Other	[8] Bec, Sal & Theo	[7] Bec, Sal & Pred

3. ASTHMA AND SELECTED HEALTH-RELATED QUALITY OF LIFE MEASURES
(show graphs on separate sheet of paper)

3.1 In general, would you say your health is:

0	1	2	3	4	5

0 = poor; 5 = excellent

3.2 In the last 2 weeks, have you been affected by shortness of breath? Please point to the number that describes your shortness of breath in the last 2 weeks.

0	1	2	3	4	5

0 = no shortness of breath; 5 = severe shortness of breath

During the last 2 weeks, how much has asthma interfered with your:

3.3 Ability to work?
(only ask if person is employed)
(activity limitation)

[9] N/A	0	1	2	3	4	5

0 = not at all; 5 = all the time

3.4 Social life such as going to church, visiting friends, family occasions etc?
(activity limitation)

0	1	2	3	4	5

0 = not at all; 5 = all the time

3.5 Day to day activities at home such as cooking, cleaning, sweeping, washing, working in garden etc?
(activity limitation)

0	1	2	3	4	5

0 = not at all; 5 = all the time

3.6 Ability to exercise, walk long distances etc?
(activity limtation - aerobic exercise)

0	1	2	3	4	5
not at all					all the time

3.7 Ability to sleep well at night?
(symptoms)

0	1	2	3	4	5
not at all					all the time

3.8 In general, how often do you feel worried that you have asthma?
(emotional function)

0	1	2	3	4	5
never					all the time

4. SELF-EFFICACY

How confident are you that you can.....

4.1 control your asthma so that asthma does not stop you from doing the things that you want to do?

0	1	2	3	4	5
not at all confident					totally confident

4.2 use your medicines to manage your asthma?

0	1	2	3	4	5
not at all confident					totally confident

4.3 Don't think about your asthma medicines for this question
How confident are you that you can avoid the things that make asthma worse?
(avoiding trigger factors)

0	1	2	3	4	5
not at all confident					totally confident

5. KNOWLEDGE OF ASTHMA AND ASTHMA MANAGEMENT - PIL 1

5.1 Which part of your body is not working properly when you have asthma?

Don't Know[1]	Lungs[2]	Chest[3]
Other[4]		

*Details of other*_____

5.2 *If answered lungs or chest for 3.1,* What happens in the lungs/chest when you have asthma?

N/A[0]	Don't Know[1]	Correct[2]	Incorrect[3]
Partially correct[4]			

(Correct = swelling, tightness & phlegm; Partially correct = mentioned 2 of previously mentioned)

5.2.1 Mentioned swelling?

N/A[0]	Yes[1]	No[2]

5.2.2 Mentioned tightness?

N/A[0]	Yes[1]	No[2]

5.2.3 Mentioned phlegm?

N/A[0]	Yes[1]	No[2]

Show PIL 1 and explain what asthma is

5.3 Do you think it is important to take your medicines for asthma? | Yes[1] | No[2] | Unsure[3]

If yes, explain why. _____

_____

If no, explain why not. _____

Explain that it is important to take your medicines.

5.4 Do you think that if you stop taking your asthma medicines that your asthma will get worse? | Yes[1] | No[2] | Unsure[3]

If yes, explain why. _____

_____

If no, explain why not. _____

Explain that it is possible for asthma to get worse if medicines are stopped.

5.5 Do you think that if parents have asthma, then their children may also have asthma? | Yes[1] | No[2] | Unsure[3]

Explain that children may get asthma if their parents had asthma

5.6 Do you think it is possible to get asthma by being in the same room as another person (not a family member) with asthma? | Yes[1] | No[2] | Unsure[3]

Explain that a person cannot get asthma from being in contact with people with asthma. Asthma is not infectious.

5.7 Do you think that it is possible to live a normal, active life if you have asthma? | Yes[1] | No[2] | Unsure[3]

Explain that it is possible to lead a normal, active life if asthma is controlled.

5.8 Do you think that a person can die from having asthma that is not well controlled? | Yes[1] | No[2] | Unsure[3]

Explain that it is possible to die from asthma that is not well controlled.

5.9 Do you think that asthma can be cured by taking medicines for asthma? | Yes[1] | No[2] | Unsure[3]

Explain that asthma cannot be cured but that medicines can reduce the number and severity of asthma attacks.

5.10 Do you know what causes your asthma attacks? | N/A[0] | Yes[1] | No[2]

If yes, can you tell me what causes your asthma? _____

_____

Show PIL 1 and explain trigger factors. Emphasise that the triggers do not affect everyone and that where possible, they should be avoided.

7. USE OF SALBUTAMOL MDI (BLUE PUMP)

(N/A = not using salbutamol MDI)

7.1 Do you think that the blue pump helps your asthma? | N/A 0 | Yes 1 | No 2 | Unsure 3

7.2 How many puffs do you use each time you use it? | |

7.3 How many times a day do you use it? | N/A 0 | p r n 1 | |

7.4 Does patient's response correspond to health passport?

N/A 0	Yes 1	No 2	Dose not in passport 3

7.5 Do you ever take more puffs than what you told me just now?
You said that you take ....puffs. | N/A 0 | Yes 1 | No 2 |

7.6 If yes, how many puffs would you take? | N/A 0 | |

7.7 If incorrect, explanation given.

N/A 0	dose according to health passport explained. 1
	no dose in passport, advised 2 puffs every 4-6 hours prn 2
	advised 2 puffs every 4-6 hours prn 3

7.8 Do you know how the blue pump works in your body? | N/A 0 | Yes 1 | No 2

7.9 If yes, give details._____ | N/A 0 | Correct 1 | Incorrect 2

_____

Explanation given: how blue pump works in the body (PIL 1)

7.10 Where do you keep your blue pump?_____ | N/A 0 | Correct 1 | Incorrect 2

If incorrect, explanation given: Keep the blue pump with you at all times in case you need it for an asthma attack.

8. USE OF BECLOMETHASONE (BROWN PUMP)

(N/A = not using beclomethasone MDI)

8.1 Do you think that the brown pump helps your asthma? | N/A 0 | Yes 1 | No 2 | Unsure 3

8.2 How many puffs do you use each time you use it? | N/A 0 | |

8.3 How many times a day do you use it? | N/A 0 | |

8.4 Do you use it every day? | N/A 0 | Yes 1 | No 2

8.5 If yes, do you know why you need to use it every day? | N/A 0 | Don't know 1 | Correct 2 | Other 3
(Correct = to prevent asthma attacks)

Details of other: _____

8.6 Does patient's response regarding dose correspond to health passport?

N/A 0	Yes 1	No 2	Dose not in passport 3

If no, correct dose explained to patient according to health passport

*If dose not in passport, referred to sister.*_____

8.7 Do you know how your brown pump works in your body? | N/A [0] | Yes [1] | No [2]

If yes, explain._____ | N/A [0] | Correct [1] | Incorrect [2] | Partially correct [3]

(correct = reduces swelling and phlegm)

If incorrect or partially incorrect, explanation given: how brown pump works in the body (PIL 1)

It stops you getting lots of bad asthma attacks.

It takes between 1-4 weeks after starting the brown pump for it to work.

8.8 Do you ever miss a dose? | N/A [0] | Yes [1] | No [2] | Sometimes [3] | Not taking daily [4]

8.9 What do you do if you miss a dose? | N/A [0] | Double the next dose [1] | Wait until it is time for the next dose [2] | Other [3]

_____

Explanation: If it is almost time for your next dose, wait until then to use the medicine.
Do not use extra medicine because it is not good to have too much medicine in your body.
The brown pump must be used every day even if you are feeling well.

8.10 Do you rinse your mouth out after using the brown pump? | N/A [0] | Yes [1] | No [2] | Sometimes [3]

8.11 If yes or sometimes, why do you rinse your mouth out? | N/A [0] | Correct [1] | Incorrect [2]

_____

Explanation: You must rinse your mouth out to remove any medicine left in your mouth. Spit the water out.

8.14 Where do you keep your brown pump?_____ | N/A [0] | Correct [1] | Incorrect [2]

(correct = away from children)
If incorrect, explanation given.

9. MDI TECHNIQUE - PIL 2.

(Placebo to be used).

Using the placebo pump ask the respondent to inhale 2 puffs.
Explain that the placebo does not contain any medicine. Patient may taste the "air" in the inhaler.

			Correct [1]	Incorrect [2]
9.3	step 1	Remove mouth piece cap		
9.4	step 2	Hold pump upright with thumb on base, below mouthpiece		
9.5	step 3	Shake pump		
9.6	step 4	Tilt head slightly backwards		
9.7	step 5	Breathe out through the mouth		
9.8	step 6	Put mouthpiece in mouth with lips closed tightly round it		
9.9	step 7	Actuate pump once during inspiration		
9.10	step 8	Remove pump from mouth		
9.11	step 9	Hold breath for 5-10 seconds		
9.12	step 10	Breathe normally through the nose		
9.13	step 11	Wait approx 30-60 seconds before next inhalation		
9.14	step 12	Replace the cap		

9.15 All steps correct | Yes [1] | No [2]

9.16 Number of steps correct ☐

If necessary, demonstrate correct procedure - PIL 2 and placebo.

If necessary, ask respondent to repeat the procedure

			Correct[1]	Incorrect[2]
9.17	step 1	Remove mouth piece cap		
9.18	step 2	Hold pump upright with thumb on base, below mouthpiece		
9.19	step 3	Shake pump		
9.20	step 4	Tilt head slightly backwards		
9.21	step 5	Breathe out through the mouth		
9.22	step 6	Put mouthpiece in mouth with lips closed tightly round it		
9.23	step 7	Actuate pump once during inspiration		
9.24	step 8	Remove pump from mouth		
9.25	step 9	Hold breath for 5-10 seconds		
9.26	step 10	Breathe normally through the nose		
9.27	step 11	Wait approx 30-60 seconds before next inhalation		
9.28	step 12	Replace the cap		

9.29 All steps correct Yes[1] No[2]

9.30 Number of steps correct ☐

9.31 If necessary, demonstrate correct procedure a second time - PIL 2. N/A[0] Done[1]

10. REFERRAL

10.1 Referral to health care system. Yes[1] No[2]

*If yes, reason(s) for referral*_____

_____

11. ACCEPTABILITY OF PILS

11.1 Do you think it was easy to read these pamphlets? Yes[1] No[2] Can't read[3]

If yes, explain why_____

If no, explain why not_____

11.2 Is the writing big enough? Yes[1] No[2] Can't read[3]

11.3 Are there any words in the pamphlets that you did not understand? Yes[1] No[2] Can't read[3]

If yes, please point out_____

_____

11.4 *Number of words not understood?* ☐

11.5 Do you like having pictures in the pamphlets ? Yes[1] No[2]

11.6 Are there any pictures that you did not understand? Yes[1] No[2]

If yes, please point out. _____

_____

11.7 Did the pamphlet help you to understand what asthma is? Yes[1] No[2]

If yes, how did the pamphlet help you? _____

_____

If no, what else could I do to help you to understand what asthma is? _____

_____

11.8 Did the pamphlet help to remind you about what can possibly start an asthma attack? Yes[1] No[2]

If yes, how did the pamphlet help you? _____

_____

If no, what else could I do to help you to know what can start an asthma attack? _____

_____

11.9 Did the pamphlet help you to use your asthma pump correctly? Yes[1] No[2]

If yes, how did the pamphlet help you? _____

_____

If no, what else could I do to help you to use your pump correctly? _____

_____

11.10 Did any of your family members read this pamphlet? Yes[1] No[2]

If yes, why did they read it? _____

_____

If no, why didn't they read it? _____

11.11 Did the pamphlets help you in any other way? Yes[1] No[2]

If yes, give details. _____

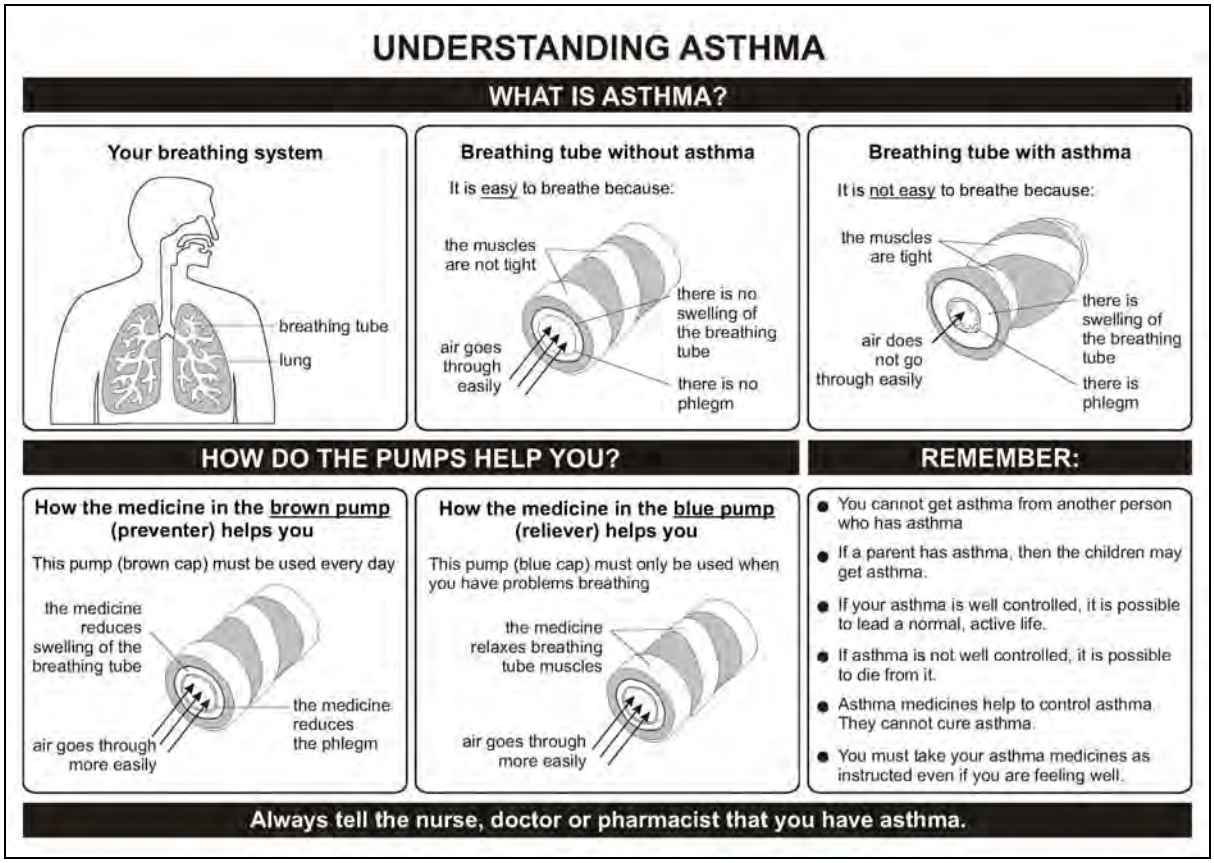
_____

Thank you for your time. Please sign for the R30 for your time and transport costs. I will ask the clinic to let you know if I need to see you again.

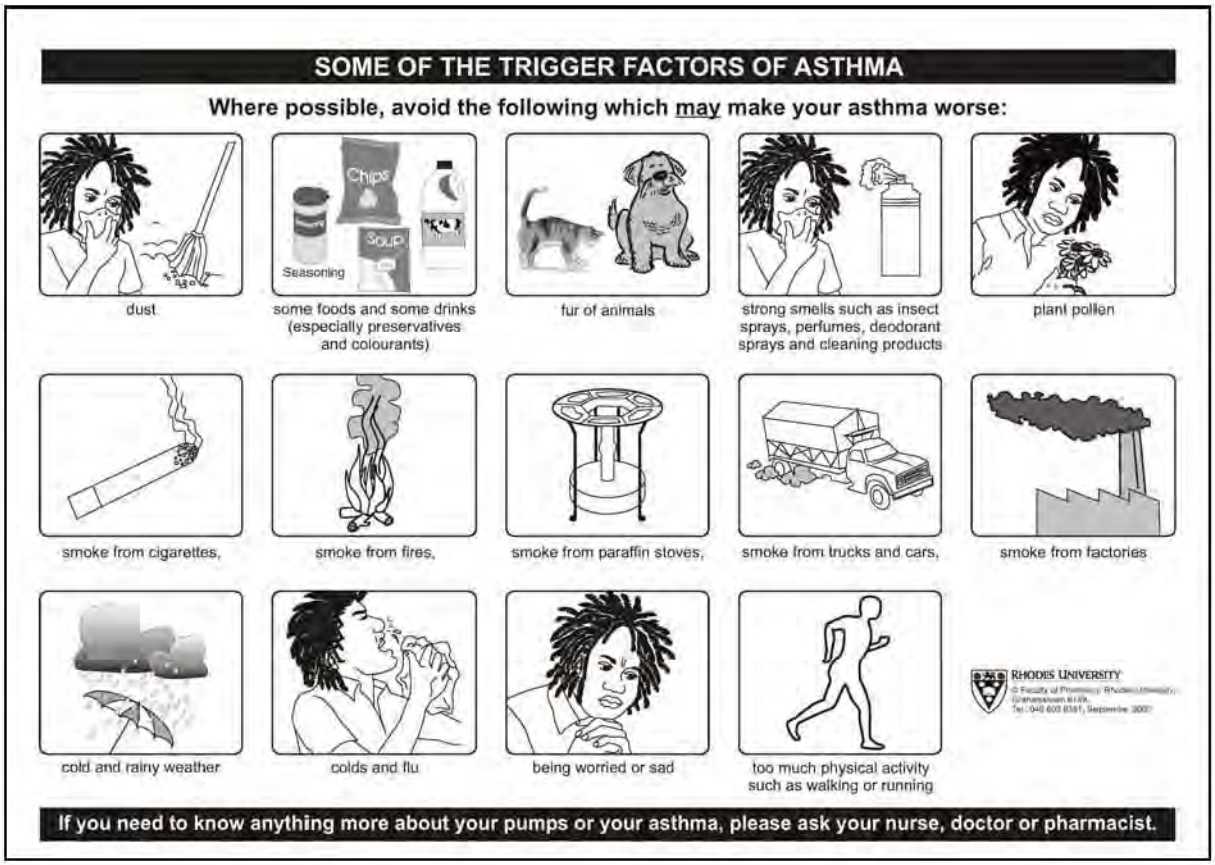
QNA = question not asked

Appendix A19

Main study PIL: 'Understanding asthma and trigger factors of asthma' (pg 1)

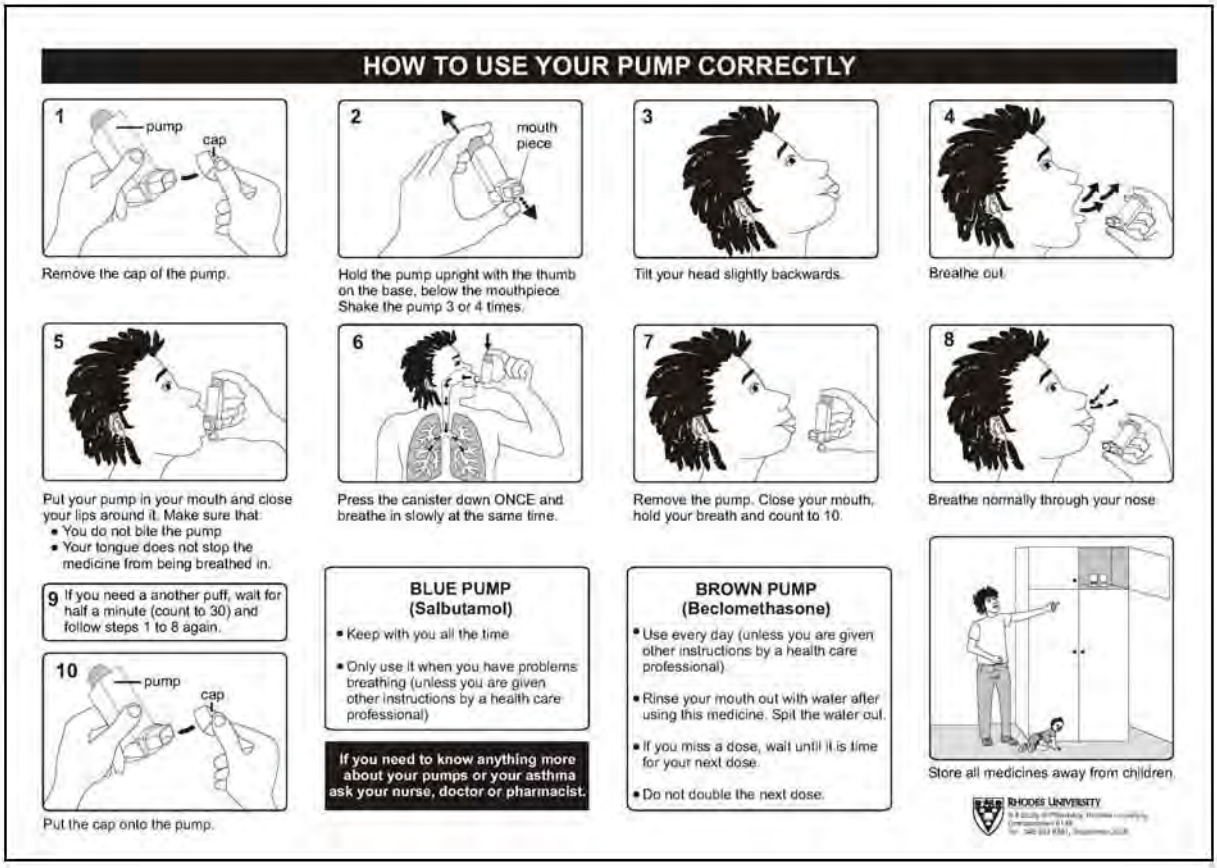


Main study PIL: 'Understanding asthma and trigger factors of asthma' (pg 2)



Appendix A20

Main study PIL: 'How to use your pump correctly'



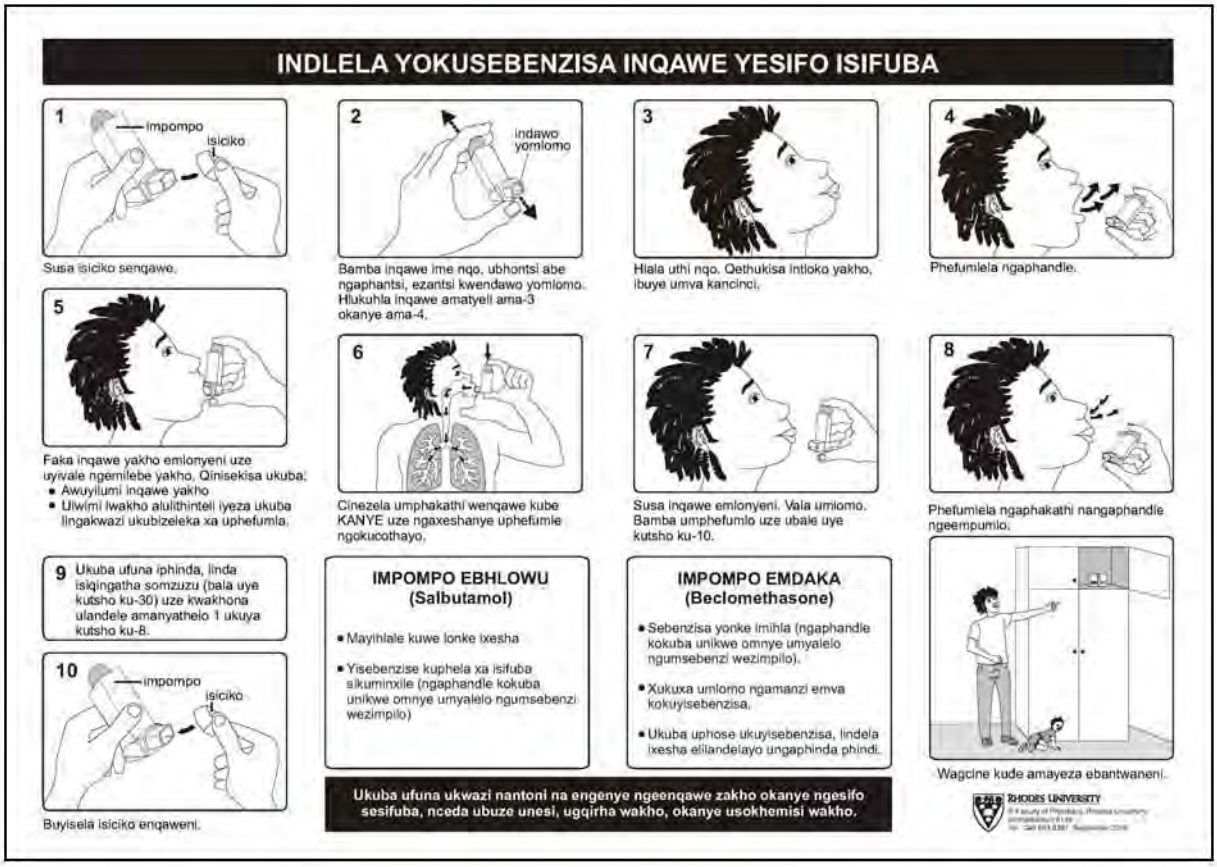
Appendix A21

Main study PIL: ‘Understanding asthma and trigger factors of asthma’ (isiXhosa) (pg 1)

Main study PIL: 'Understanding asthma and trigger factors of asthma' (isiXhosa) (pg 2)

Appendix A22

Main study PIL: ‘How to use your pump correctly’ (isiXhosa)



Appendix A23

Main study: information for patients before partaking in the study

RHODES UNIVERSITY
Faculty of Pharmacy

INFORMATION FOR PARTICIPANTS IN MASTERS RESEARCH:

WENDY WRENCH

(To be read by participants or to be explained to participants.)

My name is Wendy Wrench and I am registered for a postgraduate degree at Rhodes University. My supervisors are Prof S. Srinivas and Prof R. Dowse. My area of research is asthma and I would therefore like to invite you to take part in this research. I have designed new information leaflets on asthma and asthma medicine and I would like to test them. I also want to find out how asthma affects your life.

This information form gives detailed information about the research study. You may read the information or have it explained to you. You may ask me any questions as it is important that you understand the research. You will be asked to sign a consent form if you wish to take part. You will receive a copy of the information to take home as a record.

WHY ARE WE DOING THIS STUDY?

The purpose of this study is to give patients like you information about asthma and asthma medicines in a format that I hope you will be able to read and understand. I would like to test if the information you are given helps you understand more about your asthma. I would also like to find out about your asthma medicine, how you take it and the effect it has on your body. I do not want to test your intelligence; I only want to test how good the leaflets are and to see if they improve your understanding and knowledge of asthma and asthma medicines.

I am looking for people who:

- are 21 years or older
- are dependant on public sector health care facilities in the Makana, and/or Ndlambe LSAs.
- have been diagnosed with asthma
- have been prescribed a metered dose inhaler (beclomethasone and/or salbutamol) for at least one month
- are English or Xhosa-speaking

WHAT WILL YOU DO IF YOU TAKE PART IN THIS STUDY?

I will interview you twice at the primary health care clinic that you attend in the Makana or Ndlambe local services area. I may use an interpreter to help me understand what you are saying. Each interview will take about 1 hour. In the first interview I will ask you questions about yourself and about your asthma. I will explain the information on the leaflets which I will then give to you to take home. I may use visual images (photos, videos, etc.) of you during the interviews. Please read/look at the leaflets when you are at home as they were made to help you understand asthma, what causes an asthma attack, as well as how to use your asthma pump (inhaler) correctly. The second interview will take place about 1-3 months after the first interview. This interview should also take about 1 hour. I may do a third interview after this. You will be paid R30 per interview.

HOW WILL THIS STUDY HELP PATIENTS LIKE YOU?

After testing the leaflets, I will know which ones are better in helping you to understand more about your asthma and asthma medicines. I will also be able to improve them. The more you understand, the better you will be able to take care of yourself and your asthma. In the future, I would like to give these leaflets to health care providers (e.g. nurses, doctors, pharmacists and community health workers) and patients in South Africa so that people can understand asthma better and have less asthma attacks.

PRIVACY

I will need to look at your health passport to record information such as what medicine you are taking and how asthma is affecting your life. Please would you give me permission to look at your health passport? All your details will be kept confidential – this means that only I will know your name and your personal details. None of this information will appear in the published results from this study.

DO YOU HAVE THE RIGHT TO REFUSE OR LEAVE THE STUDY?

If you take part in the study, you have the right to leave the study at any time. If you do leave, I would like you to tell me, Wendy Wrench, why you want to leave the study, but you do not have to do this if you do not want to.

WHAT SHOULD YOU DO NEXT?

Please ask me any questions. If you understand the information and have decided that you would like to take part in the study, could you please sign the Consent Form. If you have decided not to take part, thank you for reading this and I wish you well.

Many thanks, Wendy Wrench.