"Knowing how" is not enough:
A Mixed Methods Exploration of Inhaler Technique Maintenance in Patients with Asthma

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DECLARATION

This thesis details research conducted in the Faculty of Pharmacy, the University of Sydney, under the supervision of Associate Professor Sinthia Bosnic-Anticevich and Doctor Lorraine Smith.

The research presented in this thesis is original to the best of my knowledge. Full acknowledgement is made where the work of others is cited or used. No portion of this work has been submitted in part or whole for the award of a degree at any other university.

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ABSTRACT

Poor inhaler technique maintenance amongst patients with asthma is a persistent problem. Importantly, it contributes to suboptimal disease control. Why inhaler technique deteriorates, even in the absence of identifiable barriers (e.g. lack of technique education), is unknown. This thesis aimed to address this gap in knowledge via research exploring the phenomenon of inhaler technique maintenance. This research was empirically and theoretically underpinned and conducted in two phases.

The first phase of research was designed to identify the determinants of inhaler technique maintenance via quantitative methods. It involved trained community pharmacists delivering inhaler technique education to patients with asthma at baseline and re-assessing patients' technique after one month. Data were collected on patients' inhaler technique scores, demographics, medical history, clinical factors, past inhaler technique education and a range of psychosocial aspects of disease management. Three significant predictors of inhaler technique maintenance were identified: 1) device type, 2) asthma control, and 3) motivation to practice correct technique [X^2 (N=125,3)=16.22, p=.001]. This study revealed, for the first time, the important role that patient psychosocial factors, motivation in particular, may play in inhaler technique maintenance.

The second phase of research aimed to gain a better understanding of the novel relationship identified between patient motivation and inhaler technique maintenance, via qualitative methods. In-depth semi-structured interviews were conducted with patients with asthma. Several themes were found to illuminate why some patients possessed higher, whereas others possessed lower, motivation to maintain correct inhaler technique. These themes were: 1) motivation to engage in asthma management, 2) motivation to self-manage via a preventative-medication based

approach, and 3) self-management self-efficacy. Health care professionals were also found to have an influence on patient motivation to maintain correct inhaler technique, particularly amongst those patients who were more receptive to their health care providers' input. This study deepened understanding of the interrelationships between patient psychosocial and behavioural factors in the context of inhaler technique maintenance.

The body of work presented in this thesis has generated new insights in the field of inhaler technique research. This work highlights that the key to ensuring optimal inhaler technique maintenance may lie in more holistic approaches to inhaler technique interventions that address, not only physical skill related barriers, but also patient psychosocial barriers in technique maintenance.

CONTENTS

COMMUNICATIONS

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Ovchinikova, L., Smith, L. & Bosnic-Anticevich, S. Inhaler Device Use – A Review of the Literature to Date. *Oral presentation at the Faculty of Post-graduate Forum (2008)*

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LIST OF ABBREVIATIONS

ACAM: Australian Centre for Asthma Monitoring

ACC: Accuhaler™

AMH: Australian Medicines Handbook

BA-MDI: Breath Activated Metered Dose Inhalers

BMQ-S: Beliefs about Medicines Questionnaire Specific

CFC: Chlorofluorocarbon

COPD: Chronic Obstructive Pulmonary Disease

CPE: Continuing Professional Education

CSM: Common Sense Model of Illness Regulation

DPI: Dry Powder Inhaler

FSLT: Fitts' Skill Learning Theory

GINA: Global Initiative for Asthma

HCP: Health Care Professional

HFA: Hydrofluoroalkane

ITBQ: Inhaler Technique Beliefs Questionnaire

ITMAM: Inhaler Technique Maintenance and Motivation

ITMF: Inhaler Technique Maintenance Framework

M: Maintainer

MARS-5: Medication Adherence Report Scale (5 items)

NAC: National Asthma Council Australia

NM: Non-maintainer

pMDI: pressurised Metered Dose Inhaler

PSA: Pharmaceutical Society of Australia

QUIP: Quality Use of Inhalers in Pharmacy workshop

S-ACQ: Shortened Asthma Control Questionnaire

SCT: Social Cognitive Theory

SDT: Self Determination Theory

TH: Turbuhaler™

WIMR: Woolcock Institute of Medical Research

— CHAPTER 1 —

INTRODUCTION TO THESIS

"There are not too many things worse than not being able to breathe… It's terrible, it's frightening, it's scary. So it's very important to be in control" – F.E.

THE STATEMENT ABOVE is from a patient who has been living with asthma, a chronic respiratory disease, for the past 20 years. It was sourced from an interview conducted as part of this thesis and offers a window through which the personal impact of asthma can be glimpsed. Asthma, however, is not only a costly disease because of its negative impact on the quality of life and productivity of individual sufferers, but also because of its burden on the community at large. Australia has one of the highest rates of asthma globally (Australian Centre for Asthma Monitoring and Woolcock Institute of Medical Research [ACAM and WIMR], 2011), and the resultant costs, to both the patient and community, are not only associated with that of health care utilisation, but notably, also due to the consequences of poorly controlled disease (Barnes, Jonsson and Klim, 1996). As such, asthma has been deemed by the Australian Government as a National Health Priority Area (Australian Institute of Health and Welfare, 2013).

A. Motivation for research

Poor asthma control is a widespread, yet often preventable phenomenon, since effective and long standing treatment options are available to mitigate both the acute symptoms and underlying inflammation of the disease (Australian Medicines Handbook [AMH], 2013). The efficacy of these treatment options, however, is largely dependent on the degree to which patients actively and optimally engage in their use. How patients self-manage their asthma, on a day-to-day basis and over time, is therefore a key determinant of asthma outcomes (Smith et al., 2007). Patients' asthma self-management and how it may be improved, thus forms the broad foundations of this thesis.

Patients with asthma need to effectively engage in a range of self-management activities, on a persistent basis, as an important part of maintaining well controlled asthma. Successfully using inhaled therapy is an indispensable part of the asthma self-management process. Fundamental to efficacious inhaled therapy, is whether patients are using their asthma inhalers with the correct technique. That is, patients need to use their devices with the correct inhaler technique in order to gain the benefits, and reduce the chances of experiencing adverse effects, with their prescribed asthma therapy (Haughney et al., 2010, Lindgren, Bake and Larsson, 1987, Mirza et al., 2004, Newman 1991).

Suboptimal inhaler technique, however, is demonstrated by large proportions of patients (Lavorini et al., 2008, Melani et al., 2004, 2011), and has been since the introduction of the first hand-held inhaler device in 1955 (Freedman, 1956). Incorrect inhaler technique, and its cumulative effects over time, is detrimental to patients' asthma. This is especially so in the context of preventer therapy, aimed at improving asthma control by reducing the underlying inflammation of the disease. Significant associations between poor asthma control and poor preventer inhaler technique, have been shown in large cross sectional studies (Giraud and Roche, 2002) as well as randomised controlled trials (Basheti, Reddel, Armour and Bosnic-Anticevich, 2007).

Given the important therapeutic implications of poor inhaler technique, improving how patients use their inhalers has attracted much research attention for over fifty years. The fruits of this research include: innovations in inhaler device design and the availability of a variety of device types to suit a spectrum of patients' physical needs (Dolovich and Dhand, 2011), improvements in drug formulations that, for example, result in more comfortable inhalations (Crompton, 1990), and innovations in patient education for teaching and learning inhaler technique (Basheti, Armour, Bosnic-Anticevich, and Reddel, 2008).

Nevertheless, suboptimal asthma outcomes are still being attributed to patients using their inhalers with poor technique (Haughney et al., 2008). Various studies have also shown that inhaler technique tends to deteriorate over time. This can occurin patients who demonstrate no physical difficulties using their inhaler device, and who have been educated on inhaler technique (Bosnic-Anticevich, Sinha, So, Armour, & Reddel, 2003, 2010, Hardwell et al., 2011). Despite advancements in treatment technology and inhaler technique education over the decades, the improvements patients initially achieve in inhaler use do not appear to be maintained over time. Further, the current clinical recommendation to rectify this situation – repeating inhaler technique instructions – does not appear to result in lasting improvements either (Basheti et al., 2007). The reason/s why patients do not maintain correct inhaler technique over time, despite being capable of demonstrating the manoeuvre, remains unknown.

It is at this juncture in the literature, that inhaler technique *maintenance* in patients with asthma was identified as a phenomenon worthy of further research. Despite the plethora of studies on inhaler device use and technique, no published research had focused on investigating the long term maintenance of inhaler technique. In particular, it was not possible to identify any evidence based reasons in response to the question of *why patients did not maintain correct inhaler technique despite "knowing how" to perform correct technique*. Discovering the answers to this important question was thus the overarching driver behind the research presented in this thesis.

Overarching research question:

Why do patients with asthma not maintain correct inhaler technique despite "Knowing how"?

B. Approach and scope of research

Quantitative and qualitative studies are presented in this thesis, and both adopt an exploratory approach. An exploratory approach was deemed necessary and appropriate, given that the phenomenon of inhaler technique maintenance was being examined for the first time, and also because there was a lack of clear evidence to inform investigations in this area. Taking an exploratory approach to this research meant that several fields of literature, not only the traditional asthma and inhaler technique literature, were consulted. This resulted in well-established theories and empirical evidence being drawn upon in this thesis to underpin both the quantitative and qualitative studies presented.

Further, a patient-centred approach, delving into patients' behaviours, views and experiences around asthma, was considered highly relevant to this research. This type of patient-centred stance was found to be clearly lacking in the existing literature around inhaler technique and device use. Published evidence often focuses on the inhaler device itself, or inhaler device education centred on the transfer of physical skill. Inhaler technique research, which encompasses behavioural and psychosocial considerations, is rare. This is rather surprising given the clearly recognised need to improve patients' inhaler technique (Haughney et al., 2008, Price et al., 2013) and the fact that practicing inhaler technique is an activity embedded in patients' day-to-day asthma self-management. Factors that influence patients' self-management behaviour would thus seem relevant to consider in the context of inhaler technique maintenance.

The research presented in this thesis is clinically oriented and set in the context of primary health care, specifically, community pharmacy. The primary health care setting is where the bulk of asthma care occurs in Australia (ACAM and WIMR, 2011). Further, the community pharmacy is an ideal environment for service delivery aimed at optimising asthma medication use because it is readily accessible to patients. In addition, pharmacists have a fundamental role in ensuring the safe and efficacious use of medicines, which in asthma includes the correct administration of inhaled therapy.

Most patients are likely to access their local pharmacy more frequently than any other health care setting for their asthma. . On every occasion during which a patient obtains asthma related medication, a pharmacist will be involved in the interaction. This is the case for preventer, reliever, and oral asthma medication. For some patients, the pharmacist may be the only health care professional with whom they are in contact for their asthma. For example, those patients who only use reliever medication purchased over the counter at their local pharmacy. Pharmacists are also involved when patients obtain medication for allergic rhinitis, a comorbidity in 80% of asthma patients (Bousquet, Van Cauwenberge, Khaltaev and the WHO, 2001). The important role that community pharmacists have in the context of asthma management is further illustrated by randomised controlled trials showing improved patient and cost related outcomes after the delivery of asthma self-management services by pharmacists (Armour et al., 2013).

Pharmacists, based in community pharmacies, are thus in a prime position to improve and monitor asthma patients' medication therapy, including how they maintain inhaler technique over time. In addition, since pharmacists are the community's medication experts, they are the ideal health care professional to be involved in any innovative strategies around the quality use of asthma medications that may evolve from the body of research in this thesis. Thus the community pharmacy was chosen as the ideal setting for the studies of this thesis.

C. Structure of thesis

The ensuing chapters present the first body of research investigating the phenomenon of inhaler technique maintenance in patients with asthma. In particular, the chapters address the gap identified in the current literature by:

- Reviewing the current literature around inhaler device use and technique (Chapter 2).
- Explaining the empirical and theoretical underpinnings guiding both the quantitative and qualitative studies conducted (Chapters 3 and 4, section A).
- Discussing how the study findings deepen our understanding of inhaler technique maintenance (Chapters 3 and 4, section E).

Practical recommendations for how health care professionals can facilitate better inhaler technique maintenance in patients with asthma, as well as future directions for research, are also advanced (Chapter 5)Ultimately this thesis hopes to contribute in some way to reducing the burden of asthma on the community and the individual patient by shedding more light on a very fundamental, yet problematic, aspect of asthma therapy – *maintaining correct inhaler technique*.

— CHAPTER 2 —

INHALER DEVICE USE IN PATIENTS WITH ASTHMA, THE CURRENT UNDERSTANDING: A LITERATURE REVIEW

THIS LITERATURE REVIEW is divided into three sections, A, B and C. Section A highlights the fact that asthma remains a high burden disease in Australia despite the availability of effective treatment options in the form of inhaled therapy. Section B provides a more in depth view of inhaled asthma therapy, with a focus on patients' inhaler technique as a significant determinant of the efficacy of inhaled therapy and therefore, patients' asthma control status. Finally, section C reviews the prevalence of poor inhaler technique amongst asthma patients, explores the barriers to good technique, and concludes by highlighting the problem of the poor inhaler technique maintenance in the absence of known barriers.

A. Introduction to asthma

Asthma is a high burden disease in Australia for individual sufferers, their families and the community at large. This section examines the burden of asthma at multiple levels, outlines asthma pathophysiology, examines the difference between asthma severity and control, and outlines the main classes of medication used in current asthma therapy.

i. Asthma burden in Australia

The prevalence of asthma in Australia is one of the highest by international comparison, with the latest figure on the incidence of asthma at approximately 10% in both adults and children in the year 2007-8 (ACAM and WIMR, 2011). Death caused by asthma is the gravest result of the disease, and here Australian mortality rates also remain one of the highest internationally with the latest statistics attributing four hundred and eleven deaths due to asthma in 2009, representing 0.29% of all deaths that year (ACAM and WIMR, 2011). Fortunately, deaths due to asthma have been on the decrease since its last peak in the late 1980s and are a relatively uncommon occurrence today (ACAM and WIMR, 2011, Garrett, Kolbe, Richards, Whitlock, and Rea, 1995). However, it should be noted that the burden of asthma is not evenly distributed within Australian society, with both prevalence and death due to asthma overrepresented in some populations, namely amongst those from areas of lower socio-economic status and indigenous Australians (ACAM and WIMR, 2011).

Simply having an asthma diagnosis is associated with reduced quality of life in both the physical and psychosocial domains for individual patients. People diagnosed with asthma experience reduced physical functioning (Marks et al., 2007), reduced participation in social roles (Collins et al., 2008, King, Kenny and Marks, 2009), increased depression and anxiety (Scott et al., 2007, Vuillermin et al., 2010, Wilson et al., 2010) and poor perceived health status (ACAM and WIMR, 2011). The physical and psychosocial burden of asthma is exacerbated by poorly controlled disease (Vollmer et al., 1999). Poor levels of disease control are a common feature amongst asthma patients (Haughney et al., 2008), characterised by frequent symptoms and symptom exacerbations (National Asthma Council Australia [NAC], 2006).

Fortunately effective pharmacological treatments to bring asthma under control are available. Typically over half the government's total expenditure ($606 million in 2004-05) on asthma health care is attributed to subsidising such medicines via the Pharmaceutical Benefits Scheme (ACAM and WIMR, 2011), reflecting the priority given to pharmacological management in asthma. Poorly controlled asthma, however, persists despite these support mechanisms (availability of effective medication at subsidised cost), suggesting that these health care resources are not being utilised to their full benefit and that most patients with poor disease control are shouldering an unnecessary burden.

On a societal level, poor disease control is an economic burden. Greater demand for emergency or acute health care services due to uncontrolled asthma is more costly than planned treatment (Barnes et al., 1996, Boyd et al., 2009, Castro et al., 2003). Indirect economic costs related to poorly controlled asthma can result from lost productivity arising from days away from work, study and performance of other necessary duties (ACAM and WIMR, 2011, NAC, 2006). Asthma, and in particular, poorly controlled asthma, is thus a significant burden, associated with increased costs, to both the patient and community.

ii. Asthma pathophysiology, severity and control

Patients with asthma suffer from a complex, heterogeneous respiratory disease characterised by chronically inflamed airways that are hypersensitive to a range of stimuli, resulting in widespread variable airflow obstruction. Airways inflammation is chronic and is mediated by many different cells and cellular components, whereas airways narrowing is episodic and triggered by allergens or non-allergens such as acute respiratory infections, gastor-oesophageal reflux, tobacco smoke, air pollutants, occupational chemicals, certain drugs, cold air and exercise. Symptoms of asthma include wheezing, shortness of breath, chest tightness and coughing, particularly at night or in the early morning, and are typically reversible with or without acute treatment (i.e. reliever medication) (Global Initiative for Asthma [GINA], 2012, NAC, 2006). There is no firm evidence regarding the cause/s of asthma, although it has been associated with environmental (e.g. viral infections), lifestyle (e.g. tobacco smoking) and genetic factors (e.g. atopy) (ACAM and WIMR, 2011).

The severity of asthma varies among individuals and relates to the extent of underlying disease as well as its responsiveness to treatment (Greening, Stempel, Bateman and Virchow, 2008, Fuhlbrigge, 2004). Symptoms can present as mild and episodic in some individuals, compared to severe and persistent in others. In a few individuals, asthma can be very severe, life threatening and resistant to pharmacological treatment, even at maximal doses (GINA, 2012). Severe asthma can be attributed to both environmental and genetic factors, however the actual occurrence of severe disease is very rare and in general, the majority of patients are treatment responsive (Barnes, 2013). Despite the variation in asthma severity amongst individuals, the goal of treatment remains unchanged, and that is to achieve and maintain optimal asthma control (GINA, 2012).

Asthma control refers to the prevention or management of the negative impact of the disease on individuals (Juniper, 2007, Taylor et al., 2008). To have well-controlled asthma means that the patient experiences minimal symptoms, symptom flare-ups, and interference with usual activities and has normal lung function (Clatworthy et al., 2009). Well-controlled asthma indicates that a patient's asthma is mild in severity (i.e. well controlled with minimal need for regular medication), or that their asthma is well managed (i.e. well controlled with regular medication treatment). On the contrary, poor asthma control indicates that a patient's asthma is either more severe or is poorly managed (Fuhlbrigge, 2004). In this way, the concepts of asthma control and asthma severity are related.

Classification of asthma according to asthma control rather than asthma severity has taken precedence in the clinical management of asthma in recent years (Humbert, Holgate, Boulet and Bousquet, 2007). Earlier, classifying asthma according to its severity was the recommendation for clinical practice, to aid in the selection of appropriate medication therapy, although its practical application proved to be limited. This is the case because asthma severity measures disease status in the absence of medication treatment (Taylor et al., 2008). This limits its clinical use in adjusting treatment appropriately (stepping up or down) in line with changing symptom presentation. Severity classifications also do not account for the potential change in disease severity over time – the degree of asthma severity, although a relatively stable disease feature, is not fixed and can vary over months or years. Asthma severity measures thus have a static quality in the face of a dynamic disease. Further, asthma severity measurements are not validated, nor well adopted in the primary care setting (Humbert et al., 2007).

Clinical assessment of asthma control taps into factors such as the frequency of symptom experience, exacerbations, night time asthma, reliever/rescue medication use, degree of physical limitations in daily activities, current lung function and degree of airway hyperresponsiveness (Juniper, 2007, Ko et al., 2009, Revicki and Weiss, 2006). Thus, unlike asthma severity, asthma control measurements account for individuals' asthma status both in the presence and absence of medication (Fuhlbrigge, 2004). Asthma control measurements can be taken at any point in time and various validated instruments for measurement are available for use (Boulet, Boulet and Milot, 2002, Juniper, O'Byrne, Guyatt, Ferrie and King, 1999, Juniper, Svensson, Mork and Stahl, 2005, Nathan et al., 2004, Schatz et al., 2007). This renders asthma control a useful tool to aid ongoing monitoring of the responsiveness of disease to different treatment regimens and adjustment of medication in accordance with fluctuating asthma symptoms, as recommended in national and international guidelines (GINA, 2012, NAC, 2006).

iii. Medication therapy in asthma

Medication treatment is key in asthma management and with the current therapies available, the goal for well controlled asthma is attainable even in patients who have severe asthma (Therapeutic Guidelines, 2012a). There are currently three main classes of pharmacological agents available: "relievers", "preventers" and "symptom controllers". While relievers target asthma symptom relief, preventers and symptom controllers mainly target symptom prevention (AMH, 2013).

Reliever medications, also known as bronchodilators, are inhaled and provide rapid symptomatic relief within a matter of 5 to 15 minutes (AMH, 2013). They are used on an as-needed basis during symptom exacerbations (bouts of shortness of breath, chest tightness and wheezing), or for the immediate prevention of exercise induced asthma. $Beta_2$agonists (salbutamol and terbutaline) are the most commonly used reliever medications, although occasionally, short-acting anticholinergic drugs (ipratropium) are also used (AMH, 2013).

Preventer medications ease the airways inflammation and control asthma by reducing the incidence of symptom onset and exacerbation. Currently, inhaled corticosteroids (beclomethasone, budesonide, fluticasone and ciclesonide) used in low doses, are highly effective for attaining well controlled asthma in most adult patients (Therapeutic Guidelines, 2012b, Adams, Bestall and Jones, 2000, Powell and Gibson, 2003). Regular (daily or twice daily) inhaled corticosteroid preventer therapy is recommended for people experiencing persistent symptoms of asthma.

Oral medications (montelukast and zafirlukast) can also be used as preventive therapy, however they are less effective compared to inhaled corticosteroids (Chauhan and Ducharme, 2012), and in Australia treatment can be costly for people over 12 years of age in whom these medications (montelukast and zafirlukast) are not subsidised by the government (Australian Government Department of Health and Ageing, 2014). Inhaled corticosteroids remain the pillar of asthma control therapy. Preventer medication regimens need to be reviewed regularly and be adjusted with the aim of using the lowest possible dose of inhaled corticosteroids (to reduce the likelihood of drug side effects) while maintaining the best possible level of asthma control (AMH, 2013, Therapeutic Guidelines, 2012b).

Symptom controller medications, in the form of long-acting $beta_2$agonists (salmeterol and formoterol), are used in combination with inhaled preventer therapy to achieve equivalent or better levels of asthma control whilst reducing the amount of inhaled corticosteroids required. This “corticosteroid sparing” effect of symptom controllers reduces the likelihood of side effects resulting from high doses of inhaled corticosteroids (Kuna et al., 2007).

Recently, the combination of rapid onset long-acting $beta_2$agonists with inhaled corticosteroids has been approved to be used in people with asthma (12 years and over) for the dual purposes of symptom relief as well as prevention. The Symbicort™ maintenance and reliever program (SMART) makes use of formoterol (long-acting $beta_2$agonist) and budesonide (inhaled corticosteroid) in one combined formulation and is prescribed on a daily (for asthma control) and an as-needed (for symptom relief) basis (Bateman et al., 2010, Welsh and Cates, 2010).

Over the past decade there has also been an injectable drug available to people with moderate to severe allergic asthma. Omalizumab is an immunoregulatory medication (anti-IgE monoclonal antibody), given every two to four weeks, and can be used effectively in conjunction with inhaled corticosteroids to achieve asthma control (Walker, Monteil, Phelan, Lasserson and Walters, 2006). The cost of this medication ($425 per 150mg vial in June 2012) can be prohibitive for widespread use in Australia; subsidies to patients are only granted in exceptional cases under the S100 Highly Specialised Drugs scheme (Australian Government Department of Health and Ageing, 2014). The three main classes of inhaled therapies described earlier (relievers, preventers and symptom controllers), however, are subsidised and/or much less costly to produce, and are therefore much more accessible to patients. Importantly, these inhaled therapies are also highly effective in keeping asthma well controlled in the majority of patients, provided they are used to appropriately. The next section will focus on inhaled medication therapies in asthma.

B. Inhaled medication therapies in asthma

Asthma therapies are predominantly administered via the inhaled route using small hand-held inhaler devices (AMH, 2013, Rees, 2005). In this section, the literature regarding the importance of correct inhaler technique for the efficacy of inhaled therapy is discussed, and the steps required for correct inhaler technique for three of the most commonly used inhaler devices in asthma therapy are outlined and explained.

i. The inhaled route and inhaler technique as a determinant of drug deposition

Medications delivered via the inhaled route directly target the site of action in asthma – bronchial smooth muscles and tissues of the respiratory tract – and are immediately absorbed via the vast epithelial surface areas of the lung. Direct delivery to the airways reduces the amount of medication required to produce therapeutic results (Newman and Clarke, 1983) by up to ten fold (McFadden, 1995). This therefore reduces the potential for systemic side effects (Newhouse and Dolovich, 1986), and also results in faster onset of action, which is critical for obtaining rapid relief during asthma exacerbations (Everard, 2001).

The deposition of inhaled drug in the lung, and therefore its clinical efficacy, is dependent on various factors, including the formulation and design of the inhaler device, patient airway anatomy, the properties of the aerosol cloud generated and patient inhaler technique (Haughney et al., 2010). Of these, patient inhaler technique is the only immediately modifiable factor. Importantly patient inhaler technique also has a direct influence on the physical properties of the aerosol generated, as explained below.

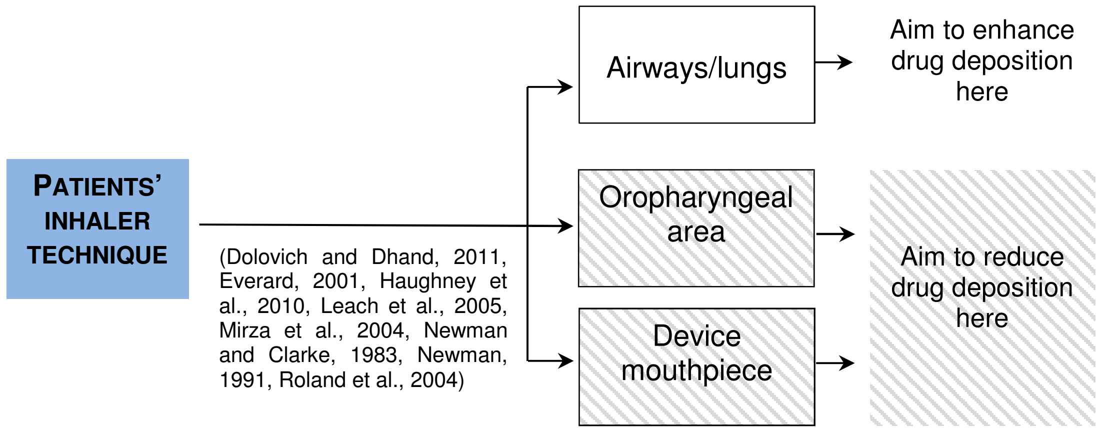
Each time a dose of drug is discharged from an inhaler device it takes the form of an aerosol cloud, a rapidly moving suspension of particulate matter in the air. Ideally the particles of drug in the aerosol should be from 1 to 5 microns (Frijlink and De Boer, 2004) to enable drug deposition both in the large and conducting airways (target for bronchodilator therapy) and in the inflamed tissues in the smaller peripheral airways of the lungs (target for inhaled corticosteroid therapy) (Haughney et al., 2010). Larger particles tend to deposit in the upper airways and the mouth/oropharyngeal area, where they have no clinical effect but can cause local and systemic (when swallowed) side effects (Haughney et al., 2010). Smaller particles, on the other hand, can be exhaled and lost with the next breath, although this drug loss can be considered to be off-set by the greater extent that smaller particles deposit in the lungs compared to larger particles (Martin, 2008, Newman and Clarke, 1983, Orehek, Gayrard, Grimaud and Charpin, 1976).

In relation to patient inhaler technique – the positioning of the mouthpiece, the force and speed of inhalation from an inhaler device, whether breath was exhaled before inhalation and held after inhalation, and how inhalation and dose actuation is coordinated – are examples of specific steps which influence the physical properties of the aerosol such as the size of drug particles and the speed and direction of the aerosol cloud, and therefore the location and degree of deposition of the inhaled drug (Newman and Clarke, 1983).

Various clinical studies demonstrate the direct relationship between patient inhaler technique and inhaled drug deposition, showing diminished drug deposition in the lung as a result of sub-optimal inhaler technique. For example, Leach, Davidson, Hasselquist and Bodureau (2005) showed (using HFA-134a-beclomethasone dipropionate radiolabeled with technetium-99m) that patients who used their pressurised Metered Dose Inhaler with better technique had 22% more drug depositing in their lungs compared to those patients with poor technique. These findings, i.e. significant reductions in lung drug deposition as a result of poor inhaler technique, are echoed in other studies employing similar methods (Newman, 1991). Further it is possible that in some cases of poor inhaler technique, no drug actually deposits in the lungs (Newman 1991).

Since patients' inhaler technique influences the physical properties of the drug aerosol and its deposition, this means that it can impact on the degree to which drug deposits both in the patient's airways, where it is desired for clinical efficacy; as well as in the patient's oropharynx and the inhaler device mouthpiece, where deposition is not desired as it increases the risk of local side effects and reduces the available dose respectively (Mirza, Kasper Schwartz and Antin-Ozerkis, 2004, Newman, 1991). This is illustrated in Figure 2.01. Thus the benefits of administering asthma medication via the inhaled route can only be gained if patients use their inhaler devices with optimal technique (Cochrane, Bala, Downs, Mauskopf and Ben-Joseph, 2000, Dolovich and Dhand, 2011).

Figure 2.01: Influence of patients' inhaler technique on drug deposition in the airways, oropharyngeal area and inhaler device mouthpiece.



ii. Inhaler technique and its clinical implications

Patients' inhaler technique, in using both asthma reliever and preventer therapy, is a vital determinant of the therapeutic efficacy, as well as the propensity for adverse effects of these treatments. In regard to reliever therapy, inhaler technique can influence the rapidity and degree of symptom relief obtained. Poor inhaler technique with reliever medication is associated with reduction in bronchodilatory relief obtained (Shim and Williams Jr, 1980) to the magnitude of 30% (Lindgren et al., 1987). In the face of inadequate symptom relief, additional doses of reliever medication are likely to be used by patients, which can result in unnecessarily excessive amounts of medication being used, increasing the likelihood of adverse drug effects such as tremor, palpitations and headache (AMH, 2013). However, it should be noted that even with poor inhaler technique, patients often still obtain adequate symptom relief with their short-acting medication. Further, with reliever therapy, there is immediate feedback in the event of inadequate relief (i.e. patients will notice if their symptoms have not improved), which prompts further action such as taking another dose or seeking urgent medical care.

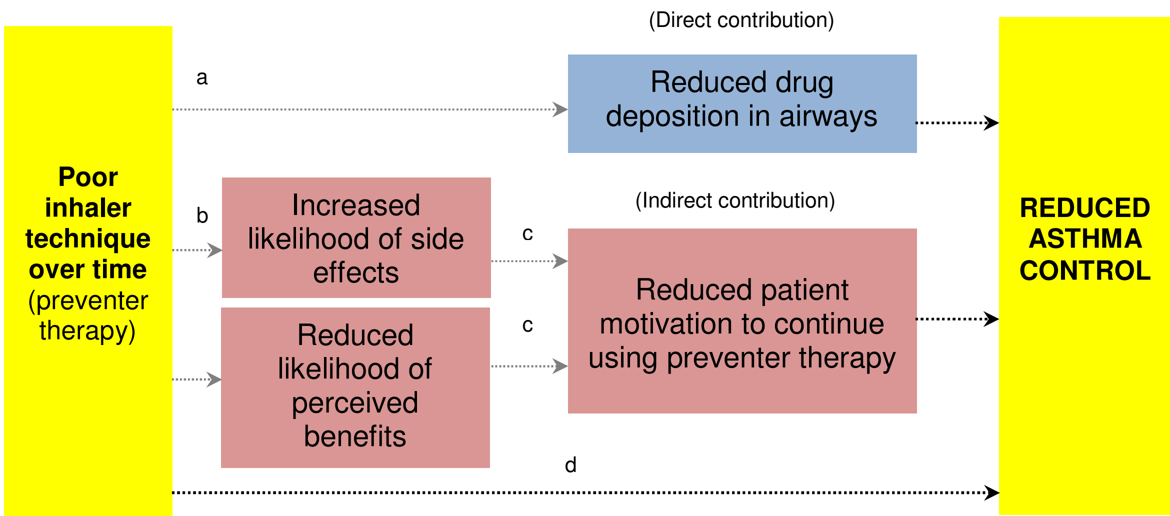
The consequences of poor inhaler technique with preventer therapy, however, are not immediately detectable by the patient. What is of clinical concern is that asthma control can be compromised as a result of undetected and persistently poor inhaler technique over time with preventer therapy (Haughney et al., 2008). Achieving and maintaining good asthma control often remains problematic despite the availability of effective preventative treatment (outlined in section A, iii) (Giraud, Allaert, and Roche, 2011). Although the factors contributing to poor asthma control are multi-factorial (e.g. smoking, co-morbid rhinitis, resistance to therapy and patient perceptual barriers) (Haughney et al., 2008), poor inhaler technique has been consistently shown to be an independent and significant contributor (Basheti et al., 2007, Giraud et al., 2011, Giraud and Roche, 2002).

The association between poor inhaler technique (with preventer therapy) and reduced asthma control has been demonstrated in many studies, several of which are large scale clinical studies (Basheti et al., 2007, Giraud et al., 2011, Giraud and Roche, 2002, Lindgren et al., 1987, Melani et al., 2011, Molimard and Le Gros, 2008). For instance, data from 4362 patients with persistent asthma in an European hospital outpatient setting reveal that those demonstrating optimal inhaler technique were more likely to have good asthma control (63% good control) compared to those demonstrating poor inhaler technique (47% good control) (Molimard and Le Gros, 2008). Further, amongst 3955 adult patients with asthma in a general practice setting, not only was inhaler technique significantly associated with asthma control but, interestingly, it was shown that asthma control worsened as the number of inhaler technique mistakes increased (Giraud and Roche, 2002). In Australia, randomised control trials solely focused on inhaler technique have also shown a significant association between patients' inhaler technique and asthma control status, and have highlighted a trend toward worse asthma control with poorer inhaler technique (Basheti et al., 2007).

Inhaler technique can affect the level of asthma control in various ways (Basheti et al., 2007, Price, Thomas, Mitchell, Niziol, and Featherstone, 2003). As shown earlier, poor inhaler technique reduces the degree of medication depositing in the target sites in the airways (Leach et al., 2005, Newman, 1991), which results in less than the intended treatment dose available and therefore diminishes the efficacy of preventer therapy to control the underlying inflammation in asthma, leading to poor asthma control. Further it may be speculated that, from the patient's perspective, amongst those with suboptimal inhaler technique, the chances of experiencing and perceiving the benefits of preventer therapy (i.e. better asthma control and therefore less symptom experience) is reduced; yet simultaneously, the chances of experiencing and perceiving the adverse effects of preventer therapy (e.g. local side effects such as oral candidiasis) is increased, and that with these two sets of beliefs, patients may be less motivated to use their preventer therapy.

To elaborate on the situation from the patient's perspective, the lack of perceived benefit of preventer therapy may be attributed to the reduced therapeutic efficacy of medication inhaled with poor technique, as described earlier. On the other hand, perceived harm of preventer therapy can be attributed to the fact that poor inhaler technique increases the likelihood of drug deposition in the oropharyngeal area, which with the use of inhaled corticosteroids leads to higher incidence of oral mucosal irritation, candidiasis and dysphonia (McFadden, 1995, Mirza et. al., 2004, Roland, Bhalla and Earis, 2004). Although these local side effects do not generally pose a serious health threat in-and-of themselves, they may reduce patient motivation to use preventer therapy regularly. The proportion of patients who discontinue preventer therapy after experiencing inhaled corticosteroid induced oropharyngeal side effects has been shown to be as high as 31%, and further, patients who report these side effects were more likely to have poor asthma control (Fitzgerald, Chan, Holroyde and Boulet, 2008). Thus, preventer therapy, administered with poor inhaler technique can compromise asthma control in various ways, directly (reduced dose of drug reaching airways) and indirectly (reduced patient motivation to use preventer therapy). These mechanisms are illustrated in Figure 2.02 below.

Figure 2.02: Association between poor inhaler technique, with proposed mechanisms of action (a, b, c), and reduced asthma control (d) over time.



a. Leach et al., 2005, Newman, 1991.
b. Mirza et al., 2004, Roland et al., 2004.
c. Fitzgerald et al., 2008
d. Basheti et al., 2007, Giraud et al., 2011, Giraud and Roche, 2002, Molimard and Le Gros, 2008.

iii. Current inhaler devices and their features

In this section, the range of inhaler devices currently available for asthma treatment and their features is examined. An awareness of the features of various inhaler devices, how they compare and contrast, and how their design and technology have evolved over time can perhaps lead to a greater appreciation of the steps which need to be taken to ensure optimal administration (explained in the next section: B, iv). In current clinical practice, inhaled therapy is delivered either via nebulisers or hand-held inhaler devices consisting of either pressurised Metered Dose Inhalers (pMDIs) or Dry Powder Inhalers (DPIs) (Dolovich and Dhand, 2011). These three classes of inhaler devices/systems are discussed in detail below.

1. Nebulisers

Nebulisers are devices that generate aerosols from solution or suspension (Dolovich and Dhand, 2011) and have been used for centuries to treat lung conditions (Muers, 1997). Early nebulisers (1930s) used in asthma were cruder in design and technology and would generate aerosol outputs consisting of a wide range of particle sizes, much of which was non-respirable, they were also more costly and fragile, being made of glass (Muers, 1997). Current nebulisers have been improved so that the aerosols generated will more likely be in the respirable size range, i.e. 1-5 microns. They are available as either jet nebulisers (where liquid is converted to mist driven by compressed gas) or ultrasonic nebulisers (where liquid is converted to mist driven by an ultrasonically vibrating crystal) (Dolovich and Dhand, 2011). Nebulisers, once set up for use, do not require any special technique on the patient's part to consume the dose. The inhalation procedure is relatively passive, and this makes nebulised therapy suitable for some patient populations who do not have the functional capacity to self-administer treatment using hand-held inhaler devices, such as young children below the age of five or six (Dolovich and Dhand, 2011, Haughney et al., 2008).

Nebulisers, in comparison to hand-held inhaler devices, however, remain more costly, bulky and inconvenient to administer. That is, they are not portable, require electricity, are noisy, and a single dose requires 5-10 minutes to fully inhale (Therapeutic Guidelines, 2012c). Nebulisers also have low dose consistency and poor delivery efficiency (Chrystyn and Price, 2009, Dolovich and Dhand, 2011). Local side effects such as skin and eye irritation often result when nebulisers are used with a face mask. Nebulisers also require thorough cleaning in order to decontaminate all of the connecting tubing and mouthpiece or mask. Generally, nebulised therapy in asthma can be readily replaced with hand-held inhaler devices that are more convenient (e.g. small and portable, quicker dosing), less costly, and when used properly, are just as therapeutically effective as nebulised therapy (Amirav and Newhouse, 1997, Cates, 2003, Turner, Patel, Ginsburg and FitzGerald, 1997).

2. Hand-held inhaler devices

The first hand-inhaler device was a pressurised Metered Dose Inhaler (pMDI) introduced in 1955 and formulated with adrenaline and isoprenaline for asthma reliever therapy (Freedman, 1956).I It was considered a breakthrough as it superseded the need for inconvenient and costly nebulised therapy. The successful uptake of the pMDI fuelled further innovations in inhaler device therapy, and the first DPI, the Spinhaler™, was introduced in 1971 (Bell, Hartley and Cox, 1971). Currently there is a large range of hand-held inhaler devices that have been developed from these original prototypes. The advantage of this large range is that it allows inhaler device therapy to be tailored to individual patient preferences and needs. For this to be of practical significance however, care and attention by health care professionals and patients must be given to appropriate inhaler device selection and use, especially considering that each device will have different requirements for optimal use due to their unique features. The features of the most commonly available pMDIs and DPIs for asthma treatment are examined below.

a. Pressurised Metered Dose Inhalers

The physical design of current pMDIs remains very much unchanged from its original form. Current pMDIs are small and portable and consist of a cylinder shaped canister, containing approximately 200 doses of drug in solution or suspension (AMH, 2013, Dolovich et al., 2005). This canister is inserted into an outer plastic casing which at the other end has a nozzle projecting into a rectangular mouth piece. Doses of drug are emitted automatically and driven by propellant when the patient pushes down on the top of the canister. As the emitted dose is consistent each time, the device is called a "metered-dose" inhaler.

There has, however, been a major change in the formulation of drugs made for use with pMDIs as a result of the phasing out of Chlorofluorocarbon (CFC) propellants between 1994 and 2005 (under The Montreal Protocol on Substances that Deplete the Ozone Layer) (Hendeles, Colice, and Meyer, 2007). Hydrofluroalkane (HFA) propellants have since been used in place of CFC propellants and this has altered some of the physical characteristics of the aerosol cloud generated from pMDIs, which in turn may have therapeutic implications both directly (via changes in degree of drug deposition) and indirectly (by affecting patient handling) (Dolovich, 1999). Hydrofluoroalkane containing formulations produce finer drug particles and warmer and softer aerosol clouds compared to CFC containing formulations (Gabrio, Stein, and Velasquez, 1999). The finer drug particles produced has been shown to result in enhanced drug deposition to the distal airways of the lungs, with one study indicating a 48% increase in airways deposition from 7% with CFCs to 55% with HFAs (Haughney et al., 2010). Further, the warmer and softer (i.e. lower impact force) aerosol cloud produced by HFAs reduces the “cold-freon effect” typical of CFC containing aerosols. The cold-freon effect is a sudden, cold sensation felt at the back of the throat from the impact of a fast-moving CFC containing aerosol cloud, which would often stop patients from completing their inhalation properly and thus hinder optimal pMDI use (Crompton, 1990). Although the introduction of HFA propellants may have reduced the cold-freon effect and therefore potentially improved pMDI use, other aspects of pMDI use can still pose a challenge for many patients.

The ability to coordinate dose actuation and inhalation is a critical requirement for optimal pMDI use. Patients must be able to actuate a dose (by pressing down on top of the canister) and then inhale the dose simultaneously, with 0-0.2 seconds being the optimum time frame to start inhaling after releasing a dose (Broeders, Molema, Hop and Folgering, 2003). This narrow time window perhaps illustrates why so many patients find the coordination steps with pMDI use to be challenging (Hampson and Mueller, 1994). There is evidence to show that a 90% reduction in drug deposition occurs if a patient starts to inhale a mere one second after dose actuation (Fink and Rubin, 2005).

Recently it has been argued that perfect coordination perhaps should not be the goal, and that rather, it is just as therapeutically effective for patients to start with a slow inhalation of a few seconds first, which is then followed by actuation of the dose with continued inhalation for approximately 5 seconds (Haughney et al., 2010). Although this sequence of manoeuvres may be less difficult to master, patients must still ensure they are correctly performing other critical elements of pMDI technique, namely that their inhalation is slow, steady and continuous. This type of breathing pattern is important because the cloud of aerosol that is emitted from a pMDI is travelling rapidly (10 - 100m/sec) and requires sufficient time to slow down in order for the drug particles to reduce to sizes small enough to settle in the distal airways of the lungs (Hiller, Mazumder, Wilson, Renninger, and Bone, 1981). Many patients however find difficulty with performing these critical steps, which unfortunately reduces the potential for drug efficacy while increasing the potential for adverse drug effects with pMDI therapy.

〉 ***Breath Activated Metered Dose Inhalers (BA-MDI)***

Breath Activated Metered Dose Inhalers (BA-MDI) were designed with the intention to reduce the coordination difficulties patients found with pMDI use. Breath Activated Metered Dose Inhalers are almost identical in appearance to pMDIs, similar in shape and size. They use the same pressurised canister, with the addition of a lever at the top of the device. The lever is pulled up in order to prime the BA-MDI for use, after which the patient begins to inhale through the mouth piece. Only when the patient reaches an inspiratory rate of approximately 30 L/min (the rate required to trigger the rotation of a vane in the device responsible for dose release) is the dose actuated (Ruggins Milner, and Swarbrick, 1993).

Breath Activated Metered Dose Inhalers therefore do not require patients to have the level of coordination that pMDIs do, and are thus considered to be an easier to use device (Hampson and Mueller, 1994), and an option that can result in better asthma control (Price et. al., 2003). However, Newman (1991) showed that while BA-MDIs are beneficial in patients who find difficulty with pMDI coordination steps, they do not confer any benefit to those patients who can use their pMDI correctly.

Further, although some patients may find BA-MDIs easier to use than pMDIs, care must still be taken to ensure correct BA-MDI use, that is, patients are still required to perform an optimal inhalation that is slow, steady and continuous, just as for the pMDI (since the properties of the aerosol cloud, once actuated from a BA-MDI, are similar to those of a pMDI, the same principles regarding optimal inhalation apply).

Finally, a practical implication with the BA-MDI is that, unlike the pMDI, there are only a limited number of drugs formulated for this device (AMH, 2013) and so it often does not present as an option to patients for asthma therapy.

〉 ***Spacers***

Spacers are an add-on device and used in conjunction with a pMDI, connected to its mouthpiece. Spacers are available in a variety of shapes and sizes, however as its name implies, the spacer's essential function is to create a space between the moving aerosol cloud and the patient's mouth. Using spacers can improve the therapeutic efficacy obtained from treatment with pMDIs.

Spacers can increase the likelihood of optimal pMDI use in those patients who have difficulty with pMDI coordination steps. That is, spacers allow patients to actuate and then inhale the drug dose in two separate steps, rather than simultaneously. The use of spacers also enables the aerosol cloud to develop more favourable characteristics before it is inhaled by the patient. The size and speed of the drug particles in the aerosol cloud are reduced (due to evaporation of the aerosol cloud and the impaction of larger particles on the spacer's inside surfaces) as they travel through the spacer (Lavorini and Fontana, 2009). These physical drug properties enhance therapeutic efficacy and reduce the potential for adverse drug effects, as discussed earlier (section B, ii).

Despite the benefits that the use of spacers offer to patients on pMDI therapy, uptake of these add-on devices is poor, and may be related to the perceived inconvenience of using such a bulky device (Brennan, Osman, Graham, Critchlow, and Everard, 2005, Rees, 2005, Virchow 2004). A recent review indicated that spacers are patients' least preferred device (Capstick and Clifton, 2012).

b. Dry Powder Inhalers

Dry Powder Inhalers were introduced approximately two decades after the first pMDI. In their physical design features they are markedly different compared to pMDIs with the only commonalities being that DPIs are also small, portable and hand-held. Dry Powder Inhalers, as the name indicates, contains drug formulated as inert dry powder. DPIs are available in a much wider variety of shapes and forms than pMDIs and can be classified as either single-dose or multiple-dose devices. Single dose DPIs require patients to load the medication (formulated in individual capsules) into the device during each use, examples include the Aerolizer™, Spinhaler™, Handihaler™ and Rotahaler™. Multiple-dose DPIs can either contain many individually blister-packed doses that sit within the device, e.g. the Accuhaler™; or an enclosed drug reservoir, e.g. the Turbuhaler™. Dry Powder Inhalers are often embedded with dose counters to aid in the tracking of medication use (Aerosol Drug Management Improvement Team [ADMIT], 2013, AMH, 2013).

A common feature across DPIs is that they are breath-activated devices. DPIs, unlike pMDIs, are propellant free and thus doses of drug are not automatically emitted. Instead, the inert drug powder contained within a DPI relies on the patient's inspiratory effort to actuate and draw-out of the device (Haughney et al., 2010). This feature has meant that DPIs have often been perceived to be easier to use than pMDIs because patients do not need to coordinate dose actuation with inhalation when using a DPI (Blaiss, 2007, Rees, 2005, Virchow, 2004).

The notion that DPIs are more user friendly that pMDIs however is not necessarily the case. Evidence shows that poor inhaler technique with DPIs is just as prevalent amongst asthma patients as that with pMDIs (Brocklebank et al., 2001, Lavorini et al., 2008, Melani et al., 2011). This may not be surprising given that the unique features of various DPIs require patients to be accurate and careful during its use, just as for the pMDI. Two critical elements relating to DPI technique that are common sources of patient error relate to dose loading and inspiratory flow rates (Dolovich and Dhand, 2011, Sanchis, Corrigan, Levy, and Viejo, 2012).

Correct dose loading procedure for DPIs (whether it is a single or multiple-dose device) is essential for ensuring that the full amount of drug is made available in the dose path, ready for the patient to inhale (Sanchis et al., 2012). The dose loading procedure varies for each differently designed DPI and therefore calls for special attention. For example, single dose capsule DPIs (e.g. the Handihaler™, Spinhaler™ and Aerolizer™) require the patient, with each use, to open the device, place a single capsule to fit into a receptor in the device, and pierce the capsule (by pressing a set of buttons on the side of device attached to internal needles) to release the dose. In contrast, a multi-dose DPI such as the Accuhaler™ requires the patient to pull down on a lever until a click is heard. The Turbuhaler™, although also a multi-dose device, has yet another loading procedure – it requires patients to hold the device upright whilst twisting the base back and forth until a click sounds (Wieshammer and Dreyhaupt, 2008). Immediately after dose loading, patients should also take care not to blow or exhale into the device for risk of displacing the drug from the dose path (Dolovich and Dhand, 2011). These examples indicate the precision that is required to correctly load a DPI, and the marked differences in the procedure for various devices, highlighting the attention required to correctly perform the procedure.

Once the dose in a DPI has been loaded, it needs to be de-aggregated into a fine-powder before it can deposit in the lungs, and the degree to which this is achieved depends on the patient's inspiratory flow rate (Newman, 2004). The optimal inspiratory flow rate varies between 30 and 90 L/min (Fink and Rubin, 2005) for different types of DPIs and is related to the level of internal resistance of the device. Dry Powder Inhalers are often described as having low (e.g. Spinhaler™), medium (e.g. Accuhaler™) or high (e.g. Turbuhaler™) internal resistance (Frijlink and De Boer, 2004). DPIs with a low internal resistance require a greater inspiratory flow rate to reach a turbulent force strong enough to de-aggregate the powder in the dose path and vice versa (Frijlink and De Boer, 2004). For DPIs with medium internal resistance, 60 L/min is the optimal flow rate (Dolovich and Dhand, 2011). Further, for some DPIs like the Turbuhaler™, it is not only important to reach the maximum inspiratory flow rate, but also to do so as quickly as possible at the beginning of the inhalation (Frijlink and De Boer, 2004).

Inhalation flow rates that are not within the recommended range can compromise therapy by making it less likely to produce drug particles optimal for inhalation (i.e. particles that are de-aggregated to an extent that enhances lung deposition whilst reducing oropharyngeal deposition). De-aggregation of the dose powder can also be compromised if there is additional moisture introduced into the device, as moisture increases adhesive forces in the powder. Thus it is important that patients do not blow or exhale into their device or store their device where it is likely to be contaminated with moisture (Frijlink and De Boer, 2004).

◇

This section, on *current inhaler devices and their features*, has thus discussed, with reference to a wide range of inhaler devices, the broad elements necessary for correct device use. Given the different types of inhaler devices available to patients, each with its unique technological features, achieving correct inhaler technique is not as simple and intuitive as some may perceive (Crompton, 2006). Both patients and health care professionals can underestimate the precision and attention to detail required for correct inhaler technique (Molimard et al., 2003, Pinto Pereira, Clement, and Simeon, 2001), resulting in a critical "blind-spot" in asthma management (Crompton, 2006). The details of inhaler technique are important and warrant attention due to its implications for asthma outcomes (Basheti et al., 2007). In the next section the precise steps required for correct inhaler technique will be elaborated upon, with reference to three specific devices – the pMDI, Turbuhaler™ and Accuhaler™.

iv. Steps for correct inhaler technique

The three most commonly used inhaler devices in Australia for asthma therapy are: the pMDI, Turbuhaler™ and Accuhaler™ (Turbuhaler™ and Accuhaler™ being DPIs) (AMH, 2013). In order to use these devices with the correct technique, patients must follow a specific sequence of steps. Instructions for correct inhaler technique can be sourced from manufacturers' drug information pamphlets, clinical guidelines (Asthma Australia, 2013, AMH, 2013, National Asthma Council Australia, 2008) and the published literature (Basheti et al., 2008, Melani et al., 2011, Melani et al., 2004, van der Palen, Klein, Kerkhoff, and van Herwaarden, 1995). There are slight variations in the way in which instructions are presented between various sources (e.g. some are more detailed as instructions are broken down into smaller steps), however, all up-to-date instructions encapsulate what is required for optimal inhaler use.

Using an inhaler device with the correct technique may demand more than what is initially expected with checklists usually comprising of at least 7 steps. Performing all of the stipulated steps, rather than a select few, is important because there is a rationale behind each instruction for enhancing the efficacy and safety of inhaled therapy. The steps for correct inhaler technique for the pMDI, Turbuhaler™ and Accuhaler™ are detailed in Table 2.01, with an explanation of how each contributes to the safe and effective use of inhaled medication. These instructions have been derived from the clinical guidelines and published checklists (as cited above), however they are conceptualised here as three distinct stages, namely: 1. preparing for inhalation, 2. performing the inhalation, and 3. completing the inhalation. Inhaler technique instructions are conceptualised as such here in order to make it clearer to compare the steps and to view the similarities and differences among the three devices.

Table 2.01: Correct inhaler technique for the pressurised Metered Dose Inhaler, Turbuhaler™ and Accuhaler™

Phases	Pressurised Metered Dose Inhaler Step (Purpose)	Turbuhaler™ Step (Purpose)	Accuhaler™ Step (Purpose)
1. Preparing For Inhalation	1. Remove cap (makes dose available to inhale) 2. Shake inhaler well (mixes drug and propellant) 3. Exhale air out of lungs (allows greater lung capacity to perform continual steady inhalation) 4. Hold inhaler upright (positions device optimally for aerosol to travel to the lungs) 5. Put mouthpiece between teeth and seal with lips (positions device optimally for aerosol to travel to the lungs and prevents drug escaping)	1. Unscrew and lift off cap (makes dose available to inhale) 2. Hold inhaler upright (ensures dose will be loaded into dose path) 3. Rotate grip one way, then back until click is heard (to load dose and make available for inhalation) 4. Exhale air out of lungs (allows for greater lung capacity to perform inhalation manoeuvre) 5. Exhale away from mouthpiece (prevents drug from being blown out of dosing chamber; reduces moisture contamination of device which causes powder to aggregate) 6. Put mouthpiece between teeth and seal with lips (positions device optimally for aerosol to travel to the lungs)	1. Open inhaler (makes dose available to inhale) 2. Push lever back completely to load dose (ensures dose will be fully loaded) 3. Exhale air out of lungs (allows for greater lung capacity to perform inhalation manoeuvre) 4. Exhale away from mouthpiece (prevents drug from being blown out of dosing chamber; reduces moisture contamination of device which causes powder to aggregate) 5. Hold inhaler horizontally (positions device optimally for aerosol to travel to the lungs) 6. Put mouthpiece between teeth and seal with lips (positions device optimally for aerosol to travel to the lungs)

2. Performing Inhalation	6. Inhale slowly *and* press canister firmly 7. Continue slow and deep inhalation (allows time for smaller particles to develop, enhances drug lung deposition and reduces oropharyngeal deposition)	7. Inhale forcefully and deeply (generates the required force to de-agglomerate drug into small particles that can reach lungs)	7. Inhale steadily and deeply (generates the required force to de-agglomerate drug into small particles that can reach lungs)
3. Completing Inhalation	8. Hold breath, aim for ten seconds (permits more time for particles to deposit in lungs via sedimentation) 9. While still holding breath remove inhaler from mouth (minimises chance of moisture clogging nozzle) 10. Exhale away from mouthpiece (minimises chance of moisture clogging nozzle) 11. Replace cap (for hygienic storing, protects from dust)	8. Hold breath, aim for ten seconds (permits more time for particles to deposit in lungs via sedimentation) 9. While still holding breath remove inhaler from mouth (reduces moisture contamination of device) 10. Exhale away from mouthpiece (reduces moisture contamination of device) 11. Replace cap (for hygienic storing, protects from dust)	8. Hold breath, aiming for ten seconds (permits more time for particles to deposit in lungs via sedimentation) 9. While still holding breath remove inhaler from mouth (reduces moisture contamination of device) 10. Exhale away from mouthpiece (reduces moisture contamination of device) 11. Close cover (for hygienic storing, protects from dust)

1. Preparing for inhalation

During this first phase a common instruction across all three devices is for patients to empty out their lungs as much as possible, this allows for a greater lung capacity to perform the inhalation manoeuvre. The remaining steps during this preparation phase relate to dose loading and differ for each device.

For the Turbuhaler™ and Accuhaler™ (both DPIs), the correct dose loading procedure is critical for making the drug available for inhalation (as explained in section B, iii, 2, b). Inside the Turbuhaler™, a measured dose of drug from a powder reservoir is loaded into the dose path by firstly keeping the device upright and then twisting its base one way and then another until a click sound is heard (Frijlink and De Boer, 2004). Inside the Accuhaler™, a unit dose of drug contained within a foil pack is loaded into the dose path when patients pull down a lever (Sanchis et al., 2012).

By contrast, pMDIs do not require patients to manually load the drug into a dose path since a metered dose, driven by propellant, is automatically released when the patient pushes down on the canister. Shaking of the canister before use, however, is required for some pMDIs, specifically those containing drug in suspension rather than in solution, in order to uniformly mix the drug and propellant phases.

Patients who have completed all of the steps in this first phase correctly are now adequately prepared to inhale the drug dose from their inhaler. However, for those who have not correctly performed the technique steps, even during this early stage, the beneficial effects of treatment will be compromised.

2. Performing the inhalation

During this second phase it is important that patients inhale at the optimal rate determined for the device that they are using, in order to generate the most favourable physical conditions in the aerosol cloud that they are inhaling for lung deposition. Key differences exist among all three devices regarding optimal inhalation rates.

As mentioned earlier, the inhalation rate for pMDIs must be slow and steady (approximately 25 L/min) in order to allow adequate time and space for the fast moving propellant-driven aerosol to slow down and reduce in particle size to be small enough for lung deposition (Newman, Pavia and Clarke, 1981).

In contrast, the inhalation rate for breath-activated DPIs must be markedly higher to produce enough energy to de-agglomerate the larger drug particles sitting inertly in powder form into finer particles for lung deposition. The Turbuhaler™ requires patients to inhale deeply and forcefully, and further it is important that patients reach a peak inspiratory flow rate at the beginning of the inhalation to enhance the amount of fine particles present in the aerosol that is generated (Everard, Devadason, and Le Soue, 1997). The Accuhaler™ also requires a similar inhalation manoeuver as that for the Turbuhaler™, i.e. one that is strong, deep and continuous, although, reaching a peak inspiratory flow rate at the beginning of the inhalation is not critical for the Accuhaler™.

3. Completing the inhalation

During this final phase, across all three inhaler devices, a breath hold for approximately ten seconds after inhalation is stipulated as this enhances the amount of drug depositing in the lungs through sedimentation (Newman et al., 1981). When patients complete their breath hold and begin to exhale, they should direct this exhalation away from the inhaler device mouthpiece to reduce moisture contamination, a more critical instruction for DPIs than pMDIs.

Patients must be careful to protect their DPI from any additional moisture because this makes the powder more adhesive and less likely to de-agglomerate into a fine powder (Price, Young, Edge, and Staniforth, 2002). The Turbuhaler™ is especially sensitive to moisture contamination since its entire drug doses are contained in one reservoir rather than separately packed as in an Accuhaler™.

Finally, to maintain the hygiene of the inhaler device for the next use the last steps remind the patient to replace the mouth piece cover. The steps discussed for correct use of the pMDI, Turbuhaler™ and Accuhaler™, in the three phases above, are summarised in Table 2.01 and accompanied by photographs of the three devices in Figure 2.03.

Figure 2.03: The pMDI (A), Turbuhaler™ (B) and Accuhaler™ (C).

A.

B.

C.

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Section B of this literature review has highlighted the importance of correct inhaler technique for the effective and safe use of inhaled therapy in asthma. It has also discussed the wide range of inhaler devices currently available for asthma treatment, with a focus on the three most common – the pMDI, Turbuhaler™ and Accuhaler™. Further, step-by-step instructions exists for the correct use of all inhaler devices, and these instructions should be accessible to both patients (e.g. via manufactures' pamphlets that accompany each device dispensed, Asthma Australia website, and National Asthma Council Australia website) and health care professionals (e.g. via clinical guidelines and the patient sources mentioned above). However, as will be shown in the final section of this literature review, despite the availability of clearly articulated technique instructions, having patients achieve and maintain correct inhaler technique has not proven to be a straightforward process.

C. Inhaler technique in patients with asthma

This section outlines the evidence showing suboptimal inhaler technique as a common occurrence amongst patients with asthma, the reasons that contribute to suboptimal technique, and current recommendations on how technique can be improved. The final part of this section highlights the gaps in the literature, where it remains uncertain why poor inhaler technique persists despite the absence of known barriers.

i. Prevalence of suboptimal inhaler technique

The use of inhaler devices with incorrect or suboptimal inhaler technique can be found in a large proportion of patients with asthma, which is of course of concern given the clinical implications of poor inhaler technique discussed previously (section B, ii). Incorrect inhaler technique during device use has been observed from the outset of inhaled therapy, with the introduction of the first pMDI.

Amongst pMDI users, the proportion of patients demonstrating incorrect inhaler technique can be between 17 and 90% based on a range of both relatively older and newer studies (Broeders et al., 2003; Broeders, Sanchis, Levy, Crompton, and Dekhuijzen, 2009; Epstein, Manning, Ashley, and Corey, 1979; Melani et al., 2011; Orehek et al., 1976; Saunders, 1965). As can be seen, there is somewhat of a variation in the rates of suboptimal inhaler technique reported, which makes it difficult to quote a definitive proportion of patients who demonstrate incorrect pMDI technique. An explanation for the variation in figures reported may lie in the differences in the methods employed between studies (e.g. various versions of inhaler technique checklists are used and different criteria for determining what constitutes correct/incorrect inhaler technique exist). Nevertheless, regardless of these study inconsistencies, a key point to note is that a sizeable proportion of patients still cannot use their pMDI with the correct inhaler technique, despite the device having been in use for over half a century.

Patient problems with inhaler technique were anticipated to be a thing of the past with the introduction of the DPI after the pMDI. Dry Powder Inhalers were initially perceived to be more "user friendly" than pMDIs, mainly based on the fact that DPIs did not require patients to coordinate dose actuation and inhalation, a manoeuvre observed to be problematic for many from the outset (Crompton, 1990, Epstein, Maidenberg, Hallett, Khan and Chapman, 2001, Paterson and Crompton, 1976). It is now clear however, that patients may find DPIs just a problematic to use as pMDIs.

In a large European study comparing the inhaler technique of patients using a pMDI compared to three types of DPIs (Diskus™, Turbuhaler™ and Aeroliser™), almost identical rates of suboptimal inhaler technique were found to exit between the four devices (24%, 24%, 23% and 17% respectively) (Melani et al., 2004). Similar rates of incorrect inhaler technique between pMDIs and DPIs have been shown in various other studies (Brocklebank et al., 2001, Cochrane et al., 2000, Fink and Rubin 2005). Further, the proportion of patients demonstrating poor inhaler technique with DPIs can be quite high, with international data reporting up to 94% (Lavorini et al., 2008) and local data identifying 87 to 93% of patients to have poor inhaler technique with DPIs (Basheti et al., 2007).

The evidence thus shows that both pMDIs and DPIs (in their various designs) are used with suboptimal inhaler technique by a substantial proportion of patients. Further, suboptimal inhaler technique has persisted over time despite predictions that advances in inhaler device design and technology would reduce or eliminate this problem. This suggests that the problem of poor inhaler technique cannot be adequately addressed only from the stance of improving drug design and technology, especially since optimal inhaler technique ultimately depends on how the inhaler device is handled by the patient (or carer).

This human element means that the reasons behind poor inhaler technique are multi-dimensional and can be complex. Gaining an understanding about these patient related factors, however, may be an important part of achieving effective and safe use of inhaled therapy in asthma. Patient related factors behind poor inhaler technique have been explored in various studies, although from a predominantly practical standpoint. That is, patient related factors previously examined, in the context of inhaler technique, mainly pertained to functional barriers during device use. Other barriers in optimal device use that have been investigated in the literature relate to inhaler technique education (or rather its lack thereof). These main factors, established in the literature as barriers to good inhaler technique, have been brought together and are now further examined.

ii. Known barriers to optimal inhaler technique

Poor inhaler technique can be associated with patient functional limitations (physical and cognitive) and lack of effective inhaler technique education. Both factors are discussed below along with the evidence indicating how they can be overcome.

1. Patient functional limitations

Patient functional limitations are a well-established reason for poor inhaler technique. Not surprisingly, patients with physical and cognitive limitations will find it more challenging to perform the manoeuvres required for correct inhaler technique (Broeders et al., 2003, Rees, 2005) compared to patients who do not experience these limitations. Medication administered using inhaler devices demands greater skill and manipulation than other commonly self-administered dosage forms (e.g. oral medication) and functional limitations, such as reduced hand strength, dexterity, eyesight, lung capacity and hand-lung coordination, increase the difficulty in achieving correct inhaler technique and sometimes make it impossible with certain devices (Blaiss, 2007, Broeders et al., 2003, Gray et al., 1996, Haughney et al., 2008, McFadden, 1995, Ruggins et al., 1993, Sestini et al., 2006, Shim and Williams Jr, 1980, Tsang et al., 1997, Wieshammer and Dreyhaupt, 2008).

The very young and elderly constitute specific patient groups who are more likely to have difficulty with inhaler technique due to physical and cognitive barriers (Lavorini et al., 2008). Children below the age of four have been shown not to have the physical or cognitive skills (e.g. coordination and inspiratory capacity) to self-administer inhaler device therapy, and therefore depend on their parents or carers to do so for them (Goren et al., 1994). Parents and carers, however, often do not possess the skills themselves to correctly administer inhalation therapy to their child (Aziz, Norzila, Hamid, and Noorlaili, 2006). Even amongst parents and carers who can administer correctly, challenges still exist because some manoeuvres are largely dependent on the child's own ability, for example children still need to know how to inhale at the correct rate whether a pMDI or DPI is used.

Elderly patients, on the opposite end of the age spectrum, often possess or develop over time, a decline in physical function that make them prone to suboptimal inhaler technique. Many elderly patients show a reduction in hand strength and dexterity (Gray et al., 1996) which can be further compromised by co-morbidities such as arthritis (Wolstenholme, Shettar, Taher and Hatton, 1986). These factors can pose as barriers, particularly in pMDI use, since reduced hand strength and dexterity makes well timed dose actuation and inhalation difficult (Cochrane et al., 2000, Hampson and Mueller, 1994, Sestini et al., 2006, Shim and Williams Jr, 1980). Many elderly patients also experience reduced vision, which can make it difficult particularly when using DPIs that require individual capsules to be loaded before each use (Press et al., 2011). Further, elderly patients with reduced lung capacity (such as those with more prolonged asthma or respiratory co-morbidities, such as COPD) will likely find it difficult when using those DPIs that require deep and forceful inhalations to activate the dose (Broeders et al., 2003, Ruggins et al., 1993, Wieshammer and Dreyhaupt, 2008).

Although patient functional limitations clearly pose as a barrier to optimal inhaler technique, given the variety of inhaler devices, add-on devices and delivery systems currently available for asthma therapy (section B, iii), a suitable inhaler device/delivery system to meet different functional abilities should exist for the majority of patients and parents/carers. For example, children can be prescribed nebulised therapy as it provides a more passive delivery system that does not require as much skill during dose inhalation or coordinated effort between child and parent/carer compared to hand-held devices (Rees, 2005). Another suitable option for children is the use of a pMDI with a spacer and facemask, which if well adopted is just as effective as nebulised therapy with the added advantage of being less expensive, quicker to administer and easier to keep clean (Brand, 2005).

In elderly patients, before selecting a DPI for asthma therapy, it should be ascertained whether the patient has the sufficient inspiratory force to use the device. Since this can be challenging to detect via observation alone, there are various tools available (both sophisticated and simple) to assess the adequacy of patients' inspiratory force such as the InCheck Dial™, Turbuhaler Trainer™, 2-Tone Trainer™ and the Vitalograph™ (Capstick and Clifton, 2012). For patients with insufficient inspiratory force, a better alternative to a DPI is the pMDI. While of course challenges may still exist in the use of the pMDI, they too can be overcome. For example, add-on devices can assist those patients who find it difficult to actuate a dose from a pMDI due to reduced hand strength and dexterity. The Haleraid™ (Pierce and Rubinfeld, 1990, Wolstenholme et al., 1986) is one such device which clips over the pMDI and is quite easily squeezed to then release a dose. A spacer used in conjunction with a pMDI is another alternative that can reduce difficulties with pMDI use.

The examples given above illustrate some of the important issues to be taken into consideration when selecting an appropriate inhaler device/delivery system for a patient. Further and more importantly, these examples highlight the range of inhaler devices/delivery systems available to patients which should (if due consideration is given during the selection process by health care professionals) minimise the limitations posed by any patient functional issues, so that they are no longer significant barriers to optimal inhaler device use.

2. Inadequate inhaler technique education

Inadequate inhaler technique education has been shown to be another barrier to correct inhaler technique, and it is considered here as either the lack of inhaler technique instruction, or the provision of ineffective inhaler technique instruction. Inadequate inhaler technique education perhaps explains why, in patients where there are no functional barriers to device use, poor inhaler technique can still exit.

A large proportion of patients, 16 to 40%, have never received any inhaler technique education from their health care providers (Basheti et al., 2007, Giraud and Roche, 2002, Lavorini et al., 2008, Melani et al., 2004, King, Earnshaw and Delaney, 1991) and this can be associated with both misconceptions and lack of skill on health care professionals' part. Firstly, regarding misconceptions, many health care professionals may not be aware of the problem of suboptimal inhaler technique and its magnitude amongst their own patients, especially if they rely on patients' self-appraisals of inhaler technique, which tend to be large overestimations (Erickson, Horton, and Kirking, 1998, Pinto Pereira et al., 2001, Souza, Meneghini, Ferraz, Vianna, and Borges, 2009). Some health care professionals also believe that using an inhaler device correctly is a self-explanatory and straightforward process which therefore does not warrant time to be spent on instructing patients during the limited consultation period (Fink and Rubin, 2005). However, all the existing evidence regarding patient inhaler device use and clinical guidelines emphasising the need to train patients on technique, indicate achieving correct inhaler technique is not as intuitive as it may first appear (Crompton, 2006, Molimard et al., 2003, Pinto Pereira et al., 2001).

Secondly, some health care professionals' own lack of ability to perform correct inhaler technique is another contributing factor as to why many patients do not receive technique education. Although some variation in technique skill may exist amongst different types of health care professionals, (Guidry, Brown, Stogner and George, 1992, Hanania, Wittman, Kesten and Chapman, 1994), overall, suboptimal inhaler technique has been identified amongst many types of health care professionals (including physicians, nurses, pharmacists and respiratory therapists), from diverse clinical settings, and across a range of inhaler devices (Cain, Cable and Oppenheimer, 2001, Guidry et al., 1992, Hanania et al., 1994, Kesten, Zive and Chapman, 1993, Scarpaci, Tsoukleris and McPherson, 2007). This suggests that, for both patients and health care professionals alike, correct inhaler technique is not a skill that is intuitive.

On a more promising note however, health care professionals' inhaler technique is highly amenable to improvement after technique education, even with training as brief as 10 minutes (Basheti, Armour, Reddel and Bosnic-Anticevich, 2009, Cain et al., 2001, Guidry et al., 1992). Further, health care professionals who have successfully learned correct inhaler technique have been shown to maintain these skills for the entire duration in a longitudinal study of up to 2 years (Basheti et al., 2009).

Referring back to inadequate inhaler technique education in asthma patients, it is important to note that this can be the case even amongst those patients who do receive education from their health care professional. This can be due to health care professionals using ineffective methods to teach inhaler technique. Inhaler technique education can be delivered in various ways, for example, via written instructions, verbal explanations, physical demonstration, one-on-one between patient and health care provider or via video recording (van der Palen et al., 1995, van der Palen et al., 1997). Some methods have been shown to be more effective than others and thus, whilst many patients may have received inhaler technique instructions, it may not have resulted in improved technique due to the method of education adopted.

Physical demonstration of inhaler technique supplemented with verbal counselling and written information has been shown to be the most effective means of inhaler technique education over time. Various comparative studies shows that the addition of physical demonstration to verbal and written information, as opposed to verbal and/or written information alone, markedly improves patients' ability to learn the correct inhaler technique (McElnay, Scott, Armstrong and Stanford, 1989, Roberts, Robinson, Doering, Dallman and Steeves, 1982, Self, Brooks, Lieberman and Ryan, 1983, van der Palen, Klein, Kerkhoff, van Herwaarden and Seydel, 1997). Further, demonstrations occuring face-to-face or via video recordings have been shown to be equally effective methods (van der Palen et al., 1995, van der Palen et al., 1997). Face-to-face sessions, though, allow for interactive teaching and learning between patients and health care providers, which may have benefits such as patients receiving real-time tailored feedback on their learning.

Drawing together the two components discussed in this section, it can be observed that inadequate inhaler technique education can be due to the absence of education or ineffective delivery of education. Both instances contribute to the suboptimal inhaler technique observed amongst patients. Nevertheless, there are successful strategies for overcoming these barriers. Evidence show that health care professionals can be educated to learn and retain correct inhaler technique, and that subsequently patients can be educated on correct technique, featuring physical demonstrations of proper inhaler device use as part of the instruction (Basheti et al., 2008, 2009, 2007). Patients who have received gold-standard inhaler technique education (i.e. those that include physical demonstration) successfully learn and show marked improvements in their inhaler technique (Basheti et al., 2007).

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The known barriers to optimal inhaler technique presented in this section (C, ii) can all be associated with evidence based strategies in how to overcome them. In practice, assuming that these strategies are adopted, problems with suboptimal inhaler technique should recede. Of course it must be acknowledged that, in practice, there are often environmental impediments to implementing the strategies discussed, such as time pressures. However, in the study-setting, this is not usually the case, especially in those studies focused solely on inhaler technique (e.g. Basheti et al., 2007). Interestingly and perhaps unexpectedly, it is in such study settings that patient inhaler technique has been shown to be suboptimal. This is despite the absence of known barriers (i.e. no issues with patient functional limitations, patient lack of education, health care provider lack of education, ineffective education, busy practice/lack of time). Further, the evidence to guide recommendations to overcome this particular problem is lacking. The problem of poor inhaler technique in the absence of known barriers will be elaborated upon in the following and final section of this literature review.

iii. Suboptimal inhaler technique persists in the absence of known barriers

Although patients can successfully learn to use their inhalers with the correct technique – provided a suitable device/delivery system is chosen and effective instruction is given – optimal inhaler technique is not maintained and there is no clear evidence as to why this deterioration in technique occurs in the absence of known barriers. Correct inhaler technique amongst patients with asthma (and parents/carers) has been shown to decline in many studies regardless of the clinical setting, time frame involved or the type of education provided. The evidence for this is presented in Table 2.02, which provides a summary of the existing prospective, repeated measures studies that have measured patients' inhaler technique status over time. Table 2.02 includes studies involving both asthma and non-asthma patients. This is simply to point out the fact that inhaler technique decline is not a problem exclusive to asthma patients. Although there are differences in the reported figures concerning technique decline , which may be explained by the different study methods used (e.g. setting of study, subjects involved, type of education provided and how inhaler technique was assessed and classified), it is worth noting that, even in those studies where gold-standard technique education was provided, large proportions of patients/subjects still did not maintain optimal inhaler technique (Aziz et al., 2006, Basheti et al., 2007, Bosnic-Anticevich et al., 2010). Further, inhaler technique has been found to deteriorate in as little as a few days after education (Shim and Williams Jr, 1980).

Table 2.02: Prospective repeated measures studies, showing decline in inhaler technique post education, across various settings.

Study (author, year, setting)	Type of inhaler technique education	Time period between baseline/ previous visit and final visit	Proportion of patients with *incorrect* technique at final visit.
Studies with asthma patient as subjects			
Bosnic-Anticevich et al., 2010. N=52 asthma or COPD patients ≥18 years; pMDI used; set in community pharmacy.	Two education groups were compared: 1. Intervention: written, verbal and physical demonstration (n=26) 2. Control: written and verbal (n=26) Technique reinforcement occurred up to 3 times for both groups.	2 months	40% intervention group patients, 80% control group patients.
Basheti et al., 2007. N=97 asthma patients ≥14 years; DPIs used (Turbuhaler™ and Accuhaler™); set in community pharmacy.	Two education groups were compared: 1. Intervention: written, verbal and physical demonstration (n=53) 2. Control: standard care (n=44) Technique reinforcement occurred up to 3 times for both groups.	3 months	17% (Accuhaler™ users) and 35% (Turbuhaler™ users); both intervention group patients.
Aziz et al., 2006. N=85 parents of children 1-12 years; pMDI with spacer used; set in hospital primary care clinic.	One technique education session with physical demonstration and written information (on asthma in general) lasting 25-30 minute.	2 months	35% parents
Broeders et al., 2003. N=58 asthma and COPD patients >37 years; Turbuhaler™, Accuhaler™ or pMDI used.	Written and verbal instructions	5 weeks	Inhaler technique values not reported; inhalation profile values reported; deterioration shown in some values for Turbuhaler™ and Accuhaler™ users; and in all values for pMDI users.
Shim et al., 1980. N=30 hospitalised asthma patients; pMDI used.	Physical demonstration with a 'horn' audio signalling teaching device	1 day-1 month	50% patients

De Blaquiere et al., 1989. N=100 asthma and COPD patients ≥24 years; pMDI used; set in hospital outpatient clinic.	Two education groups were compared: 1. Verbal instruction 2. Verbal instruction + visual signal during inspiration	6-10 weeks	Technique declined for all users – 45% for initial 'incorrect users' and 20% decline in initial 'correct users'.
Studies with non-asthma patient as subjects			
Chafin et al., 2000. N=83 pharmacy students; pMDI with spacer used.	20min in-lecture physical demonstration followed by one-on-one assessment and feedback	1 week	11% students
Van der Palen et al., 1997. N= 152 COPD patients ≥18 years; pMDI, Turbuhaler™, Diskhaler™, or Rotahaler™, used; set in pulmonary outpatient clinic.	Four education groups were compared: 1. One-on-one physical demonstration 2. Video recorded demonstration viewed at home 3. Small group physical demonstration (5-7 patients per group, 45minutes per session) 4. Control group: technique assessment only	19-26 weeks	- 25% first group - 24% second group - 3% third group - 51% fourth group
Gray et al., 1996. N=29 COPD patients and n = 42 healthy volunteers, ≥50 years; pMDI used; set in hospital clinic.	Verbal, written, physical demonstration with practise time and feedback; training lasted for up to 30min.	1 week	20% patients and volunteers (pooled data)
McElnay et al., 1989. N=150 device naïve non-medical hospital staff volunteers; pMDI used.	Three education groups were compared: 1. Written instruction and placebo practise for the patient. 2. Physical demonstration by pharmacist and written information, and placebo practise for the patient. 3. Video presentation	2 weeks	Technique declined regardless of method of education (values not reported).

Although the reasons for inhaler technique deterioration are unclear, the current consensus recommendation to overcome this problem is to repeat inhaler technique instructions to patients on a regular basis (Aziz et al., 2006, Basheti et al., 2007, Blaiss, 2007, Cochrane et al., 2000, Crompton et al., 2006, Cross, 2001, Haughney et al., 2008, McFadden, 1995, Mehuys et al., 2006, Sestini et al., 2006, van Beerendonk, Mesters, Mudde, and Tan, 1998, Virchow 2004), this seems to suggest that the problem is simply related to patients forgetting how to use their inhaler. However evidence supporting this notion is sparse, and on the contrary, studies have shown that inhaler technique declines even with repeated instructions (Basheti et al., 2007).

The inhaler technique education provided to patients involved in a study conducted by Basheti et al. (2007) is summarised here in some detail in order to suggest how unlikely it would seem for patients to simply *forget* how to use their inhaler after receiving such robust training. In this study, community based patients with asthma using either a Turbuhaler™ or Accuhaler™ for regular preventer therapy were recruited. Although baseline technique was poor for most patients, after the provision of gold-standard education by a trained pharmacist – i.e. that which involved repeated physical demonstrations of inhaler technique by both the pharmacist and the patient (for assessment purposes) – the vast majority of patients could successfully demonstrate correct technique. A written technique checklist printed on a sticker (on which the steps that the patient needed to pay extra attention to was highlighted) was affixed to the patient's inhaler device as a constant and accessible reminder of correct technique each time the patient used their device. Further, as reinforcement, patients' inhaler technique was re-assessed and inhaler technique instructions were repeated if necessary (i.e. if patient's technique had deteriorated) during four follow up visits spaced at monthly intervals.

Despite the intensity of this educational intervention that focused purely on inhaler technique, it is interesting to note that amongst patients in this study, at the final visit (which occurred three months after the last follow up visit), correct inhaler technique had deteriorated in 35% of Turbuhaler™ users and 17% of Accuhaler™ users. Further evidence to substantiate these findings is provided by a study conducted by Bosnic-Anticevich et al. (2010) which showed a decline in correct inhaler technique amongst 40% of the study patients, who had, of note, previously achieved and demonstrated, correct technique. This was despite repetition, on three separate occasions, of gold-standard inhaler technique education. Clearly, it seems that simply repeating inhaler technique instructions is not enough as a recommendation to ensure patients not only achieve, but *maintain* optimal inhaler technique over time.

Poor inhaler technique that persists over time, i.e. poor inhaler technique maintenance, if unaddressed, is likely to continue to contribute to the high rates of suboptimal disease control and the overall burden of asthma in Australia. Currently, there is no clear evidence as to why, amongst those patients who can successfully learn to use their inhalers with the correct technique, that this skill and practice is not maintained for the duration of their treatment. Therefore it is imperative for future studies to not only consider the notion of optimal inhaler technique, but more importantly optimal inhaler technique *maintenance*. This thus forms the underpinning motivation for the work subsequently presented in this thesis. That is, to explore the phenomenon of inhaler technique maintenance, with the aim of understanding why patients with asthma do not maintain correct inhaler technique despite "knowing how" to perform correct technique and in the absence of known barriers.

D. Overarching aim of thesis

To explore the phenomenon of inhaler technique maintenance, and to investigate why patients with asthma do not maintain correct inhaler technique despite "knowing how".

— CHAPTER 3 —

DETERMINANTS OF INHALER TECHNIQUE MAINTENANCE IN COMMUNITY BASED ASTHMA PATIENTS IN SYDNEY, A QUANTITATIVE STUDY

THE IMPORTANT ROLE of inhaler technique in asthma management was established in the previous chapter. Specifically it was shown that how patients *maintain* inhaler technique over time has significant implications for their asthma outcomes, including asthma control. (Chapter 2, section B, ii). Suboptimal inhaler technique that persists over time is especially problematic with respect to the preventative inhaled corticosteroid class of inhalers. Poor handling of these inhalers contributes to reduced asthma control and increased chances of medication side effects (Chapter 2, section B, ii). Despite its important clinical implications, currently there are no-known studies directly investigating the phenomenon of inhaler technique maintenance, and what is poorly understood in particular is why many patients fail to maintain correct inhaler technique in the absence of known barriers (Chapter 2, section C, iii). This chapter thus commences exploration of inhaler technique maintenance at this juncture. A quantitative study aiming to identify the underlying determinants of inhaler technique maintenance in patients with asthma, with a focus on preventative inhaled corticosteroid therapy, in the community pharmacy setting will be presented.

A. Background

i. Framework for conceptualising inhaler technique maintenance

Establishing a conceptual framework to better understand the phenomenon of inhaler technique maintenance is an important first step for commencing investigations in the area. Literature in the inhaler device use domain however, offers a rather narrow perspective for this purpose, as poor inhaler technique is typically presented as either a problem relating to adherence, or one that is predominantly practical in nature. These existing conceptualisations of inhaler technique will be explored further below.

Inhaler technique is often considered to be a part of adherence, with poor technique classified as “unintentional non-adherence/compliance”, describing the scenario where a patient is adhering to the use of their preventer therapy, only with the incorrect inhaler technique (Cochrane, Horne, and Chanez, 1999, Haughney et al., 2008, Price et al., 2013). At first glance, the concepts of *adherence to,* and *inhaler technique maintenance with,* preventer therapy may appear to be closely linked. This is because both concepts refer to persisting with an inhaler device related activity over time. However, maintaining regular use of one’s preventer inhaler (adherence), compared to using one’s preventer inhaler with the correct technique at every instance of device use (correct inhaler technique maintenance) are separate concepts. Further, a clear relationship between adherence and inhaler technique maintenance has never been unequivocally demonstrated.

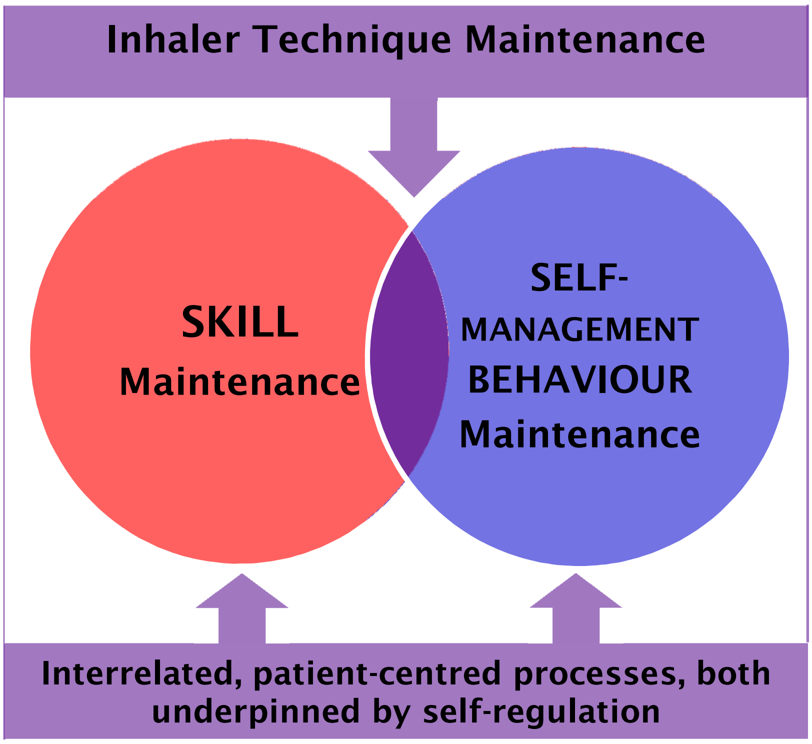
Although some studies indicate an association between adherence and inhaler technique (showing better inhaler technique amongst those patients using their preventer inhalers on a more regular basis) (Epstein et al., 1979, Sestini et al., 2006), 1979), others show no relationship (Chan et al., 2006, Dompeling et al., 1992). Further, while a recent cross-sectional study showed that repeated inhaler technique *instruction* correlated with better adherence to preventer therapy, no results were reported on the relationship between adherence and inhaler technique itself (Takemura et al., 2010). Based on these findings, and for the purposes of this study, it thus seems best to draw a clear distinction between the processes of adherence and inhaler technique maintenance. Without doing so, and by closely relating the two processes as has been done in the past, the perspective required for gaining understanding into inhaler technique maintenance may be clouded.

Poor inhaler technique is also often classified as a “practical barrier” in asthma management (Haughney et al., 2008), with much attention currently placed on the physical aspects of patient inhaler device use. Numerous studies detail patient physical considerations in inhaler device use (e.g. hand-lung coordination, dexterity, lung capacity, hand strength, eye sight etc.) (Chapter 2, section C, ii, 1). Further, the research into technique education, likewise, focuses on practical teaching and learning strategies (e.g. examining the role of repeat instruction in technique maintenance) (Chapter 2, section C, ii, 2). Although the physical and practical are undeniably important elements of inhaler technique maintenance, it is worth reiterating that, in many patients, technique is poor even when the physical and practical issues have been addressed (Chapter 2, section C, iii). Thus focussing only on literature in the inhaler technique domain is insufficient for the purposes of creating a conceptual framework to understand inhaler technique maintenance in more depth.

Maintaining inhaler technique clearly involves an element of physical skill and coordination, however the enactment of this skill does not occur in isolation, but exists in the context of a patient’s overall asthma self-management repertoire. Thus an alternative framework is proposed in this thesis that conceptualises inhaler technique maintenance as consisting of two interrelated processes, namely that of: 1) *skill maintenance* and 2) *self-management behaviour* maintenance (Figure 3.01). This conceptual framework will be referred to as the "Inhaler Technique Maintenance Framework" (ITMF) and will be used to guide this first in-depth exploration of inhaler technique maintenance.

In an area with a paucity of research, the ITMF allows for a richer, multi-dimensional exploration of inhaler technique maintenance, whereby two well established bodies of literature (i.e. skill learning and asthma self-management literatures) can be drawn upon in order to identify relevant factors to explore and test in the context of technique maintenance. That is, this framework suggests that potential determinants of inhaler technique maintenance may be related to those factors instrumental in the processes of skill and asthma self-management behaviour maintenance.

Figure 3.01: The Inhaler Technique Maintenance Framework (ITMF) – a conceptual framework for exploring inhaler technique maintenance.



The two processes proposed to form the basis of inhaler technique maintenance, as shown in Figure 3.01, are interrelated by their patient-centred orientation and by virtue that both are underpinned by the process of self-regulation. The important role of self-regulation is described in both the skill learning and self-management literatures. In the health-care context, self-regulation has been defined as a patient's ability to exercise control over their thoughts, emotions and behaviours (e.g. inhaler technique), and to monitor their present condition and make behavioural adjustments, for the attainment of health-related goals (or desired outcomes/states) (Maes and Karoly, 2005, Rothman, Baldwin and Hertel 2004). Further, an implicitly important consideration in the process of self-regulation is that of patient motivation (Bandura, 2005b). That is, a certain level and/or quality of motivation are required in order for patients to self-regulate effectively. By applying these principles in the context of inhaler technique maintenance it appears that the level and/or quality of a patient's motivation may influence how successfully they maintain inhaler technique over time. Specifically, it is hypothesised that the greater a patient's motivation to maintain correct inhaler technique, the more likely they are to achieve this(Hypothesis 1).

The patient-centred nature of skill and self-management behaviour maintenance stems from the notion that both processes are embedded in patients' daily routines, and it is patients themselves who largely determine their successful implementation. Although there may be initial and subsequent intermittent external input, for example, from health care professionals and other social support networks, the bulk of the responsibility for inhaler technique maintenance during the course of preventer therapy lies with the patient. With this in consideration, the next two sections will examine inhaler technique maintenance from the perspectives of patient skill learning and self-management behaviour.

ii. Inhaler technique maintenance from the perspective of patient skill learning

There is a large body of literature in the area of skill learning and development with important implications for various fields where skill learning and teaching are relevant. However, despite this, the understanding and application of the principles behind this science in those contexts where it may be relevant, including the health care setting, have been very limited (Cornford, 2008). It is somewhat surprising that inhaler technique has not lent itself to investigations in the past through the perspective of skill learning, given that it is recognised that a relatively high degree of skill is involved in self-administrating inhaled therapy (Chapter 2, section B, iv).

Skill can be briefly defined as “the ability to do something well, expertise” (The Oxford English Dictonary, 2000). Cornford (1996), however, has articulated “skill” and the performance of a skill, in a more substantial way, with nine defining attributes, listed in Figure 3.02. From this list, what is most noteworthy in the context of inhaler technique maintenance is the defining attribute recognising the important role of motivation and self-regulation in the maintenance of optimal skill performance (in bold). This adds further support for the hypothesis made earlier that patient motivation may play a role in technique maintenance (Hypothesis 1).

Figure 3.02: Cornford's nine defining attributes of skill and skilled performance (Cornford, 1996).

- Skill is learned.
- **Skill involves motivation, purpose and goals; motivation is especially important for maintenance of optimal skill performance.**
- Mental models are required in memory detailing the steps, processes, sequencing, and timing of a skill.
- Skills are context specific, with performance of the skill triggered by specific cues.
- Skills involve context-relevant problem solving.
- Skills involve relative judgements with individual differences in skill performance evident.
- Standards of excellence exist to judge skill performance against.
- Skill performance can be comparably replicated to similar standards by the performer.
- Considerable periods of time are required to achieve high levels of skill.

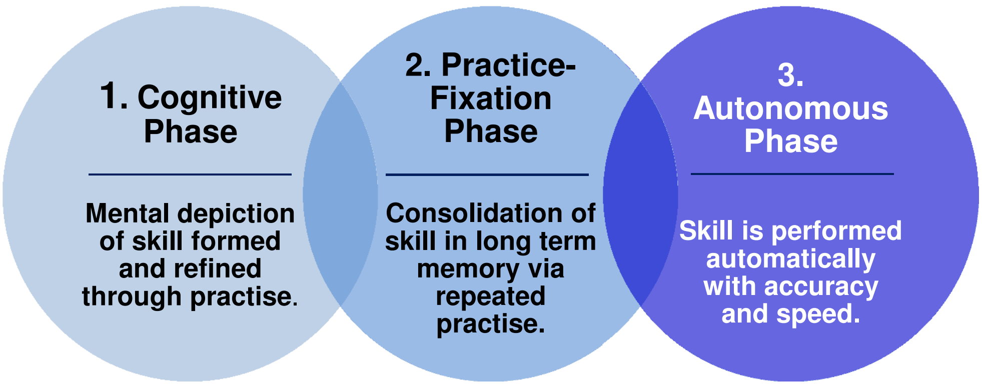
The list of defining attributes of skill and skill performance above may provide valuable insight into the nature of skills. Although, further understanding of skill development in the context of inhaler technique maintenance may be gained through taking a more structured approach in examining the phases involved in the skill learning and maintenance process. In order to understand the process of skill development and the implications for inhaler technique maintenance, a theoretical basis was adopted through the use of Fitts' Skill Learning Theory (Cornford, 2008, Fitts and Posner, 1967).

Fitts' Skill Learning Theory (FSLT)

Fitts' Skill Learning Theory (FSLT) was selected as the guiding theoretical framework here as it is well established and endorsed (Annett, 1991, VanLehn, 1996), and it can effectively account for the learning stages across all types of skills, including single-task skills, such as inhaler technique (as opposed to more complex and multi-task skills, e.g. professional development) (Cornford, 2008). Thus by drawing on a theory with the features of FSLT to explore inhaler technique maintenance, potentially new insights may be gained about the phenomenon.

Fitts' Skill Learning Theory describes the process of skill development as occurring in three distinct phases: 1) the cognitive, 2) the practice-fixation, and 3) the autonomous phase (Cornford, 2008, Fitts and Posner, 1967). During each phase a predominant type of skill learning activity occurs. The phases, however, are not mutually exclusive and the process of skill development is not linear. The three main phases of FSLT are depicted in Figure 3.03. In line with these principles it is proposed that patients may transition backwards and forwards between the three phases during the process of learning and maintaining inhaler technique. In the following sections these phases will be analysed in the context of inhaler technique maintenance. Further it will be argued that autonomy failure may occur due to inadequate development of skills at the cognitive and practice-fixation phases.

Figure 3.03: The three phases of Fitts' Skill Learning Theory (FSLT) and the predominant type of activity that occurs at each phase (Cornford, 2008, Fitts and Posner, 1967).



The first phase of FSLT, the *cognitive phase*, represents the learner's initial attempts to grasp a skill through the formation of a mental depiction (Cornford, 2008, Fitts and Posner, 1967). In the context of inhaler technique, during this phase patients would be learning to use an inhaler device for the first time and attempting to build an overall representation in their minds of the correct technique manoeuvre, patients may notice the individual steps, their timing and how they fit into a sequence. Mental depictions of inhaler technique that are higher in accuracy and detail (as opposed to less accurate and detailed depictions), serve as a better reference point and guide for monitoring and enacting future performances of inhaler technique. Self-regulation of skill performance may therefore be more effective with more detailed and accurate mental depictions (Schmidt, 1975).

This principle offers further insight into why better inhaler technique learning occurs after patients have viewed a physical demonstration, rather than having received written and/or verbal instruction only (as discussed in Chapter 2, section C, ii). That is, through observing an expert physically demonstrating correct inhaler technique, a richer and more accurate mental depiction of inhaler technique may be formed by patients to guide and monitor their future technique demonstrations, as compared to reading and/or listening to technique instructions alone. These mental representations of a skill are enriched and refined through practise of the skill, and this interfaces with the second phase of FSLT.

The *practice-fixation phase* is the second phase in FSLT, and as the name implies, the predominant activity in this phase entails the repeated practise of a skill until it becomes "fixed" or consolidated in long term memory (Cornford, 2008, Fitts and Posner, 1967). More complex skills tend to require a greater degree of practise before consolidation occurs, however this is not to say that less complex skills require minimal practise. Skills at all levels of complexity can benefit from increased practise.

Continued practise of a skill, even after competence has developed, such as after a patient has initially grasped and demonstrated correct inhaler technique, may enhance skill consolidation and maintenance (Healy and Sinclair, 1996).

The principles behind skill practise and consolidation may offer some insight into the positive correlation found between inhaler technique and adherence in some studies, as discussed earlier (Epstein et al., 1979, Sestini et al., 2006). That is, a patient's level of adherence with preventer therapy, *after* having competently learned the correct technique, can be an indicator for the degree of inhaler technique practise that they engage in, with greater or more consistent practise enhancing the likelihood of better consolidation of inhaler technique. Thus, it is hypothesised that the regularity of inhaler technique practise, as indicated by subsequent adherence (and *after* the patient demonstrates ability to perform the skill correctly), may predict how well a patient maintains inhaler technique over time (Hypothesis 2).

A critical consideration beyond the degree of practise, is the accuracy of the practise, during the *practise-fixation phase* of FSLT. Accurate practise is essential to prevent an incorrect version of the skill being consolidated in long term memory. The repeated incorrect enactment of a skill may result in its consolidation, and once this occurs it may be difficult and time consuming to undo and to re-learn the correct version. This is especially the case in skills involving a significant physical component such as inhaler technique (Cornford, 2008). Interestingly this possibility was commented upon decades ago in the inhaler technique literature – "many years of inhaling incorrectly, often thousands of times, must have established a habit difficult to break" (Shim and Williams Jr, 1980), however little has been done to further investigate this mechanism.

How well a skill has been initially learned/mastered has also been shown to predict its long term maintenance in other domains (e.g. cardiopulmonary resuscitation)

(Glendon, McKenna, Hunt and Blaylock, 1988). These observations, supported by skill learning theory, imply that patients' accuracy during practise may mediate the relationship between the degree of inhaler technique practise that they engage in and whether they maintain correct inhaler technique. This also suggests that how well a patient learns the correct inhaler technique for their device from the out-set (i.e. at the commencement of their inhaler therapy) may impact on their inhaler technique over time.

Thus if the initial teaching and learning conditions were not supportive of accurate practise, patients may not master correct inhaler technique to begin with, and subsequent poor technique demonstrations can reinforce and entrench poor technique over time. Patients' baseline inhaler technique may be a useful indicator of how accurately (after past technique education) they have consolidated the skill. Further, patients demonstrating correct (as opposed to incorrect) baseline technique are proposed to have more successfully consolidated the skill. Thus, it is hypothesised that patients demonstrating correct inhaler technique at baseline, compared to those with incorrect baseline technique, are be more likely to maintain optimal inhaler technique over time (Hypothesis 3).

During the *practise-fixation* phase, the act of showing others how to use their inhaler device may also constitute technique practise. There is some evidence to suggest that this form of practise can foster optimal inhaler technique maintenance. In the study by Basheti et al. (2009), both pharmacists and patients were taught inhaler technique via similar methods of repeat physical demonstration. The results revealed that pharmacists were more successful at maintaining correct inhaler technique for up to two years after training, than patients were during the six month study period. Interestingly, while both the pharmacists and patients received almost identical training on inhaler technique, one of the key differences between the two groups is that the pharmacists, who although would not personally use the inhaler on a day-to-day basis for asthma as the patients would, did regularly engage in teaching and showing others correct inhaler technique. This implies that the act of showing others correct inhaler technique may be a further means of consolidating this skill beyond the initial training received.

Similar implications can be found in an unpublished study (conducted at the Faculty of Pharmacy in 2010), involving 200 pharmacy students who had received inhaler technique training (in a similar fashion as in the study by Basheti et al., 2009, described above), and who were followed up 12 months later. The study showed that the students who were most likely to maintain correct inhaler technique were those who were working in the clinical practice setting and had engaged in teaching patients, via physical demonstration, inhaler technique (Hendricks, Bosnic-Anticevich and Smith, 2010). Based on the importance placed on skill practise in FSLT and these empirical observations, it can thus be hypothesised that patients who have engaged in showing others how to use an inhaler device (similar to their own device) are more likely to maintain correct inhaler technique over time (Hypothesis 4).

Feedback is another important factor to consider during the *practise-fixation* phase of FSLT and is critical in enabling the learner of any skill to appropriately monitor and adjust their skill enactments, that is, to self-regulate their skill enactments (Cornford, 2008). Without appropriate feedback during the initial learning period, achieving competence with a skill may be compromised and this may lead to a poorly or inaccurately consolidated skill, which over time can be difficult to unlearn and then relearn in the correct manner (as discussed above).

Timely and accurate provision of feedback by experts during inhaler technique education can help shape the mental depiction of the skill that patients hold in memory, and can impact on patients' ability to correctly master inhaler technique. Feedback derived from the learning environment, also known as external feedback (as opposed to intrinsic feedback generated from the task itself), can be classified as either quantitative or qualitative in nature (Kilduski and Rice, 2003). Quantitative feedback (e.g. *"you scored 8 out of 11 for your puffer technique"*) tends to provide concrete information on performance outcomes and details specific areas for improvement. Whereas qualitative feedback (e.g. *"your technique is getting better"*) can serve as verbal guidance and encouragement and has been shown to improve skill performance, possibly through enhancing motivation to persist with learning a skill (Chitwood, Moffatt, Burke, Luchino and Jordan, 1997). Encouragement and motivation derived from the learning environment during inhaler technique learning would seem especially important given that there may be minimal feedback from the activity itself (or intrinsic feedback) to guide patients to improve their technique.

There is, however, some evidence to suggest that intrinsic feedback during inhaler use may have an impact on patients' inhaler technique. That is, patient perceived feedback after inhaler use has been implicated to play a role in inhaler technique. In one study involving short-acting reliever inhalers, patients who obtained a greater degree of relief immediately after consuming a dose (measured by the degree of bronchodilation), were more likely to demonstrate correct inhaler technique compared to those who were less sensitive to the effects of the reliever medication (i.e. received less somatic feedback after dosing) (De Blaquiere, Christensen, Carter and Martin, 1989). Further, in a large cross-sectional study investigating a range of inhaler devices (the pMDI and three types of DPIs: Aerolizer™, Turbuhaler™, and Diskus™), more patients who used the Aerolizer™ demonstrated better technique compared to patients using any other device (Melani et al., 2004). The Aerolizer™ is a single dose DPI that provides immediate *visual feedback* of the amount of drug powder consumed. That is, after inhaling patients can open the device's dosing chamber to see if any medication remains and if further inhalations are required (Aerosol Drug Management Improvement Team).

In a less direct fashion, patient-perceived asthma control (or asthma symptoms) may also act as feedback on inhaler technique performance and potentially impact on technique maintenance. As discussed in the Literature Review (Chapter 2, section B, ii) there may be a relationship between inhaler technique maintenance and asthma control mediated by patient perceptions of the benefits and risks of inhaled therapy over time. This, albeit limited, empirical evidence, supported by the principles of skill learning theory, suggests that patient-perceived feedback during inhaler device use (e.g. symptom and visual feedback), may have an influence on how they maintain inhaler technique. Further, it is hypothesised that patient-perceived feedback in the form of asthma control may have an influence on inhaler technique maintenance over time. That is, more accurate perceptions of feedback may result is better inhaler technique maintenance (Hypothesis 5).

The third and final phase of FSLT, the *autonomous phase*, was so named to indicate that the individual is primarily in control of their own skill performances with much less reliance on external support and feedback compared to the earlier stages. Successfully reaching this stage means that individuals are effectively self-regulating their skill performances (i.e. the performance is being monitored and adjusted according to an accurate mental model) so that skill is enacted with competence, accuracy and speed (if necessary) (Cornford, 2008). In the context of inhaler technique, reaching the *autonomous phase* would mean that patients are correctly maintaining inhaler technique in their day-to-day inhaler use.

In reality however, a large proportion of patients never successfully reach the autonomous stage. That is, many patients do not maintain optimal inhaler technique despite having seemingly mastered correct technique after receiving education (Chapter 2, section C, iii). With the application of FSLT, potential reasons for poor inhaler technique maintenance in the *autonomous phase* may be understood by examining what occurred (or did not occur) during the previous two phases, that is, the *cognitive* and *practice-fixation* phases.

For example, poor technique maintenance may result if patients are not presented with learning opportunities that facilitate the formation of an accurate and vivid mental depiction of the correct inhaler technique manoeuver (important feature in the *cognitive phase*); or if patients did not engage in accurate and sufficient practise guided by timely and accurate feedback from an expert (important aspects during the *practice-fixation phase*). Under these circumstances patients are less enabled to engage in the optimal self-regulation of inhaler technique when they are using their inhaler device on a day-to-day basis. In other words, patients are less likely to appropriately monitor and adjust their inhaler technique according to an accurate and well consolidated mental reference point.

Thus it can be seen that by exploring inhaler technique maintenance from the perspective of skill learning, and specifically through the application of FSLT, much insight can be gained into the phenomenon. In particular, new light can be shed on interpreting existing findings, and directions provided for generating hypotheses regarding the skill learning related factors influencing inhaler technique maintenance. Further exploration of inhaler technique maintenance from the second domain of the ITMF, i.e. from the perspective of self-management, will now follow.

iii. Technique maintenance from the perspective of patient asthma self-management

Inhaler technique maintenance can also be explored from the perspective of asthma self-management as it can be considered a specific type of self-management behaviour. Self-management plays a critical role in asthma treatment and can be considered to encompass the strategies that patients adopt to cope with both the physical and emotional challenges presented by their illness (Smith et al., 2007). In asthma, good self-management requires the patient to carry out a range of activities including monitoring symptoms, identifying and avoiding triggers, knowing when to seek health care professionals' assistance and using their medications optimally (NAC, 2006). Maintaining correct inhaler technique is clearly a vital part of optimal medication use and therefore an indispensable part of a patient's self-management repertoire.

Placing inhaler technique maintenance in the context of patient self-management further highlights the need to adopt a patient-centred perspective as discussed earlier (section A, i). Notably, from this perspective it can be seen that potential reasons for poor inhaler technique maintenance, despite the lack of currently known barriers (Chapter 2, section C, iii), may lie beyond those factors pertaining to the physical/practical and skill development process, and be related to various less tangible patient-centred factors. However, since the relationship between self-management behaviours (such as inhaler technique maintenance) and patient-centred factors can be complex and multidimensional, the use of well-established theories in the area can be instrumental.

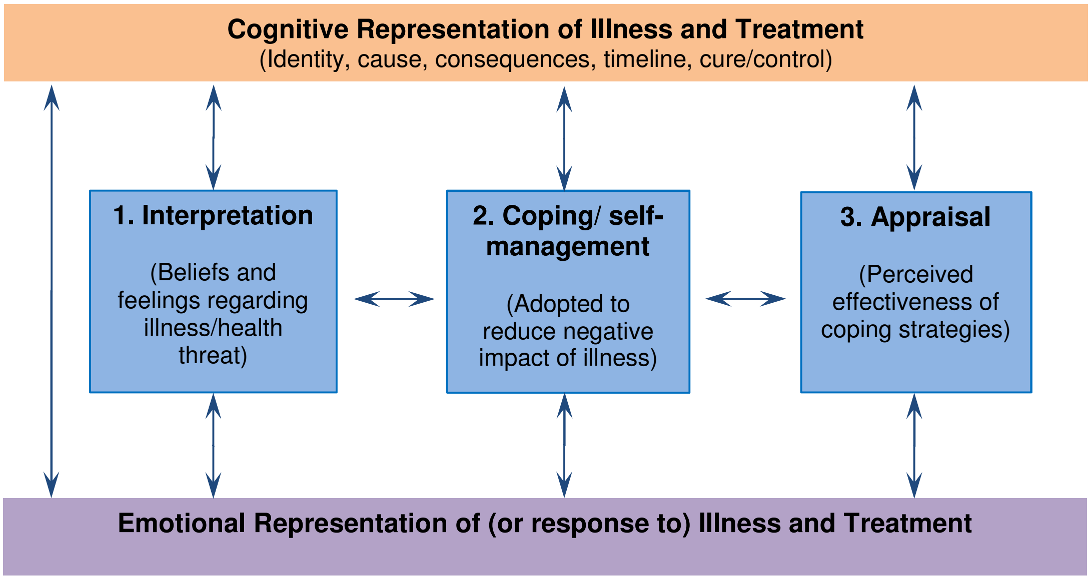
The Common Sense Model of Illness Regulation (CSM)

One such theory, used extensively to study self-management behaviour in chronic illnesses, including asthma, is Leventhal's Common Sense Model of Illness Regulation (CSM) (Leventhal, Brissette and Leventhal, 2003). At the core of the CSM is the notion that how patients cope with their chronic illness, or patient self-management behaviour, is influenced by their "common sense" interpretations relating to their illness and its treatment (Diefenbach and Leventhal, 1996, Horne and Weinman, 2002). In particular, patient cognitions (i.e. beliefs, knowledge, interpretations) and affect (i.e. feelings) regarding their illness and treatment can influence self-management behaviours, and have in fact been shown to play a role in asthma (Horne and Weinman, 1999, Osman, 1997). By extension, this suggests that such patient-centred factors may also be relevant to explore in relation to inhaler technique maintenance.

To examine the CSM more closely, three principal components can be identified in the model depicting how patients self-manage and self-regulate around their illness. They are: 1. interpretation, 2. coping (or self-management) and 3. appraisal (Leventhal et al., 2003). The first component of the CSM refers to how patients interpret their illness, specifically in terms of their beliefs and feelings regarding the identity (label and symptoms connected with the illness), cause, time course, amenability to cure/control and consequences of the illness (Leventhal et al., 2003). In addition, patients' beliefs and feelings regarding the treatment prescribed for their illness (with inhaled corticosteroids being the mainstay of preventative treatment in asthma), in terms of perceived necessity and concerns, are also important considerations (Horne and Weinman, 2002).

The second component of the CSM, *coping*, refers to the actual self-management strategies and behaviours that patients enact. This would include how patients maintain their inhaler technique. The third component of the CSM, *appraisal*, refers to patient evaluations regarding the effectiveness of their coping (or self-management) strategies for reducing the perceived negative impact (physical and emotional) of their illness (Leventhal et al., 2003). For example, to what extent does the patient believe that maintaining correct inhaler technique makes a difference to their experience of asthma? The relationship between the various components of the CSM is dynamic and interconnected (Diefenbach and Leventhal, 1996, Orbell, 2007) as represented in Figure 3.04.

Figure 3.04. The Common Sense Model of Illness Regulation (CSM) (Horne and Weinman, 2002, Leventhal et al., 2003).



The CSM can be a useful tool for highlighting the challenges that patients may experience in self-managing and self-regulating around their asthma, including with activities such as inhaler technique maintenance. Considering the interrelatedness of the various components represented in the CSM, it is perhaps not surprising to suggest that lack of consistent and immediate feedback from both the condition of asthma and its treatment could be a potential barrier in asthma self-management and self-regulation. That is, asthma can often be a "silent illness", where symptoms are not always present to remind patients to actively self-manage, and feedback in terms of perceived benefits after using preventer therapy is delayed (AMH, 2013). This may do little to motivate patients to persist with optimal inhaler use – the importance of feedback in motivating persistence with skilled performance was discussed earlier (section B, ii). It may not make sense to the patient, as a "common sense problem solver" (according to the CSM), to enact what are considered appropriate/effective coping strategies (e.g. maintaining correct inhaler technique), in the absence of cues from their condition (e.g. change in symptoms) and its treatment (e.g. lack of immediate feedback after using preventer therapy).

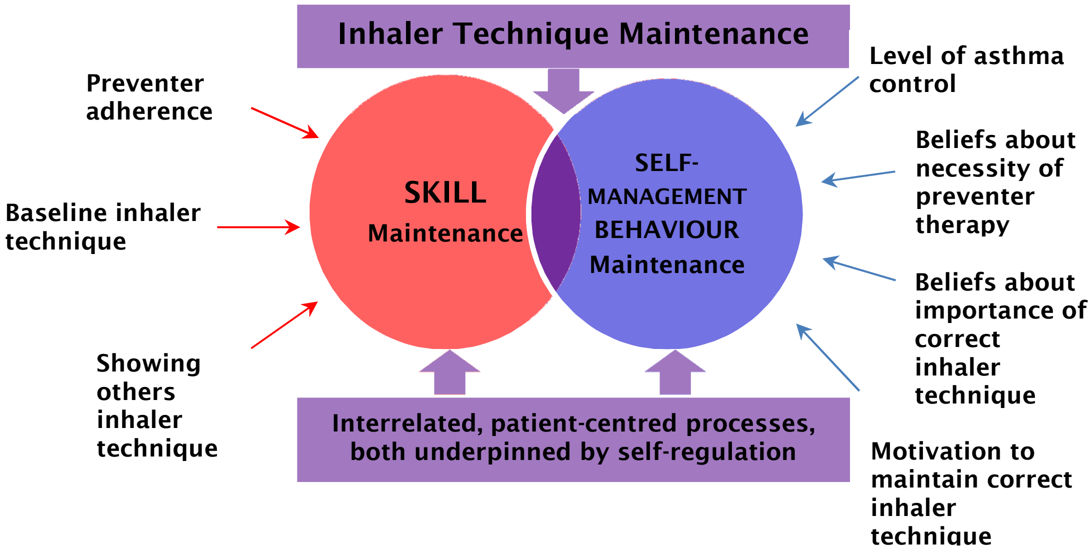
Further, due to the fact that various other factors, separate to a patient's medication related coping/self-management, may impact on their symptom experience (e.g. exposure to triggers, respiratory tract infections, strong emotions), the value of practicing optimal self-management behaviours (such as persisting with correct inhaler technique) may become less, or not, apparent. The CSM highlights the intricacies and challenges involved in asthma self-management, and from this perspective it is not surprising to note, again, the important role that patient motivation may play in facilitating optimal self-regulation and self-management around key areas such as inhaler technique maintenance (Hypothesis 1).

As illustrated in Figure 3.04, self-management behaviours (coping) are embedded in various interrelationships with patient cognitive and affective factors. This suggests that in order to improve self-management behaviours, such as patient inhaler technique maintenance, better understanding of the potential patient psychological determinants of the behaviour is required. There are numerous studies in asthma that have shown various patient psychological factors to be determinants of self-management behaviour. For example, patient beliefs about the consequences and time course of asthma, and beliefs regarding the necessity of, and concerns relating to, preventer asthma therapy, have been linked to self-management behaviours. In particular these patient beliefs have been linked with medication adherence (Clifford, Barber and Horne, 2008, Horne and Weinman, 2002, Mardby, Akerlind and Jorgensen, 2007, Menckeberg et al., 2008, Ponieman, Wisnivesky, Leventhal, Musumeci-Szabo and Halm, 2009, Rand, 2005).

In relation to inhaler technique maintenance as the self-management behaviour of focus, however, there is a dearth of studies. Yet there does exist limited empirical evidence to suggest that the role of patient psychological factors in the context of inhaler technique maintenance is an avenue worthy of further exploration. In one study involving patients who were using inhaler device therapy (reliever therapy via pMDIs), those who believed more strongly that using inhaler therapy was an important and necessary part of their treatment, were more likely to demonstrate and maintain correct inhaler technique (De Blaquiere et al., 1989). Although this finding was noted over thirty years ago it has never been followed up on. Thus, supported by the principles of the CSM and to pursue the available empirical evidence, it is hypothesised that patient beliefs regarding the necessity of preventer therapy, and the importance of correct inhaler technique, may have an influence on their inhaler technique maintenance behaviour over time (Hypotheses 6 and 7).

In summary, despite the paucity of existing studies, the phenomenon of inhaler technique maintenance has been explored from multiple perspectives in this Background (Chapter 3, section A). The ITFM, a framework conceptualising inhaler technique maintenance (Figure 3.01), was set up in this thesis, grounded in well-established theories in the fields of skill learning and self-management behaviour. The ITMF allowed for a multi-faceted exploration of inhaler technique maintenance. Through this exploration, a pool of potential predictors of inhaler technique maintenance warranting further investigation has been identified. This is illustrated in Figure 3.05.

Figure 3.05: Potential predictors of inhaler technique maintenance after exploring the Inhaler Technique Maintenance Framework (ITMF).



In order to address the aim of this study – to uncover the determinants of inhaler technique maintenance in patients with asthma – various hypotheses have now been generated that lend themselves to further testing.

B. Aim and hypotheses

The aim of this study is to investigate, from a patient-centred perspective, the determinants of inhaler technique maintenance in patients with asthma.

Based on the literature presented in the Background to this chapter (section A), it is hypothesised that how patients maintain inhaler technique over time may be influenced by the following factors:

1. Motivation to maintain correct inhaler technique
2. Preventer adherence (indicating regularity of inhaler device use and therefore degree of inhaler technique practise)
3. Baseline inhaler technique (indicating whether or not there was accurate consolidation of inhaler technique)
4. Showing and teaching others inhaler technique (indicating nature of inhaler technique practise)
5. Level of asthma control (indicating patient-perceived feedback on inhaler technique performance)
6. Beliefs about the necessity of regular preventer therapy
7. Beliefs about the importance of correct inhaler technique

C. Methods

i. Overview

The study conducted was exploratory in nature and involved repeated measures over two time points. The initial phase of the study consisted of the recruitment and training of community pharmacists, who then in the subsequent phase, enrolled and delivered an inhaler technique assessment and intervention to study participants. Study participants were community dwelling patients with asthma who were required to visit their local pharmacy on two occasions, approximately one month apart in order to complete the study.

This study was approved by the University of Sydney Human Research Ethics Committee (Appendix 3.01: Quantitative study ethics approval).

ii. Phase 1: Study Pharmacists

1. Sampling and recruitment

A purposive sample of community pharmacists was recruited from the Sydney metropolitan region. That is, community pharmacies located from a wide range of Sydney suburbs were approached in order to maximise the socio-demographic variation in the patients recruited into the study. Pharmacists were invited to participate in the study by the researcher (LO) either in person (at their pharmacies), over the telephone or via email. A letter of invitation to participate in the study was also given (Appendix 3.02: Pharmacist letter of invitation).

Incentives for pharmacists to take part included the opportunity to attend a free training workshop to update skills and knowledge on inhaler device therapy in asthma management, and Continuing Professional Education (CPE) points (3.5 points) available upon completion of the workshop (Appendix 3.03: PSA CPE accreditation). Pharmacists who expressed an interest were further provided with written information about the study (Appendix 3.04: Pharmacist study information statement).

All pharmacists who agreed to participate were visited by the researcher (LO) at their pharmacies. During this visit, pharmacists' written consent to participate in the study were obtained (Appendix 3.05: Pharmacist study consent form). Subsequently, an appointment to attend a training session on inhaler device therapy and the study protocol, the Quality Use of Inhalers in Pharmacy workshop, was made.

2. The Quality Use of Inhalers in Pharmacy workshop

The Quality Use of Inhalers in Pharmacy (QUIP) workshop was a 2 hour training session that all study pharmacists completed before enrolling patients into the study.

The aims of the QUIP workshop were to:

1. Update pharmacists' skills and knowledge on inhaler device therapy in asthma.
2. Teach pharmacists to demonstrate correct inhaler technique for the pressurised Metered Dose Inhaler, Turbuhaler™ and Accuhaler™ (the three most commonly prescribed devices for asthma treatment).
3. Teach pharmacists how to accurately assess and teach inhaler technique to asthma patients.
4. Inform pharmacists about the study protocol and how to effectively implement it.

a. Development and delivery of the QUIP workshop

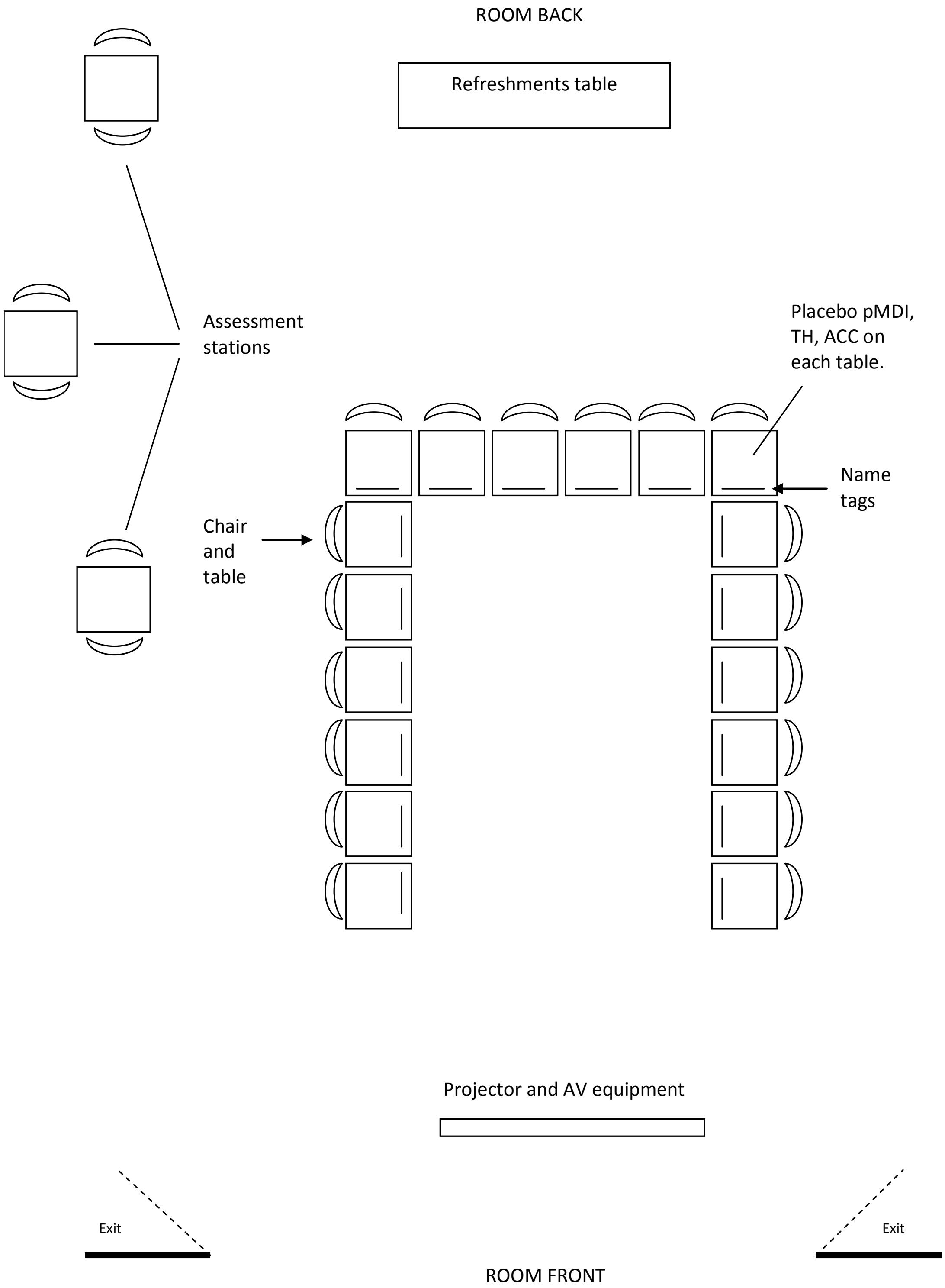
The QUIP workshop was developed with reference to previous studies that delivered inhaler technique education to community pharmacists (Basheti et al., 2009). In addition, theories relevant in adult education, including skill learning and small group education theories were also referred to during the development of the QUIP workshop (Bandura, 2005a, Cornford, 2008, Olmstead, 1974). The purpose of using such theories was to create a learning environment that would enhance pharmacists' motivation to be engaged in the learning activities and achieve the QUIP workshop aims as detailed above. How specific tenets of skill development and small group learning theories were applied to the QUIP workshop will be elaborated upon in the upcoming sections.

The QUIP small group workshop was presented and facilitated by three researchers (LO, LS, SBA) on 2 scheduled sessions, pharmacists could choose to attend either a Saturday morning (9-11am) or a Monday evening (7-9pm) training session. Both sessions were held at the Faculty of Pharmacy, the University of Sydney. Pharmacists who could not attend either session were trained individually at their pharmacies by one researcher (LO). The same content was delivered in both the individual and group training sessions. Continuing Professional Education points were available after the completion of all training sessions and demonstrated competency with inhaler techniques (Appendix 3.03: PSA CPE accreditation).

b. QUIP workshop room arrangement

The QUIP workshop was interactive in nature and therefore its physical set-up aimed to enhance communication between pharmacists and facilitators and amongst pharmacists themselves. Figure 3.06 shows the set-up of the workshop room during the small group training sessions. Pharmacists' tables and chairs were arranged in a U-shaped configuration, unlike previously, when they have been placed in straight rows configuration (Basheti et al., 2009). The purpose of this modification was to better use the physical space to facilitate interaction, that is, in this arrangement pharmacists can better see, hear and speak with the rest of the group. Large, visible name tags identifying workshop participants were placed at the front of each table also to facilitate communication.

Figure 3.06: The QUIP workshop training room arrangement.



c. Facilitating pharmacists' motivation to learn during the QUIP workshop

Enhancing pharmacists' motivation to learn was an important process goal that guided how the QUIP workshops were facilitated and delivered. Motivation to learn has been shown to be a key determinant of the extent to which adults actively participate and persist with learning activities during training workshops. Further, how the training is delivered can influence participants' motivation to learn (Klein, Noe and Wang, 2006).

In order to sustain pharmacists' interest and motivation, during the delivery of the QUIP workshop, various modalities of teaching and learning were used. For example, a brief interactive lecture supported by power point slides, inhaler technique demonstrations with commentary, hands on learning with placebo devices and interactive peer learning (explained in detail in Table 3.02). Further, the duration of the QUIP workshop was kept as brief as possible (2 hours) without compromising the ability to achieve the learning outcomes, and refreshments and lunch were provided.

In a small group learning environment, individual participants' motivation to learn can also be influenced by the group dynamics. Although group dynamics cannot be completely pre-determined, as it is unique to each specific group on each separate occasion, it can be steered, to some extent, by the facilitators (Olmstead, 1974). The QUIP workshop was facilitated to promote group dynamics that were conducive to learning, specifically via the strategies of: establishing rapport, clearly stating group goals, and conveying the group norms (Olmstead, 1974), and using various modalities of teaching and learning to maintain interest and engagement. The various methods used to enhanced pharmacists' motivation to actively learn during the QUIP workshops is summarised in Table 3.01.

Table 3.01: Delivery of the QUIP workshop – strategies to enhance pharmacists' motivation to engage in active learning and their implementation.

STRATEGY	IMPLEMENTATION
Establish rapport	1. Pharmacists were greeted and welcomed by facilitators. 2. A round of self-introductions was made. 3. A brief comic video about inhaler technique was shown as an ice-breaker.
Clearly state group goals	1. The workshop aims were re-framed to focus on the pharmacists and were presented at the start. They were stated as the following group goals: i. To become inhaler technique experts. ii. To master correct inhaler technique with the pMDI, Turbuhaler™ and Accuhaler™. iii. To accurately assess and teach inhaler technique to asthma patients. iv. To understand the study protocol.
Convey group norms	1. Pharmacists' existing knowledge regarding asthma and inhaler device use was acknowledged. Simultaneously, the high rates of incorrect inhaler technique amongst health care professionals were also communicated. This was normalised to facilitate pharmacists to feel open to recognising and learning from any mistakes identified in their own inhaler techniques. 2. Pharmacists were encouraged to work at their own pace and focus on accurate practise of inhaler technique. 3. Pharmacists were informed of the interactive nature of the workshop, encouraged to ask questions at any time, and encouraged to support each other in learning.
Use multiple modalities of teaching and learning	1. The teaching and learning was interactive between pharmacists and facilitators and amongst pharmacists themselves. 2. Various materials were used for teaching and learning correct inhaler techniques (these are explained in detail in Table 3.02).

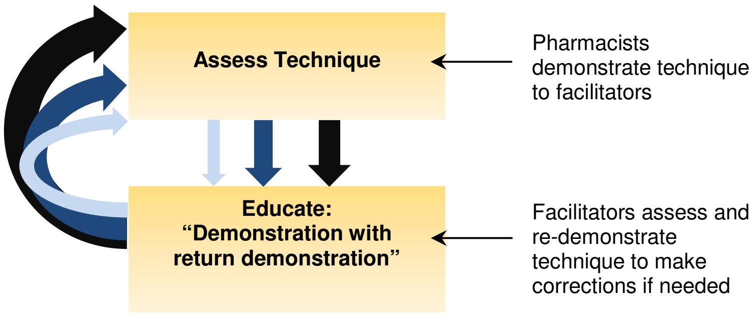
d. QUIP workshop content and activities

The content and activities of the QUIP workshop were developed to be aligned with the workshop aims. Table 3.02 shows each of the four workshop aims, and the related content/activities developed around each aim. Figure 3.07 is also incorporated at the end of the table to illustrate how workshop content/activities were developed based on the theoretical principles of Fitts' Skill Learning Theory (as discussed in the

Background, section A, ii). For a timetable of the QUIP workshop activities, see Appendix 3.06.

Table 3.02: The QUIP workshop – alignment of aims and content, and theoretical basis for content development.

WORKSHOP AIMS	RELATED CONTENT/ACTIVITIES
1. To update pharmacists' skills and knowledge on inhaler device therapy in asthma.	A ten-minute interactive lecture accompanied by power point slides was presented. The prevalence of poor technique and its consequences, and the importance of correct technique and need for improvement in the context of asthma management were highlighted (Appendix 3.07: QUIP lecture slides).
2. To teach pharmacists to demonstrate correct inhaler technique for the pMDI, Turbuhaler™ and Accuhaler™.	a. Physical demonstrations of correct inhaler techniques for the pMDI, Turbuhaler™ and Accuhaler™ were given by facilitators. Techniques were demonstrated by one facilitator whilst another explained the purpose behind each step. Power point slides listing the technique steps accompanied the demonstrations (Appendix 3.08: QUIP workshop slides).
	b. Individual hands-on practise of inhaler techniques by pharmacists (using a personal set of placebo inhaler devices supplied) occurred after facilitators' demonstrations. Pharmacists were asked to practise until they felt confident.
	c. Peer feedback on inhaler technique was obtained after individual practise. Pharmacists worked in pairs, demonstrating inhaler technique to one another. During this process pharmacists assessed each other's demonstrations of inhaler techniques using print outs of the 11-step technique checklists (Appendix 3.09: Technique checklists for peer assessment) and gave each other feedback and guidance.
	d. Facilitators provided feedback during individual and peer practise with techniques if requested.
	e. Assessment of pharmacists' inhaler techniques were conducted by facilitators towards the end of the workshop. This was based on the "train the trainer" strategy developed by Basheti et al. (2009) previously, depicted in the diagram below:

	 "Train the trainer" strategy developed by Basheti et al. (2009)
	a. A five-minute presentation accompanied by power point slides was given to explain the iterative "train the trainer" approach (Basheti et al., 2009), also shown to be effective for teaching patients inhaler technique (Appendix 3.08: QUIP workshop slides).
3. *To teach pharmacists how to accurately assess and teach inhaler technique to asthma patients.*	b. Pre-recorded video footage of an individual of *incorrectly* using the pMDI, Turbuhaler™ and Accuhaler™ were shown to pharmacists. i. For the pMDI video demonstration, inhaler technique was incorrect at steps 3 (exhale air out of lungs), 6 (inhale slowly and press canister firmly), 7 (continue slow and deep inhalation), 8 (hold breath, aim for ten seconds) and 9 (while still holding breath remove inhaler from mouth). Therefore an accurate assessment of this video demonstration by pharmacists would result in a score of 6 out of 11. ii. Similarly, for the Turbuhaler™ video demonstration, inhaler technique was incorrect at steps 2 (hold inhaler upright), 4 (exhale air out of lungs), 5 (exhale away from mouthpiece), 8 (hold breath, aim for ten seconds) and 9 (while still holding breath remove inhaler from mouth). Therefore an accurate assessment of this video demonstration by pharmacists would result in a score of 6 out of 11. iii. Finally, for the Accuhaler™ video demonstration, inhaler technique was incorrect at steps 3 (exhale air out of lungs), 4 (exhale away from the mouthpiece) and 10 (exhale away from the mouthpiece). Therefore an accurate assessment of this video demonstration by pharmacists would result in a score of 8 out of 11.

	Pharmacists used checklists to assess the 3 pre-recorded video demonstrations shown and thus gained practise with technique assessment. The 3 checklists that pharmacists used to assess the video demonstrations were the same as those used during the peer assessment activity (Appendix 3.09). The 3 checklists that pharmacists marked their assessment and scores on were collected. The data on how pharmacists scored each pre-recorded video demonstration were collected. This gave an indication of how accurate the pharmacists would be in assessing patients' inhaler techniques (note: the pre-recorded videos ensured that pharmacists across all training sessions viewed identical demonstrations, thus rending their assessments comparable).
	c. A role play between a pharmacist and a pseudo-patient was conducted as a final activity to consolidate the learning around this aim. The role play required the pharmacist to approach the pseudo-patient in order to assess their inhaler technique, whilst contending with barriers that are likely to occur in practice (in this case the pseudo-patient was in a rush and did not perceive their technique to be problematic). Facilitators provided feedback on pharmacists' performance. Learning points and questions arising from the role play were discussed with the entire group.
4. To inform pharmacists of the study protocol and how to effectively implement it.	a. Pharmacists were asked to recruit 5 patients each and then to assess patients' inhaler technique in their pharmacies on two occasions one month apart and to facilitate the completion of questionnaires collecting patient data.
	b. Recruitment challenges and strategies were discussed. The group brainstormed recruitment strategies. Pharmacists who were involved in past studies involving patient recruitment shared their experiences and insights.
	c. An "Inhaler Technique Maintenance"/"ITeM" study manual was allocated to each pharmacist to refer to whilst facilitators explained the study protocol (Appendix 3.10: ITeM study manual). The ITeM manual consisted of: ▪ a one page study protocol summary ▪ 5 sets of data collection forms

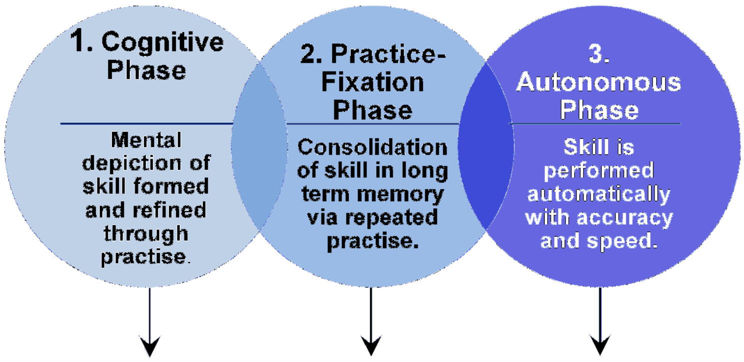
	▪ tips for recruiting ▪ laminated bench top technique checklists ▪ inhaler technique stickers for affixing onto patients' inhaler devices ▪ patient gift vouchers ▪ patient appointment reminder cards ▪ workshop power point slides ▪ inhaler technique literature
	d. At the end of the workshop, each pharmacist was equipped with various resources for conducting the study. They were: ▪ the ITeM study manual. ▪ A3 and A4 posters to aid in recruitment (Appendix 3.11: Recruitment posters). ▪ placebo inhaler devices (pMDI, Turbuhaler™ and Accuhaler™). ▪ the National Asthma Council of Australia's Asthma Handbook 2006.

THEORETICAL UNDERPINNINGS OF WORKSHOP CONTENT

The principles outlined in Fitts' Skill Learning Theory (FSLT) were implemented to facilitate pharmacists developing and maintaining the correct inhaler techniques. This is illustrated in Figure 3.07.

Figure 3.07: Implementing Fitts' Skill Learning Theory (FSLT) in the QUIP workshop

The three interacting phases of FSLT:



Workshop activities developed based on principles of FSLT

- Correct techniques physically demonstrated by facilitators, with verbal explanations. - Correct technique demonstrations serve as initial model for pharmacists to base mental depiction on.	- Technique practise with placebo devices, individually and with peers. - Peer and facilitator feedback on techniques provided using written checklists. - Practise in assessing technique via peer work, pre-recorded video demonstrations and role play.	- Accuracy of pharmacists' techniques assessed at end of workshop. - Facilitators ensured all pharmacists demonstrated correct techniques before leaving, additional feedback and training was provided if necessary. - Skill consolidation expected to continue for pharmacists during day-to-day practice.

e. QUIP workshop evaluation

In order for pharmacists to be credited CPE points for participating in the QUIP workshop, the professional body, the Pharmaceutical Society of Australia (PSA), required pharmacists to complete a brief evaluation of the workshop. The PSA asked pharmacists to respond in writing and anonymously to the following three questions:

1. To what extent were the workshop aims met?
2. To what degree were your own learning needs met though participating in this activity?
3. To what degree was this activity relevant to your practise?

Responses were tick box, with the options – “Entirely met”, “Partially met” or “Not met” and with space for written comments after each question.

Finally, at the end of the QUIP workshop, pharmacists received a certificate recognising their participation in the training and 3.5 CPE points (Appendix 3.12: QUIP workshop certificate of completion).

iii. Phase 2: Study Patients

Community based patients with asthma were recruited into this study by their local pharmacist (i.e. those pharmacists who had completed the QUIP workshop described in the previous section). Patients eligible to participate in this study had to meet the following inclusion criteria:

- Over 18 years of age
- Able to speak English
- Have a previous diagnosis of asthma
- Using preventative asthma treatment in the form of a pMDI, Turbuhaler™ or Accuhaler™ .
- Able to attend the follow up visit in one month

A further two criteria excluded patients who were:

- Not self-administering their inhaler therapy
- Involved in another clinical asthma study

To identify potential patients for the study, pharmacists were instructed to approach consecutive customers who had entered their pharmacy with a prescription for a pMDI, Turbuhaler™ or Accuhaler™ device, used for preventative asthma therapy. Pharmacy dispensary records could also be used to identify potential patients.

Pharmacists were asked to explain the study to the patient with the provision of written information (Appendix 3.13: Patient study information statement). Benefits and incentives for patients to participate in the study included the opportunity to learn more about using their inhaler device and a twenty dollar gift voucher to spend in the pharmacy when they completed the final study visit. Written informed consent was obtained from those patients who agreed to participate in the study (Appendix 3.14: Patient study consent form).

1. Study Visits

Patients enrolled in the study were required to complete two visits approximately one month apart. At each visit patients were required to fill out a brief questionnaire (approximately 10 minutes in duration). Patients were then required to demonstrate their inhaler technique to the pharmacist using their own device. The pharmacist would assess and, if necessary, educate patients on correct inhaler technique (via repeat demonstration using placebo devices). The patient data collected at each visit are summarised in Table 3.04.

a. Visit 1

At visit 1 (baseline) patients completed a questionnaire seeking information regarding their demographics, asthma history, medical history, past inhaler device use history, past inhaler technique education received, asthma control, preventer adherence and beliefs and motivations around inhaler use (Appendix 3.15: Patient visit 1 questionnaire_F4). In addition, a record of patients' current medications (asthma and non-asthma) was completed by the pharmacist (Appendix 3.16: Patient medication record_F5).

After patients completed the questionnaire, their inhaler technique was assessed by the pharmacist. Using their own device, patients were asked to demonstrate how they would usually use their inhaler. The pharmacist assessed patients' inhaler technique using the appropriate 11-step checklist (for pMDI, Turbuhaler™ or Accuhaler™) (Appendix 3.17: Visit 1 patient technique checklist_F6).

Patients with suboptimal technique were educated by pharmacists via an iterative process of repeat demonstrations (Basheti et al., 2007). That is, pharmacists demonstrated correct inhaler technique (using a placebo device) to the patient and then assessed the patient's technique demonstration. This was repeated until the patient could demonstrate correct inhaler technique.

Finally, a sticker was affixed to the patient's inhaler device, printed with all 11 technique steps for the use of their device. Any step/s that proved problematic for the patient during visit 1 were highlighted on the sticker by the pharmacist to draw awareness to in daily use (Basheti et al., 2008) (Appendix 3.18: Stickers affixed on patients' inhaler device).

b. Visit 2

At visit 2, approximately one month after visit 1, patients returned to their pharmacy and completed a questionnaire that collected follow up data on asthma control, preventer adherence and beliefs and motivations around inhaler use (Appendix 3.19: Patient visit 2 questionnaire_F7). Patients' inhaler technique was re-assessed by the pharmacist and, if necessary, patients were re-educated on correct inhaler technique via the same process as described for visit 1 (Appendix 3.20: Visit 2 patient technique checklist_F8).

2. Quality control and support measures

The patient recruitment phase lasted approximately 3 months and to sustain pharmacists' motivation to complete both visits with patients and reach the target sample size, the researcher (LO) kept in regular communication in person, via phone calls and newsletters (5 in total). Feedback regarding the number of patients recruited and the numbers required to reach the target sample size (quantitative feedback) as well as tips from fellow pharmacists who had successfully recruited (qualitative feedback) were features of the newsletters (Appendix 3.21: Newsletters to pharmacists).

Approximately halfway through the patient recruitment phase (14^{th} - 23^{rd} May 2010), audits were conducted to review the data collection process and documentation. This was undertaken via the researcher visiting all pharmacies and consulting with the study pharmacists. The audit served two purposes. Firstly, to ensure data were being collected and recorded accurately. Secondly, to identify pharmacists experiencing difficulty with recruitment and to offer them support. This included assistance with recruitment in person, at the pharmacy, by the researcher.

iv. Study Data

1. Pharmacist data

Table 3.03 below summarises the data relating to pharmacists collected during the QUIP workshops, as well as the method of data collection.

Table 3.03: Pharmacist data collected during the QUIP workshops and method of collection.

Data	Method of Collection
Pharmacist Demographics: i. age group ii. gender iii. job description	Self-report questionnaire
Past inhaler technique education	Self-report questionnaire
Pharmacy demographics: i. location of pharmacy ii. average number of scripts dispensed per week iii. whether any specialised services were provided	Self-report questionnaire
Pharmacists' assessment of the pre-recorded video demonstrations of inhaler technique for the pMDI, Turbuhaler™ and Accuhaler™ (described in the Methods, Table 3.02).	Self-complete inhaler technique checklists
Pharmacists' workshop evaluation (described in the Methods, section ii, 2, e).	Self-complete evaluation survey

2. Patient data

Patient data on inhaler technique, asthma control, demographics, medical history, inhaler device history, inhaler technique education history and beliefs and motivations around inhaler use were collected. Table 3.04 outlines the patient data collected, the method of data collection and the time point/s at which the data were collected. In regards to the method of data collection, "patient self-report" refers to the data collected from questionnaires completed by patients during visits 1 and 2 (Appendices

3.15 and 3.19). "Pharmacist-report" and "pharmacist assessment" refers to any patient data that pharmacists collected (Appendices 3.16, 3.17 and 3.20).

Table 3.04: Patient data collected during study – what, how and when.

Data type	Data collected	Method of collection	Visit 1	Visit 2
Outcome variable	Inhaler technique (11 point checklist)	Pharmacist assessment	✓	✓
Demographics and clinical/medical history	Age	Patient self-report	✓	
	Gender	Patient self-report	✓	
	Education level	Patient self-report	✓	
	Asthma duration	Patient self-report	✓	
	Asthma control (Shortened Asthma Control Questionnaire) (Juniper et al., 2005)	Patient self-report	✓	✓
	Number of asthma related emergency care and hospitalisations in past year	Patient self-report	✓	
	Number of asthma related health care provider consultations in past year	Patient self-report	✓	
	Respiratory co-morbidities	Patient self-report	✓	
	Other co-morbidities	Patient self-report	✓	
	Oral asthma medication used	Pharmacist report	✓	
	Other regular medications used	Pharmacist report	✓	
	Dose of preventer medication	Pharmacist report	✓	
Inhaler device factors	Type of preventer device used	Pharmacist report	✓	
	Duration of preventer device use	Pharmacist report	✓	
	Number of different types of inhaler devices used (for any chronic respiratory conditions)	Pharmacist report	✓	
Technique education and learning factors	Health care provider/s who gave past technique education	Patient self-report	✓	
	Method of past technique education	Patient self-report	✓	
	Time since last inhaler technique education	Patient self-report	✓	
	Number of times technique was re-check (by a health care professional) since starting preventer therapy	Patient self-report	✓	
	If and number of times patient has shown others inhaler technique	Patient self-report	✓	
	Preventer adherence (Medication Adherence Report Scale-5) (van de Steeg et al., 2009)	Patient self-report	✓	✓
Psychological factors	Necessity of preventer medication (Beliefs about Medicines Questionnaire) (Horne et al., 1999)	Patient self-report	✓	✓
	Importance of correct inhaler technique (Inhaler Technique Beliefs Questionnaire; devised for this study)	Patient self-report	✓	✓
	Motivation for correct technique (motivation for correct inhaler technique question; devised for this study).	Patient self-report	✓	✓

3. Development of data collection tools

a. Inhaler technique and technique maintenance assessment

The inhaler technique checklists (for the pMDI, Turbuhaler™ and Accuhaler™) used throughout this study were based on published studies, clinical guidelines and manufactures' instructions (as reviewed in Chapter 2, section B, iv). The checklists were also based on discussion and consensus between three researchers, one of whom is an expert in the area (SBA). The 11 steps for correct inhaler technique in each of the three checklists are shown in Figure 3.08. Copies of the actual checklists that pharmacists used in the study were only different in appearance and format (shown in Appendices 3.17 and 3.20).

Figure 3.08: The inhaler technique checklists used in this study to assess pMDI, Turbuhaler™ and Accuhaler™ techniques.

pMDI Checklist	Turbuhaler™ Checklist	Accuhaler™ Checklist
1. Remove cap	1. Unscrew and lift off cap	1. Open inhaler
2. Shake inhaler well	2. Hold inhaler upright	2. Push lever back completely to load dose
3. Exhale air out of lung	3. Rotate grip one way, then back until click is heard	3. Exhale air out of lungs
4. Hold inhaler upright	4. Exhale air out of lungs	4. Exhale away from mouthpiece
5. Put mouthpiece between teeth and seal with lips	5. Exhale away from mouthpiece	5. Hold inhaler horizontally
6. Inhale slowly and press canister firmly	6. Put mouthpiece between teeth and seal with lips	6. Put mouthpiece between teeth and seal with lips
7. Continue slow and deep inhalation	7. Inhale forcefully and deeply	7. Inhale steadily and deeply
8. Hold breath, aim for 10 seconds	8. Hold breath, aim for 10 seconds	8. Hold breath, aiming for 10 seconds
9. While still holding breath remove inhaler from mouth	9. While still holding breath remove inhaler from mouth	9. While still holding breath remove inhaler from mouth
10. Exhale away from mouthpiece	10. Exhale away from mouthpiece	10. Exhale away from mouthpiece
11. Replace cap	11. Replace cap	11. Close cover

"Correct" **inhaler technique** was used to describe patients who (prior to education by the pharmacist) performed all steps on the checklist correctly, these patients scored 11 (out of 11) on technique.

"Incorrect" **inhaler technique** was used to describe patients who (prior to education by the pharmacist) did not perform all steps on the checklist correctly, these patients scored < 11 on technique.

Further, "***correct inhaler technique maintenance",*** was used to describe those patients who scored 11 on technique at visit 2. "***Incorrect inhaler technique maintenance"*** was used to describe those patients who scored <11 on technique at visit 2.

b. Questionnaire design: format and style

The questionnaires used in this study were designed to be as clear and simple as possible in order to maximise accurate completion. Patient questionnaires were written in plain English (as conferred by 3 researchers) and printed in black, size 14, Arial Rounded MT Bold font. The questionnaires that pharmacists were to complete (on patient medication history and inhaler technique score) were also written in plain English and printed in black, size 12, Arial Rounded MT Bold font. Different coloured paper was used to print the patient (gold) and pharmacist (green) questionnaires so that they could be readily differentiated. The questionnaires were kept as brief as possible to encourage completion in the often busy community pharmacy setting. In addition, to ensure the set of data collection forms for each patient were matched accurately (for the purposes of data entry and analysis) all documents used in data collection were coded prior to dissemination (e.g. 001605 identified patient number 5, recruited by pharmacist number 16).

c. Questionnaire design: Instruments used

The two patient questionnaires used in this study (Appendices 3.15 and 3.19) were each composed of various instruments, selected individually to be used in this study to measure the areas of relevance. As a priority, previously validated instruments were sought out and used, however if this did not exist, instruments that were frequently reported in the literature were incorporated. Where neither of these two options existed, questions were generated by the researchers and used as instruments; these questions were underpinned by literature and tested for face-validity. The 5 individual instruments used in the patient questionnaires are listed and explained below under individual headings.

〉 *Asthma control (S-ACQ)*

The validated Shortened Asthma Control Questionnaire (S-ACQ) was used to assess patients' asthma control at visits 1 and 2 (Juniper et al., 2005). This instrument consisted of 6 items measuring asthma symptom experience, asthma-related limitations in daily activities and short-acting bronchodilator use on a seven point scale that ranged from 0 to 6, with the numerical increase indicating increase in frequency or intensity. The mean asthma control score was calculated by adding the scores from each item (ranging from 0 – 6) and dividing by the total number of items (6). Well controlled asthma was indicated by mean scores < 1.5, and poorly controlled asthma was indicated by mean scores ≥ 1.5 (Clatworthy et al., 2009).

〉 *Adherence/Regularity of inhaler technique practise (MARS-5)*

The validated Medication Adherence Report Scale (MARS-5) was used at visits 1 and 2 to assess patients' adherence to preventer therapy, as an indicator of how regularly patients practised inhaler technique (Horne and Weinman, 2002, van de Steeg, Sielk, Pentzek, Bakx and Altiner, 2009). The MARS-5 consists of 5 items and measures the extent to which patients believe they enact the following behaviours relating to preventer inhaler use: “I alter the dose”, “I forget to use it”, “I stop taking it for a while”, “I decide to miss out on a dose”, and “I take less than instructed” (van de Steeg et al., 2009). Each of the items are rated on a five point Likert scale (where 1 = always; 2 = often; 3 = sometimes; 4 = rarely; 5 = never), and scores from all five of items are summed. Scores can range from 5 to 25, with higher scores indicating a greater adherence (Menckeberg et al., 2008).

〉 ***Beliefs about preventer medication – necessity and concerns (BMQ-S)***

The validated Beliefs about Medicines Questionnaire Specific (BMQ-S) was used at visits 1 and 2 to assess patient beliefs about inhaled preventer medication (Horne, Weinman and Hankins, 1999). The BMQ-S consists of 10 items in total with 5 items relating to each of two subscales, the necessity and concerns subscales. The *necessity subscale* measures the strength of patient beliefs regarding the necessity of taking inhaled preventer medication (e.g. “my health at present depends on this medicine”, “this medicine protects me from becoming worse”), and the *concerns subscale* measures the strength of patient beliefs regarding concerns about taking inhaled preventer medication (e.g. “having to take this medicine worries me”, “this medicine disrupts my life”).

Patients rated each item in the BMQ-S using a five point Likert scale (where 1 = strongly agree; 2 = agree; 3 = uncertain; 4 = disagree; 5 = strongly disagree). Scores from the necessity and concerns subscales were summed separately, and ranged from 5 to 25, with higher scores indicating stronger beliefs in either the necessity or concerns domain. Subsequently, the “necessity-concerns differential” was calculated by subtracting the *concerns subscale scores* from the *necessity subscale scores*. The necessity-concerns differential scores ranged from –20 to +20. Negative scores indicated that patient concerns over preventer medication were stronger than their beliefs in the necessity of preventer medication; whereas positive scores indicated the opposite (necessity beliefs were stronger than concerns).

〉 ***Beliefs about the importance of correct inhaler technique (ITBQ)***

The 3-item Inhaler Technique Beliefs Questionnaire (ITBQ) was used at visits 1 and 2 to measure patient beliefs about the importance, or value, of practising correct inhaler technique. This instrument was devised by the current researchers as there are no previously published instruments for use in this area. The ITBQ was assessed for face validity (i.e. three researchers, LO, SBA, LS, discussed the items and reached consensus that they reflected patients' beliefs concerning the importance of correct inhaler technique). The 3 items in the ITBQ were:

- "It is important to follow the correct steps every time I use my inhaler"
- "My inhaler will work just as well if I follow *most* of the correct steps"
- "The way I use my inhaler will *not* affect my asthma"

Patients rated each item listed above on a ten point Likert scale ranging from 1 (strongly agree) to 10 (strongly disagree). The scores from all three items were summed with higher scores indicating stronger beliefs regarding the importance of practising correct inhaler technique and lower scores indicating weaker beliefs in the importance of practising correct inhaler technique.

〉 ***Motivation for practising correct inhaler technique***

The level of patient motivation to practise correct inhaler technique was measured at visits 1 and 2 using the following item:

- “I am motivated to follow the correct steps when I use my inhaler”.

This item was devised by the current researchers as there are no previously published instruments measuring patient motivation in relation to inhaler technique. The item was assessed for face-validity (i.e. three researchers, LO, SBA, LS, conferred that the item reflected inhaler technique specific motivation). Patients rated the item using a ten point Likert scale ranging from 1 (strongly agree) to 10 (strongly disagree). Higher scores indicated greater patient motivation to practise correct inhaler technique and lower scores indicated less patient motivation to practise correct inhaler technique.

4. Statistical analyses

a. Descriptive statistics

Descriptive statistical analyses were conducted on the pharmacist data and patient data relating to demographics, medical and asthma history, history of inhaler device use, and past inhaler technique education.

b. Changes in repeat measure variables

Variables that were measured at both visits 1 and 2 (S-ACQ, MARS-5, BMQ-S, ITBQ and motivation) were tested for changes over time. To do so, firstly the normality of distribution for each variable (using the difference in scores between visits 1 and 2 for each specific variable) was assessed both visually (using distribution histograms and P-P plots) and statistically (using measures of skewness and kurtosis and the Kromologov-Smirnov and Shapiro-Wilks tests). For variables which were normally distributed, the parametric *dependent-t-test* (or *paired-samples t-test)* was used to test for changes over time. For variables which were not normally distributed, the non-parametric *Wilcoxon signed-rank Test* was used (Field, 2009).

c. Logistic regression analysis

In order to determine the predictors of patient inhaler technique maintenance over time, logistic regression analysis was conducted. The dependent (outcome) variable was *inhaler technique maintenance*. That is, whether patients maintained (technique scored = 11) or did not maintain (technique score < 11) correct inhaler technique at study visit 2. The independent (predictor) variables consisted of the remaining study variables collected, listed previously in Table 3.04.

〉 ***Fitting procedure***

The backward stepwise (likelihood ratio) fitting procedure was selected to perform the logistic regression. The backward stepwise method is favoured over the forward stepwise method as it accounts for suppressor effects, that is, when a variable exerts a significant influence only when another variable is held constant (Field, 2009). The likelihood ratio was used as the removal criterion as it is more reliable than methods such as the Conditional or Wald removal criteria (Field, 2009).

Stepwise fitting procedures for logistic regression have been criticised for being more likely to be affected by random variations in data – it relies on mathematical criteria for variable selection, as opposed to prior researcher assumptions (in the hierarchical entry procedure), or the simultaneous entry of all variables (in the forced entry procedure). However, the stepwise fitting procedure was deemed the most suitable for the purposes of this study (Field, 2009) (Appendix 3.23: Rationale for statistical selection of independent variables).

The stepwise fitting procedure was chosen because no previous research exists to clearly identify those factors likely to be predictors of inhaler technique maintenance. It was therefore deemed inappropriate to make assumptions in variable selection (as would be required using the hierarchical entry method) without firm evidence. Further, it was not within the scope of this study to reliably use the forced entry procedure as it required a sample size that would not have been feasibly achieved (i.e. $n \geq 560$ patient cases in order to test for all of the 28 unique study variables collected).

Stepwise fitting procedures may run the risk of "over-fitting", having too many variables in the model with minimal contribution to outcome prediction (Field, 2009). This may also increase the risk of the model being unduly influenced by random variations in the sample data (Bagley, White and Golomb, 2001). In order to mitigate this, initial statistical screening of variables, via univariate regression and bivariate correlations, was conducted as described below.

〉 ***Statistical screening of predictor variables***

Selection of independent variables for inclusion in the logistic regression was performed statistically. This was based on the results of univariate logistic regressions and bivariate correlations between the dependent (inhaler technique maintenance) and the independent variables (remaining study variables). The independent variables tested were deemed suitable for inclusion in the logistic regression if $p<0.25$, a level large enough to reduce the potential for overlooking any significant interactions between variables (Hosmer and Lemeshow, 2000).

Appendix 3.24 (Univariate logistic regression results) shows the variables selected for inclusion in the logistic regression.

All potential significant first degree interactions between the qualifying predictor variables were also tested for (Kleinbaum, Kupper, Nizam and Muller, 2008).
During the interpretation of the final logistic regression model produced, significance levels were set at $p<0.05$.

〉 ***Sample size for regression***

The sample size was calculated based on the hypothesised number of independent variables which would be included in the logistic regression model, i.e., 7 independent variables (section B, Aims and hypotheses). Thus, based on a statistical significance level of 0.05, dropout rate of 40% and 7 independent variables, a sample size of n = 150 patients was calculated (50 + [8 x 7] x 1.4 = 148.4) (Field, 2009).

〉 ***Assessing the regression model: goodness of fit and diagnostic statistics***

Various steps were taken to ascertain the goodness of fit and the generalisability of the final regression model. After the regression model was generated, it was tested to see how well it represented the overall data and whether there were any outliers or cases exerting disproportionate influence and therefore biasing the model (Bagley et al., 2001, Field, 2009, Ottenbacher, Ottenbacher, Tooth and Ostir, 2004). Residual and influence statistics were examined to:

- Isolate cases for which the model fits poorly (Standardized Residual and deviance statistics), and

- Isolate cases that exert an undue influence on the model (Cooks Distance, DFBeta, Leverage)

Further, any outliers identified were not eliminated but examined to determine the reasons for their deviance. The diagnostic statistics generated and their criteria for determining data cases that were outliers, or disproportionately influential, can be found in Appendix 3.25 (Diagnostic statistics conducted).

〉 ***Assessing the regression model: generalisability and assumption testing***

After the model was assessed for goodness of fit, it was the assessed for generalisability. This was to indicate whether the findings can be used to make inferences beyond the study sample, to a broader community of patients using inhaler devices (Field, 2009). In order to generalise a regression model, various assumptions must be met (Bagley et al., 2001, Field, 2009, Ottenbacher et al., 2004). The assumptions tested for and their criteria can be found in Appendix 3.26 (Assumption testing conducted).

d. Statistical software used

Statistical analyses in this study were performed using the software PASW version 18 (IBM, Inc., Chicago, IL, USA).

D. Results

i. Pharmacists

1. Pharmacist recruitment

A total of 31 pharmacists were recruited who actively participated in recruiting patients for this study. Initially, 62 pharmacists were invited to participate in the study via email, telephone or in person. The majority of pharmacists who consented to take part were those who were approached in person (67%), followed by those contacted via telephone (52%) and then via email (35%). This is shown in Table 3.05.

Table 3.05: Pharmacist recruitment

Method of contact	Numbers contacted	Numbers consented
Email	17	6 (35%)
Telephone	21	11 (52%)
In-person	24	16 (67%)
Total	62	33 (53%)

Pharmacists who consented to participate in the study received training through the CPE accredited QUIP workshop (explained in Methods, section C, ii, 2). Table 3.06 shows the number of pharmacists who participated in the workshop either in its small group format (at the Faculty of Pharmacy) or its individual one-on-one format (at their pharmacy).

Table 3.06: Pharmacists completing the QUIP workshop in its small group and individual format.

Format of workshop	Numbers attending
SMALL GROUP (Faculty of Pharmacy) i) Saturday 9-11am (27th February 2010) ii) Monday 7-9pm (1st March 2010)	 i) 9 ii) 17

INDIVIDUAL (in pharmacy, 25th February - 8th April 2010)	7
Total pharmacists completing training workshop	33
Total study pharmacists (after drop-out post workshop)	31

After receiving training, two pharmacists dropped out of the study (one going on annual leave, and another relocating away from Sydney), leaving a total of 31 pharmacists to conduct the study. Therefore the results presented henceforth pertain only to the 31 participating pharmacists.

2. Pharmacist demographics and past inhaler technique education

Table 3.07 shows the demographics of the pharmacists who participated in the study. Notably, a large majority of pharmacists reported having received some form of inhaler technique related education in the past.

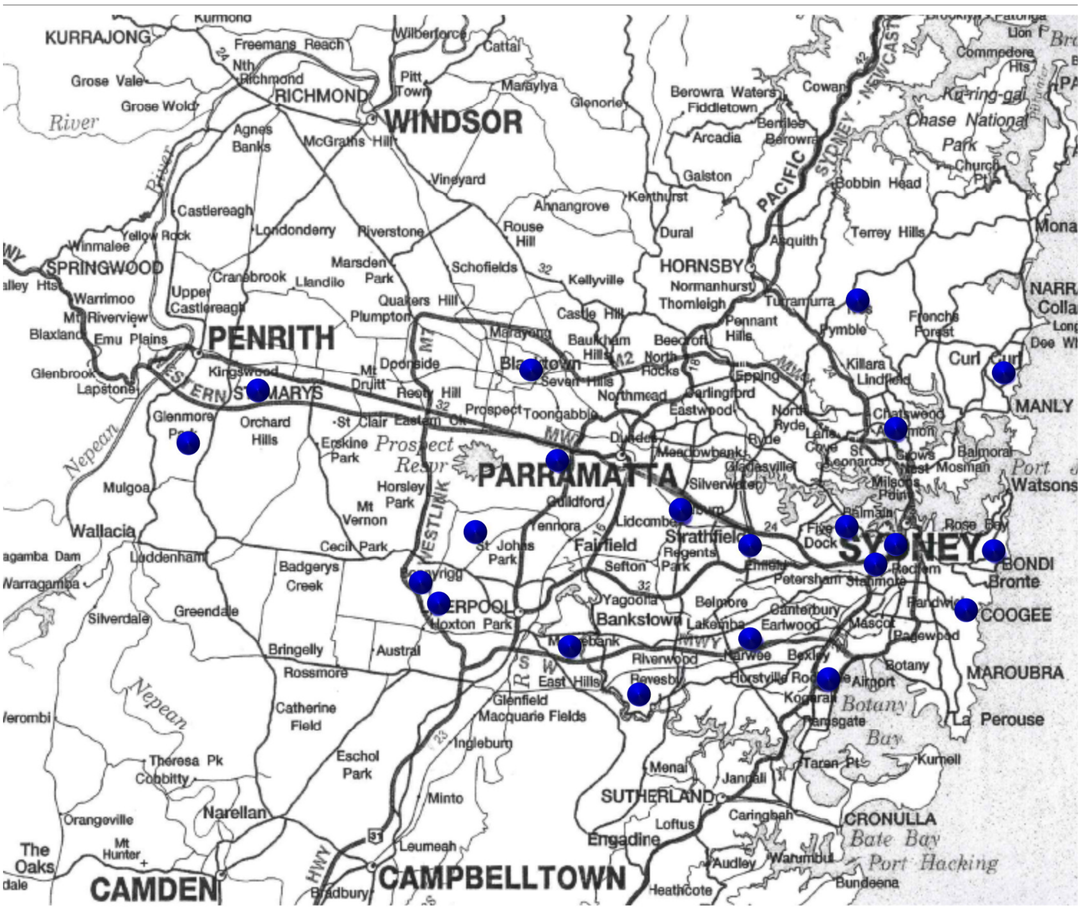
Table 3.07: Pharmacist demographics and past inhaler technique education

Age (years)	21-30	N=19 (61%)
	31-40	N=5 (16%)
	41-50	N=5 (16%)
	51-60	N=1 (3%)
	61-70	N=1 (3%)
Gender	Male	N=12 (39%)
Job description	Pharmacist in charge	N=22 (71%)
	Sole proprietor	N=4 (13%)
	Partner proprietor	N=2 (6%)
	Pharmacist intern	N=3 (10%)
Past inhaler technique education received	Yes	N=23 (74%)

3. Pharmacy demographics

The pharmacists who participated in this study worked in 23 different pharmacies located across twenty-one suburbs in the Sydney metropolitan region (Annandale, Artarmon, Auburn, Bonnyrigg, Blacktown, Brighton-le-sands, Broadway, Burwood, Coogee, Edensor Park, Glenmore Park, Green Valley, Kingsgrove, Kingswood, Manly Vale, Moorebank, Mt Pritchard, Parramatta, Picnic Point, Rozelle and St Ives). It is from these pharmacies that patients were recruited for this study. The locations of study pharmacies are marked (blue dots) on a map of metropolitan Sydney in Figure 3.09.

Figure 3.09: Geographic distribution of study pharmacies



Study pharmacy characteristics in regards to store location, prescription volume and provision of specialised services are shown in Table 3.08.

Table 3.08: Characteristics of study pharmacies

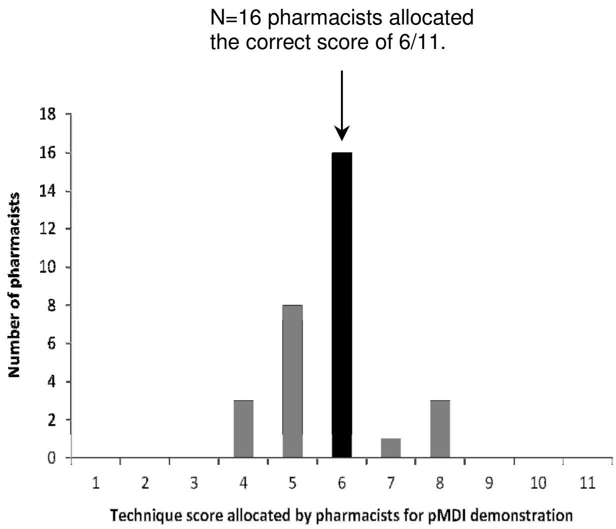
Location	Shopping centre	N=10 (43%)
	Isolated stand alone	N=1 (4%)
	Neighbourhood stand alone	N=10 (43%)
	Medical centre	N=2 (9%)
Estimated number of prescriptions dispensed per 7 days	<300	N=4 (17%)
	301-800	N=8 (35%)
	801-1200	N=3 (13%)
	1201-2000	N=5 (22%)
	2001-3000	N=3 (13%)
Provision of specialised services	Yes	N=22 (96%)
Type/s of specialised service provided (*note: each pharmacy usually provided multiple services*)	Home Medicines Review	N=19
	Dosage Administration Aids	N=21
	Patient Medication Profile	N=14
	Diabetes Medication Assistance Service	N=6

4. Accuracy of inhaler technique assessment by pharmacists

Pharmacists' accuracy in assessing inhaler technique after watching pre-recorded video demonstrations of the pMDI, Turbuhaler™ and Accuhaler™ was measured, as explained in Table 3.02, next to workshop aim 3b (Methods, section C, ii, d). For the pMDI, 52% (N=16) of pharmacists made a correct assessment of the video demonstration (i.e. allocated a score of 6 out 11) (Figure 3.10). For the Turbuhaler™, 58% (N=18) of pharmacists made a correct assessment of the video demonstration (i.e. allocated a score of 6 out 11) (Figure 3.11). The greatest accuracy in assessment occurred with the Accuhaler™, where 74% (N=23) of pharmacists made a correct assessment of the video demonstration (i.e. allocated a score of 8 out of 11) (Figure 3.12).

*Figure 3.10: **A.** Pharmacists' assessment of pMDI technique after viewing the pre-recorded video demonstration. **B.** Allocation of scores using the pMDI checklist to give a correct assessment of the video demonstration (i.e. score of 6 out of 11).*

A.



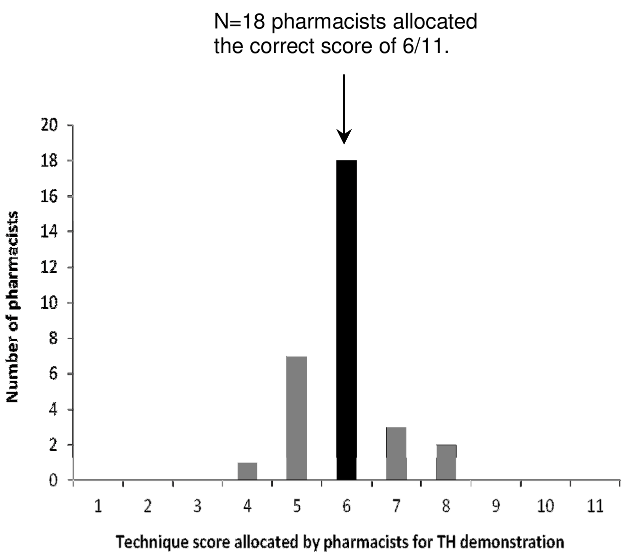
B.

☑1. Remove cap
☑2. Shake inhaler well
☒3. Exhale air out of lungs
☑4. Hold inhaler upright
☑5. Put mouthpiece between teeth and seal with lips
☒6. Inhale slowly and press canister firmly
☒7. Continue slow and deep inhalation
☒8. Hold breath, aim for 10 seconds
☒9. While still holding breath remove inhaler from mouth
☑10. Exhale away from mouthpiece
☑11. Replace cap

<u>Correct assessment score: 6/11</u>

*Figure 3.11: **A.** Pharmacist assessment of Turbuhaler™ (TH) technique after viewing the pre-reorded video demonstration. **B.** Allocation of scores using the Turbuhaler™ checklist to give a correct assessment of the video demonstration (i.e. score of 6 out of 11).*

A.



B.

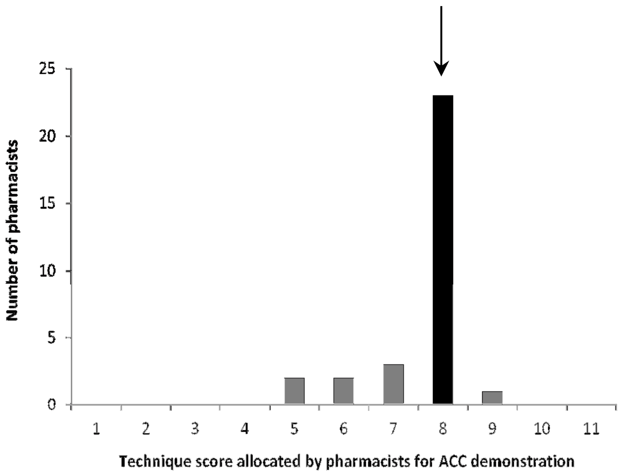
☑1. Unscrew and lift off cap
☒2. Hold inhaler upright
☑3. Rotate grip one way, then back until click is heard
☒4. Exhale air out of lungs
☒5. Exhale away from mouthpiece
☑6. Put mouthpiece between teeth and seal with lips
☑7. Inhale forcefully and deeply
☒8. Hold breath, aim for 10 seconds
☒9. While still holding breath remove inhaler from mouth
☑10. Exhale away from mouthpiece
☑11. Replace cap

<u>Correct assessment score: 6/11</u>

*Figure 3.12: **A.** Pharmacist assessment of Accuhaler™ (ACC) technique after viewing the pre-recorded video demonstration. **B.** Allocation of scores using Accuhaler™ checklist to give a correct assessment of the video demonstration (i.e. score of 8 out of 11).*

N=23 pharmacists allocated the correct score of 8/11.

A.



B.

☑1. Open inhaler
☑2. Push lever back completely to load dose
☒3. Exhale air out of lungs
☒4. Exhale away from mouthpiece
☑5. Hold inhaler horizontally
☑6. Put mouthpiece between teeth and seal with lips
☑7. Inhale steadily and deeply
☑8. Hold breath, aiming for 10 seconds
☑9. While still holding breath remove inhaler from mouth
☒10. Exhale away from mouthpiece
☑11. Close cover

Correct assessment score: 8/11

5. Evaluation of the QUIP workshop

On completion of the QUIP workshop, pharmacists evaluated the training they received by completing a brief questionnaire in response to three questions set by the CPE accrediting organisation, the PSA. The results of the evaluation indicated that all pharmacists believed that the learning objectives were entirely met; most pharmacists believed that their personal learning needs were entirely met; and most pharmacists believed that the training was relevant to their day-to-day practice. This is summarised in Table 3.09.

Table 3.09: Pharmacists' evaluation of the QUIP workshop – number of pharmacists rating "entirely met", "partially met" or "not met" for each item, and any comments written.

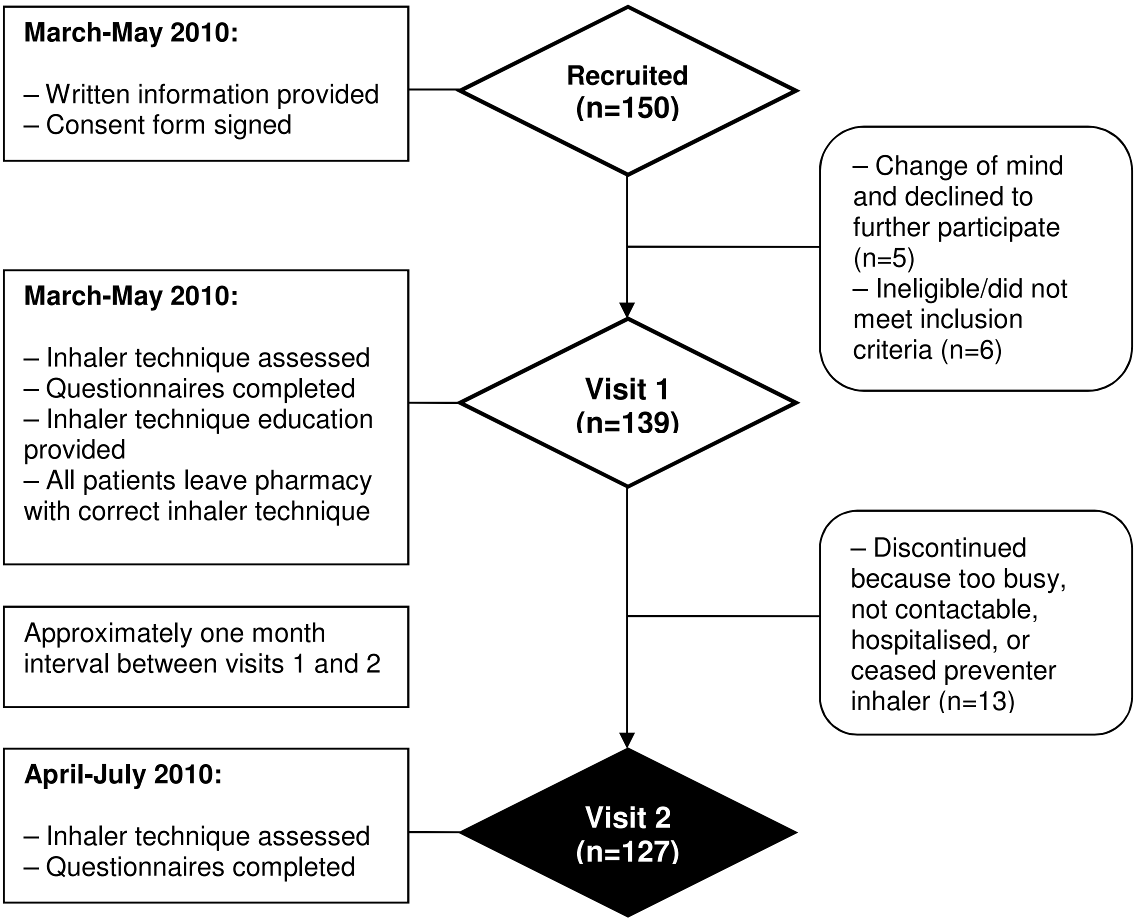
PSA evaluation question	Pharmacists' responses: ratings and comments		
	ENTIRELY MET	PARTIALLY MET	NOT MET
1. To what extent were the workshop aims met?	**N=31 (100%)** *"The demonstration coupled with the scoring, getting participants to demonstrate and be scored were great in reinforcing what was being taught."* *"Quite thorough"* *"Well done"* *"Really good to have training on the devices again, each process broken down into steps and explained."* *"Excellent workshop"* *"The activity comprehensively met the objectives outlined above"* *"Very well presented and made sure I understood techniques through demonstration."* *"Very thorough"*	**N=0**	**N=0**
2. To what degree were your own learning needs met through participating in this activity?	**N=30 (97%)** *"Greater insight on how to assess patient inhaler technique correctly."* *"I found the workshop helped clarify my understanding and technique of the devices."* *"Nice to review technique now and then."* *"Able to get hands-on practise for using more than one device."* *"Excellent to have hands-on practise to gain complete practical experience."* *"Concise but good and relevant info"* *"Great, more confident with how to show inhaler technique and why it is important."* *"Very valuable in reinforcing of correct technique."*	**N=1 (3%)** *"Need some further private time with the devices plus checklists"*	**N=0**
3. To what degree was this activity relevant to your practice?	**N=29 (94%)** *"We have a high proportion of customers on asthma inhaler medications with varying levels of asthma control. Have a better understanding of the difficulty that may be experienced by patients using a pMDI. Coordination was difficult along with creating a good seal around mouthpiece as experienced using placebo device."* *"We dispense many inhaler devices daily therefore I think that this was really important."* *"Nice to review technique now and then."* *"Useful information for patients"* *"I believe most of our customers would not realise how much they can benefit from re-assessing their techniques."* *"Anything concerned with health is relevant"* *"We have many elderly patients on inhalers who most likely do not use their inhalers properly. Also very useful to hear pointers on how to approach patients about their inhaler technique."* *"Many customers on asthma medication"* *"Asthma management is a crucial component in delivering the best possible care for patients at our practice."* *"More confident to instruct patients with the proper techniques."*	**N=2 (6%)** *"Lack of time is always a barrier in community pharmacy"*	**N=0**

ii. Patients

1. Patient recruitment

One hundred and fifty patients were enrolled in the study of whom 139 (excluding the 6 ineligible patients who were enrolled) completed the first visit and 127 (85%) returned to complete the second visit. Figure 3.13 shows the flow of patients through the study from March to July 2010.

Figure 3.13: Patient recruitment and retention throughout study



2. Patient demographics and asthma history

Table 3.10 summarises the data relating to patient demographics and asthma history. Notably, there were no statistically significant differences between patients who maintained and those who did not maintain correct technique based on these demographic variables (p>.05, Mann Whitney U test or Chi-square test for independence).

Table 3.10: Demographics and asthma history of study patients

Age (years)	Range	18 - 88
	Mean	53 (±19)
Gender	Male	N=43 (31%)
Highest level of education	Primary	N=1 (0.01%)
	Secondary	N=61 (44%)
	TAFE	N=34 (24%)
	Tertiary	N=42 (30%)
Asthma duration (years)	Range	0.08 - 81
	Mean	26 (±18)
Visit/s to a health care professional for asthma in past year	0	N=25 (18%)
	1	N=31 (22%)
	2	N=33 (24%)
	3	N=20 (14%)
	>3	N=30 (22%)
Other (non-asthma) medications taken	No	N=48 (35%)
	Yes, <5	N=63 (46%)
	Yes, ≥5	N=27 (19%)
≥ 1 other medical condition experienced	N= 83 (60%)	
≥ 1 other respiratory condition experienced	N=33 (24%)	
≥ 1 visit/s to hospital/emergency room for asthma in past year	N=27 (19%)	

3. Inhaler devices used and previous technique education

Table 3.11 summarises the data relating to patients' inhaler device therapy and the nature of previous inhaler technique education received.

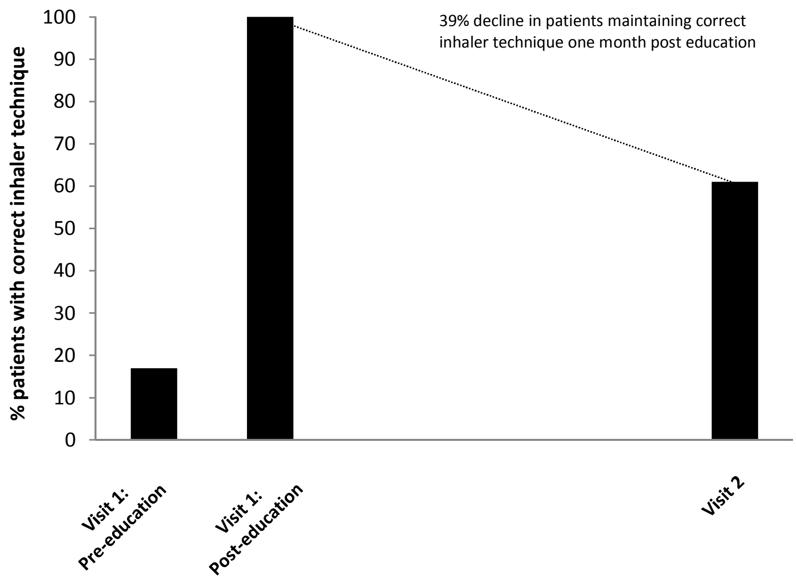
Table 3.11: Inhaler devices used and previous technique education in study patients

Type of preventer device used	pMDI	N=55 (40%)
	Turbuhaler™	N=41 (30%)
	Accuhaler™	N=43 (30%)
Duration of preventer use [mean (±SD)]	7(±7) years	
Patients using > 1 type of inhaler device for asthma therapy	N=81 (58%)	
Previous technique education received	N=133 (96%)	
Previous technique education given by	GP	N=65 (49%)
	Pharmacist	N=18 (14%)
	Respiratory physician	N=10 (8%)
	Nurse	N=6 (5%)
	Other	N=2 (1%)
	> 1 Health care professional	N=32 (23%)
Time since last technique education [mean years (±SD)]	7(±7)	
Physical technique demonstration included in previous education	N=74 (53%)	
Reinforcement of technique education received on 1 occasion in past	N=17 (12%)	
Reinforcement of technique education received ≥ 2 occasions in past	N=14 (10%)	
Patient has shown another person inhaler technique	N=35 (29%)	

4. Inhaler technique at visits 1 and 2: technique maintenance

At Visit 1, at baseline and prior to the delivery of education, 17% (n=24) of patients demonstrated correct technique (i.e. a score of 11). Following the inhaler technique education delivered at visit 1, all participants (n=139) demonstrated correct inhaler technique. Approximately one month later (visit 2) only 61% (n=77) of patients *maintained* correct inhaler technique. The remaining 50 patients, although having demonstrated the ability to correctly use their inhaler device at visit 1, were not able to do so at visit 2. Correct inhaler technique maintenance varied across the three devices used in the study. That is amongst pMDI, Turbuhaler™ and Accuhaler™ users; 49% (n=25/51), 69% (n=27/39) and 68% (n=25/37) maintained correct inhaler technique respectively. The trend in patients' inhaler technique for all devices over both visits is shown in Figure 3.14 below.

Figure 3.14: Proportion of patients maintaining correct inhaler technique one month post education

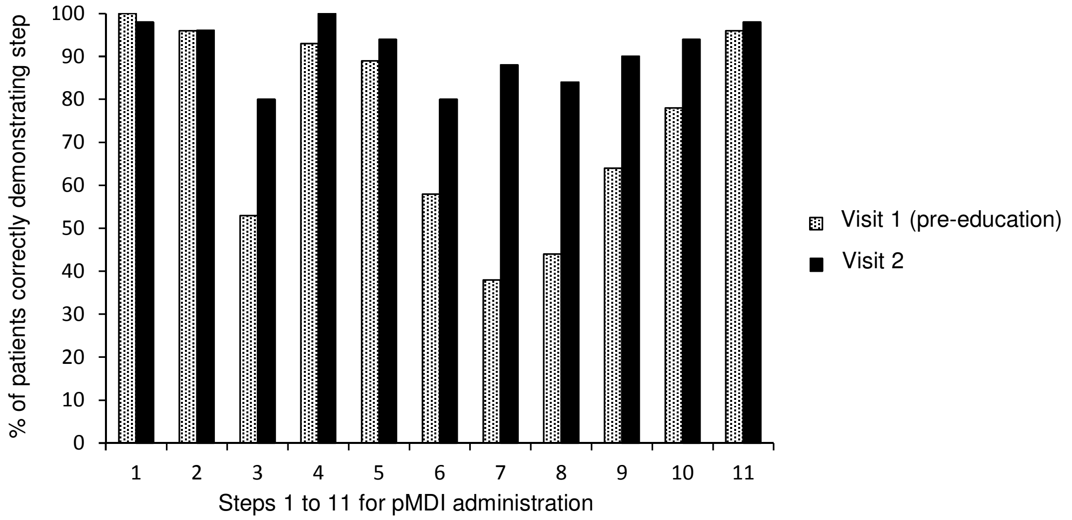


5. Individual inhaler technique steps at visits 1 and 2

At visit 1 (pre-education) the inhaler technique steps patients most frequently demonstrated incorrectly were: step 7 for the pMDI (continue slow and deep inhalation), step 2 for the Turbuhaler™ (hold inhaler upright) and step 3 for the Accuhaler™ (exhale air out of lungs). At Visit 2 errors in some technique steps were still evident despite the fact that patients had demonstrated the ability to correctly perform all steps for their inhaler device after education at visit 1. The steps that were most frequently performed in error at visit 2 were steps 3 and 6 for the pMDI (exhale air out of lungs and inhale slowly and press canister firmly), step 2 for the Turbuhaler™ (hold inhaler upright) and step 4 for the Accuhaler™ (exhale away from mouthpiece). Figures 3.15, 3.16 and 3.17 below show the proportion of patients correctly performing each step for the pMDI, Turbuhaler™ and Accuhaler™ at visits 1 (pre-education) and 2.

*Figure 3.15: **A.** Proportion of patients correctly performing inhaler technique steps 1 to 11 required for pMDI administration at visit 1 (pre-education) and visit 2. **B.** Steps for pMDI administration.*

A.

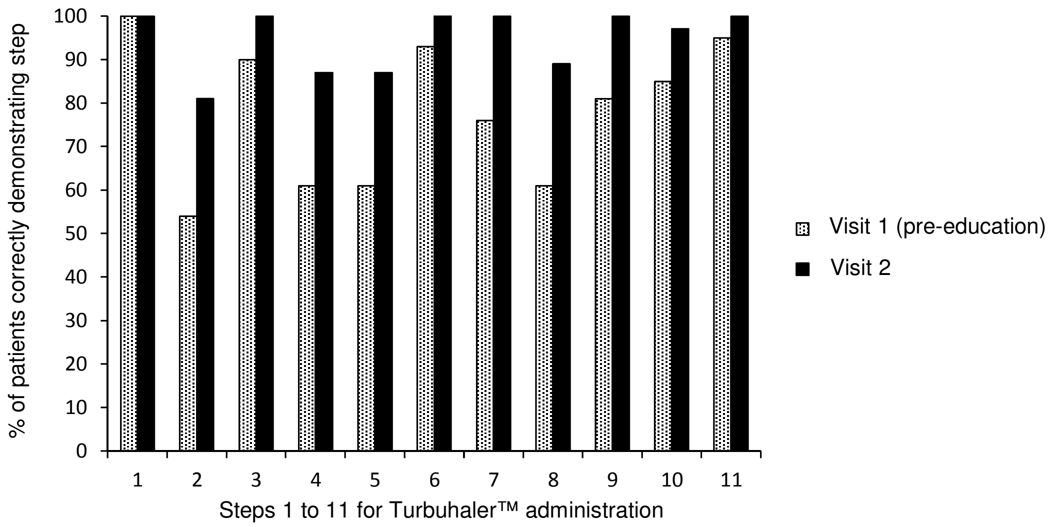


B.

1. Remove cap
2. Shake inhaler well
3. Exhale air out of lungs
4. Hold inhaler upright
5. Put mouthpiece between teeth and seal with lips
6. Inhale slowly and press canister firmly
7. Continue slow and deep inhalation
8. Hold breath, aim for 10 seconds
9. While still holding breath remove inhaler from mouth
10. Exhale away from mouthpiece
11. Replace cap

*Figure 3.16: **A.** Proportion of patients correctly performing inhaler technique steps 1 to 11 required for Turbuhaler™ administration at visit 1 (pre-education) and visit 2. **B.** Steps for Turbuhaler™ administration.*

A.

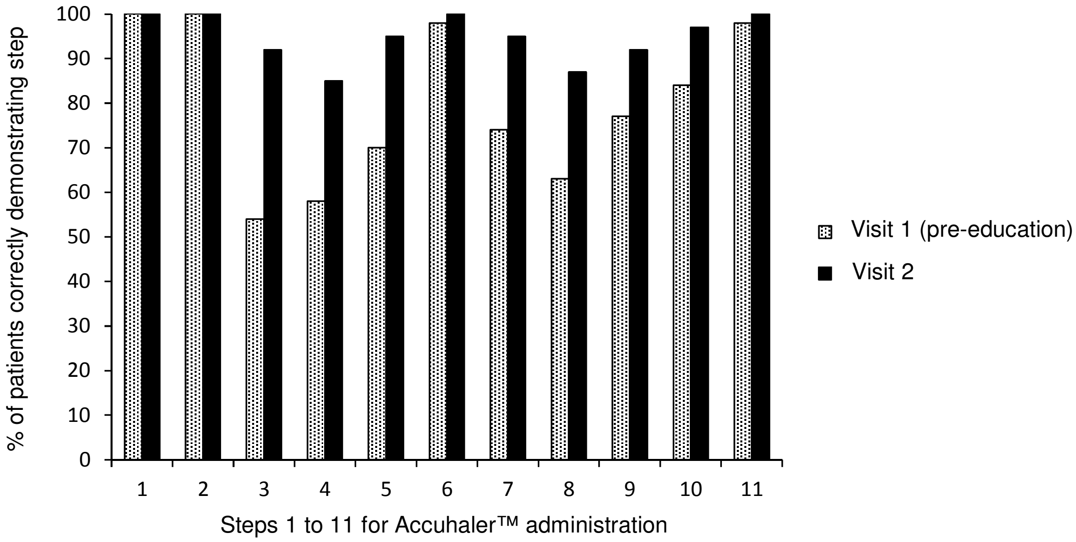


B.

1. Unscrew and lift off cap
2. Hold inhaler upright
3. Rotate grip one way, then back until click is heard
4. Exhale air out of lungs
5. Exhale away from mouthpiece
6. Put mouthpiece between teeth and seal with lips
7. Inhale forcefully and deeply
8. Hold breath, aim for 10 seconds
9. While still holding breath remove inhaler from mouth
10. Exhale away from mouthpiece
11. Replace cap

*Figure 3.17: **A**. Proportion of patients correctly performing inhaler technique steps 1 to 11 required for Accuhaler™ administration at visit 1 (pre-education) and visit 2. **B.** Steps for Accuhaler™ administration.*

A.



B.

1. Open inhaler
2. Push lever back completely to load dose
3. Exhale air out of lungs
4. Exhale away from mouthpiece
5. Hold inhaler horizontally
6. Put mouthpiece between teeth and seal with lips
7. Inhale steadily and deeply
8. Hold breath, aiming for 10 seconds
9. While still holding breath remove inhaler from mouth
10. Exhale away from mouthpiece
11. Close cover

6. Change in repeated measures variables

Changes over time (i.e. during the approximate one month period between visits 1 and 2) in asthma control (S-ACQ), adherence (MARS-5), preventer necessity and concerns beliefs (BMQ-S), inhaler technique beliefs (ITBQ) and motivation for correct technique were tested for. Tests for normality (histograms, kurtosis and skewness, Kolmogorov-Smirnov and Shapiro-Wilk tests) revealed non-normal distributions for all five data measures (Appendix 3.22: Normality statistics for repeat measures variables).

Wilcoxon Signed Rank Test (for non-parametric analysis) was used and showed:

- A statistically significant decrease in asthma control scores between visit 1 (median score=1.2) and visit 2 (median score=1), T=1829, $p<0.05$, r= -0.22.
- A statistically significant increase in adherence scores between visit 1 (median score=21) and visit 2 (median score=21.50), T=1691, $p<0.05$, r= -0.13.
- No statistically significant differences in the remaining repeated measures variables collected ($p>0.05$).

7. Determinants of inhaler technique maintenance: regression results

Four independent variables qualified for inclusion in the backwards stepwise logistic regression after statistical screening ($p<.25$) as previously described (Methods, section iv, 4, c). The screening results for each of the 28 unique study variables are shown in Appendix 3.24 (Univariate logistic regression results). The four qualifying independent variables were:

- Inhaler technique at visit 1
- Asthma control at visit 1
- Motivation to practise correct inhaler technique at visit 1
- Preventer device type (i.e. pMDI or DPI).

After running the backwards stepwise logistic regression, with the four independent variables above, a statistically significant model was produced: X^2 (N=125,3)=16.22, p=0.001. The model generated could correctly classify 67.2% of patients (as either maintaining or not maintaining correct inhaler technique at visit 2), and explain between 12.2% and 16.5% of the variance in patients' inhaler technique maintenance (Appendix 3.27: Logistic regression statistical output).

The statistically significant model generated consisted of 3 out of the four independent variables tested. They were:

1) Preventer device type,
2) Asthma control at visit 1, and
3) Motivation to practice correct technique at visit 1.

Each of these 3 variables were also individually statistically significant. The strongest predictor of technique maintenance was the type of preventer used with an odds ratio of 2.6, indicating that patients who used DPIs were 2.6 times more likely to have maintained correct inhaler technique at one month compared to patients who used pMDIs, controlling for all other factors in the model. Similarly, patients who had good asthma control at baseline were 2.3 times more likely to have maintained correct inhaler technique at one month. Patients who were more motivated to practice correct technique at baseline were 1.2 times more likely to have maintained correct inhaler technique at one month. Table 3.12 illustrates the logistic regression model described.

Table 3.12: The backward logistic regression model, and its 3 significant variables, predicting the likelihood of maintaining correct inhaler technique[a] at one month.

								95% C.I. for odds ratio[c]	
Predictor	Coding	B	SE	Wald	df	p	Odds Ratio	Lower	Upper
Preventer Device Type	0=pMDI (n=50) 1=DPI[b] (n=75)	.97	.40	5.91	1	.02	2.64	1.21	5.79
Asthma Control	0=scores≥1.5 (n=52) 1=scores<1.5 (n=73)	.82	.40	4.23	1	.04	2.23	1.04	4.99
Motivation	Score range 1-10	.22	.10	4.54	1	.03	1.24	1.02	1.52

[a] Outcome variable coding: 0 = Visit 2 technique score < 11/11 (n=50), 1 = Visit 2 technique score is 11/11 (n=77)

[b] Turbuhaler™ and Accuhaler™ groups were combined under "DPI" (Dry Powder Inhaler) to achieve sufficient group size for logistic regression analysis

[c] C.I. = Confidence Interval

8. Test for interaction terms

All potential first degree interaction terms were tested for using the same fitting procedure (stepwise backwards logistic regression). The ten variables entered into the regression were:

- Inhaler technique
- Device type
- Asthma control
- Motivation
- Inhaler technique x Device type
- Inhaler technique x Asthma control
- Inhaler technique x Motivation

- Device type x Motivation
- Device type x Asthma control
- Asthma control x Motivation

The regression model generated using these variables was significant [X^2(n=125, 5) = 23.1, p=.0005, R^2=16.9-22.8%]. However, the *significant* predictor variables at the final step of the regression were the same as those in the original main effects model reported above (i.e. Device type, Asthma control and Motivation). Although two extra variables (Inhaler Technique, and Asthma control x Motivation) appeared in the final step of the regression model, they were not significant and did not have reliable regression terms (i.e. confidence interval crossed 1; implausibly large odds ratio of 202) (Appendix 3.28: Interaction terms statistical output). Thus, no interaction terms were found that would enhance the predictive power without compromising the reliability of the final regression model.

9. Goodness of fit of regression model: diagnostic statistics

The diagnostic statistics indicated that the logistic regression model fitted the data set well. The standardised residuals, cooks distance and DFBeta did not identify any outliers. The leverage statistics indicated two potentially influential cases; however these cases were highly unlikely to have a significant effect on the regression analyses because their cooks distance was < 1 (Field, 2009). The statistical results testing the goodness of fit of the regression model are summarised in Appendix 3.29 (Diagnostic statistics results).

10. Generalisability of regression model: assumption testing

The tests for assumptions indicated that:

- There was independence of error (all cases were independent).
- The model was based on sufficient events per independent variable (4 independent variables = 12.5 cases per variable, based on the sample of the smaller group).
- There were no multicollinearity issues with any variables (all Tolerance values > 0.9 and mean Variance Inflation Factor=1.08).
- Variables (motivation score) conformed with linear gradients (non-significant interaction term, $p>.05$).
- There was a projected 5% loss of predictive power to the model if it were to be generalised to the sample population.

The results of assumption testing for the regression model generated are summarised in Appendix 3.30 (Assumption testing results).

E. Discussion

This is the first study to have explored inhaler technique maintenance in depth as the subject of focus. As a starting point, a broad framework, conceptualising the phenomenon of inhaler technique maintenance, was set up in the Background (i.e. the "Inhaler Technique Maintenance Framework" illustrated in Figure 3.01). This conceptual framework, importantly, allowed the potential determinants of inhaler technique maintenance to be explored from a theoretically grounded perspective. Established theories in the areas of skill learning (i.e. FSLT) and self-management (i.e. CSM), in particular, were used. Subsequently, a wide range of patient factors – classified as demographic, clinical, inhaler device related, technique education related, and psychological – were explored in relation to inhaler technique maintenance.

Three factors were identified through quantitative investigations as determinants of inhaler technique maintenance – inhaler device type, asthma control and motivation. That is, patients who were more likely to maintain correct inhaler technique one month after education were those who used a DPI as opposed to a pMDI, had better baseline asthma control, and had higher baseline motivation to practice correct inhaler technique. Of note is the fact that patient motivation has been shown for the first time to play a role in the inhaler technique domain, specifically with regards to how patients maintain inhaler technique over time.

Prior to commencing discussion of the determinants of inhaler technique maintenance, it bears mentioning that the levels of inhaler technique recorded throughout this study are comparable to what has been reported previously (Basheti et al., 2007, Bosnic-Anticevich et al., 2010). It was not surprising to find that the overwhelming majority of patients had poor inhaler technique at baseline (83%), nor to find that the educational intervention was successful in improving inhaler technique in those patients with poor baseline technique, similar to what was achieved in other studies (Press et al., 2011). The fact that these improvements were not maintained (i.e. 39% of patients reverted to poor technique one month later), reflect the deterioration in technique over time also observed in past studies (Chapter 2, section C. iii, Table 2.02). Notably, the reason/s patients revert to poor inhaler technique, despite having received technique education, and in the absence of other known barriers, is the gap in the literature that this study addresses.

Device type was the first factor identified as a significant predictor of inhaler technique maintenance in the regression analysis. Patients using a DPI (Turbuhaler™ or Accuhaler™) to administer their preventer medication were more likely to maintain correct inhaler technique at one month than patients using pMDIs. Device type was not originally hypothesised to be a significant predictor of inhaler technique maintenance. These results seem to suggest that DPIs are easier to use than pMDIs, however, this may be too simplistic an explanation in and of itself. Despite some suggestion in the existing literature that DPIs are more "user friendly" than pMDIs (Rees, 2005) various past studies show that inhaler technique can be problematic across all devices, and further, that the rates of misuse with DPIs is commensurate with, or even greater than, that with pMDIs (Melani et al., 2011).

Closer scrutiny of individual patient's relative physical compatibility with, and preference for, various types of inhaler devices available for their treatment may have provided more insight regarding device type as a significant predictor of technique maintenance. It is possible that due attention may not have been given in the past to selecting the most physically suitable device for patients in this study, since notably, past inhaler technique education for a large proportion of patients did not involve any form of physical demonstration. Therefore in these patients, known barriers to technique maintenance (e.g. physical device use issues) may not have been adequately addressed, and this in turn may have unduly influenced this study's finding regarding device type as a predictor of technique maintenance. Future studies may be improved by better controlling for issues relating to patient device compatibility, via, for example, recruiting inhaler device naïve patients and implementing a process of optimal device selection; or in patients already using an inhaler, implementing a process of re-assessing for device suitability and patient preferences, and changing the prescribed device if required. This allows more scope to identify novel reasons behind poor inhaler technique maintenance, and further, to confirm if device type truly makes a difference to how patients maintain inhaler technique.

Patients' asthma control at baseline was the second predictor found to be significant in determining inhaler technique maintenance. Specifically, patients with better baseline (visit 1) asthma control were more likely to maintain correct inhaler technique compared to patients with poorer baseline asthma control (i.e. there was a significant association between baseline/visit 1 asthma control and inhaler technique at visit 2). However, it was interesting to note that despite this association, no significant relationship was found between baseline/visit 1 asthma control and baseline/visit 1 inhaler technique. This could be related to statistical issues (i.e. the number of patients in the group with correct compared incorrect baseline technique, n=24 and n=115 respectively, was not sufficiently large enough to allow for meaningful correlations to be calculated) and/or to the possibility that other factors impacting on patients' baseline asthma control (Haughney et al., 2008) outweighed any contribution inhaler technique may have had.

This second explanation above, implying the negligible effect of inhaler technique on baseline asthma control, however, seems rather insufficient given that inhaler technique has been demonstrated in various past studies to be independently and significantly associated with asthma control (Basheti et al., 2007, Giraud and Roche, 2002, Giraud et al., 2011). Thus it seems possible that the lack of association between baseline inhaler technique and baseline asthma control may be due to statistical anomalies. However, having said this, alternative explanations are available for understanding the relationship between inhaler technique and asthma control shown in this study.

Alternative explanations for the changing relationship between asthma control and inhaler technique over the course of this study, implicate the role of patient motivation. Firstly, it was observed that an improvement in inhaler technique coincided with an improvement in asthma control (from visit 1 pre-education, to visit 2), and therefore there was a lag in time before asthma control and inhaler technique status were commensurate. That is asthma control (baseline/visit 1) became associated with inhaler technique (visit 2) only after the passage of one month (note, visit 2 asthma control and visit 2 inhaler technique were correlated as expected).

Secondly, when testing for interaction terms in the regression analysis (Results, section ii, 8) it appeared that the relationship between baseline/visit 1 asthma control and visit 2 inhaler technique (i.e. technique maintenance) was mediated by patient motivation (however the statistical results generated were not robust enough to confirm this relationship). Based on these implications and the observed lag period discussed above, an explanation can be forwarded suggesting that patients with existing good asthma control are aware of this status, and that this awareness served as positive feedback and motivation for patients to persist with optimal asthma self-management practices, including maintaining correct inhaler technique (provided patients are made aware of these practices, such as during the educational intervention at visit 1).

In contrast, amongst those patients with poor existing asthma control, recent positive personal experiences regarding asthma may not be available to reinforce the benefits of, and act as a source of motivation to persist with, optimal self-management practices such as correct technique maintenance. This explanation thus reveals that patient-centred psychological factors such as perceptions and motivations may be playing a role in mediating the relationship between asthma control and inhaler technique maintenance.

From a clinical perspective, relating to health care provision, these results regarding the relationship between asthma control and inhaler technique maintenance lends further support to past studies establishing the necessity of optimising inhaler device use (via improved technique education) as an important step towards achieving good asthma control (Basheti et al., 2007). Although a large proportion of patients did not maintain correct inhaler technique, this study did show improved asthma control following improved inhaler technique from baseline, pre-education (17% of patients with correct technique), to visit 2 (60% of patients with correct inhaler technique). Further, in exploring the dynamics in the relationship between asthma control and inhaler technique, this study is able to contribute a unique patient-centred perspective to the matter. Specifically, the potentially important role of patient psychological factors, i.e. perceptions and motivation, in the relationship between asthma control and inhaler technique maintenance is emphasised.

An interesting implication arising from this study is that patients who experience improved asthma control may be more motivated to maintain the self-management strategy/ies they perceive to have led to the improvement, for example, maintaining correct inhaler technique. Thus a reinforcing feedback loop between asthma control and inhaler technique, mediated by patient perceptions and motivations is postulated. An important further implication is that, in order to mitigate a negative feedback loop from becoming entrenched, patients with poor asthma control are compelling candidates for inhaler technique education (and asthma reviews in general). These interrelationships however are complex, and it is beyond the scope of this study to make definitive statements or to draw clear conclusions in relation to them. The nature of this feedback loop, and implications for inhaler technique maintenance, may be better understood through further studies that delve more deeply into the relationship between patient clinical and psychological factors in technique maintenance.

Patient motivation was identified as the final predictor of inhaler technique maintenance, with patients who indicated higher levels of motivation to practise correct inhaler technique during routine use being more likely to maintain correct inhaler technique. From a theoretical perspective, given the important role of motivation in both skill and self-management behaviour maintenance (Bandura, 2005, Cornford, 1996), it was perhaps not surprising to find motivation also having a role to play in inhaler technique maintenance. The novel association uncovered in this study begins to establish some empirical evidence – more so than the above speculative interpretations regarding the mediating effect of motivation between asthma control and technique maintenance – for the role of patient motivation in inhaler technique maintenance. This finding adds strength to the premise that inhaler technique maintenance involves more than maintaining a physical skill, and that promoting optimal inhaler technique maintenance lies beyond practical considerations.

Precisely how patient motivation works to influence inhaler technique maintenance is yet to be determined. However, in referring back to the unexplained observations of past studies, coupled with the new insights of this study, there is the possibility that social factors – specifically, regular contact with health care providers – may be facilitating patient motivation around inhaler technique. Various studies have shown that patients tend to maintain correct inhaler technique so long as they are in regular contact (monthly basis) with a health care professional (Basheti et al., 2007, Bosnic-Anticevich et al., 2010). In these studies, although the basis of the clinical visits were for the purpose of assessing patient inhaler technique, it must be noted that the proportion of patients maintaining correct inhaler technique as reported reflected the scenario *before* any re-education or corrections to technique occurred. This seems to indicate that patients are more motivated to maintain correct inhaler technique simply by virtue of keeping in regular contact with their health care provider.

Interestingly, similar conclusions have been drawn further afield regarding long term preventative health care behaviours (dental flossing) that also require a certain level of skill/technique. McCaul, Glasgow and O'Neill (1992) showed in several prospective studies that participants' adherence to dental flossing seemed contingent on the degree of continued contact with study program personnel. Thus, the social determinants of patient motivation regarding inhaler technique maintenance forms another area identified for further study.

Patient beliefs/perceptions around inhaler technique and device use may also be potentially facilitating the relationship identified between motivation and inhaler technique maintenance. That is, there were study correlations that showed that patients who believed that practising correct inhaler technique would make a positive difference to their asthma experience, and in the benefits of regular inhaler use, were more motivated to maintain correct inhaler technique over time. Notably, these correlations suggest that while patient beliefs (regarding inhaler technique and preventer therapy) did not have a direct influence on inhaler technique maintenance as hypothesised, they may be having an impact in an indirect manner, namely via modulating patient motivation. However these speculations regarding the precise role of motivation in inhaler technique maintenance are not robust enough to draw clear conclusions in this complex area, thus warranting further studies of this novel finding.

Having discussed the factors found to be significant determinants of inhaler technique maintenance, other factors hypothesised, but not found to be significant determinants of technique maintenance, will now be examined. Firstly, practise with inhaler technique seemed to have no significant bearing on its maintenance, with no associations found between the degree of practise (i.e. regularity of inhaler device use as indicated by MARS-5 adherence scores) or the nature of practise (i.e. whether or not patients showed others' how to use their inhaler) and inhaler technique maintenance. This may be related to the fact that whilst patients may have been engaged in technique practise, the *accuracy* of this practise could not be ascertained, since it was not within the scope of this study to measure how patients were using their inhaler device on a day-to-day basis.

As discussed in the Background (section ii), even high levels of skill practise may prove to be fruitless if done so inaccurately and unfortunately may even be detrimental to optimal skill development due to the challenge involved in unlearning "bad habits" (Cornford, 2008, Shim and Williams Jr, 1980). In terms of implications for health care provision, these observations suggest that although the brief nature of inhaler technique interventions may be advantageous in time poor clinical settings (such as the community pharmacy), extending the time for these interventions so that patients have more opportunity to engage in *accurate* practise, monitored by an expert, may ensure that the correct version of the skill is more successfully consolidated, thus enhancing the chances of optimal inhaler technique maintenance.

Further, contrary to what was hypothesised, patients' baseline level of inhaler technique was not shown to be a significant predictor of inhaler technique maintenance in the regression analysis. Baseline inhaler technique was proposed to be an indicator of how well patients have learned and consolidated the skill of inhaler technique based on past technique education. Thus those patients who demonstrated correct baseline inhaler technique (i.e. 17% of patients at visit 1) were considered to have more successfully consolidated the skill compared with those who demonstrated incorrect baseline technique. Despite the regression results, preliminary analysis did in fact show a significant positive correlation between the two terms. This relationship was perhaps lost in the regression analysis due to random variations in data that can occur with the backwards stepwise fitting procedure (Field, 2009), and also possibly because the significantly smaller numbers of patients belonging to the group with correct versus incorrect baseline technique (n=24 and n=115 respectively) affected the regression results.

Nevertheless the positive correlation found between baseline technique and technique maintenance lends support to the importance of implementing processes and strategies from the *outset* of inhaler device therapy to help patients develop and consolidate correct inhaler technique skills. As discussed earlier, it is not ideal for patients to have to unlearn and re-learn the correct version of technique; rather it is preferable for patients to master the correct technique from the beginning of their inhaler therapy. Beyond these considerations however, it is interesting to note that the lack of firm evidence for the role of skill learning related-factors in inhaler technique maintenance found in this study lends further support to the premise that inhaler technique maintenance involves more than physical/practical skill based issues.

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Various study methodological considerations and limitations will now be discussed so that the findings of this exploratory study may be interpreted with caution and also as a means to offer some insight into how future studies of a similar nature may be improved. Firstly, having multiple pharmacists (n=31) involved in assessing patients' inhaler technique during this study potentially resulted in some inconsistencies regarding inhaler technique scores. Data collected during the QUIP workshops did in fact reveal a level of inconsistency in pharmacists' inhaler technique assessments (Results, section i, 4). However every effort was made to reduce the likelihood of this occurring in the study setting, including dedicating learning activities not only to the skill of inhaler technique but also the skill of *how to assess* patient inhaler technique, and providing additional feedback and training to those pharmacists who required it (Methods, section ii, 2, d).

One way of enhancing the level of assessment consistency in future would be to limit the number of pharmacists involved in technique assessment (e.g. having one or two pharmacists recruit and assess inhaler technique over all study visits for all patients), however, this alternative would have reduced the likelihood of reaching the target sample size (n=150 patients) within the set time frame of this study. Thus a compromise was struck and, in choosing to involve multiple pharmacists, a method was used that was similar to that of past studies conducted in the same setting (i.e. Sydney metropolitan community pharmacies) (Basheti et al., 2007). Further, through using this method, the target sample size was achieved.

A second methodological consideration concerns the use of self-report methods to measure patient asthma control and adherence. The self-report method has been criticised for being less objective in nature as patients have been found to overestimate their own asthma control (Laforest et al., 2007) and adherence (Foster et al., 2012). However, the alternative more objective methods suggested – such as spirometry and airways hyperresponsiveness tests for asthma control (Greening et al., 2008), and blood assays and electronic device-docked monitors for adherence (Rand

and Wise, 1994) – are not without their limitations in terms of cost, invasiveness and practically of administration.

Whilst acknowledging the limitations of the self-report method, it was nevertheless deemed to be the most suitable method of measurement (for asthma control and adherence) given both the constraints of this study, and the advantages of the self-report method, i.e. its cost-effectiveness, minimum patient invasiveness and practicality to administer in the community pharmacy setting (Rand et al., 2012). Further, self-report instruments used to measure asthma control and adherence were both derived from validated (in asthma patients) sources, and have been shown to be comparable to the more objective measures (Cohen et al., 2009, Juniper, O'Byrne, Guyatt, Ferrie and King, 1999).

A third methodological consideration lies in the way in which patient motivation was investigated. The item used to measure patient motivation for optimal inhaler technique maintenance (i.e. *"I am motivated to follow the correct steps when I use my inhaler")* was developed specifically for, and used for the first time in this study (although, given the option, a previously validated instrument would have been used). Due to study time constraints, the item devised was only tested for face-validity. However the development and use of a fully validated instrument would add strength to future studies.

Further, in retrospect – now that patient motivation has emerged a significant predictor of inhaler technique maintenance – the item used to measure motivation seems inadequate for understanding the nuances and complexities in the relationship between the two phenomena. More broadly, the quantitative methodology itself may not be enough to achieve this goal. The reason for using a brief single item to measure motivation, instead of something more elaborate, was in-part, to minimise the potential for respondent fatigue when filling out lengthy questionnaires, thereby managing the risk of patient drop-outs. In addition, since there was no bulwark of existing evidence attesting to role of motivation in technique maintenance, and the need to measure and test for the multiple other hypotheses in the questionnaires, it was deemed most appropriate not to overinvest in what was still a tentative area. However, given the results of this study, further investigations are warranted in which a more in-depth approach in examining the role of patient motivation in inhaler technique maintenance is adopted.

As a final methodological consideration, it bears mentioning that while the regression model generated proved to fit the study data well, as indicated by goodness of fit diagnostic statistics, its capacity to be generalised to a broader population of patients using inhaler device therapy is limited without further studies. Although most of the diagnostic tests for generalisability of the regression model were satisfied (i.e. independence of errors, low multicollinearity and conformity with linear gradients for continuous variables), cross validation calculations (using adjusted R^2) indicated a 5% loss of predictive power (from 16.2% to 11.3%) if the model were to be generalised to the sample population (Results, section ii, 10).

Further, the fact that a substantial degree of variance remains unexplained, before and after cross validation, cautions against generalising this model. However, having said this, it should be noted that being designed as exploratory in nature, the thrust of this study was not to generalise its findings. Rather, this study was designed as a first step in the in-depth examination of the phenomenon of inhaler technique maintenance and to generate evidence-based leads to guide further investigations.

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In concluding this chapter it can be said that a better understanding of the phenomenon of inhaler technique maintenance has been gained, and that preliminary evidence now exists to address the gap in the literature which begs the question, *why do patients not maintain correct inhaler technique despite "knowing how"?* Contrary to the current literature which approaches inhaler technique issues from a predominantly practical and physical device-use based perspective, this study emphasises the skill development and patient self-management contexts in which inhaler technique maintenance is embedded. Through this approach, less tangible, patient-centred factors were revealed to have an impact on technique maintenance. For the first time there is evidence to indicate that patient psychosocial factors, particularly motivation, may play a role in how they maintain inhaler technique. This bolsters the premise that the reasons behind poor inhaler technique maintenance are more than simply practical and physical device-use related.

This study strongly suggests that attempts to facilitate optimal technique maintenance must involve more than repeating inhaler technique instructions (as is the current practice recommendation), especially given the diminishing returns of this strategy (i.e. the benefits appear to wear off over time) (Basheti et al., 2007, Bosnic-Anticevich et al., 2010), and instead, take into greater consideration the patient-centred issues identified in this study. Although it is not within the scope of this study to confirm precisely how these issues should be integrated into future interventions, further investigations from the perspective of patient motivation may provide greater understanding of the psychosocial reasons behind poor technique maintenance, and may ultimately lead to improved interventions for facilitating optimal inhaler technique maintenance over time.

F. Summary

- This chapter aimed to explore the phenomenon of technique maintenance and to identify its determinants.
- The ITMF, a conceptual framework, was set up to explore inhaler technique maintenance. Hypotheses regarding the predictors of technique maintenance were generated based on empirical and theoretical research from the skill learning and health behaviour literatures.
- Backwards stepwise logistic regression identified three significant determinants of inhaler technique maintenance: device type, asthma control and patient motivation.
- The association between motivation and inhaler technique maintenance is novel and tentative and may provide greater insight into the reasons behind poor inhaler technique maintenance given further investigation.

— CHAPTER 4 —

INHALER TECHNIQUE MAINTENANCE FROM THE PERSPECTIVE OF PATIENT MOTIVATION, A QUALITATIVE STUDY

THIS QUALITATIVE STUDY builds upon the findings of the previous study and further examines the novel association that was identified between patient motivation and inhaler technique maintenance (Chapter 3). Specifically it aims to understand the influential factors determining why some patients had relatively higher, while others had relatively lower, motivation to maintain correct inhaler technique (and therefore tended to maintain or not maintain correct technique). Further, a qualitative approach was chosen as it allows for a more in-depth and finer grained exploration in this relatively new area of patient motivation in inhaler technique maintenance. This study will add to addressing the overarching question of this thesis (i.e., *Why patients do not maintain correct inhaler technique despite knowing how?*) and may also have important practice implications in terms of how patient motivation can be enhanced or facilitated by health care providers to promote optimal inhaler technique maintenance in asthma self-management.

A. Background

i. Defining motivation

Motivation has been broadly defined as "the reason a person has for acting in a particular way", and more specifically, as the conscious or unconscious incentive for action towards a desired goal, with the incentives giving purpose or direction to behaviour and typically arising from psychological or social factors (The Oxford English Dictonary, 2000). Hence, in essence, the study of motivation is about understanding "why people do the things that they do" (Russell, 2008). This construct of "motivation" can provide vital insight into identifying areas for improvement and facilitating change in people's actions or behaviours (Russell, 2008). This is of particular interest in the context of chronic conditions, where patient actions and behaviours, especially self-management behaviours (e.g. inhaler technique maintenance), can be very influential on disease outcomes (Ryan, Patrick, Deci, and Williams, 2008).

Motivation has been further defined as a "process whereby goal directed activities are energised, directed and *sustained*" (Schunk and Usher, 2012). The last word of this definition has been highlighted here to emphasise that motivation is an important determinant not only for the initial stages of behaviour change, but also for the *maintenance* of behaviours over time (Rothman et al., 2004, Ryan and Deci, 2000b). Motivation is thus an especially important consideration in the context of a chronic condition such as asthma, whereby good patient health outcomes (e.g. in terms of asthma control, quality of life and health care costs) are heavily reliant on the *maintenance* of optimal self-management behaviours, including the maintenance of correct inhaler technique (Chapter 2, section B, ii). A more in-depth investigation of patient motivation in the context of inhaler technique maintenance is not only supported by the theoretical and empirical evidence (Chapter 3), but seems imperative based on the fundamental characteristics that define motivation.

ii. Empirical evidence to guide an in-depth exploration of patient motivation in inhaler technique maintenance.

Given the centrality of motivation in understanding the issues around behaviour maintenance, it is rather surprising that no known studies (barring the quantitative study reported in the previous chapter) have investigated this construct in relation to patients' inhaler technique maintenance behaviour. This may be related to the fact that the phenomenon of inhaler technique maintenance itself has only recently, in the body of work presented in this thesis, been a focal point of research. Although there is a lack of further direct empirical evidence (i.e. on patient motivation in inhaler technique maintenance) to guide this current study, identifying past research that has examined patient motivation in the broader context of asthma may provide useful insights regarding influential factors on patient motivation in asthma self-management, which by extension may also have bearing on inhaler technique maintenance.

To determine the nature and extent of existing research on patient motivation in asthma, a review of the literature was conducted using the search terms "asthma and motivation" (via the Medline and PsycINFO databases). This process identified 213 studies, of which 13 indicated in the abstract that motivation was the focus of the study, or was included as a research variable, and thus their full-text versions were retrieved for further examination. The existence of numerous studies in this area seemed to suggest that researchers acknowledged or recognised the importance of patient motivation in asthma self-management. Upon closer scrutiny, however, it became clear that the nature of these investigations, and therefore the subsequent insight that they could provide for the purposes of this study (aimed at an *in-depth* examination of patient motivation in inhaler technique maintenance), were quite limited. There were numerous reasons for this, including that studies: a) did not define motivation, and/or b) did not measure motivation, and/or c) used unvalidated instruments to measure motivation, and/or d) did not distinguish between the motivation to initiate versus the motivation to *maintain* self-management behaviours (a critical consideration for research on inhaler technique maintenance). The details of these studies, including how motivation was investigated, are summarised in Table 4.01.

Table 4.01: Existing studies on motivation and asthma, and their limitations for guiding this research.

Studies on motivation and asthma		Limitations of studies for informing this research
Allen et. al., 2000.	Assessing pediatric clinical asthma practices and perceptions: A new instrument	▪ Did not investigate *patient* motivation (measured clinician's perception of their patients' motivation regarding various aspects of asthma management instead).
Cochrane and Clark, 1990.	Benefits and problems of a physical training programme for asthmatic patients	
Creer, 1991.	The application of behavioral procedures to childhood asthma: Current and future perspectives	▪ Not a research study, but a commentary article. ▪ Motivation is not defined.
Bennett, Rowe and Katz, 1998.	Reported adherence with preventive asthma medication: A test of protection motivation theory	▪ Motivation is implicit rather than well defined in Protection Motivation Theory (PMT). ▪ PMT does not differentiate between initiation and maintenance of health behaviours (Orbell, 2007).
Schaffer and Tian, 2004.	Promoting Adherence: Effects of Theory-Based Asthma Education	
Steven, Morrison and Drummond, 2002.	Lay versus professional motivation for asthma treatment: A cross-sectional, qualitative study in a single Glasgow general practice	▪ Brief results reported on "influences on motivation… to undertake behaviour change"; 3 quotes were given, but were not related back to behaviour change. ▪ Not investigation of behaviour maintenance.
Wells et al., 2008.	Race-ethnic differences in factors associated with inhaled steroid adherence among adults with asthma	▪ Did not measure motivation (or did not specify how motivation was measured).
Gustafson et al., 2012.	The effects of combining Web-based eHealth with telephone nurse case management for pediatric	

	asthma control: a randomized controlled trial	
Riekert, Borrelli, Bilderback and Rand, 2011.	The development of a motivational interviewing intervention to promote medication adherence among inner-city, African-American adolescents with asthma	▪ Motivation was measured using single item questions, very similar to that used in the previous quantitative study (Chapter 3). E.g. *"On a scale of 1-10, where 1 is not motivated at all and 10 is very motivated, how motivated are you to take your [name of ICS] everyday?" (Foster et al., 2012).* ▪ Questions were devised by the authors and not validated. ▪ Motivation for behaviour maintenance was not investigated.
Halterman et al., 2011.	A pilot study to enhance preventive asthma care among urban adolescents with asthma	
Foster et al., 2012.	Identifying patient-specific beliefs and behaviours for conversations about adherence in asthma	
Miles, Sawyer and Kennedy, 1995.	A preliminary study of factors that influence children's sense of competence to manage their asthma	▪ Used the "Health Self-Determinism Index for Children" to measure intrinsic versus extrinsic motivation to achieve healthy functioning. ▪ There were no measures of behaviours or outcomes. ▪ Motivation for behaviour *maintenance* was not investigated. ▪ The adult version of the questionnaire the "Health Self-Determinism Index" is validated in the general adult population and used in health promotion but not in chronic illness contexts (Cox, 1985).
Kyngas, 1999.	Compliance of adolescents with asthma	▪ The questionnaire used to measure motivation was designed for use in adolescents with diabetes; and not validated in asthma patients. ▪ The questions used to measure motivation were not specified.

At this juncture, after considering the empirical evidence in relation to motivation in asthma, it became clear that direction for an in-depth qualitative investigation into patient motivation in inhaler technique maintenance could not be gained in a substantive way from existing studies. Therefore, as in the previous quantitative study, theoretical guidance was sought.

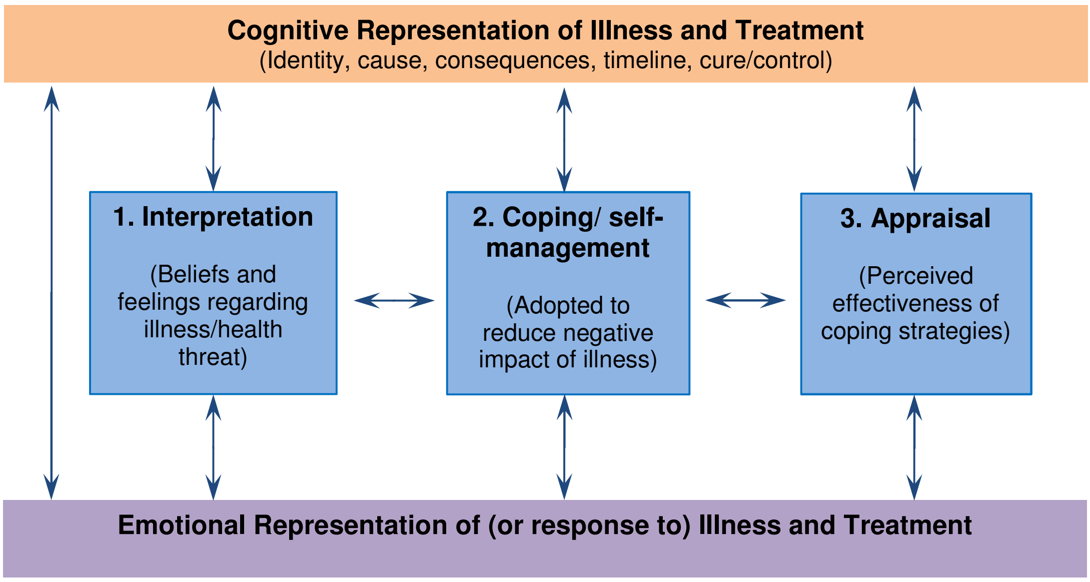
iii. Theoretical underpinning to guide an exploration of patient motivation in inhaler technique maintenance.

Many theories and models exist in the health psychology field that aim to understand and explain the motivations behind patient health behaviours and the process of behaviour change (e.g. the Health Belief Model, Health Promotion Model, Theory of Reasoned Action, Self-efficacy theory, Protection-Motivation Theory, Common Sense Model, Self Determination Theory) (Bandura, 1997, Carter and Kulbok, 2002, Fishbein and Ajzen, 1980, Glanz, Rimer and Viswanath, 2008, Janz and Becker, 1984, Leventhal, 2003, Orbell, 2007, Pender, 2010, Rogers, 1975, Williams, 2002). All such theories, depending on the purpose of their application, invariantly have strengths and weakness. However, the important strengths of a theory (or theories) chosen for the purposes of this study would include a theory/ies that: a) has been designed for and/or has been applied to study health behaviours in the chronic illness and asthma contexts (as opposed to a theory that focuses on preventative health care behaviours in healthy individuals, or health behaviours in individuals with acute illnesses); b) can be used to study the *maintenance* of self-management behaviours, rather than only the initial stages of behaviour change (i.e. ideally the theory specifies the motivational factors involved in behaviour *maintenance* as opposed to only behaviour change or initiation); and c) clearly defines the concept of motivation in relation to health behaviour mainteance Two theories were identified, that together, met these criteria and were selected to guide this study – Leventhal's Common Sense Model of Illness Regulation (CSM) (Leventhal et al., 2003) and Ryan and Deci's Self-Determination Theory (SDT) (Ryan and Deci, 2002).

1. The Common Sense Model of Illness Regulation (CSM)

The Common Sense Model of Illness Regulation (CSM) was introduced and discussed in the previous chapter and hence will only be revised briefly here. Figure 3.04 from the previous chapter is included below for reference; for an explanation of the individual components of the CSM in Figure 3.04, see Chapter 3, Background, section iii.

Figure 3.04 (from Chapter 3). The Common Sense Model of Illness Regulation adapted from the works of Leventhal, Horne and colleagues (Horne and Weinman, 2002, Leventhal et al., 2003).



a. Implications for patient motivation in inhaler technique maintenance

The previous use of the CSM (Chapter 3) focused on identifying potential factors predicting inhaler technique maintenance behaviour in a direct fashion. Here, the CSM is used to explore the potential factors influencing the *motivation behind* patients' technique maintenance behaviour. Although the CSM is not explicitly described as a theory of motivation, it has been applied extensively in chronic illness settings, including in asthma, to understand why patients adopt the self-management or coping behaviours that they do. The way in which the CSM functions to understand patients' self-management behaviours closely reflects the elements that define motivation (i.e. to understand "why people do the things that they do") (Russell, 2008). Further, the CSM is a model based on self-regulation (Chapter 3, section A, i), and notably, motivation is implicitly important in self-regulation (Bandura, 2005b).

To briefly revise, the CSM seeks to understand why patients engage (or do not engage) in various self-management behaviours in chronic conditions by examining how patients consciously interpret the nature of a health threat (Orbell, 2007). In asthma, patient beliefs and feelings relating to their condition (shown in Figure 3.04 as *cognitive* and *emotional representations* of *illness*) (Leventhal et al., 2003), as well as its treatment (shown in Figure 3.04 as *cognitive* and *emotional representations* of *treatment*), can influence the self-management behaviours that they adopt (Horne, 1999, Horne and Weinman, 2002). Further, patient evaluations regarding the effectiveness of their self-management behaviours, on reducing the perceived negative impact of their illness, can also influence their long term self-management behaviours (shown in Figure 3.04 as *appraisal*) (Leventhal et al., 2003).

The relevance of the CSM, in the context of patient motivation in inhaler technique maintenance, seems to be supported by correlations found in the previous quantitative study (Chapter 3). Previously, via logistic regression, patient motivation to maintain correct inhaler technique was found to be one of the three significant predictors of inhaler technique maintenance (out of 28 variables tested). Further, patient motivation to maintain correct inhaler technique, was found to be correlated to asthma treatment beliefs (specifically, the necessity of preventer medication and the benefits of practicing correct inhaler technique).

Based on both the theoretical principles of the CSM and the correlations found in Chapter 3, it is proposed that patient motivation in inhaler technique maintenance may be influenced by their perceptions of asthma, as well as perceptions of asthma treatment (this forms Hypotheses 1-3).

b. Limitations of the CSM for this study

Utilising the CSM was found to have several limitations in the context of this study. Firstly, the CSM does not lend itself to clearly articulating *specific types* of asthma and treatment beliefs and *how* they may be influencing patient motivation to self-manage, i.e. do certain asthma and treatment beliefs enhance or diminish patient motivation to self-manage?. Although certain patient treatment beliefs (i.e. necessity and concerns regarding inhaled corticosteroids) have consistently predicted medication adherence (Clifford et al., 2008, Horne and Weinman, 2002, Mardby et al., 2007, Menckeberg et al., 2008, Ponieman et al., 2009), much less is known about how treatment beliefs may be influencing other self-management behaviours, including inhaler technique maintenance.

Even less is known about how specific patient beliefs and feelings around the condition of asthma itself may be influencing self-management. For example, Horne and Weinman (2002) hypothesised that patients who more firmly believed that their asthma was a serious condition would be more likely to adopt better self-management in terms of adherence to inhaled corticosteroids. The study findings, however, showed that these beliefs around asthma both inhibited as well as facilitated adherence, with unknown reasons for this seemingly contradictory finding. The lack of specificity regarding the *types* of patient beliefs and feelings regarding asthma and asthma treatment, and *how* that may be influencing patient motivation in self-management is thus one of the limitations of the CSM in the context of this study.

Further limitations of the CSM include: not explicitly defining motivation and relating it to the constructs in the model (Figure 3.04), the absence of measures for motivation, and not distinguishing between the factors that may be relevant in predicting the *maintenance* as opposed to the initiation of self-management behaviours. Highlighting the predictors of behaviour *maintenance* is clearly important for this study investigating inhaler technique maintenance. This is especially pertinent given that previous research shows that the factors motivating a patient to initially adopt a specific behaviour can be different to those that motivate them to maintain the behaviour over the long term (Rothman, 2000, Rothman et al., 2004). Thus an additional theory was selected to complement the CSM in guiding this current study – Ryan and Deci's Self-Determination Theory (SDT).

2. Self-Determination Theory (SDT)

Self-Determination Theory is a well-established theory of human motivation. It is useful for this study because it defines and operationalises motivation, emphasises the motivational factors predictive of behaviour *maintenance*, and has been applied across various chronic illness contexts (Conner, 2008, Ryan and Deci, 2000b).

Fundamentally, SDT is concerned with various "motivational states", i.e. the *type* of motivation a person possesses, and how they may impact on a person's behaviour (Deci and Ryan, 2012). Notably, the *type* of motivation a person possesses is said to be a more important predictor of behavioural outcomes than the overall *amount* of motivation they possess (Deci and Ryan, 2012). Interestingly, a bias for a quantitative approach to investigating patient motivation can be seen in many of the studies summarised earlier in Table 4.01. In light of SDT, it is perhaps clearer why these studies, being predominantly quantitative in nature, offered limited insight (over and above what was gained in Chapter 3), to guide a more in-depth exploration of patient motivation.

According to SDT, exploring the *nature* of patient motivation in inhaler technique maintenance may provide additional and unique insight into the relationship between motivation and technique maintenance. In particular, the factors predicting why some patients have higher whereas others have lower motivation to maintain optimal inhaler technique may be identified.

Self-Determination Theory distinguishes between three broad types of motivation – amotivation, extrinsic motivation and intrinsic motivation. A state of amotivation is when there is a lack of intention to act so that a person does not act, or acts passively. This occurs when a person does not value the activity, does not feel competent to perform it, or does not expect it to result in a desired outcome (Ryan and Deci, 2000b). When a person becomes motivated to act, either intrinsic motivation or extrinsic motivation (in its various forms) is said to be at play (Ryan and Deci, 2000b). In a state of intrinsic motivation (also known as "autonomous motivation") a person engages in performing an activity or behaviour predominantly due to the internal sense of satisfaction that they derive from this. This "internal satisfaction" is experienced as interest and enjoyment, and it is this quality which drives people to maintain the performance of intrinsically motivated activities over time (e.g. play) (Deci and Ryan, 2012, Ryan and Deci, 2000a).

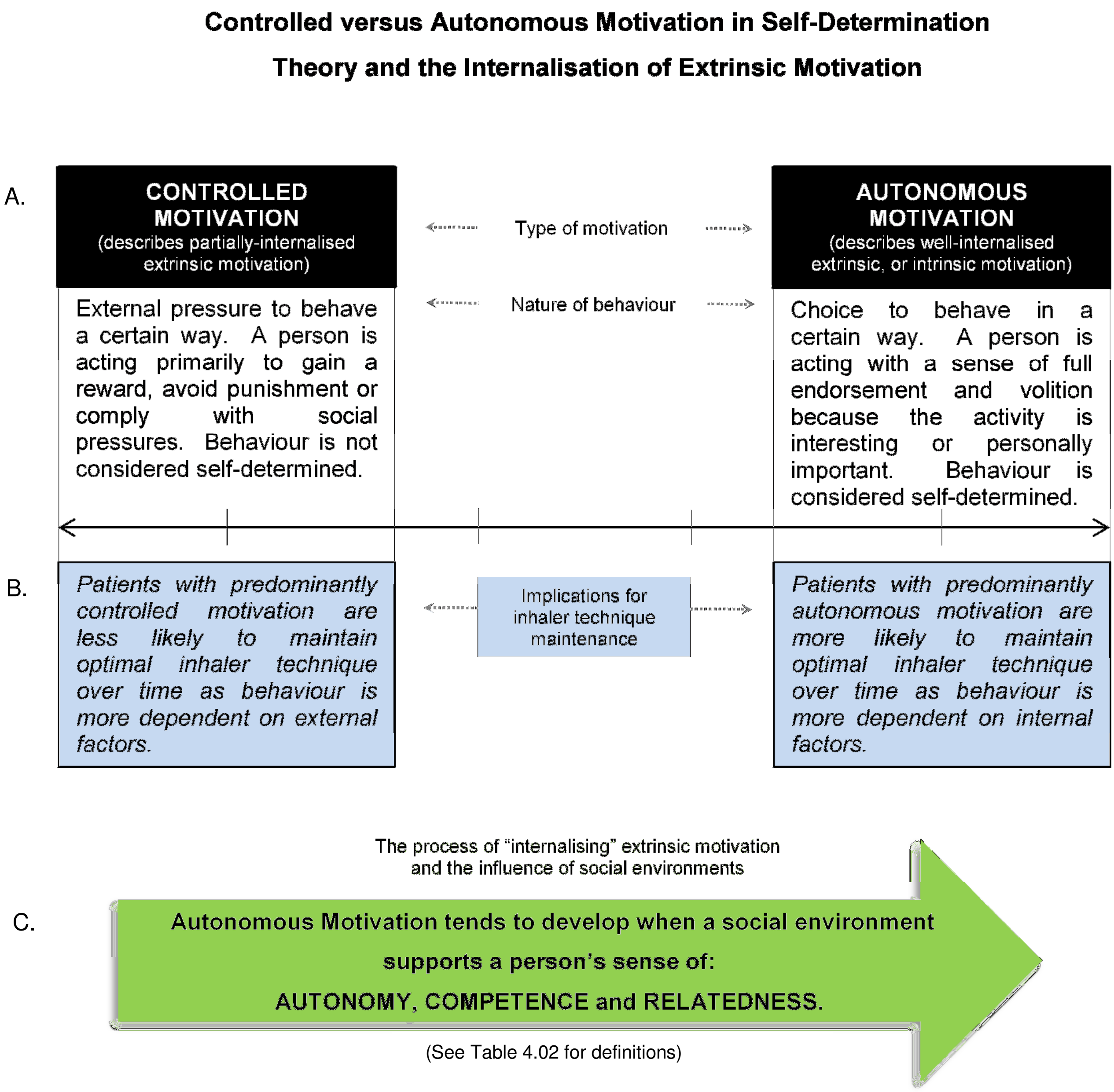
Extrinsic motivation, in contrast, governs those activities that people engage in, by and large, not out of an inherent sense of satisfaction tied to performing the activity, but to obtain some sort of separate outcome that is distinct from the actual activity itself (Deci and Ryan, 2012, Ryan and Deci, 2000a). The scenario of inhaler technique maintenance, therefore, more readily lends itself to be interpreted according to the principles around extrinsic motivation than intrinsic motivation. That is, for the patient, there is no inherent purpose to maintaining correct inhaler technique, in and of itself, without relating it to a separate result, e.g. to experience less asthma symptoms. Further, most health-related behaviours are not considered to be intrinsically motivated or inherently enjoyable (Ryan et al., 2008), and it is highly unlikely that patients will experience a sustaining sense of interest or enjoyment linked to the activity of performing inhaler technique in and of itself. That is, patients may enjoy the outcomes of maintaining correct inhaler technique, but not maintaining correct inhaler technique itself. Inhaler technique maintenance can thus be considered an activity predominantly driven by extrinsic motivation, and therefore the following sections will be framed around this construct.

a. Extrinsic motivation: controlled versus autonomous – implications for inhaler technique maintenance

Extrinsic motivation is not a unitary concept, rather it is regulated by various distinct contingencies resulting in either more "*controlled",* or more "*autonomous",* types of motivation (Deci and Ryan, 2012). Any action or behaviour can be viewed in terms of the degree to which it is driven by controlled versus autonomous motivation (Williams, 2002). This is represented in Figure 4.01. Notably, since the varying states of motivation lie on a continuum and are not dichotomous, they are represented by the black arrow with gradations. Since the type of extrinsic motivation may influence behavioural outcomes, the nature of patients' motivation during inhaler technique practice, whether predominantly controlled or autonomous, may have important implications for whether correct technique is maintained over time or not.

Figure 4.01: "Controlled" versus "Autonomous" motivation and the process of "Internalising" Extrinsic motivation in Self-Determination Theory (SDT).

A. *Explanation and characteristics of predominantly Controlled compared to predominantly Autonomous motivation in SDT.*
B. *Implications for inhaler technique maintenance.*
C. *The social environments that support the internalisation of extrinsic motivation so that it becomes more Autonomous in nature (Deci and Ryan, 2012, Ryan and Deci, 2002, Ryan and Deci, 2000b, Ryan et al., 2008).*



Controlled motivation has been described as motivation that is contingent on external "carrots and sticks" (Deci and Ryan, 2012), so that a person is acting primarily to gain a reward, avoid punishment or to comply with social pressures (Ryan et al., 2008). People who perform an activity primarily driven by controlled motivation are considered not to have fully understood, accepted or "internalised" (Ryan and Deci, 2000a) the personal importance of the activity. Actions or behaviours arising from controlled motivation are not considered to be "self-determined" and *tend not to be maintained* when the external "carrots and sticks" are not in function (Deci and Ryan, 2012).

Autonomous motivation, on the other end of the spectrum, drives those actions and behaviours that a person performs out of their own choice and full endorsement because the behaviour has been identified as personally important to them (Deci and Ryan, 2012, Williams, 2002). The quality of a person's motivation can shift from one that is predominantly controlled to one that is more autonomous via a process called "internalisation", represented by the green arrow in Figure 4.01 (note this process is only relevant in extrinsic motivation; intrinsic motivation is always considered to be autonomous in nature and "fully internalised") (Ryan et al., 2008). The process of internalisation describes the extent to which a person comes to embrace the importance or value of, and regulation over, a certain action or behaviour (Ryan and Deci, 2000a). The greater the extent to which the process of internalisation occurs, the more a person is said to have "inwardly grasped the meaning and worth" (Ryan and Deci, 2000a) of an activity, and the more autonomous in nature this person's motivation will be for that activity (Ryan and Deci, 2000b).

Importantly, behaviours arising predominantly from autonomous motivation are considered to be "self-determined" and are better maintained (Deci and Ryan, 2012). This has been shown across various health care contexts, where people with chronic conditions or health issues, who possessed greater degrees of autonomous motivation to enact various health behaviours, were more successful at improving and maintaining these behaviours over time. Examples of improved health behaviour maintenance (and improved health outcomes) associated with greater autonomous motivation include: better adherence to medication (Williams, Rodin, Ryan, Grolnick and Deci, 1998b), better glucose control in diabetes (Williams, Freedman, and Deci, 1998a), better rates of smoking cessation (Williams, Gagne, Ryan, and Deci, 2002), greater attendance at addiction programs (Ryan, Plant and O'Malley, 1995), and maintained weight loss (Williams, Grow, Freedman, Ryan and Deci, 1996).

Based on this evidence and the principles of SDT, it is proposed that patients with a greater degree of autonomous motivation to practice correct inhaler technique are more likely to maintain this practice over time (indicated in Figure 4.01, part B). Further, according to SDT, such a patient may be characterised as someone who has personally grasped the importance of practicing correct inhaler technique and one who takes ownership over this practice. In contrast, correct inhaler technique maintenance is less likely to be demonstrated by those patients whose inhaler technique practice is driven largely by controlled motivation, that is, those patients who less resolutely identify practicing optimal inhaler technique as a personally important activity (Hypothesis 4).

b. Health care professionals' influence on patient motivation – implications for inhaler technique maintenance.

The extent to which motivation for any activity is autonomous, is influenced by both innate personal factors (e.g. personality) and the social environments that people interact within (e.g. relationships with health care providers) (Deci and Ryan, 2012). Investigating innate personal traits is beyond the scope of this thesis, and further, may do little to improve health care initiatives around optimising inhaler technique maintenance since these personal factors may not be easily modifiable. Social contexts, however, may be of greater relevance due to their implications for the patient-health care provider relationship and how they may be structured to help patients "internalise" motivation for inhaler technique maintenance and therefore be more likely to maintain correct inhaler technique.

The social contexts that a person exists and interacts within, can either enhance or inhibit their development of autonomous motivation for various activities, depending on the degree to which it supports their sense of *"autonomy", "competence" and "relatedness"* (Figure 4.01, part C). Autonomy, competence and relatedness are constructs which form another key component of SDT. They are what Deci and Ryan propose, based on empirical research, to be the "basic psychological needs" of a person (Deci and Ryan, 2012). (Note, the concept of "autonomy" in SDT is complex and can refer to both a "motivational state", as it has been discussed up until now, as well as a "basic psychological need", as is discussed here).

Table 4.02 explains each of these three basic psychological needs, in the patient self-management context, and stipulates how health care professionals can structure their interactions with patients to support these needs in order to enhance patients' autonomous motivation to self-manage (Ryan et al., 2008). Numerous studies indicate that the more autonomy supportive patients perceive their health care providers to be, the better they maintain recommended health behaviours (Münster Halvari, Halvari, Bjørnebekk and Deci, 2010, Williams et al., 1996, Williams et al., 2006, Williams, McGregor, Zeldman, Freedman and Deci, 2004).

Table 4.02: "Autonomy", "Competence" and "Relatedness" in the context of patient self-management, and how they can be facilitated by health care professionals.

Basic psychological need:	Explanation in the context of patient self-management behaviour:	How health care professionals can support patients' Autonomy, Competence and Relatedness to enhance autonomous motivation:
AUTONOMY	A patient experiences a sense of autonomy, when performing self-management behaviours, to the degree that the self-management behaviour is perceived to arise from their own free will and choice. A high degree of autonomy is indicated by a patient who personally values and takes responsibility/ownership over self-management. (Autonomy does not, however, refer to acting independently without support from others) (Williams, 2002, Ryan and Deci, 2002).	▪ Provide relevant information and meaningful rationales for behaviour change. ▪ Offer the patient opportunities to choose. ▪ Minimise the use of pressure and control that detract from patients' sense of choice (e.g. trying to motivate by leveraging position of authority, conveying conditional approval depending on patient's actions). ▪ Encourage patients to accept more responsibility for their self-management behaviours. ▪ Interact meaningfully with the patient (e.g. suspending judgement, listening, encouraging questions) and acknowledge their views so patients feel understood. ▪ Support patients when they encounter resistances and barriers to change and help patients identify compatible self-management options (Deci and Ryan, 2012, Ryan et al., 2008, Williams et al.,1998b, Williams, 2002). (Note, through supporting a patient's sense of autonomy, health care professionals can also enhance a patient's sense of competence and relatedness) (Halvari and Halvari, 2006, Ryan et al., 2008, Williams et al., 2009).
COMPETENCE	Competence refers to the degree to which a patient feels that they have the technical skill and confidence to achieve desired outcomes or goals (Williams, 2002). It is a patient's "felt sense of confidence" (Ryan and Deci, 2002) and "efficaciousness" (Ryan and Deci, 2000b) to self-manage. It is closely related the construct of "perceived self-efficacy" – the belief in one's ability to succeed at performing a certain activity, as defined by Bandura (Bandura, 1997). Note: Competence alone is not	▪ Support patients' sense of autonomy as described above. ▪ Provide patients with the skills and tools required to enact self-management (e.g. provision of gold-standard inhaler technique education via physical demonstration). ▪ Provide informational feedback (or meaningful feedback in a genuine and positive manner) to help patients master self-management (Deci and Ryan, 2012). ▪ Provide information in a measured way so that the patient is not overwhelmed and has the

	enough for the maintenance of self-management; it must be accompanied by a sense of autonomy (Ryan et al., 2008).	opportunity to experience mastery relating to their self-management (Ryan et al., 2008).
RELATEDNESS	Relatedness refers to the extent to which a patient feels connected to others – notably their health care providers in the self-management context – in a warm, positive and interpersonal manner (Williams, 2002). Where there is a high level of relatedness in the patient-health care provider relationship, patients will feel respected, understood and cared for in the process of health care delivery (Ryan et al., 2008).	▪ Support patients' sense of autonomy as described above. ▪ Spend time with the patient to understand their feelings and perspectives. ▪ Express care (e.g. through empathy and good communication and interpersonal skills). ▪ Establish trust and rapport with the patient (Deci and Ryan, 2012).

Based on these principles of SDT, it is proposed that patients, who during the course of their asthma treatment, maintain relationships with health care professionals who enhance rather than diminish their sense of "autonomy", "competence" and "relatedness", are more likely to maintain correct inhaler technique. In these types of therapeutic relationships, patients are likely to experience a greater sense of satisfaction, trust and rapport with their health care providers (Hypotheses 5 and 6).

iv. A qualitative, theoretically underpinned study.

Despite the limited empirical evidence which could be drawn upon for the development of this study, a firm theoretical basis has now been established to inform and support this investigation of patient motivation in inhaler technique maintenance. In examining and applying the principles of the CSM and SDT, it appears that patient motivation in inhaler technique maintenance may be more complex than shown in the previous quantitative study (Chapter 3). The advantage of taking a qualitative approach in this study is its amenability to uncovering richer levels of data (Miles and Huberman, 1994). Thus the nuances of patient motivation in inhaler technique maintenance may be better examined in this study to build upon the findings of the previous quantitative study. Ultimately, this study may contribute to a greater understanding of why some patients are more, whereas others are less, likely to maintain optimal inhaler technique, as well as strategies for improving inhaler technique maintenance.

B. Aim and hypotheses

The aim of this qualitative exploratory study is to gain a deeper understanding of the relationship between patient motivation and inhaler technique maintenance, identified in the previous quantitative study. Specifically, this study aims to understand the factors influencing why some patients had relatively higher, while others had relatively lower, motivation to maintain correct inhaler technique

Factors hypothesised to influence (i.e. enhance or diminish) patient motivation in inhaler technique maintenance are:

1. Patient beliefs and feelings regarding asthma (to explore *cognitive and emotional illness representations* – CSM).
2. Patient beliefs and feelings regarding asthma preventer therapy (to explore *treatment representations* – CSM).
3. Patient beliefs about the benefits of correct inhaler technique maintenance (to explore *appraisal* – CSM).
4. Patients' perceived importance of, and ownership over, correct inhaler technique maintenance (to explore *autonomy* – SDT).
5. Patients' perceived confidence regarding correct inhaler technique maintenance (to explore *competence* – SDT).
6. Patients' perceived satisfaction, trust and rapport with their asthma health care providers (to explore *relatedness* – SDT).

C. Methods

i. Overview

The following study was qualitative and exploratory in nature involving semi-structured interviews with community based asthma patients. Semi-structured interviews were conducted because they are conducive to in-depth examinations of topics (Minichiello, Aroni, Timewell and Alexander, 1995), and hence apt in this study aiming at a more detailed investigation of patient motivation in inhaler technique maintenance. In a broader sense, the qualitative method itself has the capacity to “supplement, validate, explain, illuminate, or re-interpret quantitative data gathered from the same setting” (Miles and Huberman, 1994), thus again, fitting for the purposes of this study. Qualitative data is also richer, more holistic, and focuses on people’s “lived experiences” in natural social settings. (Miles and Huberman, 1994, Pope and Mays, 1995). This makes it a useful method for understanding the personal “meanings” (Miles and Huberman, 1994) that people create about their experiences, which in this study, relate to patient experiences around asthma, self-management and inhaler device therapy.

The Sydney University Human Research Ethics Committee approved this study prior to commencement (Appendix 4.03: Qualitative study ethics approval).

ii. Recruitment and patient sample

The patients who participated in this study were selected from amongst those who had previously completed the quantitative study (Chapter 3). Recruitment occurred between March and November 2011 via written and telephone invitation. Initially, a letter of invitation was mailed out to each patient who had completed the quantitative study (N = 127). The letter explained the reason for this follow-up study, the requirements (i.e. sharing personal views and experiences about one's asthma), and informed patients that they may receive a telephone call in the near future inviting them to participate in this study (Appendix 4.01: Letter of invitation for interview).

Subsequently, telephone recruitment occurred, during which patients were purposively selected (Mays and Pope, 1995) before being contacted. The selection rationale was to achieve representation from those patients who, in the previous quantitative study, expressed *higher* as well as *lower* levels of motivation for practicing correct inhaler technique (i.e., both "Maintainers" and "Non-maintainers" were selected; these terms will be further explained in section iv, Data analysis). Further, selection occurred so that there would be representation from both males and females, patients at various ages, patients with various levels of asthma control and patients using different types of inhaler devices. Through maximising the variation in the patients recruited, the sampling aimed to increase the range in patient responses achieved (Kitto, Chesters and Grbich, 2008, Mays and Pope, 1995), and therefore allow for a more holistic understanding of the relationship between inhaler technique maintenance and patient motivation.

iii. Patient Interviews

1. The semi-structured interview guide

A semi-structured interview guide was developed with questions that delved into the factors hypothesised (based on the CSM and SDT) to influence patient motivation in inhaler technique maintenance. That is, questions centred on patient experiences, perceptions and feelings relating to inhaler technique and device use, as well as broader issues regarding asthma and self-management were asked.

The interview guide evolved throughout the study as questions were reviewed and refined after each interview to improve their clarity and effectiveness in eliciting rich and candid responses from patients (Appendix 4.02: Interview guide, version 8/final). The factors hypothesised to influence patient motivation in inhaler technique maintenance were explored during the interviews. The typical questions asked around each factor are detailed in Table 4.03.

Table 4.03: Factors, explored during interviews, hypothesised to influence patient motivation in inhaler technique maintenance, with the typical questions asked.

Factors explored during interviews (theoretical basis)	**Typical interview questions**
Beliefs and feelings around the condition of asthma (Hypothesis 1: *cognitive and emotional illness representations* – CSM). (Leventhal et al., 2003)	*"Could you tell me about your experience of asthma?" (probe into beliefs about identity, cause, cure, duration consequences); "How did that make you feel?"*
Beliefs and feelings around preventer therapy (Hypothesis 2: *treatment representations* – CSM) (Horne and Weinman, 2002)	*"Tell me about the medication you are taking for your asthma"; "How necessary is it for you to have the (preventer) in your life?"; "Is there anything that concerns you about using your (preventer)?"*
Beliefs about the benefits of correct inhaler technique maintenance (Hypothesis 3: *appraisal* – CSM) (Leventhal et al., 2003)	*"Do you think the way you use your inhaler makes a difference to your asthma? – How so?"*
Perceived importance of, and ownership over, maintaining correct inhaler technique. (Hypothesis 4: *autonomy* – SDT) (Deci and Ryan, 2012)	*"What's the most important thing that you need to do when taking your (preventer) – why?"; "Who do you think is responsible for ensuring your inhaler technique is as good as it can be?"*
Perceived confidence regarding performing and maintaining correct inhaler technique. (Hypothesis 5: *competence* – SDT) **Note, all interviewed patients received gold-standard inhaler technique education in the previous study (Chapter 3) to equip them with the skills that enable a sense of competence as stipulated by SDT* (Deci and Ryan, 2012).	*"How confident or capable do you feel about sticking to all of the steps every time you use your (preventer)?"*

Perceived satisfaction, trust and rapport with health care providers (Hypothesis 6: *relatedness* – SDT) (Deci and Ryan, 2012).	*"What is your (doctor, pharmacist etc.) like when it comes to your asthma?"; "How helpful or supportive do you find them?"*

2. Conducting interviews

In-depth telephone interviews were conducted with patients who consented to participate in this study. Interviews were conducted until saturation of themes, that is, until no further variation was found in how patients responded in terms of their experiences, perceptions and feelings relating to inhaler technique and device use, asthma and self-management.

a. Telephone interviewing method

Telephone, as opposed to face-to-face, interviewing was chosen due to its benefits in terms of being more flexible, being more time effective and reducing study costs. Further, this method has been used extensively in academic research (Gillham, 2000). However, the challenges in sustaining a conversation during a telephone interview due to the loss of non-verbal communication (e.g. eye contact and body language), and the potential resistance from interviewees receiving unsolicited or poorly timed calls were anticipated (Gillham, 2000). Several measures were taken to mitigate these potential drawbacks of the telephone interviewing method:

- To reduce the potential for resistance amongst patients, "cold-calling" was avoided. That is, each patient was sent a letter of invitation (as explained earlier) at least a week prior to being contacted over the telephone by the researcher.

- Patients were contacted for the interview at a time that was suitable for them. In a few cases, interruptions occurred in the patient's setting during the interview that may have affected engagement. In these situations, permission was obtained to pause the interview, and for the researcher to re-contact the patient at a better time to re-commence the interview.

- Special attention to verbal communication, including the use of appropriate tones of voice throughout the interview, using verbal signs to indicate listening (e.g. "uh-huh"), and being attentive to the appropriateness of interrupting or re-directing the conversation.

- To maintain focus, the telephone calls were made in a closed room free of interruptions and all relevant documents were at hand during the interview process (i.e. the interview guide and patient files from the quantitative study).

b. Line of questioning

Interviews commenced with a general line of inquiry, i.e., *"Please tell me about your asthma…",* before more specific aspects relating to inhaler device use and technique were delved into. This "funnelling approach" (Minichiello et al., 1995) encourages patients to think about issues in broader terms at first and is proposed to create a more relaxed atmosphere (Minichiello et al., 1995). That is, patients may feel like they are being "tested" if the interview commenced with narrower questions which may appear to be evaluative and judgemental in nature (e.g*. "How capable do you think you are at managing your asthma?"),* potentially reducing the likelihood of patients being relaxed and forth-coming during the rest of the interview. Once the interview commenced with patients reflecting broadly on their asthma, the order of the subsequent questions tended to be guided by the issues that patients brought up. The rationale for this was to pay attention those areas that were personally important to the patient, and to encourage patients to be elaborative by facilitating a more free-flowing conversation.

iv. Data analysis

All interviews were audio recorded and transcribed verbatim. Immediately after each interview, notes were taken of first impressions, reflections, and salient points regarding the conversation, thereby commencing the preliminary stages of data analysis (notably, this qualitative data analysis was a much more iterative, and less demarcated and linear process, compared to the previous quantitative data analysis) (Creswell, 2003, Minichiello et al., 1995). Subsequently content analysis was conducted.

1. Content Analysis based on the Framework Approach

The Framework approach (Ritchie and Spencer, 1994) is a method of content analysis. Several distinct features allow it to be particularly suitable for application in the health care setting (Pope, Ziebland and Mays, 2000). Developed by the National Centre for Social Research (Dixon-Woods, 2011), Framework analysis was designed to generate, based on the findings of qualitative data analysis, practice-orientated strategies to research questions (Green and Thorogood, 2004). Themes can be generated via deductive (i.e. informed by theory) as well as inductive (i.e. informed by data) means (Ritchie and Spencer, 1994), compatible with the evolution and design of this study.

The activities undertaken during data analysis are presented in Table 4.04 and are categorised into five main stages, based on those stipulated by the Framework approach (Ritchie and Spencer, 1994). Notably, the themes of this study constituted of the range of patient responses regarding their experiences, perceptions and feelings relating to inhaler technique, device use, asthma, and self-management. That is, factors that have the potential to provide insight into patient motivation in inhaler technique maintenance (as outlined in the Background).

Beyond descriptive theme identification, the Framework approach endorses a more sophisticated qualitative data analysis, requiring investigation into more complex theme connections (Creswell, 2003). This is stipulated in the final stage of analysis, "Interpretation and mapping", which is a key distinction of Framework analysis. This stage, in addition to stage 4, "Charting", was instrumental in addressing the aim of this study to understand the factors influencing why some patients had relatively higher, while others had relatively lower, motivation to maintain correct inhaler technique.

Further, the terms **"Maintainers"** and **"Non-maintainers"** should be noted as they are used throughout this study for the purposes of addressing the aim stated above. These terms are based on the results of the previous quantitative study and are used here to indicate the relative level of patient motivation for inhaler technique maintenance.

In the previous study (Chapter 3), patient motivation was found, via logistic regression, to be one of 3 significant predictors of inhaler technique maintenance (out of a total of 28 variable tested). Specifically, those patients who maintained correct inhaler technique (at visit 2, one month later) scored relatively higher on the motivation variable. Whereas patients who did not maintain correct inhaler technique (at visit 2, one month later) scored relatively lower on the motivation variable.

Therefore in this qualitative study, each patient interviewed was considered as either a:

> **Maintainer:** a patient who tended to possess a ***higher level of motivation*** to practice and maintain correct inhaler technique and who demonstrated correct inhaler technique maintenance (in the quantitative study, Chapter 3).

OR,

Non-maintainer: a patient who tended to possess a ***lower level of motivation*** to practice and maintain correct inhaler technique and who did not demonstrate correct inhaler technique maintenance (in the quantitative study, Chapter 3).

A key task during data analysis was to compare and contrast the interview responses of Maintainers and Non-maintainers. This was in order to determine whether certain factors (i.e. patient experiences, perceptions or feelings) had the tendency to enhance and/or diminish motivation in inhaler technique maintenance. The steps involved in this analysis are detailed in Stages 4 and 5 in Table 4.04.

Table 4.04: The data analysis conducted in this study as guided by the five stages of the Framework approach (Ritchie and Spencer, 1994).

Stage of analysis	Analysis activities
1. Familiarisation	▪ Familiarisation with the data was achieved through immersing in it. The researcher re-played and listened to audio recordings, read and re-read transcripts, flagged emergent themes and noted preliminary reflections on the data.
2. Identifying a thematic framework	▪ A set of themes were identified, based on the 3 initial interviews conducted, and formed the initial thematic framework used for coding data. ▪ The thematic framework was revised throughout the study, as necessary, as new themes emerged from subsequent interviews. ▪ The thematic framework aimed to be comprehensive and account for all of the variation in patient responses on the core topics discussed (note, a comprehensive rather than parsimonious approach was taken given that there is little is known about patient motivation in inhaler technique maintenance; and further because motivation is a complex, multidimensional phenomenon that can be influenced by a combination of patient experiential, cognitive, and affective factors).
3. Coding or indexing	▪ All transcribed interview data were systematically coded using the thematic framework developed. ▪ Nvivo 9 (QSR International Pty Ltd) software was used to aid data management and organisation.
4. Charting	▪ The themes identified in this study were summarised and displayed in a structured way to enable the responses from Maintainers and Non-maintainers to be readily and visually comparable.
5. Interpretation and mapping	▪ The relationships between various themes were mapped out. This allowed for a deeper interpretation of study findings via examining the inter-connectedness of themes in relation to patients' inhaler technique maintenance status. ▪ At this level of analysis it was possible to determine some of the characteristics of Maintainers and Non-maintainers based on the patterns of their responses.

2. Validation of Themes

To enhance the interpretive vigour in the process of theme identification in this study, a sample of transcripts (n = 3) were independently read and coded for themes by three researchers (LO, SBA, LS) (Kitto et al., 2008). Extensive discussion between the three researchers occurred before a consensus was reached on the final thematic framework.

In addition, various other measures were taken to ensure that the study was conducted in a robust manner (Creswell, 2003, Kitto et al., 2008, Mays and Pope, 1995). They included:

- Documenting the data collection and analysis process through keeping a written log book and organising and storing data on computer software (NVivo). This readily retrievable documentation allows for other researchers to trace and scrutinise the data analysis conducted.
- Summarising key statements back to patients at various points throughout the interview process to ensure accurate interpretation of patient responses.
- Supporting the reported findings with an extensive range of patient quotes.
- Triangulating the findings of this study with the results of the previous quantitative study and established theories (CSM and SDT).

D. Results

The bulk of the study findings in this results section are conveyed in the form of a narrative passage (Creswell, 2003) featuring discussions of the core themes identified and their interconnectedness with each other, as well as with the other emergent themes. This narrative passage is supported by verbatim quotes from patients, as well as various figures and models illustrating the relationships between themes. Some preliminary results regarding the recruitment process and the patient sample, however, will be presented first.

i. Recruitment and patient sample

Twenty patients, from a pool of 127 who completed the previous quantitative study (Chapter 3), were interviewed between April and November 2011, with Figure 4.02 showing the recruitment process. As illustrated, one patient contacted the researcher to be interviewed in response to the letter of invitation mailed out. Subsequently, the researcher telephoned 45 patients and invited them to participate in this study, of whom 22 answered the telephone and 20 agreed to be interviewed. The reasons why the two patients declined to be interviewed were time constraints and discontinuation of preventer therapy.

Table 4.05 summarises the demographic and clinical backgrounds of the patients interviewed in this study (obtained from the baseline data collected in the quantitative study, Chapter 3), as well as the duration of the interviews.

Table 4.05 shows that representation from both Maintainers (n=9 patients with higher motivation to maintain correct technique) and Non-maintainers (n=11 patients with lower motivation to maintain correct technique) was achieved.

Figure 4.02: Patient recruitment into this study between March and November 2011.

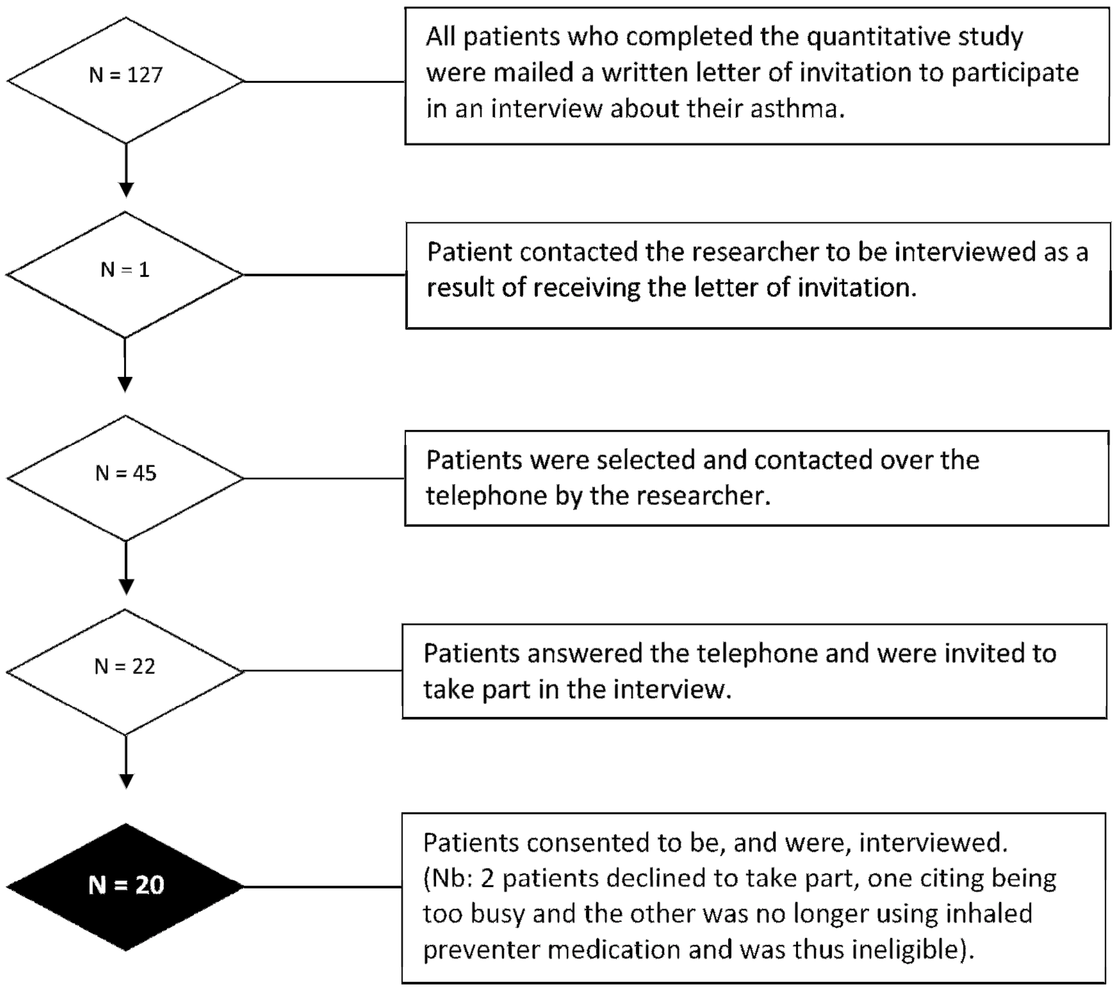


Table 4.05: Patient demographic and clinical characteristics

Note:

- *Patients are identified numerically (indicating the order the interviews occurred in) and by their initials.*
- *Abbreviations: ACC (Accuhaler™), TH (Turbuhaler™), pMDI (pressurised Metered Dose Inhaler), DPI (Dry Powder Inhaler).*
- *Rows for Non-maintainers (patients with lower motivation to maintain correct technique) are shaded.*

Patient identifi-cation	Interview Duration	Age (years)	Gender: Female (F), Male (M).	Asthma Duration (years)	Preventer Inhaler Used for Asthma	Reliever Inhaler Used for Asthma	Other Inhalers Used	Maintainer (M) or Non-maintainer (NM)
1:PS	47min	77	F	20	ACC (Seretide 250/50 1bd)	pMDI (Ventolin)	No	M
2:JH	65min	62	M	2	pMDI (Qvar 100 2bd)	pMDI (Ventolin)	No	NM
3:RL	48min	72	M	30	TH (Seretide 500/50 2bd)	pMDI (Ventolin)	DPI (Spiriva Handihaler)	M
4:DR	62min	76	M	70	TH (Symbicort 200/6 2bd)	pMDI (Asmol)	No	M
5:LJ	106min	54	M	33	pMDI (Flixotide250 4bd)	pMDI (Ventolin, Oxis, Atrovent)	No	NM
6:LN	47min	69	F	20	ACC (Seretide 250/20 1bd)	pMDI (Ventolin)	No	M
7:GW	62min	44	M	35	pMDI (Seretide 250/25 1bd)	pMDI (Ventolin)	No	NM
8:RH	49min	63	M	40	ACC (Seretide250/50 1bd)	pMDI (Ventolin)	No	M
9:BB	30min	74	M	74	ACC (Seretide 250/50 1bd)	pMDI (Ventolin)	DPI (Spiriva Handihaler)	M

10:DD	60min	62	F	20	TH (Symbicort 400/12 2bd –tds)	pMDI (Asmol)	No	M
11:SM	67min	62	F	15	pMDI (Seretide 250/25 1-2bd)	pMDI (Ventolin)	No	M
12:KK	53min	70	F	65	pMDIs (Seretide250/25 2bd and Tilade)	pMDI (Ventolin)	DPI (Spiriva Handihaler)	M
13:CH	72min	69	F	50	pMDI (Seretide 250/50)	pMDI (Ventolin)	No	NM
14:MC	119min	63	F	10	pMDI (Seretide 250/25 1bd)	pMDI (Ventolin)	No	NM
15:LF	45min	65	F	45	ACC (Flixotide 250 1d)	pMDI (Ventolin)	No	NM
16:VT	25min	49	M	34	pMDI (Seretide 250/25 2bd)	pMDI (Ventolin)	No	NM
17:JC	53min	24	F	18	ACC (Seretide 500/50 2bd)	pMDI (Ventolin)	No	NM
18:FE	67min	67	F	20	TH (Symbicort 200/6 2bd)	pMDI (Ventolin)	No	NM
19:PF	47min	76	F	30	pMDI (Seretide 250/25 1bd)	pMDI (Ventolin)	DPI (Spiriva Handihaler)	NM
20:PL	72min	72	F	20	TH (Symbicort 200/6 1n)	pMDI (Ventolin)	No	NM

ii. Patient interviews and emergent themes

The interviews generated a substantial volume of data regarding patient psychosocial factors that were potentially influential on patient motivation to maintain correct inhaler technique. That is, patient experiences, perceptions and feelings in relation to inhaler technique and device use, asthma, health and quality of life, asthma self-management, and social and therapeutic relationships. The range of patient responses across these topic areas formed the individual themes identified in this study and is summarised in Appendix 4.04 (Qualitative study themes and how Maintainers and Non-maintainers responded). It is not, however, within the scope of this thesis to report on all of the themes at length. Therefore the most relevant themes in addressing the aim and hypotheses of this study were selected and reported here.

The themes that will be focused upon in this results section can be grouped under three domains as listed below.

1. Inhaler technique and device use related themes (emerging from questions based on hypotheses 3-5):

   a. Ease of device use

   b. Confidence for correct inhaler technique

   c. Ownership over correct inhaler technique

   d. Importance of correct inhaler technique

   e. Inhaler use as an "unconscious habit"

2. Asthma and self-management related themes (emerging from questions based on hypotheses 1 and 2):

   a. Motivation to actively engage in asthma management *b. Motivation for a preventative-medication based asthma self-management approach*

c. Confidence in one's ability to effectively self-manage

3. Themes on therapeutic relationships (emerging from questions based on hypotheses 6):

a. Satisfaction, trust and rapport with health care providers

b. Receptiveness to health care provider influence

The themes that provided the most insight regarding the characteristics of Maintainers compared to Non-maintainers were found to be those in the second and third domains. These themes will be explained in detail in the subsequent sections. The themes in the first domain, contrary to what was hypothesised, were much less insightful. The themes in the first domain will also be briefly reported upon, for the purposes of illustrating why they were less powerful in characterising Maintainers and Non-maintainers, compared to the themes in the second and third domains.

The patient quotes reported are referenced with the patient's interview order, initials and inhaler technique maintenance/motivation status (where M indicates Maintainer, and NM indicates Non-maintainer). For example, (3:RL, M), means that the third interviewee was patient RL (initials), who was a Maintainer (patient with higher motivation to maintain correct technique).

"It's not bloody rocket science"

✦✦✦

1. Inhaler technique and device use related themes

Patient responses in the inhaler technique and device use domain emerged from questions based on hypotheses 3-5. It was observed that patients did not voluntarily speak about matters relating to inhaler technique or device use. Patients were specifically questioned about inhaler device use in order to illicit responses in this area. On the whole, patient responses in this domain were very similar in nature, they also lacked emotion Themes on inhaler technique and device use hence did not seem to offer clear insight into the distinguishing characteristics of Maintainers (patients with higher motivation to maintain correct technique) and Non-maintainers (patients with lower motivation to maintain correct technique), as will be explained further.

a. Ease of device use (theme)

Patients in this study used four distinct types of inhaler devices: the pressurised Metered Dose Inhaler (pMDI), Turbuhaler™, Accuhaler™ and the Handihaler™ (a Dry Powder Inhaler used by a handful of patients with co-morbid COPD). Asthma preventer therapy was delivered via a pMDI, Turbuhaler™ or Accuhaler™, whereas asthma reliever therapy was always delivered via pMDIs for patients in this study (as shown in Table 4.05). Regardless of the device/s in question, the vast majority of patients perceived inhaler device use a *"simple" (7:GW, NM)* and *"effortless" (1:PS, M)* task. This perception persisted whether patients were using only one type, or multiple different types of inhaler devices, and further, DPIs (i.e. the Turbuhaler™, Accuhaler™ Handihaler™) and pMDIs were both considered equally easy to use as illustrated in this excerpt:

" … I don't find any problem with it at all… I think they're easy to use, simple enough, like you wouldn't have to be a brain surgeon to use them would you? They're pretty basic things to use, you know they're not hard or anything, I don't understand why they (other asthma patients) can't (maintain correct technique) because like I said it's not, it's not bloody rocket science to use them… although they (the pMDI, Turbuhaler™ and Handihaler™) are three sort of various things to use I can't see where there's any hassle, in like using them the way they're suppose… the way they ought to be used" (3:RL, M)

Finding challenge or difficulty with performing inhaler technique was reported only by a few patients in relation to pMDI use, notably all of whom were Non-maintainers (patients with lower motivation for correct technique maintenance), for example:

"I think a lot of us aren't really very good at doing it… it's a tricky thing to do, you know… I think it's tricky. It looks easy and sounds easy but when you actually do it, it's trickier than you think to try and not let that escape, that propellant" (14:MC, NM)

b. Confidence for correct inhaler technique (theme)

Relatively high levels of confidence in one's ability to practice and maintain correct inhaler technique were found amongst the vast majority of patients (perhaps not surprisingly given their perceptions on ease of device use reported above). Patient responses on self-confidence around inhaler technique were direct and unequivocal, as in these examples:

"I'm very confident" (5:LJ, NM)

"Oh very capable of that" (1:PS, M)

"I was doing it properly anyway before the chemist came along" (11:SM, M)

Further, no patient responses suggested a lack of confidence in device use and inhaler technique.

c. Ownership over correct inhaler technique (theme)

The willingness to take ownership for practicing correct inhaler technique when using inhaler therapy was indicated by approximately half of the patients. These patients indicated the responsibility for correct inhaler technique maintenance should be attributed to oneself, or oneself with the support of health care professionals. The large majority of these patients were Maintainers (patients with higher motivation to maintain correct technique):

> *"No, I think it's up to me. I mean they (health care professionals) can tell me what to do but if I'm not going to do it, then I'm not taking the responsibility for it, am I?" (12:KK, M)*
>
> *"Me. People can tell you and give you all sorts of instructions, but unless you abide by them… you know it falls with you" (9:BB, M)*
>
> *"Me…they've (health care professionals) sort of like advised me what to use so, then I think it's up to me to use those…" (3:RL, M)*

In cases where there seemed to be less ownership over practicing correct inhaler technique, the responsibility was to a large degree externalised and relegated mostly to health care professionals. Incidentally, in all of these cases, the patients were Non-maintainers (patients with lower motivation to maintain correct technique):

> *Interviewer: Who do you think is responsible for making sure that you can use your inhalers properly, the right way, with the right technique?*
> *"Okay, well bodies like yourself, like I mean the people who are doing these studies… they're (pharmacists) responsible too… I thought it was part of their job to make sure that you get it right"*
> *Interviewer: Yes, and what about your role as the patient with asthma?*
> *"Well they have to be made aware, because you can't be aware unless you're taught to a point… and then people forget and they become more aware if they're contacted again the next year." (5:LJ, NM)*
>
> *"Well, I'd say that's probably going to be your pharmacist more than anything. Because they're selling you the product."(7:GW, NM)*
>
> *"Well I think that would be my pharmacist's role…" (17:JC, NM)*

d. Importance of correct inhaler technique (theme)

The vast majority of patients seemed to acknowledge the value of correct inhaler technique and the influence it can have on health outcomes. When asked*: "When you take your [inhaler name/s] what do you think is the most important thing you need to do?"*, patients typically referred to inhaler technique, for example:

> *"…making sure you do it properly" (17:JC, NM),*

or the steps involved in inhaler technique, for example:

> *"Well you got to breathe out as far as you can, and time it so that the breathing in is just a fraction after you push the plunger" (3:RL, M).*

Some patients also commented on the importance of each individual step involved in device use:

> *"I think they're all equally important because they all add up to the final result… it's like saying it's all right to… clean your front teeth but not your back teeth… But all those steps add up to the efficient way of using it and getting the best out of your medication" (10:DD, M)*

When questioned further about why correct inhaler technique was thought to be important, patients spoke about the wish to avoid undesirable therapeutic and health outcomes such as receiving an ineffective dose, worsening asthma symptoms, having to increase the dose of medication due to poor symptom control, asthma attacks. An association was even made between poor inhaler technique, poor asthma control and death. For example:

> *"…to get the full benefit of it you have to do it correctly… it's extremely important to use it properly… So you don't get any symptoms of asthma... if I use it correctly and it's to my benefit then… I won't have an asthma attack therefore I'm not putting any extra load on my lungs and if I use it incorrectly... well I just think that'll be very foolish, because you could easily get an asthma attack. And you can die." (6:LN, M)*

> *"Yes I learned to inhale slowly and hold my head sort of upright more… And the other thing is too, that I know if I get the maximum use out of the medication, I might be able to use less and at the same time my medication will help me to be more stable." (5:LJ, NM)*

The importance of practicing correct inhaler technique was challenged by only one patient, who did not consider inhaler technique to be a priority in asthma therapy and doubted the benefits of being precise with technique and, perhaps not surprisingly, such beliefs were expressed by a Non-maintainer (a patient with lower motivation to maintain correct technique):

> *"Well, I mean there's directions there for that reason but sometimes the way I look at things, being mechanically minded and things like that, I sort of ask; 'well is there any scientific sign of evidence that it has any further benefit, or any further effect of doing it one way or doing it the other way?' So you know that's why I mean if it's just about right that will still do the same job… I don't think it's so much the correct way, it's more so the consistency of using it." (7:GW, NM)*

e. Inhaler use as an "unconscious habit" (theme)

Despite the fact that the majority of patients (barring the one example above) could articulate the reasons for the importance of paying attention to correct inhaler technique, and seemed to believe that inhaler technique would make a difference to their asthma experience, on a day-to-day basis this understanding did not appear to guide how patients actually performed inhaler technique.

That is, patients did not seem to pay deliberate consideration to inhaler technique during routine use. This is implied by the responses of over half of the patients interviewed, describing inhaler technique as, for example, an *"automatic" (12:KK, M)* action, or a matter of *"habit" (4:DR, M)*, with matters concerning inhaler technique seeming to meld inconspicuously with the details of daily life. This familiar, and perhaps unthinking, attitude underpinning inhaler technique performance was a frequent theme amongst both Maintainers (patients with higher motivation to maintain correct technique) and Non-maintainers (patients with lower motivation to maintain correct technique):

> *"… it's just automatic – like cleaning your teeth every morning. It's just an automatic thing I do… You just get into a rhythm of doing it and it just, you know – five, ten minutes of your morning and that's it… you sit down and have a cup of coffee and read the paper or watch television…"(12:KK, M)*
>
> *"I mean I just do it. I guess it's programmed, I just do it but I don't know if I'm doing it correctly… I feel like I've been doing it for such a long time I probably just do it. I probably don't consciously think about steps to what I'm doing. I literally just click it back, take a breath in, hold it for a few seconds, click it back, leave it for a few seconds, breath and then I rinse my mouth out… I think as you go on you just - you get that you fall into bad patterns and bad habits… I probably do it so automatically I probably don't think ... or anything like that… I actually do do it wrong quite often really." (17:JC, NM)*
>
> *"Maybe automatically I do, do it the way I do… Familiarity breeds contempt. I think you just forget." (18:FE, NM)*

◇

Overall, patient responses relating to inhaler technique and inhaler device use were rather homogenous, with the large majority of patients conveying similar attitudes and beliefs regarding inhaler technique and device use (i.e. correct inhaler technique and device use was believed to be both important and easy, and confidence in one's abilities to practice with correct inhaler technique was unequivocally high). A familiar, habitual, or non-deliberate attitude toward inhaler technique was also conveyed by many patients, equally by Maintainers (patients with higher motivation to maintain correct technique) and Non-maintainers (patients with lower motivation to maintain correct technique).

Despite some distinguishing features (i.e. only Non-maintainers reported identifying challenges with device use, doubts with the importance of inhaler technique, and the lack of ownership over one's inhaler technique status), in the majority of cases both patients who were Maintainers and Non-maintainers echoed similar sentiments in regard to inhaler technique and device use (Appendix 4.04: Qualitative study themes and how Maintainers and Non-maintainers responded).

Without offering clear insight on the distinguishing characteristics of Maintainers compared to Non-maintainers, patient responses regarding inhaler technique were limited in illuminating the reasons why some patients were more, and others less motivated to maintain optimal inhaler technique.

"I changed my mind about two or three attacks ago"

✦✦✦

2. Asthma and self-management related themes – core factors influencing patient motivation in inhaler technique maintenance

Patient responses in the asthma and self-management domain emerged from questions based on hypotheses 1 and 2. Themes in this domain, compared to other study themes, appeared to be the most insightful in explaining patients' relative difference in motivation concerning inhaler technique maintenance. In particular, when these themes were mapped out (as per stage 5 of Framework analysis, Table 4.04) they could clearly distinguish the difference between Maintainers and Non-maintainers (this will be illustrated and explained in section 2d). These themes were thus deemed the "core" study themes. Each core theme (2a-c) reported on below is discussed with reference to various supporting or "corroborating" themes. The corroborating themes substantiate the core themes. For clarity, the subheadings in this section (2a-c) flag only the core themes (note, both core and corroborating themes will be summarised in Figure 4.03, and a full account of study themes appears in Appendix 4.04).

a. Motivation to actively engage in asthma management (core theme)

Personal wellbeing in the form of health and quality of life seemed highly valued by the patients in this study and was indicated by statements such as:

> *"That's the first thing you think about is your health. How it impacts your whole life." (15:LF, NM).*

Further, the importance of maintaining good asthma control in order to support one's desired levels of personal wellbeing was a connection many patients recognised, for example:

> *"… it (poor asthma control) would affect your life in every way, I mean you'd be struggling to carry loads, you'd be struggling to do any physical exertion… I think asthma can affect almost every part of your life… (asthma control is) critical…I'm very very serious about my health and wellbeing" (2:JH, NM)*
>
> *"Well, it (good asthma control) makes life a lot easier. And I mean, well it just lets you get on with life without being sick all the time, it's everything. It's a quality of life." (12:KK, M)*

The majority of patients considered that the threat that poorly controlled asthma may pose on one's wellbeing could be significantly detrimental. When speaking about the consequences of poorly controlled asthma, many patients would recall and recount vivid past personal experiences of acute asthma exacerbations (such as patients 1:PS and 15:LF below), or in some instances, the patient, not having had personal experience, anticipated what poorly controlled asthma would be like (such a patient 2:JH below), in both scenarios feelings of fear were clearly present:

> *"Yes it is frightening. It's a nuisance… when I've got to go and play bowls or be out in it (the wind) or… I can get quite distressed you know… I was out shopping, I was in a shop we ordered our lunch, and it was quite frightening, it's lucky I had Ventolin (reliever) with me" (1:PS, M)*
>
> *"Very hard to breathe, very hard to do anything and when you start to breathe you can breathe in but you cannot get that breath out to breathe back in again. It is really frightening." (15:LF, NM)*
>
> *" Um, it's quite scary… fortunately I haven't had a really major acute attack but, it's sort of, each time you feel that way the immediate thing comes to mind that you feel like you're going to drown, I'd hate to be in a situation where you were drowning cause that same sort of fear and not being able to breathe."(2:JH, NM)*

Salient personal experiences of asthma exacerbations often served as turning-point events in patients' lives. That is, after such experiences, many patients were prompted to evaluate (or re-evaluate) their perceptions, attitudes and behaviours around asthma and asthma management. Such experiences also heightened patients' perceptions of the threat of asthma on one's wellbeing, and subsequently, their motivation to mitigate this threat was also enhanced. Greater awareness of the threat of asthma based on experiencing significant asthma exacerbations was fundamental in motivating patients to *"do something"* about their asthma *(2:JH, NM)*, and to actively engage (or re-engage) in asthma management in order to avoid further and future loss of wellbeing. The following examples illustrate changes in patient beliefs and attitudes (acceptance of diagnosis and preventer therapy), and behaviours (use of preventer therapy), following turning-point events:

> *Interviewer: So when did the doctor first tell you that it might be asthma or this is a diagnosis of asthma?*
> *"Well that would have been about 20 years ago"*
> *Interviewer: Did you believe them?*
> *"Not really"*
> *Interviewer: When did you change your mind?*
> *"I changed my mind about two or three attacks ago" (18:FE, NM)*

> *"… that was probably the lowest point in my life with feeling unwell and wheezy and just not being able to really do anything, I mean it's quite amazing just, you know walk up stairs and you can feel it, and you know like one flight of stairs and you think 'god, gosh it's only one flight'… and it is a concern… I was concerned about my future, if that was to continue, which obviously made me do something about it." (2:JH, NM)*

A further case illustrating the impact of perceived asthma threat on patient attitudes and behaviours around asthma and asthma management concerns a patient who had, interestingly, experienced severe asthma exacerbations for the first time in her life, just prior to being interviewed. Shortly after these events, the threat of asthma to one's health and quality of life was significantly heightened in this patient's estimation, and her attitude towards asthma management, including those regarding inhaler use and technique, seemed to have transformed from *"blasé"* to *"vigilant"*, with an indication that behaviour change may also ensue:

> *"I've had an absolute shocker of a year …I'm just absolutely carked… I am really down at the moment for the simple reason I thought once the summer hit, I'd be okay… I've lost the plot this winter completely… It's never been a problem in my life up until now… it started back in about April of this year and it hasn't cleared up…I honestly thought last night I would have to call an ambulance. That was the worst I have ever lived through last night…*
>
> *Well it [inhaler technique] is [important] now. Before I was probably a little bit blasé in the past. A bit blasé… Now I'm not because I know now that it's a big problem in my life. Remembering to do things, I know I've got to be more vigilant. If it means I've got to use a preventer and if it means I've got to set it on a placemat in front of me at the table to remind me, I'm quite happy to do so" (13:CH, NM)*

There was a handful of patients who indicated markedly different sentiments to the majority (who believed that asthma – had been in the past, is in the present, or can be in the future – a significant threat to their personal wellbeing, and who were therefore more motivated to actively engage in asthma management). The handful of patients who held a differing view, perceived asthma to be a relatively minor issue in their life, and a condition that was not likely to become worse in the future and of low threat to their personal wellbeing. Further, these patients did not report experiencing episodes of asthma exacerbations that they considered to be a severe and warranting increased care. For example:

> *"…I know it's meant for preventatives, people use it all the time, but I think because I only get one attack of asthma a year I'm not a serious asthmatic." (18:FE, NM)*
>
> *"Oh, probably just gives you a shortness of breath... not too much beyond that… other people have different grades I suppose or some are worse than others where mine is probably only, you know minor... generally speaking it's not too bad…I don't know what you call an asthma attack (chuckles)… I've never been to that extent… it's just more of an inconvenience but it hasn't caused any great drama… it's (taking preventer) just something I don't do consistently… unless it's more serious I suppose (chuckles), but no way I need to worry, I might get around to it… " (7:GW, NM)*

This particular combination of experiences and perceptions – lack of salient or memorable asthma exacerbations and lower perceived threat of asthma on one's wellbeing – also coincided with lower patient motivation to actively engage in asthma management (e.g. patient 7:GW's attitude and behaviour regarding adherence to preventer treatment, above). This is perhaps not surprising, since amongst patients where asthma is not perceived to be highly problematic, issues around asthma management would seem less personally relevant. Hence motivation to engage in asthma management would be diminished.

This logic was observed to extend to patient self-management regarding inhaler technique. That is, all of the patients who perceived their asthma to be a minor/non-threatening issue, were less motivated to engage in asthma management, and were also Non-maintainers (patients with lower motivation to maintain correct technique). In contrast, those patients who did perceive asthma to be threatening to their wellbeing, were more motivated to engage in active asthma management, and were also in the majority of cases, Maintainers (patients with greater motivation to maintain correct technique).

Patients' broader sense of motivation to actively engage in asthma management, driven by perceptions of asthma threat, was thus observed to correspond, to a large degree, to the more specific motivation to maintain correct inhaler technique.

This observation did not, however, consistently hold true. For example, a handful of patients who had relatively greater motivation to actively engage in asthma management (i.e. patients 2:JH, 5:LJ, 13:CH and 15:PF, as shown in Appendix 4.05), were, contrary to what could be generalised from the observation above, Non-maintainers (patients with lower motivation to maintain correct technique).

Further analysis indicated that themes relating to patient attitudes and approaches to self-management could explain some of the inconsistency observed here.

b. Motivation for a preventative-medication based asthma self-management approach (core theme)

The core and corroborating themes reported in this section focus on the responses from those patients who perceived asthma to potentially be a significant threat to their wellbeing, and who therefore indicated greater motivation to actively engage in asthma management, as described previously (Appendix 4.05, 1b).

Amongst patients who were motivated to actively engage in asthma management, three distinct attitudes and approaches toward asthma self-management were identified, namely: *reactive*, *preventative-lifestyle based*, and *preventative-medication based*.

Patients who adopted a reactive attitude and approach tended to engage in asthma self-management after they noticed the onset, or worsening of, asthma symptoms. When symptoms subsided, these patients tended to cease all medication therapy, and thus asthma self-management was very much symptom-driven or motivated. This reactive attitude and approach were related to various factors, including: beliefs that non-medication/lifestyle self-management strategies were sufficient (e.g. quitting smoking and exercising), lack of knowledge or misinformation about preventer medication (e.g. resistance develops with regular use), lack of perceived benefits associated with preventer medication use, beliefs that medications in general should be avoided as much as possible, the belief that asthma is an episodic condition, and experiencing uncomfortable physical sensations immediately after using inhaled medication. These patients did not recognise the benefits of regular preventer medication and seemed much more reliant on using their reliever medication. For example:

"Symbicort (preventer) doesn't seem to make a difference to me. It doesn't honestly seem to make a difference. I feel as if it makes it harder to breathe - makes me worse… where the Ventolin (reliever) will clear the passage straight away, the Symbicort seems to put something… I feel as if there is a coating there that's making it harder - that's the only way I can describe it… this awful clagginess in my lungs… it seemed to be gluing me up rather than clearing me up." (18:SM, NM)

I do nothing as a prophylactic thing. I only use Ventolin through the nebuliser when I'm in the middle of a ghastly attack.. "(The preventer) probably would be no use at all… I am living without it. I don't use it as a preventer and I'm quite well in between attacks, which are generally just once a year… I take so many drugs anyway but I don't want to be adding something that isn't necessary. If someone could tell me it was definitely necessary I would - preferably not with the Symbicort because I don't think that worked…" (18:FE, NM)

"I could go 12 months and not need any puffers or anything 'cause I've given up smoking…at the moment I don't feel I need it… I just take the Asmol (reliever) just to get me through the night… as I said, I'm just one that I can't see the point in taking something all year round if I don't need it. If I'm breathing OK, why need it? Then if I do need it, it doesn't have any effect… I don't think you'd get the same… I would get the same relief… and the bottom line is you know your body you know your breathing and you know what you need without abusing it… if anything I underuse rather than overuse" (10:DD, M)

In contrast to this, patients with a preventative attitude and approach, adopted self-management strategies to stave off the onset of asthma symptoms and exacerbations, rather than reacting in response to symptoms. Amongst these patients, the vast majority believed that using preventative asthma medication was essential for avoiding deterioration in one's asthma and health and assumed this as a core self-management strategy:

"I've been there and done that... I know what it's like to have asthma...to struggle...I would not like to stop taking it (preventer) for fear that... that bloody horrible thing would come back again" (4:DR, M)

"… I guess I wouldn't really want the asthma to come back so that's (preventer use) one way of trying to prevent it." (9:BB, M)

"Oh absolutely, you've just got to keep it (preventer) going. You've gotta... you don't want to get an attack. You have to keep your preventatives going… that'd be very foolish because you could easily get an asthma attack and you can die – I mean if you don't use medication, if you don't get treated" (6:LN, M)

"Well I think it's (preventer use) important, don't have more than one chance with your health" (8:RH, M)

Although some of these patients also expressed a strong desire not to be taking regular preventative medication (e.g. due to worry over the long term side effects of inhaled corticosteroids, or having experienced these side effects), over time their experience with poorly controlled asthma and its impact on their health and quality of life seemed to have convinced them that the benefits of medication self-management exceeds the risks and has influenced them to persist with taking preventer medication despite feeling worried. For example:

> *"… I do feel if I'm a little bit that way inclined, that I feel better if I take it (preventer). If I don't take it and I might be at bowls or somewhere and I'll be coughing, say I'm out of it or something - I always try not to be – and I'll realize I haven't taken it…you know I think it is necessary, I do think it does work…But I would love not to have to (take preventer medication), but I do have to…I didn't want to take medications, as it is now, I have osteopenia… and I put that down to the steroids, but I have to take it so there you are… once in a while, when those conditions are happening…he (G.P.) said take two in the morning, double it for two weeks, which I loathe to do (emphatic)…ohhh I loathe to do that, I think it's killing me, but anyway…" (1:PS, M)*

> *"It's like a man having food and water, without that you give it 2 days you'd be dead...either that (preventer use) or I can't breathe, that's it… I read on the computer that there'll be like long term effects… people say by the time you take 4 (puffs of preventer) in the morning and 4 in the evening, you might as well be taking Prednisone anyway … they say it could have a bad effect on your lungs over time, but what do you do?" (5:LJ, NM)*

A preventative attitude and approach to asthma self-management, however, did not in every instance result in preventative medication therapy being prioritised. In the case of one patient, despite indicating a firm commitment to proactively self-managing their asthma in order to mitigate its threat on their personal wellbeing, using inhaled preventer therapy was not firmly on the agenda. Various disincentives against using preventer therapy were conveyed by the patient, including the belief that medication in general should be avoided and that lifestyle strategies were far more superior than preventer medication for managing asthma (such as maintaining fitness and reducing environmental allergen load). Further, minimal benefit was perceived after using preventer medication by this patient. Thus, although a preventative attitude toward asthma self-management was adopted, the approach this patient took differed to other patients who also had a preventative mindset. Specifically, non-medication, lifestyle strategies were prioritised, and the role of preventer therapy was relegated secondary to these preferred strategies (although it is possible that these views may be tempered if the patient should ever experience worsening asthma no longer responsive to non-medication treatment). The quote below draws together this particular patient's reasons for adopting a preventative-lifestyle based self-management approach:

> *"Look I am dead against medication of any sort, I get a headache, I hate taking a tablet so I try to use it as sparingly as I need… when I had my hernia done they gave me these really strong tablets for the pain. And I said, hang on, I believe that pain means there's something going on in your body you need to stop so masking it, that isn't going to help… I want to know when I'm doing something that's painful so that I'll stop doing it… and I said 'nah I'll let my body repair itself…*
>
> *I do my best to avoid them (triggers) – I've changed my house and my office and things like that to get rid of carpet and blinds, soft furnishings basically… I also have an air purifier in my office and as well as in my bedroom... I change my bed clothes weekly I put eucalyptus oil in the wash when I wash my bed clothes… I use a clothes dryer which de-dusts and takes all the fluff out… the asthma is much much reduced…*
>
> *I'm very very serious about my health and wellbeing and food I eat and, my exercise regime, and I think to be honest that the biggest improvement for me has been… my fitness… and the puffers aid that fitness... Qvar (preventer), really doesn't give you any, much, much of a better feeling, like a wellbeing feeling…" (2:JH, NM)*

This section has outlined the three distinct approaches to asthma management – reactive, preventative-lifestyle based, and preventative-medication based – adopted by patients who were motivated to actively engage in asthma management (Appendix 4.05, 1b).

Notably, it was found that patients with a reactive, or preventative-lifestyle based approach to asthma self-management, were all (bar one) Non-maintainers (patients with less motivation to maintain correct technique). In contrast, those patients with a preventative-medication based approach were Maintainers (patients with higher motivation to maintain correct technique) in the vast majority of cases.

It is conceivable that patients who adopted a preventative-medication based approach to asthma self-management were more attentive to matters relating to the use of inhaled medication therapy, such as correct inhaler technique (compared to patients prioritising a reactive, or preventative-lifestyle based, approach). This may explain why the majority of patients with a preventative-medication based approach were Maintainers (patients with higher motivation to maintain correct technique); and by the same logic, why all (bar one) of the patients with a reactive or preventative-lifestyle based approach were Non-maintainers (patients with lower motivation to maintain correct technique).

Taking into account the first core theme ("motivation to actively engage in asthma management") outlined earlier, in conjunction with this second core theme ("motivation for a preventative-medication based self-management approach"), provided further insight into the distinguishing characteristics of Maintainers (patients with higher motivation to maintain correct technique) and Non-maintainers (patients with lower motivation to maintain correct technique) (Appendix 4.05).

Some inconsistency still remained however. That is, there were patients who indicated that they were highly motivated to engage in asthma management, AND who were motivated to do so via a preventative-medication based approach, yet counter to what was expected based on the observations so far, were Non-maintainers (patients with lower motivation to maintain correct technique) (i.e. patients 5:LJ and 19:PF, Appendix 4.05, 2b). Further analysis indicated that themes relating to patients' confidence in their ability to effectively self-manage could explain this observation.

c. Confidence in one's ability to effectively self-manage (core theme)

The core and corroborating themes reported on in this section focus on the responses from those patients who were: 1) motivated to actively engage in asthma management, and 2) motivated to self-manage via a preventative-medication based approach (Appendix 4.05, 2b).

Amongst these patients, those revealing a relatively high level of confidence in their ability to self-manage effectively, or a high level of "self-management self-efficacy", were all Maintainers (patients with higher motivation to maintain correct technique). This confidence was clearly communicated during instances such as:

> *"Oh, I intend to stay like it [well controlled]… Very confident." (12:KK, M)*

> *"Well I've got it under control and I don't think um I'm ever gonna have any bad asthma attacks anymore" (4:DR, M)*

> *"Oh I think I'm, I think I'm very capable. I don't think I need anybody else to say to me 'Come on you better use this or use that'"(6:LN, M)*

On the contrary, a couple of patients expressed markedly lower levels of confidence in their ability to self-manage successfully. This lower confidence was associated with negative emotions, perceived social barriers to self-management, and a perceived lack of control over asthma symptoms. That is, symptom onset and exacerbations were believed to be highly unpredictable, not within personal control to avoid, and any precautionary efforts to improve one's asthma experience were seen to be in vain.

In the case below, although the patient firmly believes in the importance of actively engaging with preventative and medication based asthma self-management in order to avoid the detrimental consequences of asthma, he clearly lacks confidence in his own ability to do so. Negative emotions seem to immobilise the patient, with emotional weariness (stress and worry about asthma), physical weariness (from having severe asthma), and the perceived lack of social support, all acting to undermine the patient's confidence in their own ability to successfully self-manage their asthma.

> *"I don't know if I'm managing, I'm just coping by the skin of me teeth… Do you know that my whole day is taken up with like medications, washouts, sprays, um coughing, walking around trying to feel better... so it goes on all day do you know what I mean?... one year meshes into the next because you're seeing doctors, specialists... I've got a very good doctor, I... and the thing is that even they don't know what to do with me...And I don't know how short lived it would be, but it's taken decades to get there, and then you know I get a little bit sort of unhappy or depressed... so hopefully I'm on the straight and narrow – but I know I'm not, I just go this way for a little while and there'll be a little bit of a temperature change, and that's shocking for asthmatics...so you can give the maximum effort and you just sink… I've gone through hell… it's insane, and I'm more broke and I've had more days off than others...and not only that, it's the torture of just being sick all the time… I mean if I go somewhere I can never stay out for the whole afternoon into the evening with friends to have dinner – when I get home I'd be crook… it's like being a leper… I've never had a successful day since I got asthma… very very very tough and hard and anxious and exhausting and tiring and wearying and mentally and physically stressful. And when you don't... I remember there was a period of time in my teens where I didn't have asthma – it's another world." (5:LJ, NM)*

In another similar example, confidence to effectively self-manage seemed to be sapped by the patient's recent experiences with poorly controlled asthma, and perceptions of asthma as an overwhelming condition. Negative emotions feature again, with feelings of hopelessness, desperation, fear and stress dominating the interview:

> *"… I'm not coping well. As I mentioned previously, I need to cope at the moment… I'm struggling with every day to day things now which is not, I know is not good… I am getting very desperate… I am getting very desperate about it (asthma)… I'm really losing the plot with it all now… I feel so stressed… I do feel my stress levels are now way out of control…I'm running out of puff. I know it's an effort now to go down the supermarket and not have to stop and use the puffer… I'm struggling with every day to day things now which is not, I know is not good… I'm just in no man's land now." (13:CH, NM)*

Notably, both these patients, who responded with markedly lower levels of asthma self-management self-efficacy, were Non-maintainers (patients with lower motivation to maintain correct technique).

Accounting for themes relating to patients' perceived confidence with asthma self-management enhanced understanding of the relationship between patient motivation and inhaler technique maintenance. That is, after examining patient responses in relation to their: 1. motivation to actively engage in asthma management, 2. motivation to adopt a preventative and medication based self-management approach, and 3. confidence regarding asthma self-management, a more comprehensive understanding of the influential factors on patient motivation to maintain correct inhaler technique was achieved. These results are summarised in the form of a model presented below.

d. The "Inhaler Technique Maintenance and Motivation" (ITMAM) model: mapping out core and corroborating themes influencing patient motivation in inhaler technique maintenance

The Inhaler Technique Maintenance and Motivation (ITMAM) model (Figure 4.03), underpinned by various types of motivation and self-efficacy, summarises the findings based on the core and corroborating themes presented in sections 2a-c. This model arose from analysis that occurred predominantly during the "Interpretation and mapping" stage as per the Framework approach (Table 4.04, stage 5). The ITMAM model was developed by mapping out how individual patients responded on each core theme (Appendix 4.05).

The ITMAM model illustrates that patient motivation in inhaler technique maintenance may be contingent upon three core factors: 1. motivation to actively engage in asthma management, 2. motivation to adopt a preventative and medication based self-management approach, and 3. confidence, or belief, in one's ability to effectively self-manage (Figure 4.03).

The ITMAM model also shows how these three core themes were interrelated to progressively explain the reasons behind the relatively higher and lower motivation for correct inhaler technique maintenance demonstrated by Maintainers and Non-maintainers respectively. The various other themes reported by patients underpinning the core themes (i.e. the corroborating themes) are also illustrated in the model (left hand side of Figure 4.03). Corroborating themes were included in this model as a reference to explain the derivation of the core themes.

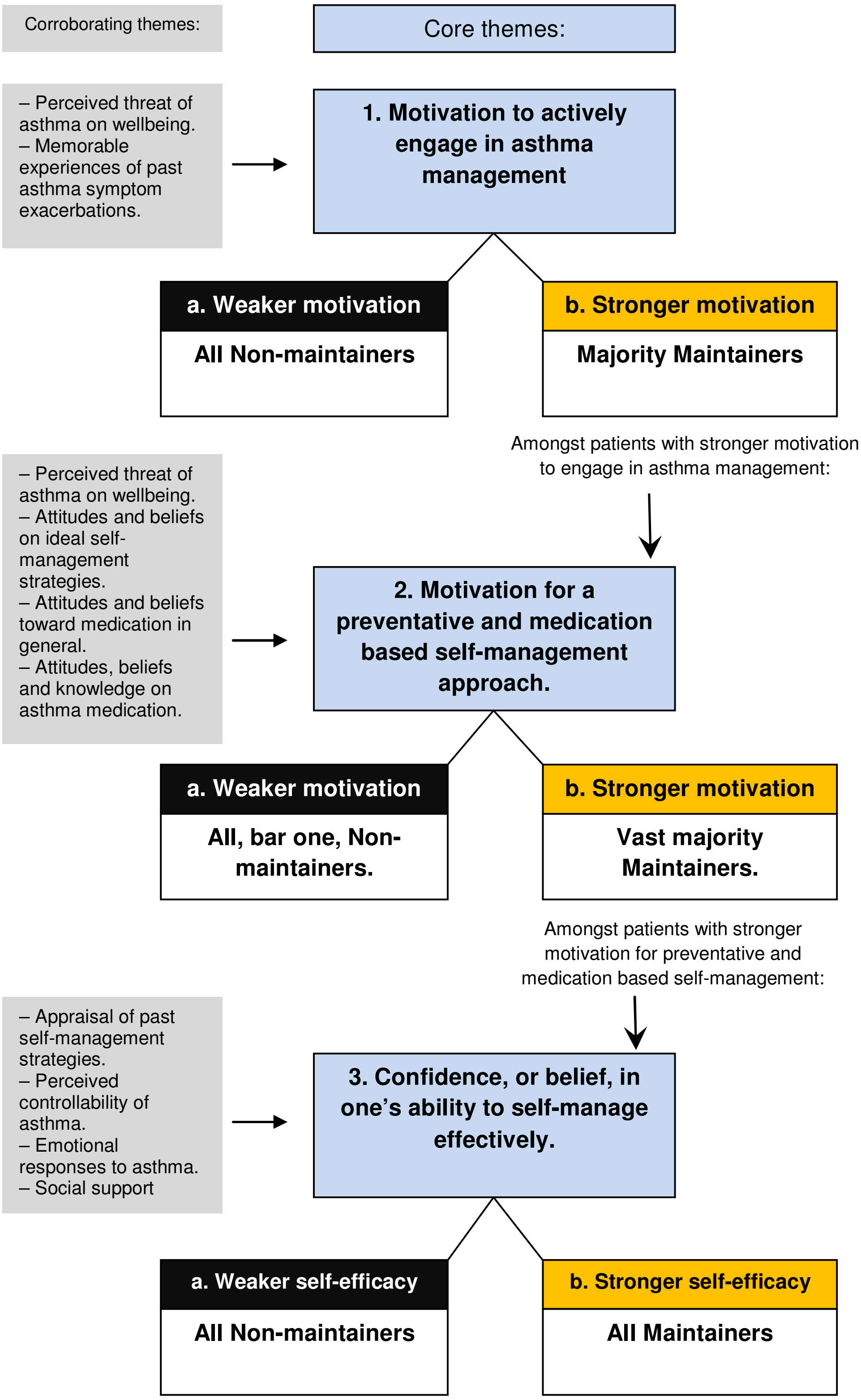
Using the ITMAM model, it can be predicted that patients who maintain correct inhaler technique, and possess higher motivation to do so, can be characterised as those who have:

1. Stronger motivation to actively engage in asthma management (in order to mitigate the threat of asthma on one's wellbeing), AND
2. Stronger motivation to adopt a preventative and medication based approach in self-management, AND
3. Stronger confidence in their own ability to effectively self-manage.

The model also predicts that patients who do not maintain correct inhaler technique, and possess lower motivation to do so, can be characterised as those who have:

1. Weaker motivation to actively engage in asthma management (in order to mitigate the threat of asthma on one's wellbeing), AND/OR
2. Weaker motivation to adopt a preventative and medication based approach in self-management, AND/OR
3. Weaker confidence in their own ability to effectively self-manage.

Figure 4.03: The Inhaler Technique Maintenance and Motivation (ITMAM) model characterising Maintainers and Non-maintainers.



The core themes are ordered hierarchically (from 1a and b, to 3a and b) in the ITMAM model as shown in Figure 4.03. This order is based on the observations and logic that, firstly, patients must be sufficiently motivated to engage in asthma self-management activities (theme 1b), before the second theme, relating to the specific approaches taken in self-management becomes a relevant consideration. Further, it was only after patients actually engaged in self-management activities, that their responses regarding confidence in self-management were deemed to be most authentic. This is due to findings that showed that patients' confidence in self-management could be influenced by how successful they evaluated their past self-management efforts to be. Thus the themes appear in the order in which they do in the model presented in Figure 4.03.

"… it does make a difference"

✦✦✦

3. Themes on therapeutic relationships

Patient responses in the therapeutic relationships domain emerged from questions based on hypothesis 6. Although patients' personal experiences were noted to be paramount in mobilising their motivations and actions in asthma self-management (Figure 4.03), health care professionals were still found to play a significant role in determining how patients coped with their asthma, especially amongst those patients most receptive to health care professional influence.

a. Satisfaction, trust and rapport with health care providers (theme)

Most patients in this study made substantive comments regarding the quality of the relationships with the health care providers they visited for their asthma, in terms of perceived satisfaction, trust and rapport. Overall, the majority of patients evaluated their therapeutic relationships in a positive light. Upon recalling past interactions, patients conveyed that knowledge, competence and good interpersonal and communication skills were attributes that some health care professionals possessed which instilled trust, satisfaction and rapport in the therapeutic relationship. For example:

> *"My two pharmacists have always been interested in our health... my children use to call my first pharmacist Uncle Dick... pharmacists were always been absolutely fabulous people… My doctor whom I trust implicitly says 'you keep taking it' so that's exactly what I do...I've been going to two pharmacists for sixty years... he's been looking after me for a long time, and I just trust him." (4:DR, M)*

> *"I'm on a few different things from my doctor and she's excellent… she has been my doctor for a while and I would trust her judgment… Yeah, very helpful. She'll sit back and answer questions if I've got any about anything... You need to know that you can go to a good GP who will listen to you and not fob you off or anything… and the pharmacist's very good too… sometimes I go in and they might say you know 'How are you going, are you OK?'… where we go they're pretty proactive with that sort of thing." (6:LN, M)*

> *"Oh I think they're wonderful, yes, they're very very helpful...getting medications they always explain everything to you…you can ask them anything, especially ____(pharmacist) and ____(pharmacist) and they will be very very helpful about everything, very knowledgeable I'd feel… they will also put you on to go to the doctor and even make an appointment for you if they think it's necessary." (1:PS, M)*

> *"My doctor … he's also a motor racing licensing doctor so we've become quite good friends, as well as my doctor… he's a pain in the bum because he takes so long with his patients (chuckles) but he'd be my first point of call… I'm quite happy to do whatever my doctor or pharmacist says. They're only telling you for one reason and that's because it's going to be better for you... the important thing is that you follow the instructions correctly" (2:JH, NM)*

Importantly, the quality of the relationship with one's health care providers, as evaluated by patients, did seem to *"make a difference" (18:FE, NM)* to patients and have an impact on their asthma self-management. For instance, the following patient drew comparison between positive and negative interactions with health care professionals, and commented upon the potential for negative interactions to inhibit help seeking behaviour and as a result, limit access to appropriate treatment:

> *"We've had excellent interaction with the majority of (health care providers) now… it does make a difference – sure it does, because if you don't like the doctor you won't go back. He might have something that will help you but you never know because you just don't go back for more insults." (18:FE, NM)*

b. Receptiveness to health care provider influence (theme)

Notably, the quality of the relationship with one's health care providers seemed to come under closer scrutiny by, and become a higher priority to, patients only after they became sufficiently motivated to actively engage in asthma self-management (i.e. as represented by theme 1b. in the ITMAM model, Figure 4.03).

These patients tended to hold much stronger views and opinions (compared to those less motivated to self-manage) regarding their trust in, and satisfaction and rapport with, the health care providers they interacted with. Importantly, these patients seemed much more receptive to the influence of their health care providers, whether in a positive or negative manner. The following example illustrates the supportive influence that a trusted health care provider had on a patient highly motivated to self-manage effectively:

> *"I was very very sick... by doing what I'm told to do is the way to get right and stay right… if you're sick enough in the beginning you're desperate enough to do as you're told… whatever the doctors prescribe for me I take because I know they're good doctors and they wouldn't prescribe it if it wasn't necessary to keep me fit... We only get one life. And if you want to live it and enjoy it, you've got to do as you're told." (12:KK, M)*

Interestingly, when patients were more receptive to the influence of supportive health care providers (i.e. those whom they had trust and rapport with), benefits were also gained in terms of enhanced patient motivation and confidence regarding self-management:

> *"I've been very very lucky that I've got good doctors... the doctors I've had have been very vigilant and supportive and my specialist is _______ at _______ and she is just wonderful... It's very very good. Very motivating you know, to get onto the right track and get better again... the pharmacists are very good...only too willing to put me aside and have a talk to me about it... I feel very confident because no matter where I go I have people that seem to care… And I think that in itself is a lot... I mean if you had doctors that didn't care and showed no initiative about your well-being...you may have a different attitude... they're only too willing to say "don't feel that you're a nuisance by coming up"...it means they care about you." (12:KK, M)*

> *"… well I think when they show you things...have a word with you about certain things...you sort of realise you're helping yourself... makes you feel a bit more sure of yourself... they're certainly there to help you" (3:RL, M)*

The next example suggests that, even amongst those patients with strong beliefs against recommended asthma self-management strategies, the persistent messages of a trusted health care provider are likely to have influence over time:

> *"it took me a long time to accept - because I wouldn't have any medications – that I had to be on a (preventer medication) program. I used to go away on a holiday and not pack it (preventer medication), you know – 'cause that's ridiculous, I don't have to take stuff everyday' … after this trip overseas… I was really sick, I just coughed non-stop… I couldn't talk to anybody, I was sick as anything... Yeah when I came back here he actually convinced me, the doctor… He just said 'you-HAVE - got- asthma. You have got asthma and you have to stay on this forever.' And I didn't want to take medications… but I have to take it so there you are." (1:PS, M)*

The next two examples illustrate how therapeutic relationship can also be perceived by patients (who were receptive to its influence) to have a negative influence on their lives. In the case below, the patient's evaluation of the relationship with their General Practitioner (G.P.) was very much negative. Previously, this patient had perceived the same G.P. as *"an extremely good doctor"*, however, after experiencing recent and unprecedented asthma exacerbations, and becoming significantly more aware of the need for good quality health care support, this patient's satisfaction, trust and rapport with this long-standing G.P. had markedly diminished. Further, continued interactions with this health care provider in whom this patient now had little trust and satisfaction with, clearly had a negative influence on her emotional state, as indicated by her responses on this topic filled with feelings of dissatisfaction and desperation:

> *"Last night would have to have been the worst night I think I've ever had… My current doctor at the moment… I will not go back to. I've been going to him for three years… It concerns me because I know I'm not getting proper help… he looked at the clock and reminded me that there's other patients outside in the waiting room… I honestly thought last night I would have to call an ambulance. That was the worst I have ever lived through last night… I've lost all confidence and faith in him… He is very short tempered. I found him an extremely good doctor, but I've lost all confidence in him now. He was very rude to me last week… I am at my wit's end because I feel I am not getting proper help… I have to find a GP and I do not know where to go… That's like finding a needle in a haystack in my opinion…" (13:CH, NM)*

In a detailed example of similar essence, it can be seen that patients' lack of satisfaction, trust and rapport with their health care providers can stem from perceptions relating to health care providers' lack of clinical as well interpersonal skills, for example, lack of appropriate advice and guidance, inconsistent advice, inability to help make improvements in one's asthma and lack of empathy:

> *"Oh I think the doctor sort of had a go at it once or twice (technique education)… everyone had all sorts of funny opinions, but in the end half of it was hearsay. Or they changed it and decided like holding the spray out of your mouth or away from your mouth... in the end they said it didn't work, so it's very difficult when you're out there being a patient... 'I was taught this way' and someone would say 'Oh no they don't do that' and then someone says 'Yes they do'... I mean oh my god, you don't know… It's insane, and I'm more broke and I've had more days off than others... it's the torture of just being sick all the time, and they (health care providers) don't see it, they expect you think logically and sane, but they don't really realise that you're not in that position… they say you're being a rebel and you're not trying to work with the system but they also change medications on the market and you say to them 'it doesn't work' and they just say 'oh no,no; who are you? You're an idiot. Medical science shows this this, this, this, and that'… there's a lot of those funny ones (G.P.s) now in some of those medical centres… they're obviously not interested in people… a lot (of pharmacists) don't care I can tell you. It's like you go there and they just say 'Here you go'… lots of them can't even be bothered looking, 'Oh there's the script, goodbye'... I went to this guy, Dr _______,… they're supposed the be… the best of the best… They took me off everything and said I didn't have asthma , and in the end I was in a car park and nearly collapsed and died, and finished back on everything…This is what I'm talking about, the journey to hell and back." (5:LJ, NM)*

In contrast to the cases discussed so far, there were various instances in this study where patient opinions regarding therapeutic relationships were much less impassioned, and rather, more indifferent and detached. These patients appeared to be less receptive to influence from health care providers (whether in a positive or negative manner). Incidentally, these patients were also those who indicated less motivation to actively self-manage (as represented in the ITMAM model, Figure 4.03, theme 1a).

The handful of patients who were less receptive to health care professionals' influence, described their interactions with their health care providers as passive and transactional in nature, and did not indicate any strong feelings of satisfaction or dissatisfaction with the status quo:

> *"I just go to the doctor to get a prescription... and then go to the chemist and pay for it… that's basically it… I don't think they (G.P. and pharmacists) actually do anything in particular; just ask if anything's going on, and it's still alright type of thing, mainly you know, 'Do you know how to use it? Have you had this before?' Or something like that, and obviously when you say you have, they don't sort of go into any further detail unless you ask them I suppose." (7:GW, NM)*

Even when there was a clear lack of support from one's health care providers, these patients revealed what appeared to be only mild dissatisfaction:

> *Interviewer: So tell me about your interaction with health care professionals when it comes to asthma. What's that been like?*
> *"Look it's sort of been a non-event honestly… there's not been a lot of health care advising… there was no direction to - it was almost like, well this is what you've got, take this medication. As much as I think the medication's helped me, I think there could have been a bit more direction." (20:PL, NM)*

The findings thus far reveal that the quality of the therapeutic relationship, as evaluated by the patient, has important implications for asthma outcomes due to its potential to affect patient self-management (e.g. via influencing patient knowledge, confidence and motivation as illustrated in previous examples). This is particularly the case amongst patients who are more receptive to health care professionals' influence (i.e. those who were more motivated to actively engage in asthma self-management).

c. Health care providers' influence on patient motivation in inhaler technique maintenance

By mapping out the relationship (as per stage 5 of Framework analysis, Table 4.04) between themes 3a-b, explained above, how health care providers influenced patients' motivation regarding inhaler technique maintenance became clearer.

It was identified that patients' evaluation of their therapeutic relationships (in terms of the degree of satisfaction, trust and rapport they had with their health care providers; theme 3a), as well as their receptiveness to health care professional influences (theme

3b), was associated with how they maintained inhaler technique. That is, it was observed that:

1. Patients who were more receptive to health care professionals' influence AND evaluated their therapeutic relationships positively, were in the vast majority, Maintainers (those with higher motivation to maintain correct technique), however,

2. Patients who were less receptive to health care professionals' influence; OR, more receptive BUT evaluated their therapeutic relationships negatively, were all Non-maintainers (those with lower motivation to maintain correct technique).

These important interrelationships are mapped out in the cross-tabulation in Figure 4.04.

Figure 4.04: The influence of therapeutic relationships on inhaler technique maintenance.

Quadrant A: *Patients more receptive to health care professional influence AND who had greater satisfaction, trust and rapport with their health care providers, predominantly were more motivated to maintain correct inhaler technique (i.e. Maintainers, denoted in brackets as "M").*
Quadrants B, C and D*: Patients less receptive to health care professional influence AND/OR had less satisfaction, trust and rapport with their health care providers, all were less motivated to maintain correct inhaler technique (i.e. Non-maintainers; denoted in brackets as "NM" and underlined).*

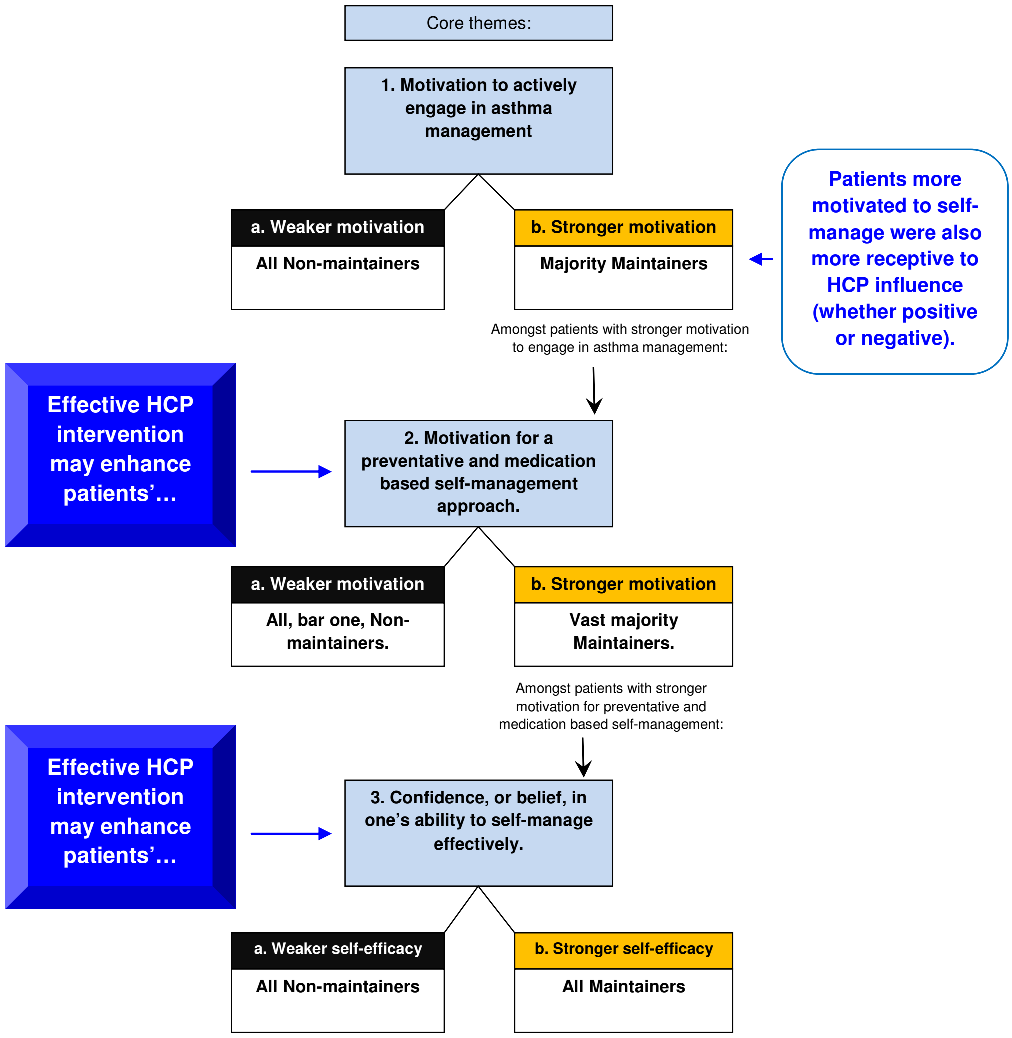
Patient receptiveness to health care professional influence

Patient perceived satisfaction, trust and rapport with health care professionals.	**HIGHER**	**LOWER**
HIGHER	A. 1:PS (M) 2:JH (NM) 3:RL (M) 4:DR (M) 6:LN (M) 8:RH (M) 10:DD (M) 12:KK (M) 19:PF (NM)	B. 14:MC(NM)
LOWER	C. 5:LJ (NM) 13:CH (NM)	D. 7:GW (NM) 15:LF (NM) 16:VT (NM) 20:PL (NM)

The quality of therapeutic relationships from the patient's perspective was found to be an important consideration for asthma management in general, and inhaler technique maintenance in particular. The key findings in this domain are summarised in Figure 4.05, which is an extension on the ITMAM model presented earlier (in Figure 4.03).

In Figure 4.05, the point at which patients tended to become more receptive to health care professionals' influence is indicated on the right hand side. Figure 4.05 also indicates the points during which supportive health care professionals, administering effective interventions, seemed to have the greatest impact on patients' skills, knowledge, motivation and confidence in asthma self-management, including in relation to inhaler technique maintenance (left hand side).

Figure 4.05: The ITMAM model, highlighting the points when patients become most receptive to health care professionals' (HCP) influence, and may most benefit from health care intervention.



E. Discussion

Through taking a finer-grained, qualitative approach, this study aimed to better understand the novel relationship between patient motivation and inhaler technique maintenance identified previously (Chapter 3). As a result, new insights were revealed about the influential factors on patients' motivation to maintain correct inhaler technique (and hence inhaler technique maintenance status). In particular, patient psychosocial factors (including perceptions relating to asthma, asthma treatment, self-management and therapeutic relationships) were found to explain in a substantive way why some patients possessed a relatively higher, whereas others possessed a lower, degree of motivation to maintain correct inhaler technique. These influential psychosocial factors were identified as the "core" and "corroborating" themes of this study.

The core and corroborating study themes highlighted the complex and multidimensional nature of patient motivation in inhaler technique maintenance and the important concept of personal relevance as a driving force behind patient motivation. These themes also formed the basis of the *Inhaler Technique Maintenance and Motivation (ITMAM)* model developed as part of the study findings (Results, section ii, 2, d), which with further testing, may have clinical application for identifying those patients at risk of developing poor inhaler technique over time. The following discussion will examine these key insights and their implications for how patients maintain inhaler technique and how health care professionals may better facilitate improvements in inhaler technique maintenance.

◇

In this section of the discussion, the influential (core and corroborating) themes identified in this study will be examined by taking into account various relevant theoretical perspectives. Firstly, however, it must be acknowledged that a diverse range of themes was identified in this study consisting of patient responses relating to their experiences, perceptions and feelings around inhaler technique, device use, asthma, self-management and therapeutic relationships (Appendix 4.04). All emergent study themes, theoretically (based on the CSM and SDT discussed in the Background), had the potential to influence patient motivation in inhaler technique maintenance, yet after deeper analysis (Methods, Table 4.04, step 5), it was clear that some themes were more influential than others.

The study themes deemed “core” and “corroborating”, were those that were found (during stages 4 and 5 of Framework analysis, Table 4.04) to carry the most weight in explaining patients’ relatively higher or lower motivation to maintain correct inhaler technique. Notably, the core and corroborating themes were closely interrelated, with corroborating themes substantiating the core themes by explaining their basis (as reported at length in the narrative passage section of the results). For example, in the first tier of themes presented in the ITMAM model (Figure 4.03), the core theme – patient motivation to actively engage in asthma management, stronger or weaker – was firmly rooted in the corroborating themes – degree of threat patients perceived asthma to pose on their wellbeing, and past experiences of asthma exacerbations.

Further, the relationships between the core and corroborating themes were frequently aligned with the theoretical principles underpinning this study. For instance, the interrelatedness of the themes in the example given above, are closely aligned with the principles of the CSM (Leventhal et al., 2003). That is, the relationship between the core and corroborating themes mirrors the relationship between the constructs of "coping" (how patients self-manage) and "interpretation" (how patients make meaning of their asthma based on their perceptions and feelings) in the CSM. Specifically, "coping", is comparable to the *core* study theme: motivation to actively engage in asthma management. Further, "interpretation" (especially relating to how patients interpret the "consequences" and "identity" of asthma) is comparable to the *corroborating* study themes: perceived threat of asthma, and experience of asthma exacerbations. Thus the interrelatedness of the first tier of themes presented in the ITMAM model (Figure 4.03) is supported by principles of the CSM.

Additional examples of how the interrelatedness of study themes align with theoretical principles can be found in both the second and third tier of themes presented in the ITMAM model. For instance, in the second tier (Figure 4.03), similar to the previous example, the relationship between the core theme – motivation for a preventative-medication based self-management approach; and corroborating themes – perceived threat of asthma, perceptions about the benefits/harms of medication in general, and preventer asthma therapy in particular; are underpinned by the CSM. The relationship is also supported by Horne et al.'s work extending the CSM to account for the influence that patients' medication related beliefs can have on self-management (Horne and Weinman, 2002, Horne and Weinman, 1999).

Further, the interrelatedness of core and corroborating themes in the third tier (Figure 4.03) are in line with tenets of the SDT, specifically in terms of how patients' confidence to self-manage, i.e. "competence" in SDT, can be influenced by the quality of a patients' social support, i.e. "relatedness" in SDT. The broad framework of Bandura's Social Cognitive Theory (SCT) (Bandura, 1997), depicting the interrelatedness between social, cognitive and behavioural factors also substantiates the relationships between this third tier of themes. That is, Bandura's SCT lends support to relationship between patients' confidence in self-management (comparable to the salient concept of "self-efficacy" in the cognitive arm of SCT) and the corroborating themes of social support (represented by the social arm of SCT) as well as appraisal of past self-management strategies (represented by the behavioural arm of SCT). These examples thus demonstrate the foundations on which the core study themes were derived, as well as theoretical support for this derivation. Both these mechanisms add depth and strength to the key study findings depicted in the ITMAM model (Figure 4.03).

To briefly review, the key study findings showed that, patients with greater motivation to maintain correct inhaler technique (and therefore more likely to do so), were characterised as those who had:

1) stronger motivation to actively engage in asthma management; AND,

2) stronger motivation to adopt preventative-medication based self-management strategies; AND,

3) stronger confidence in self-managing effectively.

On the contrary, patients with less motivation to maintain correct inhaler technique, (and therefore less likely to do so), were characterised as those who had:

1) weaker motivation to actively engage in asthma management; AND/OR,

2) weaker motivation to adopt preventative-medication based self-management strategies; AND/OR,

3) weaker confidence in self-managing effectively.

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The broader implications of this study's findings will now be discussed. Firstly, it bears mentioning that, as anticipated, the qualitative approach taken in this study did indeed allow for a more detailed understanding of the relationship between patient motivation and inhaler technique maintenance, than could have been achieved via quantitative investigations alone. In particular, this study highlighted the complex nature of patient motivation, even with respect to an activity as singular and defined as practicing inhaler technique. One demonstration of this complexity lies in the finding that the influential factors on patient motivation were multifactorial and interrelated both horizontally, i.e. between core and corroborating themes, and vertically, i.e. the hierarchical relationship between core themes. This hierarchical relationship is depicted in the ITMAM model in Figure 4.03.

Another demonstration of complexity was in regards to the nature of the influential themes identified. Surprisingly, and contrary to earlier hypotheses (hypotheses 3-5), amongst the factors found to be most influential on patient motivation in inhaler technique maintenance, none pertained to issues around inhaler technique or device use itself. Patient responses regarding inhaler technique and device use were highly homogenous (Results, section ii, 1). The large majority of patients conveyed similar sentiments regarding the ease of, and confidence in, using inhaler devices with correct technique; the importance of correct inhaler technique maintenance; and ownership over the activity. Only in a very few instances did responses in this area seem to hint at why Maintainers and Non-maintainers possessed different levels of motivation. That is, the few patients reporting difficulty with correct device use, doubt over the value of correct inhaler technique, or lack of ownership over maintaining correct inhaler technique, were all Non-maintainers. However, on the whole, the lack of variation in patient responses regarding inhaler technique and device use, rendered factors in this area very limited in their ability to explain differences in motivation regarding inhaler technique maintenance.

Further, although this was clearly *not* the case, based on patient responses around inhaler technique and device use, it would seem that the majority of patients interviewed would be considered quite motivated to maintain correct technique (i.e. were Maintainers). Yet, in fact, over half of the patients interviewed were Non-maintainers (lower motivation to maintain correct technique). These findings are clearly inconsistent with study hypotheses around inhaler technique and device use, specifically those based on the principles of SDT, i.e. that patients' sense of "autonomy" and "competence" pertaining to their inhaler technique/device use would influence their motivation in inhaler technique maintenance. This perhaps demonstrates where the limitation of SDT lies in investigating the phenomenon of inhaler technique maintenance. Through delving further into the study data, however, a compelling explanation for these unexpected findings emerged, relating to the concept of personal relevance.

The lack of perceived personal relevance by patients, regarding issues around inhaler technique and device use, seemed to be the main reason why these issues were not found to have a compelling influence on patient motivation in inhaler technique maintenance. Upon considering patient responses on inhaler technique/device use in the context of their entire interview, it appeared that they were rather superficially connected to patients' actual or prevailing beliefs and feelings around their asthma experience. Indicative of this, were patient responses featuring much less emotion when the topic shifted to inhaler technique and device use. These cues were insightful, especially given that research within the field of emotion psychology postulates that a person's primary motivational system is based on emotions, and that particularly, emotions work to mark certain events with significance and priority (Silvia, 2012). Therefore the lack of emotion found in patients' inhaler technique/device use responses, suggests the relatively low priority, in terms of personal relevance, that these matters ranked.

Further evidence for the lower personal relevance of inhaler technique/device use matters stems from the observation that patients never voluntarily spoke about these matters in response to broad questioning (e.g. *"tell me about your asthma" or "tell me about your asthma medication"*), and had to be specifically prompted to do so during each interview. In addition, reoccurring descriptions of inhaler technique and device use as a "habitual" or "automatic" activity (Results, section ii, 1, e), suggests that patients dedicated little conscious attention to this aspect of their asthma self-management. Again, this may be an indication of the lack of perceived personal relevance of inhaler technique/device use related issues.

In contrast, factors found to have a more substantial influence on patients' motivation in inhaler technique maintenance, i.e. core and corroborating themes related to asthma and self-management, appeared to be much more personally relevant to the patient. This was evident in patient responses that tended to be more voluntary, lengthy, marked with emotions (e.g. fear of asthma attacks, optimism relating to effective self-management strategies), and connected to concrete experiences (e.g. symptom flare ups, medication side effects, impact of asthma on daily activities). In this way, patients indicated that they had a good grasp of the personal implications, specifically on health and quality of life, of issues around asthma and self-management in general. Interestingly, although patients demonstrated a fair level of knowledge or intellectual awareness of the issues around inhaler technique and device use, and its implications on asthma (perhaps as a result of their sensitisation to this knowledge through participation in the previous study), they did not seem to truly "internalise" (used in the same sense as described in SDT) this message as a matter of personal importance, for the reasons outlined above.

Arguably, the themes around asthma and self-management, being more personally relevant to the patient, better represented their prevailing sentiments influencing self-management, including with regards to inhaler technique maintenance. Hence, based on this reasoning, it became less surprising that the themes around asthma and self-management were found to be much more insightful, than the themes around inhaler technique/device use, in explaining patients' varying levels of motivation in inhaler technique maintenance.

Interestingly, in looking back, some of the results of the quantitative study (Chapter 3, section E) may also substantiate the concept of personal relevance as an important consideration in examining patient motivation in inhaler technique maintenance. Specifically, patients' level of motivation to maintain correct inhaler technique was, in the previous study, associated with the extent to which they believed inhaler technique would make a difference to their experience of asthma (i.e. there was a significant negative correlation between the two items: *"I am motivated to follow the correct steps when I use my inhaler"* and *"The way I use my inhaler will not affect my asthma"*). Notably, patients who were more motivated to maintain correct inhaler technique indicated stronger beliefs in the connection between the way that they used their inhaler device, in terms of following the correct technique, and their experience of asthma, a matter of personal relevance.

Triangulating the results of the quantitative and qualitative studies suggests that future investigations aiming to further explore patients' motivations and behaviours regarding inhaler technique maintenance, must account for patient perceptions on the broader, and arguably more personally meaningful, issues relating to their experiences around asthma and self-management in general. Focusing solely on inhaler technique and device use issues will likely limit the insights generated.

Through exploring the notion of personal relevance as discussed thus far, the theoretical principles examined in the Background (section iii) seemed to hold much more pertinence. Earlier, reference was made to the possible limitations of the theories utilised in this study for interpreting its findings. This was ostensibly because the findings regarding inhaler technique/device use did not support the theoretically based hypotheses generated (i.e. hypotheses 3-5). Upon deeper reflection, it is plausible that the theories chosen did not lend themselves well to interpreting the themes on inhaler technique/device use, because these themes were not greatly influential or revealing of patients' underlying motivations for inhaler technique maintenance, as they lacked personal relevance. Interestingly, after personal relevance emerged as an important concept, striking similarities were found between it and the key tenets of SDT, particularly relating to "autonomy" and "competence" (Ryan and Deci, 2000b).

According to SDT, to review briefly, when a patient is motivated to act "autonomously", the reason/s behind their actions are likely to be *personally important* or *relevant.* Importantly, activities driven by a more autonomous quality of motivation are shown to be maintained better over time (Deci and Ryan, 2012, Williams, 2002). In this study, for example, patients were more likely to maintain correct inhaler technique in instances where relatively higher motivation to actively manage asthma (first tier of influential themes in the ITMAM model, Figure 4.03), via a preventative-medication based approach (second tier of influential themes in the ITMAM model, Figure 4.03) was observed. Notably, and corroborated by the tenets of SDT, because these themes around asthma and self-management were of greater personal relevance than themes around inhaler technique/device use (as explained earlier), they were also more influential on the patients' motivation in inhaler technique maintenance. In particular, they were influential not only with respect to the relative magnitude of motivation, but also on the *nature* of patient motivation in terms of it being more or less *autonomous*.

Further, the third tier of themes in the ITMAM model (Figure 4.03), regarding confidence to self-manage successfully is comparable to the concept of “competence” described in SDT. As outlined in the Background (section iii, 2), the constructs of competence and autonomy are interrelated in SDT. Effectively this means that a greater sense of competence to self-manage may enhance patients’ sense of autonomous motivation for self-management activities, thereby increasing the likelihood that these activities are better maintained (Figure 4.01). It is worth pointing out that the construct of competence seems most insightful when applied to the broader notion of asthma self-management, rather than the specific activity of practicing correct inhaler technique. Again this may be related to the observation that patients could more readily identify the personally meaningful rationale behind “self-management” as a general concept, rather than in the specific task of inhaler technique practice, especially since patients held different views about what constituted good or ideal asthma self-management, some of which did not even involve the use of inhaler devices.

Interestingly, there is further tentative evidence to support future investigations into the relationship between self-efficacy and inhaler technique maintenance. Specifically, a recent study demonstrated that patients with better inhaler technique also possessed greater self-efficacy (comparable to “competence”) for asthma *self-management*, rather than self-efficacy regarding inhaler technique (Sleath et al., 2012). Self-efficacy, although an important construct behind the regulation of patient motivation and behaviour (Bandura, 2004), could not, before this study, be as clearly applied the context of inhaler technique per se, due to the numerous accounts of patients’ overconfidence with, or gross overestimation of, their own inhaler technique (Erickson et al., 1998, Pinto Pereira et al., 2001, Souza et al., 2009). The findings of this study however, suggest that self-efficacy may indeed be a worthwhile avenue of further investigation in the context of inhaler technique maintenance, provided that the notion of personal relevance is also taken into account.

As a final observation around the notion of personal relevance, it was interesting to note that what appeared to be of greater personal importance to patients, was avoiding or moving away from negative asthma outcomes (such as experiencing symptom flare ups, being hospitalised and being unable to participate fully in their lives), rather than moving toward and maintaining positive outcomes (e.g. maintaining good asthma control). Although this may seem like different sides of the same coin, research indicates that such, albeit subtle, differences in perspective may have important implications regarding how patients maintain long term health behaviours. Specifically, further investigating the construct of "avoidance-based" motivation (Rothman, 2000) in the context of inhaler technique maintenance may provide further useful insights.

Avoidance-based motivation drives people to take action to move away from or prevent the occurrence of undesirable events (Rothman et al., 2004). This is in contrast to "approach-based" motivation, which drives people to take action to move toward and reach more desirable states (Rothman et al., 2004). Interestingly, Rothman et al. (2000, 2004) postulate that, while approach-based motivation provides useful insight regarding the initial stages of behaviour change, it is avoidance-based motivation that is more powerful for understanding how and why behaviours are maintained over time. That is, in theorising the salient predictors of health behaviour maintenance, Rothman et al. (2000, 2004) identify avoidance-based motivation as a key factor. Thus it is not surprising to observe the principles of avoidance-based motivation being reflected in the findings this study, and suggests that this may be another avenue worthy of further investigation.

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The focus of discussion now shifts to the clinical and practical implications of this study, particularly, how health care professionals can facilitate better rates of inhaler technique maintenance amongst patients with asthma. To start with, it was observed that patients in this study were either more or less receptive to the input, advice or influence of their health care providers. In particular, patients who were more receptive to the influence of their health care providers were those who were also more motivated to take action to manage their asthma in order to avoid the potential negative consequences of the condition (with the reverse being the case for less receptive patients) (Figure 4.05). Based on this, it would seem that a health care provider's capacity to persuade patients to engage in appropriate asthma self-management (including with respect to inhaler technique) is limited to how convinced patients are of the need to do so, based on their own experiences, rather than because of any direct input from the health care provider.

Despite the salience of patients' personal experiences, this study showed that health care professionals were far from powerless in prompting improvements in inhaler technique maintenance. One of the first steps that health care professionals can take in this process, is to understand the underlying reasons for poor inhaler technique maintenance, and in particular, the reasons that lie beyond physical skill related factors. To aid in this, and with further testing and validation, the ITMAM model (Figures 4.03 and 4.05) may be a useful clinical tool. Specifically it may remind health care professionals of the influential factors around patients' asthma self-management, including with regards to inhaler technique maintenance, as well as the points at which patients are likely to be more receptive to health care advice.

The ITMAM model may also assist health care professionals in mapping out a process of clinical reasoning that can be used to identify patients at higher risk of developing poor inhaler technique over time. In conjunction with this, evidence from this study points to two other areas that health care professionals may focus upon to affect improvements in inhaler technique maintenance: 1) delivering inhaler technique education in a more personally relevant manner, and 2) cultivating interpersonal skills that create a greater sense of positive connection or "relatedness" (as per SDT) with the patient – both of which will be discussed at length now.

Delivering inhaler technique education in a more personally relevant manner, suggests that health care professionals need to understand inhaler technique maintenance from the patient's perspective. As this study shows, patients' views and sentiments, around inhaler technique itself, do not explain their motivations and behaviours regarding inhaler technique maintenance in a compelling way. This is a strong indication that patients tend not to ascribe weight to inhaler technique issues in isolation of their broader experiences around asthma and self-management. Therefore, health care professionals who intervene on inhaler technique issues, in isolation, may be less successful at helping patients achieve lasting improvements in inhaler technique.

This offers further explanation as to why current clinical recommendations, particularly in the pharmacy setting, aimed at improving inhaler technique maintenance – focused on physical demonstrations of inhaler technique, repeated on a regular basis, independent from other aspects of asthma self-management – tend not to have lasting success (Chapter 2, Table 2.02). This is not say that the current recommendations are not effective for enabling patients to initially grasp the physical manoeuvre required for correct inhaler technique. As established earlier in this thesis, repeating inhaler technique instructions via iterative physical demonstration is far superior compared to various other methods for the purposes of teaching correct inhaler technique (van der Palen et al., 1997). Further, by focusing solely on inhaler technique instruction, health care professionals can anticipate to spend no more than five minutes with each patient (Basheti et al., 2007), a time efficiency advantageous in busy practice environments.

However, in terms of supporting patients to maintain correct inhaler technique over time, and enhancing their motivation to do so, focusing solely on inhaler technique or device use issues at each interaction seems to fall short. This study suggests that vital information about patients at risk of poor inhaler technique maintenance (i.e. the influential patient psychosocial factors) may be missed by engaging with patients only at the inhaler technique/device use level. Further, repeatedly dispensing inhaler technique instructions, without addressing patient motivation or the issues most meaningful to them, may lead to patients feeling disengaged in their therapeutic relationships. Feeling disengaged, in turn, may impair a patient's sense of satisfaction, trust and rapport with their health care providers. Hence, automatic repetition of inhaler technique instructions may not only have minimal benefit in terms of technique maintenance, but may also be potentially detrimental to the quality of the patient-health care provider relationship. This study adds further evidence to the notion that health care professionals need to go beyond current recommendations to facilitate optimal inhaler technique maintenance in patients with asthma.

In understanding and leveraging the power of personally relevant factors in mobilising patients to more actively self-manage (including with respect to practicing correct inhaler technique), health care professionals may be in a better position to facilitate optimal inhaler technique maintenance over time. Practically, this suggests that health care professionals deliver inhaler technique education in a manner that clearly allows patients to see the link between inhaler technique maintenance and matters of personal importance. One strategy for doing this involves positioning inhaler technique issues in the broader context of a patient's asthma and self-management experience, for example, demonstrations of inhaler technique may be embedded in discussions emphasising optimal inhaler technique maintenance as an important strategy for reducing the chances of experiencing asthma exacerbations. As discussed earlier, and supported by the principles of SDT, patients who have a personally meaningful rationale for maintaining correct inhaler technique are more likely to do so.

More contextualised and comprehensive inhaler technique education would of course be expected to be more complex and time consuming to deliver. Notably, in a busy primary health care setting, there are likely to be more practical barriers to this type of intervention compared to shorter education sessions. Nevertheless, it is a strategy worthy of further investigation, especially given the evidence demonstrating the diminishing benefits of current recommendations for inhaler technique education (as discussed in Chapter 2, section iii), and the potential long term clinical and cost-savings benefits of a strategy that may result in more successful inhaler technique maintenance.

Further support for investigation in this area can be found in studies that show better inhaler technique maintenance after more comprehensive self-management education. For example, in the study by Kritikos, Armour and Bosnic-Anticevich (2007), no deterioration in inhaler technique occurred in most patient groups (3 out of 4), twelve weeks after receiving inhaler technique education (via physical demonstration) that was part of a more comprehensive asthma self-management session (lasting 150 minutes). Although other studies testing similar interventions exist (Wilson et al., 1993), and allude to good inhaler technique maintenance, they were less rigorous in repeating inhaler technique measures, therefore rendering it difficult to clearly observe inhaler technique maintenance trends over time. However, to seek clarification of such studies provides additional grounds for further investigation. At this point, it is also worth noting that in such studies, patient education is typically delivered in a small group format, which in some health care practice settings, may not be possible to orchestrate. Therefore, from a clinical practice point of view, future investigations would benefit from testing in the one-on-one, patient-health care provider context, since this is how the bulk of primary health care is delivered.

Another way in which health care professionals can facilitate better inhaler technique maintenance is to cultivate interpersonal skills that create a sense of positive connection with the patient. This suggestion arises from findings indicating that the quality of therapeutic relationships, as perceived by the patient, especially amongst those who are more receptive to health care professional influence, could influence inhaler technique maintenance (Figure 4.04). In particular, patients who indicated a greater sense of positive connection – that is, greater satisfaction, trust and rapport – with their health care providers, tended to be more motivated to maintain correct inhaler technique. Importantly, these patients described their health care providers not only as technically competent (i.e. being knowledgeable), but also as professionals who possessed good interpersonal skills. Health care providers who communicated well, and with care, reassurance and empathy were valued by patients.

The association between health care professionals' interpersonal skills and patients' inhaler technique maintenance is in line with earlier hypotheses, supported by theoretical principles. To briefly review, it can be seen that the extent of positive connectedness patients felt with their health care providers, is synonymous with the concept of "relatedness" as described in SDT (Williams, 2002). According to SDT, patients who have a greater sense relatedness with their health care providers tend to develop more autonomous motivation for self-management recommendations, and therefore more likely to maintain practices such as correct inhaler technique (Williams, 2002).

It is also worth further noting that these findings highlight that the health care professionals with whom patients felt positively connected, may have been facilitating optimal inhaler technique maintenance, not necessarily because they were regularly intervening around the physical skill of inhaler technique, but because of their influence on various patient psychosocial factors. Particularly on patients' sense of social support and confidence to undertake self-management successfully, both factors which also contributed to patients' sense of motivation around asthma self-management (including with inhaler technique maintenance). These findings incidentally add support to speculations along the same lines made in the previous quantitative chapter, i.e. that the influence health care professionals can have on patient motivation and confidence, may explain why some patients maintain correct inhaler technique simply by virtue of being in regular contact with their health care provider (Basheti et al., 2007).

The quality of the patient-health care provider relationship can thus determine not only whether patients gain the requisite skills and knowledge for optimal self-management, but also the confidence and motivation to do so. From a practical standpoint, these findings add further strength to the recommendation that health care professionals must look beyond the current recommendations of repeating inhaler technique instructions, in order to support optimal inhaler technique maintenance. Instead, health care professionals who cultivate good interpersonal skills are likely to be better facilitators of optimal inhaler technique maintenance compared to those who demonstrate technical proficiency alone.

Evidence from a recent observational study by Sleath et al. (2012) emerging shortly after this study, provides additional support for the association between health care professionals' interpersonal skills and patients' inhaler technique. In their study, Sleath et al. (2012) examined the nature of health care professionals' communication with their asthma patients (children aged 8 – 16 years), as well as patients' inhaler technique (with various DPIs and pMDI) one month after visiting their health care provider. Interestingly, although this study did not appear to be designed with much theoretical guidance, its results seemed to closely resonate with the principles of SDT. Particularly with regards to the notion that health care professionals who facilitate the development of more autonomous motivation in their patients, via good interpersonal/communication skills, can better support correct inhaler technique over time.

Some of the key results of Sleath et al.'s (2012) study will now be listed to illustrate the ways in which they resonated with SDT. Further, a possible theoretical rationale explaining each result listed below, based on the principles of SDT, is included in brackets. In Sleath et al.'s (2012) study it was shown that patients were more likely to demonstrate correct inhaler technique one month after visiting their health care provider, if during the visit, the health care provider: 1) included the patient's input into the asthma treatment plan (*this may enhance patients' autonomous motivation through promoting a greater sense of ownership and choice in self-management*); 2) discussed a written action plan with the patient (*this may enhance patients' autonomous motivation because it placed inhaler technique in a meaningful context, helping the patient to more clearly see its personal relevance*); and 3) provided more education about preventer medication (*again, patients' autonomous motivation may be enhanced because a meaningful context is provided for the practice of inhaler technique*). In addition, patients who asked more medication questions during their visit also demonstrated better inhaler technique at one month (*asking more questions may enhance patients' autonomous motivation because it indicates that time was spent addressing issues of concern/importance to the patient, establishing a clearer link between inhaler technique and matters of personal relevance*). Thus, in this way, health care provider communication that appeared to foster greater levels of autonomous motivation in patients, tended to result in better inhaler technique over time.

It is important to point out that Sleath et al.'s (2012) study did not involve any active interventions on inhaler technique. Inhaler technique education was only observed during 2.4 - 14.4% of visits (depending on the type of device in question), and further, whether this education was gold-standard or not, was not commented upon. Nevertheless, significant associations were found between the quality of the patient-health care provider interaction and patients' inhaler technique. This gives rise to the interesting implication that if health care providers could consistently be more holistic in engaging with patients, i.e. demonstrating good interpersonal skills, as well as gold-standard technique instructions, an even better result may be achieved in terms of inhaler technique maintenance. Therefore the relationship between health care professionals' interpersonal skills and inhaler technique maintenance is an area worthy of further investigation.

To summarise this section regarding health care provision, a set of practical recommendations for improving patients' inhaler technique maintenance is suggested, using the ITMAM model (Figure 4.03) as a frame of reference. The first point at the top of the ITMAM model indicates that when an asthma patient presents to their health care provider, they will either be more or less motivated to actively engage in asthma management (based on their personal views and experiences around asthma). Amongst those patients who are less motivated, and hence less likely to be receptive to their health care provider's advice, health care providers may want to be mindful that any direct instructions or information they provide is not likely to be immediately or fully taken up by the patient. Nevertheless, health care professionals may encourage patients to ask questions. This may prompt patients to be more reflective of their situation, and also identify issues that are of personal importance to the patient.

On the contrary, amongst patients who are more motivated to engage in asthma management, and thus more receptive to health care professional input, health care providers may consider a more targeted counselling approach, such as identifying and addressing specific knowledge and skills gaps. Amongst all patients, however, represented at all stages of the ITMAM model, health care professionals should aim to develop a therapeutic relationship that patients can feel a positive sense of connection in. This may be achieved through cultivating interpersonal skills that build rapport and trust with patients, as well as facilitate patient motivation and confidence in self-management. Although such efforts may not produce immediate improvements, over time, patients are likely to benefit from the support of a health care provider they feel greater relatedness with (SDT). Whether these recommendations translate into significant improvements in terms of patient outcomes, however, can only be confirmed with further investigations.

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This discussion will now examine the limitations and highlight some of the methodological considerations of this study so that its results may be interpreted with caution and future studies of a similar nature may be designed with improvements. Firstly, it needs to be acknowledged that the patients in this study were interviewed approximately one year after they had completed the previous quantitative study. However, the data regarding patients' inhaler technique maintenance status and level of motivation utilised in this study, from which the classification of "Maintainer" or "Non-maintainer" was based upon (Methods, section iv, 1), was derived from the previous quantitative study. Clearly, the issue here is that, inhaler technique maintenance status and motivation, both being dynamic phenomena, may have changed between the times patients completed the quantitative study, and when they were interviewed for this present study.

In terms of inhaler technique maintenance status, it is expected, that one year after completing the quantitative study, there would have been a general deterioration in inhaler technique amongst study patients (this is based on the inhaler technique literature summarised in Chapter 2, Table 2.02; that technique tends to deteriorate over time regardless of the education received). Potentially there may have been a greater number of Non-maintainers in this study than indicated by the quantitative data. This may mean that the characteristics of Maintainers and Non-maintainers may be less clear cut or distinct than demonstrated in this study. Ideally, patients' inhaler technique could have been re-assessed at the time of their interviews to overcome this issue. However, this was not feasible as the interviews were conducted over the telephone (for reasons outlined in the Methods, section iii, 2, a).

In terms of patient motivation around inhaler technique maintenance, this study suggests that primarily, it tends to be shaped by major events such as patients' past experience of asthma exacerbation/s (i.e. first tier of core and peripheral themes, Figure 4.03). Notably, the vast majority of patients interviewed did not reveal experiencing any such major events over the past year since completing the quantitative study (the one exception being patient 13:CH, NM), suggesting that patient motivation for inhaler technique maintenance may have been relatively stable in this study. Further indication for this lies in the findings of the quantitative study that showed no significant difference in patient motivation between study visits 1 and 2 (Chapter 3, Results, section ii, 6). However whether such stability in motivation is sustained over a longer period of time is unclear, and can only be ascertained through further studies.

Overall, given the potential for patients' inhaler technique maintenance status and motivation to fluctuate over time, further investigations are required to better understand the relationship between these two phenomena over a longer period of time. Specifically, future studies may benefit from taking more frequent and/or commensurate measurements of patients' inhaler technique maintenance status and motivation around inhaler technique maintenance, whilst also investigating the factors influencing motivation around inhaler technique maintenance. However, despite these limitations, the fact that many of the findings of this study could be corroborated by the principles of long standing and well tested theories (such as SDT and CSM as discussed throughout this section), lends credence to the insights generated.

Another area for consideration, regarding this study's methodology, is related to the veracity of patient responses obtained in the interview process. It must be acknowledged that, the interview process, not being anonymous, may increase the likelihood that patients are responding in a socially desirable manner (Green and Thorogood, 2004). Further, not all patients may be as forthcoming or articulate in their responses. To minimise these possibilities, the researcher worked to establish rapport with the patients before the commencement of each interview. For example, patients were encouraged to speak freely and informed that there were no "right" or "wrong" answers and were allowed to complete the interview at their own pace and direction (described further in the Methods, section iii, 2).

In addition, the telephone interview method was also acknowledged as a potential barrier against patients disclosing their views in a forthcoming or elaborate manner. Particularly, it has been expressed that, with the important dimension of non-verbal communication removed, telephone interviews may be more difficult to sustain compared to face-to-face interviews (Gillham, 2000). Attributed to this reason, 20-30 minutes have been reported as the maximum duration for telephone interviews (Gillham, 2000). However these issues were not a noticeable problem in this study, where the vast majority of patients seemed quite eager in sharing their views, and with the resultant interviews averaging 60 minutes in duration (Table 4.05). The greatest issues associated with telephone interviewing in this study was the inability to physically re-assess patients' inhaler technique as pointed out earlier.

A final area of consideration is in regards to the qualitative study methodology in general. Often, studies of a qualitative nature are claimed to be less "objective" due to their greater scope for personal interpretation (Creswell, 2003). To add to this, studies focusing on people's perceptions, motivations and behaviours tend to require higher levels of inference compared to studies investigating less dynamic subject matters (Gillham, 2000). These considerations serve as an important reminder that steps should be taken to enhance the interpretative rigor of qualitative studies.

In this study, various measures were taken to increase interpretative rigor. For example, a clear theoretical grounding was established in the Background to inform the development of this study; the themes identified were validated (as described in the Methods, section iv, 2); and study findings were supported with a comprehensive selection of verbatim quotes to allow for readers' own interpretations (Gillham, 2000). In addition, this study's findings were also triangulated with, or interpreted in light of, the previous quantitative study, as well as with various well established theories, in particular the CSM and SDT. This represents a more comprehensive approach that mitigates the potential for bias associated with using only one method to interpret the phenomena being investigated, and strengthens the conclusions drawn (Kitto et al., 2008).

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As a concluding comment to this chapter, it can be said that this qualitative follow-up study was instrumental in providing a deeper and more nuanced understanding of the relationship between patient motivation and inhaler technique maintenance. In particular, this study has demonstrated that various interrelated patient psychosocial factors, especially those that are considered of personal relevance by the patient, can influence patient motivation to maintain correct inhaler technique. It also highlights innovative ways in which health care professionals can deliver more effective inhaler technique education and forge better therapeutic relationships to instigate improvements in patients' inhaler technique maintenance. Further investigations in the areas highlighted throughout this discussion are required to corroborate the findings of this study, as well as to test its practice recommendations. However, as it stands, this study can be considered to have enriched the findings of the previous quantitative study, adding further insight to the overarching aim of this thesis to better understand the phenomenon of inhaler technique maintenance in patients with asthma.

F. Summary

- This chapter aimed to explore the relationship between patient motivation and inhaler technique maintenance identified in the previous quantitative study.
- Using a qualitative study design, influential themes explaining the relatively different levels of patient motivation in inhaler technique maintenance were identified.
- The core set of influential study themes were: degree of patient motivation to actively engage in asthma self-management; degree of patient motivation to self-manage via a preventative-medication based approach; degree of patient confidence to self-manage effectively.
- Influential themes did not relate to any inhaler technique/device use issues. Instead they seemed to stem from matters that patients could most readily identify the personal relevance in (e.g. experience of symptom exacerbations).
- The Inhaler Technique Maintenance and Motivation (ITMAM) model was developed based on this study's findings and may be a useful tool for health care professionals to identify patients at risk of poor inhaler technique maintenance.
- Health care providers may improve inhaler technique maintenance by grounding inhaler technique education in a more personally relevant context. Cultivating interpersonal skills that enhance the sense of connectedness patients feel in their therapeutic relationships may also improve inhaler technique maintenance.
- Further evidence is required to substantiate the findings and implications of this study, and various promising areas for future investigation have been identified in the discussion.

— CHAPTER 5 —

SUMMARY AND CONCLUSIONS

"KNOWING HOW" IS NOT ENOUGH, in a phrase, points to why patients with asthma often demonstrate poor inhaler technique maintenance despite the absence of known barriers. This thesis presents the first body of work that examines the phenomenon of inhaler technique maintenance in-depth. As a result of this research, various new explanations have been identified regarding the reasons why poor inhaler technique maintenance is consistently observed amongst patients with asthma. These reasons underpin the notion that it is not enough to simply be able to use one's device correctly in order to maintain optimal technique, and that less tangible considerations, such as a patient's motivations around asthma management, are equally worthy of consideration.

A. Summary of work

Asthma, and especially poorly managed asthma, is a source of significant burden for both the patient and the community at large (ACAM & WIMR, 2011, Barnes et al., 1996). This is especially the case in Australia where the prevalence of asthma is one of the highest by global standards (ACAM & WIMR, 2011, GINA 2012). Effective treatment options for asthma do exist (AMH 2013), however, their success is contingent upon how patients engage in their use. For example, the extent to which patients adhere to preventer therapy, or whether patients use their inhalers with the correct technique. Importantly, how patients engage in using their asthma therapy has significant implications for their asthma outcomes (Chapter 2, section B, ii).

How patients maintain inhaler technique, in particular, formed the focus of this research for several important reasons. Correct inhaler technique maintenance is essential to good asthma self-management and constitutes an important strategy for improving asthma outcomes (Basheti et al., 2007, Melani et al., 2011). Although there are multiple factors that contribute to patient asthma outcomes (Haughney et al., 2008), inhaler technique has been shown to contribute both independently and significantly to patients' asthma control status as well as quality of life (Basheti et al., 2007, Giraud and Roche, 2002).

The high prevalence of suboptimal inhaler technique demonstrated by patients (Lavorini et al., 2008, Melani et al., 2004, 2011), and the imperative to improve this status, has sparked much research in the area. Gains have been made, for example, in identifying effective methods for patient technique education, through tactics such as repeated physical demonstration and "train the trainer" (Basheti et al., 2007, 2008, 2009). Nevertheless, patients' inhaler technique has been shown, across various study settings, to deteriorate over time, despite having received gold-standard technique education and initial successes in learning technique (Chapter 2, Table 2.02). These past studies, collectively, pointed to a gap in the literature concerning the reason/s why patients did not maintain correct inhaler technique, despite the absence of known barriers. Investigating the phenomenon of inhaler technique maintenance amongst patients with asthma, and identifying the reasons why inhaler technique declines, despite the initial successes of current interventions, thus formed the thrust for the studies developed in this thesis (Chapters 3 and 4).

The scope and approach taken in research conducted in this thesis can be broadly summarised as: exploratory, theoretically and empirically informed and patient-centred. Firstly, due to the lack of existing empirical evidence in the area of inhaler technique maintenance to inform the studies of this thesis in a more direct fashion, an exploratory approach was rendered as necessary initial steps. Thus, the studies presented in this thesis were exploratory in nature, with a substantial basis in relevant theories to inform their development (FSLT, CSM and SDT in particular).

Secondly, a patient-centred approach to investigating inhaler technique maintenance meant that patient behavioural and psychosocial factors were considered in this research to be potentially relevant in understanding inhaler technique maintenance. This is in contrast to the mainstay of studies published in the inhaler technique arena, that account for patient factors only so far as patient-demographic, patient-clinical, patient-device use related, or patient-technique education related. A patient-centred approach, extending beyond such traditionally investigated factors, was deemed essential because inhaler technique maintenance constitutes a type of self-management behaviour that patients adopt. Further, and importantly, patient behaviours, including in the context of chronic condition self-management, are inextricably linked to psychosocial determinants such as beliefs, attitudes, motivations and interactions with health care professionals (Glanz, Rimer and Viswanath, 2008).

The studies conducted in this thesis were also clinically oriented and based in the community pharmacy setting in the Sydney metropolitan area. The community pharmacy setting, as discussed in Chapter 1, was chosen for this study because pharmacists are health care professionals highly suited to intervene and monitor on patients' inhaler technique. The prime reasons for this are pharmacists' relative ease of accessibility to patients, their designation as medication experts in the community, and proven ability to improve asthma outcomes via service provision (Armour et al., 2013).

The research presented in this thesis unfolded in a sequential manner. An initial quantitative study (Chapter 3) was conducted that identified research leads that were pursued in a follow-up qualitative study (Chapter 4). Hence, this thesis evolved to be mixed-methods in approach (Creswell, 2003). Hence, inhaler technique maintenance was investigated utilising two distinct research methods. This allowed both breadth and depth in addressing the questions around inhaler technique maintenance (Creswell, 2003). That is, while the quantitative study explored a much broader range of factors in relation to inhaler technique maintenance, the qualitative follow-up study honed in on particular novel findings of the quantitative study (i.e. relating to patient motivation), and explored these in much greater detail than could have been achieved via a quantitative approach alone.

The key findings of this thesis are now highlighted with reference to the two studies . Firstly, the initial quantitative study (Chapter 3) explored various potential predictors of inhaler technique maintenance. Potential predictors were identified through establishing a basic framework to conceptualise inhaler technique maintenance (i.e. the "Inhaler Technique Maintenance Framework"/"ITMF", Chapter 3, Figure 3.01), and subsequently, by elaborating upon this framework (Chapter 3, Figure 3.05) via utilising well-established theories, including FSLT and the CSM (Fitts and Posner, 1967, Leventhal et al., 2003). From the pool of 28 unique variables that were tested in this study (Table 3.04), three were identified, via regression analyses, to be significant determinants of inhaler technique maintenance:

1) Device type (DPI or pMDI)
2) Asthma control (baseline)
3) Motivation to practice correct inhaler technique (baseline)

The results indicated that patients who were likely to maintain correct inhaler technique, one month after technique education (via physical demonstration), were those who were using a DPI as opposed to a pMDI, had better asthma control at baseline and possessed higher motivation to practice correct inhaler technique at baseline.

Identifying *Device type (DPI or pMDI)* as a predictor of inhaler technique maintenance can be associated with various past studies indicating that DPIs can be easier to use than pMDIs for many patients (Rees, 2005). Importantly, this finding implies that there is still much scope for health care professionals to actively address the known barriers (Chapter 2, section C, ii) to poor inhaler technique maintenance. For example, by ensuring inhaler devices are best suited to a patient's physical abilities and preferences (Dolovich and Dand, 2011).

Identifying *Asthma control (baseline)* and *Motivation (baseline)* as determinants of inhaler technique maintenance highlighted, for the first time, the potentially significant role that patient psychosocial factors may have in technique maintenance. Although the mechanism by which asthma control was having an impact on inhaler technique maintenance could not be confirmed, there was some evidence to suggest that it involved having an influence on patient perceptions and motivations. This, coupled with the fact that patient motivation was found to be an independently significant predictor of inhaler technique maintenance, provided compelling evidence for further investigations in this area.

The subsequent follow-up study conducted (Chapter 4), was qualitative in nature and designed to allow for a more in-depth exploration of patient psychosocial factors, in particular, patient motivation, in the context of inhaler technique maintenance. The aim of this study was to better understand inhaler technique maintenance from the perspective of patient motivation, by investigating what rendered patients more or less motivated to maintain correct inhaler technique. Again, as with the previous study, relevant theories (the CSM and SDT in particular) formed a very useful foundation in the development of this study (Deci and Ryan, 2012, Leventhal et al., 2003).

Through the core themes identified in the qualitative study, the "Inhaler Technique Maintenance and Motivation" (ITMAM) model was developed (Figures 4.03 and 4.05). The ITMAM model indicates that differences in patient motivation to maintain inhaler technique can be attributed to their perceptions and feelings relating to asthma and self-management, as well as the influence of the health care providers whom patients interact with. Further, "personal relevance", as an important driver behind patient motivation to engage in asthma management activities, including in relation to inhaler technique maintenance, was an important concept identified in this study.

Figure 5.01 summarises the key findings identified in this thesis. Further, it illustrates the triangulation of theories with data, and quantitative and qualitative study methods that is a feature of this research. This triangulation, notably, adds strength to the conclusions that are drawn in this thesis (Kitto et al., 2008).

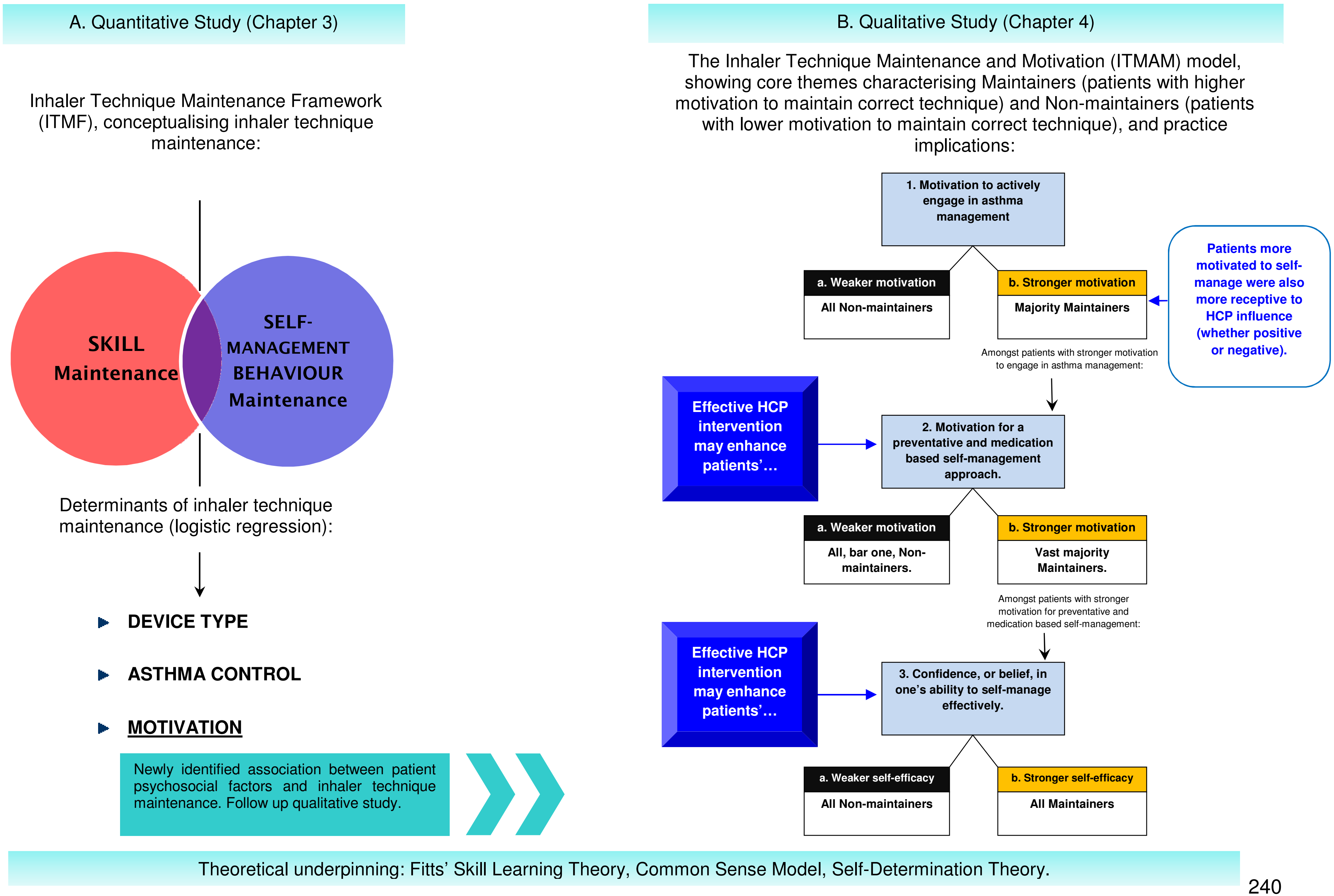

Figure 5.01: Summary of the work presented in this thesis

B. Recommendations for facilitating optimal inhaler technique maintenance

In drawing together the quantitative and qualitative studies, which were informed by both the empirical and theoretical literature, it can concluded that facilitating optimal inhaler technique maintenance, extends beyond practical or skill-related inhaler device use considerations. In fact, both studies indicated that patients' existing skills, knowledge or perceptions relating to inhaler technique or device use had little bearing on whether they maintained correct inhaler technique, or whether they were motivated to do so.

Although the provision of inhaler technique instructions, via repeat physical demonstration (Chapter 3, section C, iii, 1), is an essential part of optimal inhaler technique maintenance (Basheti et al., 2007), implemented in isolation, this strategy does not seem to offer patients a meaningful and compelling rationale to maintain correct technique over time. In order to enhance the likelihood of correct inhaler technique maintenance, it seems necessary that health care professionals interact with patients in a more holistic manner and recognise the relevance of good interpersonal or communication skills in supporting optimal patient self-management.

Based on the work undertaken in this thesis, several practical recommendations are made on how health care professionals in the primary care setting, in particular, community pharmacy, can support patients to maintain correct inhaler technique over time:

1. Address known barriers to poor technique maintenance. For example, when teaching inhaler technique, use gold-standard methods (Basheti et al., 2007, 2008, 2009), rather than less effective methods (such as giving out written

instructions alone); periodically re-assessing patients' physical compatibility with their prescribed inhaler device/s; asking about patient preferences regarding inhaler devices.

2. Allow patients more time and opportunity to engage in *accurate* inhaler technique practise guided by health care professional feedback. This contributes to the correct version of the skill being consolidated, thus enhancing the chances of optimal inhaler technique maintenance (Cornford, 2008, Shim and Williams Jr, 1980).

3. Use the ITMAM model developed as part of the qualitative study as a clinical tool to identify patients at risk of developing poor inhaler technique over time (Figure 4.03, 4.05 and 5.01). For example, health care professionals, referring to the ITMAM model, may probe into certain beliefs and attitudes that patients possess (left hand side, Figure 4.03) to gauge their relative level of motivation to participate in self-management via a preventative-medication based approach, and relative level of self-efficacy to self-manage effectively. Beliefs and attitudes indicating relatively lower patient motivation to engage in preventative-medication based self-management, and lower patient self-management self-efficacy, may flag to the health care provider those patients who are at risk of poor inhaler technique and asthma control over time. These patients may be identified as those who may benefit the most from an intervention centred on, or including, inhaler technique education.

4. Adopt a more consultative and holistic approach when providing inhaler technique education, rather than a didactic approach. For example, provide inhaler technique instructions in conjunction with discussions regarding patients' asthma management in general, or engage in a discussion regarding patients' recent experience of asthma. This is based on the notion that

enhancing patients' ability to identify with the personal importance of practicing correct inhaler technique can lead to better technique maintenance (qualitative study).

5. Identify opportune times to reinforce self-management advice, including inhaler technique education, such as when a patient has experienced a recent flare up in asthma symptoms. Notably, patients with poor asthma control may be more prone to developing poor inhaler technique over time (quantitative study). Further, patients who have experienced recent symptom exacerbations are likely to be more receptive to health care professionals' advice (qualitative study).

6. Cultivate satisfaction, trust and rapport in therapeutic relationships with patients via good interpersonal skills (as per examples in Table 4.02). This is based on the findings of the qualitative study showing that patients who were receptive to health care professionals' influence, and who perceived themselves to be positively connected in their therapeutic relationships, were more likely to have maintained correct inhaler technique.

These recommendations may require health care professionals to invest more time in their interactions with their patients, and therefore may be challenging to implement in light of the practical constraints common in many primary care practices such as community pharmacies. However, the costly burden of asthma on patients and the community, and the potential for such health care services to alleviate this burden (via improved treatment outcomes, costs and quality of life) are compelling reasons for individual practitioners as well as governments to invest in strategies that result in sustained improvements in asthma management.

C. Future research directions

As the first known body of work that has taken an in-depth investigation into the phenomenon of inhaler technique maintenance, this research would benefit from further studies corroborating its findings and recommendations. In broad terms, it would be useful to investigate the determinants of inhaler technique maintenance amongst larger and more diverse patient populations to determine the degree of generalisability of the findings identified in this thesis.

Various other specific issues have also been identified throughout the discussions in this thesis (i.e. Chapters 3 and 4, section E) as potential areas for future research. These studies, if undertaken, would provide a means to better understand the newly identified role of patient psychosocial factors in inhaler technique maintenance, and perhaps asthma self-management in general. These potential areas for future research include:

1) Developing a validated questionnaire to measure patient motivation in inhaler technique maintenance.

2) Conducting longer term studies to measure the relationship between patient motivation, inhaler technique maintenance and psychosocial factors identified in the ITMAM model (Figure 4.05); and whether/how it changes over time.

3) Measuring patient self-efficacy in self-management (confidence to self-manage effectively) and its influence on inhaler technique maintenance status.

4) Investigating the role of "avoidance-based motivation" (Chapter 4, section E) in inhaler technique maintenance.

It is also important to conduct further studies on the recommendations for practice made earlier. This is in order to determine how well these recommendations may be adapted to the clinical practice setting, how feasible they are to implement and sustain and whether they result in clinically significant improvements. Studies in this area may involve:

1) Testing and validating the ITMAM model developed (Figure 4.05) and its potential to be used as a clinical tool in asthma for identifying patients at risk of poor inhaler technique. Notably, there is also scope to investigate the ITMAM model in the context of other asthma self-management behaviours (e.g. adherence), or in relation to other chronic conditions.

2) A randomised controlled trail conducted in the community pharmacy setting comparing the impact, on patients' technique maintenance, of brief technique education (i.e. providing inhaler technique instructions alone) versus holistic asthma education (i.e. providing inhaler technique instructions as part of a more comprehensive asthma self-management intervention).

3) Investigating the influence of health care professionals' interpersonal or communication skills on patients' inhaler technique maintenance.

D. Concluding remarks

The phenomenon of inhaler technique maintenance has been investigated in-depth for the first time. Specifically, this research represents the first coordinated endeavour to identify the determinants of inhaler technique maintenance in patients with asthma. Being patient-centred, in terms of examining behavioural and psychosocial factors, and the extensive use of theory, are not common approaches in the existing inhaler technique research. In this thesis, however, these strategies have proven to be instrumental in generating new insights.

The novel work in this thesis has contributed to the field of inhaler technique research in several important ways. In particular, the exploration of patient behavioural and psychosocial factors in the context of inhaler technique maintenance has resulted in empirical evidence pointing to a significant association between these factors for the first time. The findings of this thesis have further enabled the identification of new directions for future research.

Ensuring patients maintain correct inhaler technique, although only one element of asthma management, is nevertheless highly important for its success. The way in which patients maintain inhaler technique, has a significant impact on asthma outcomes, both on a personal and community scale. Fundamentally, optimal inhaler technique maintenance contributes to better asthma control, and having well controlled asthma as put by one patient: *"… it just lets you get on with life without being sick all the time… Well it's everything. It's a quality of life" – KK.*

— CHAPTER 6 —

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APPENDICES

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10 November 2009

Dr Sinthia Bosnic-Anticevich
Faculty of Pharmacy
Pharmacy Building – A15
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Email: sinthia@pharm.usyd.edu.au

Dear Dr Bosnic-Anticevich,

Thank you for your correspondence dated 29 October 2009 addressing comments made to you by the Human Research Ethics Committee (HREC). After considering the additional information, the Executive Committee at its meeting held on **3 November 2009** approved your protocol entitled "***Improving inhaler technique maintenance – developing novel ways to optimise inhaler instruction for asthma patients".***

Details of the approval are as follows:

Ref No.:	***11-2009/12226***
Approval Period:	***November 2009 – November 2010***
Authorised Personnel:	***Dr Sinthia Bosnic-Anticevich***
	Dr Lorraine Smith
	Ms Ludmila Ovchinikova

The HREC is a fully constituted Ethics Committee in accordance with the *National Statement on Ethical Conduct in Research Involving Humans-March 2007* under *Section 5.1.29*

The approval of this project is **conditional** upon your continuing compliance with the *National Statement on Ethical Conduct in Research Involving Humans.* We draw to your attention the requirement that a report on this research must be submitted every 12 months from the date of the approval or on completion of the project, whichever occurs first. Failure to submit reports will result in withdrawal of consent for the project to proceed.

Chief Investigator / Supervisor's responsibilities to ensure that:

Appendix 3.01: Quantitative study ethics approval

(1) All serious and unexpected adverse events should be reported to the HREC as soon as possible.
(2) All unforeseen events that might affect continued ethical acceptability of the project should be reported to the HREC as soon as possible.
(3) The HREC must be notified as soon as possible of any changes to the protocol. All changes must be approved by the HREC before continuation of the research project. These include:-

- If any of the investigators change or leave the University.
- Any changes to the Participant Information Statement and/or Consent Form.

(4) All research participants are to be provided with a Participant Information Statement and Consent Form, unless otherwise agreed by the Committee. The Participant Information Statement and Consent Form are to be on University of Sydney letterhead and include the full title of the research project and telephone contacts for the researchers, unless otherwise agreed by the Committee and the following statement must appear on the bottom of the Participant Information Statement. *Any person with concerns or complaints about the conduct of a research study can contact the Deputy Manager, Human Ethics Administration, University of Sydney, on (02) 8627 8176 (Telephone); (02) 8627 8177 (Facsimile) or human.ethics@usyd.edu.au (Email).*
(5) Copies of all signed Consent Forms must be retained and made available to the HREC on request.
(6) It is your responsibility to provide a copy of this letter to any internal/external granting agencies if requested.
(7) The HREC approval is valid for four (4) years from the Approval Period stated in this letter. Investigators are requested to submit a progress report annually.
(8) A report and a copy of any published material should be provided at the completion of the Project.

Yours sincerely

Phily Beale

Associate Professor Philip Beale
Chairman
Human Research Ethics Committee

Copy: Ms Ludmila Ovchinikova lovc6632@uni.sydney.edu.au

Encl.
Approved Participant Information Statement (Pharmacist)
Approved Participant Information Statement
Approved Consent Form (Pharmacist)
Approved Participant Consent Form
Approved Letter of invitation to pharmacist
Approved Pharmacist baseline survey
Approved Patient questionnaires
Approved inhaler technique scoring sheet for pharmacists
Approved inhaler technique scoring sheet for patients

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Letter of Invitation

Dear Pharmacist,

You are invited to participate in a study which will examine inhaler device use in community based asthma patients.

As a community pharmacist you are in an excellent position to recognise patients who may have poor asthma control due to sub-optimal medication use with their inhalers. We know that large numbers of patients do not use their asthma inhaler devices with the proper technique and so do not gain the full treatment benefit. You may have noticed that pharmacists are becoming increasingly active in patient care services - these have been shown to have a positive impact on medication therapy outcomes for people with asthma.

The aim of this study is to better understand patterns of inhaler medication use in the asthma patients who visit your pharmacy. The results of the study will be used to develop tools that pharmacists can use to improve inhaler device use leading to better asthma management.

Choosing to participate in this study will mean that you will attend a 2 hour workshop on asthma management with inhaler medication at the Faculty of Pharmacy, meet your asthma patients on 2 visits over a 1 month period, complete short questionnaires, teach your patients how to use their inhaler devices and give your patients telephone reminders before their follow up visit.

The benefits of participation include:

- Customer satisfaction due to the specialised service received
- Customers spending their gift voucher in your pharmacy
- Awarding of CPE points for workshop participation
- A good opportunity to refresh your asthma management knowledge

Yours faithfully,

Ludmila Ovchinikova

Reference: DB/GO

10 December 2009

Ludmila Ovchinikova

Faculty of Pharmacy
Building A15, Science rd, Camperdown
University of Sydney
NSW 2006

Dear Ludmila,

Accreditation Application NX090016-APN

The following activity has been accredited by the Pharmaceutical Society of Australia.

Activity name	Provider/sponsor	Date and location	Accreditation number	Number and type of points allocated
Quality Use of Inhalers in Pharmacy workshop	Faculty of Pharmacy	Faculty of Pharmacy, University of Sydney February 2010 weekday evening TBC	NX090016	Group 2 = Points 3.5

The CPD&PI logo may be used on promotional material associated with this activity provided the following wording accompanies it:

Pharmaceutical Society of Australia

This activity has been accredited by the Pharmaceutical Society of Australia as a Group 2 activity for 3.5 points. Accreditation number: NX090016.

PSA is authorised by the Australian Pharmacy Council to accredit providers of CPD activities that may be used as supporting evidence of continuing competence

A participation list must be returned in electronic format (preferably *Excel*) to this office **within two weeks** of the completion of the activity. The participant list must include activity name, accreditation number, number and type of points allocated, date of participation/completion, provider and sponsor company, participant names and PSA member numbers. A template can be downloaded from www.psa.org.au/cpdpi

Please be aware that it is the provider's responsibility to ensure the activity is delivered according to the Criteria for the accreditation of activities for Continuing Professional Development and Practice Improvement and the information submitted in the application. Please notify us of any changes to the activity should they arise, as this may affect the final point allocation.

Special consideration has been granted to waive the Application fee for this event.
An invoice for the administration fee of $110 (including GST) will be forwarded to you shortly.

Yours sincerely

DOMENICA BASKIN
NSW State Manage

The University of Sydney

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PHARMACIST PARTICIPANT INFORMATION STATEMENT
Research Project

Title: The Inhaler Technique Maintenance Study

(1) What is the study about?

You are invited to take part in a research study into the use of inhaler devices by people with asthma. The aim of this study is to investigate patterns of inhaler device use in people with asthma and the factors that can impact on this. It has been shown many people using inhaler devices have difficulty getting the exact technique correct and this may compromise their levels of asthma control. Further, it known that community pharmacists can effectively educate patients to improve inhaler technique and asthma control.

(2) Who is carrying out the study?

The study is being conducted by Ms Ludmila Ovchinikova and will form the basis for the degree of Doctor of Philosophy at the University of Sydney under the supervision of Dr Sinthia Bosnic-Anticevich and Dr Lorraine Smith, all from the Faculty of Pharmacy.

(3) What does the study involve?

The study involves participation in an inhaler device evening workshop held at the Faculty of Pharmacy, University of Sydney. During this workshop you will be taught on how to train patients on the correct technique for using the pressurised Metered Dose Inhaler, Turbuhaler or Accuhaler. You will fill out a brief survey regarding past inhaler device education. You will also receive a thorough explanation of the recruitment process and conducting the study in your pharmacy.

You will be asked to aim to recruit 5 to 10 eligible patients for the study from your pharmacy by obtaining written informed consent. You will then assess patient inhaler technique, educate on inhaler technique and assist patients in filling out questionnaires.

Patients will come back for a follow up visit at your pharmacy in one month. At this point you will be asked to re-assess their inhaler technique and direct them to fill out further questionnaires.

(4) How much time will the study take?

- The evening workshop will take 2 hours
- The recruitment process will be given a 4 week period
- Both the initial and follow up patient visits should take approximately 15 minutes

(5) Can I withdraw from the study?

Being in this study is completely voluntary - you are not under any obligation to consent, and if you do consent you can withdraw at any time without affecting your relationship with the University of Sydney. However if you choose to withdraw after having already recruited patients into the study, you will be asked to give permission for the researcher to continue to conduct the study inside your pharmacy.

(6) Will anyone else know the results?

All aspects of the study, including results, will be strictly confidential and only the researchers will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

(7) Will the study benefit me?

You will be given opportunity to receive training that will update your knowledge and skills in asthma management. You will be able to extend these skills into everyday practise and enhance service delivery to your patients. Further, each patient you recruit into the study will receive a $20 gift voucher that they can spend in your pharmacy.

(8) Can I tell other people about the study?

You are free to discuss the study with others if you so wish.

(9) What if I require further information?

When you have read this information, Ludmila Ovchinikova will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Dr Sinthia Bosnic-Anticevich on (02) 9351 5818 or Ludmila Ovchinikova on (02) 9351 4501.

(10) What if I have a complaint or concerns?

Any person with concerns or complaints about the conduct of a research study can contact the Deputy Manager, Human Ethics Administration, University of Sydney on (02) 8627 8176 (Telephone); (02) 8627 7177 (Facsimile) or human.ethics@usyd.edu.au (Email).

This information sheet is for you to keep

The University of Sydney **Faculty of Pharmacy**

ABN 15 211 513 464

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Web: www.usyd.edu.au/

PHARMACIST PARTICIPANT CONSENT FORM

I, ...[PRINT NAME], give consent to my participation in the research project

TITLE: **"The Inhaler Technique Maintenance Study"**

In giving my consent I acknowledge that:

1. The procedures required for the project and the time involved have been explained to me, and any questions I have about the project have been answered to my satisfaction.

2. I have read the Participant Information Statement and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s Dr Sinthia Bosnic-Anticevich, Dr Lorraine Smith and Ms Ludmila Ovchinikova of the Faculty of Pharmacy, The University of Sydney.

3. I understand that I can withdraw from the study at any time, without affecting my relationship with the researcher(s) or the University of Sydney now or in the future.

4. I understand that my involvement is strictly confidential and no information about me will be used in any way that reveals my identity.

5. I understand that being in this study is completely voluntary – I am not under any obligation to consent.

6. I consent to: –
   i) Attending an inhaler technique evening workshop conducted by the researcher YES☐

   ii) Conducting the study in my pharmacy YES☐

   iii) Recruiting patients for the study and assessing and training them on inhaler technique YES☐

iv) Assisting patients with filling out questionnaires YES☐

v) Collecting and storing patient data in a confidential manner YES☐

vi) Participating in the follow-up YES☐

vii) Receiving Feedback YES☐

If you answered YES to the "Receiving Feedback Question (vii)", please provide your details i.e. mailing address, email address.

Feedback Option

Address: ____

____

Email: ____

Signed: ....

Name: ....

Date: ....

Appendix 3.06: Timetable of the QUIP workshop activities

Learning area	Activities	Time
Welcome and setting up group dynamics	LO: Group welcome. Housekeeping re OH&S, amenities and refreshments. Introduce presenters (LO, SBA, LS). A round of self-introductions. Ice-breaker video. Interaction protocol. Group learning goals and objectives (with slide).	5 min
	Refreshment break Monday evening workshop (15min)	
Contextualising Inhaler technique	SBA: Presentation on inhaler technique (problems and consequences) in the context of asthma self-management.	10 min
Expert inhaler technique modelling	SBA: Demonstrate technique with placebo pMDI, TH and ACC. LO: Step-by-step commentary on demonstration – rationale behind each step (with aid of checklist slides)	5 min
Hands-on interactive inhaler technique learning	Attendees: Practise inhaler technique with personal placebo devices and printed checklists until confident. Then work in pairs to assess each other's techniques with provision of feedback until competence and confidence achieved.	15 min
Interactive learning on inhaler technique assessment and instruction	LO: Explain iterative assessment and technique demonstration process for instructing patients and pointers for helping patients remember steps (with slides). LS and volunteer attendee: Role play a community pharmacy scenario on technique counselling – assessment and instruction; between pseudo-asthma patient (LS) and pharmacist (attendee). Remaining attendees: Practice assessing technique with checklist as they watch role play. Group: Feedback and questions on role play. Discussion on how to overcome communication barriers and patient resistance to inhaler technique counselling. Attendees: Watch video demonstrations (LO) of suboptimal inhaler technique with the pMDI, TH and ACC. Score technique using printed checklist for the 3 devices. Group: Feedback on assessment outcomes. Clarifications and discussion regarding the assessment procedure.	20 min
	Refreshment break Saturday morning workshop (15min)	
Study recruitment	LO: Explain workshop transition onto discussing the study protocol. Explain participant recruitment, recruitment time frame; pre-empt the possible challenges with recruitment and aids to enhance participation (flyers and posters). Group: Brainstorm on recruitment tips and strategies (on worksheets)	10 min
Study protocol	LO: Disseminate the ITeM Study Manual. Go through the manual layout; protocol step-by-step; data collection procedure; administration regarding vouchers and reimbursement process; who to contact for support.	15 min
Inhaler technique competency assessment and workshop surveys	Assess attendee inhaler technique one-on-one (LO, SBA or LS). Give feedback using printed checklist, verbal guidance and physical demonstration. Continue process until attendee demonstrates correct techniques. Remaining attendees to fill in study workshop survey, PSA evaluation form, attendance records whilst waiting.	20 min
Conclusion	LO: Recap on workshop, taking final questions. Hand out certificates of attendance. Thank attendees.	5 min
	Total time	120min

Appendix 3.07: QUIP lecture slides

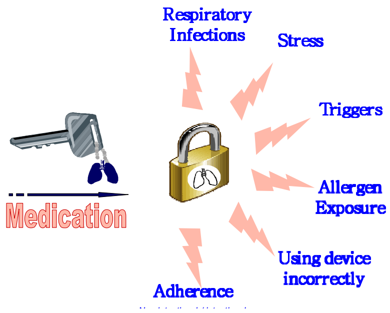
Quality Use of Inhalers in Pharmacy Workshop

Dr Sinthia Bosnic-Anticevich, Dr Lorraine Smith, LudmilaOvchinikova

ASTHMA

› Asthma is an inflammatory airways condition
› Prevalence of asthma in Australia is relatively high
  - 14-16% in children, 10-12% in adults[1]
› Optimum management important to improve patient outcomes and reduce costs
  - Lifestyle: Avoiding triggers
  - Drug: Appropriate and correct use of medication

MEDICATIONS



IT IS ALL ABOUT GOOD CONTROL !

› The right medications
› The right regimen
› At the right time
› **In the right way (inhaler technique)**

› A continual and dynamic process ……….

THE INHALER ROUTE

› All patients with asthma use inhaler devices
› The inhaled route is effective…

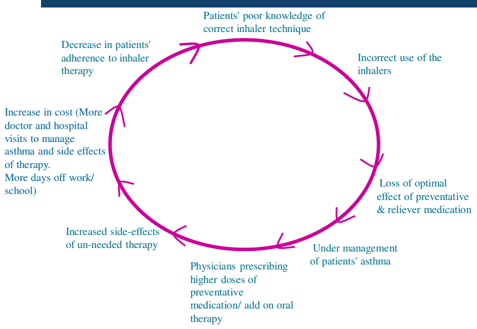
THE INHALED ROUTE

SOME PROBLEMS…

› "Aerosol deposition and the resulting therapeutic response are critically dependent on the patient's inhalation technique"
› Up to 94% of patients use their inhaler devices incorrectly
› Patients are not aware of this
› Health care professionals often focus on other things

Appendix 3.07: QUIP lecture slides

CONSEQUENCES OF POOR TECHNIQUE



MEDICATIONS – IN THE RIGHT WAY

› Assume it is poor (approx 80-90%)

› Recognise the possible consequence to medication management

› Know you can improve

› Appreciate you will need to review and re-educate

THE STATISTICS ON INHALER USE

› Efficient devices, however, incorrectly used

› Turbuhaler (TH) - Incorrect technique is common (54% of patients)

› Accuhaler/Diskus (ACC) - Incorrect technique is common (50% of patients)

› Pressurised metered dose inhalers (pMDIs) – Incorrect technique is common (56% of patients)

WHY ARE PATIENTS NOT BEING EDUCATED

› Incorrect inhaler technique: Health care providers (various devices): 31- 85%

› Pharmacists TH: 43 - 71% , ACC: 55%

› Lack of confidence

› Perception that advice may not be welcome

WHO IS CHECKING INHALER TECHNIQUE ?

Source of advice on inhaler use:

› Regular medical practitioner 75%

› Pharmacist 8%

Mode of education

› Both verbal information and physical demonstration 47%

When was instruction received

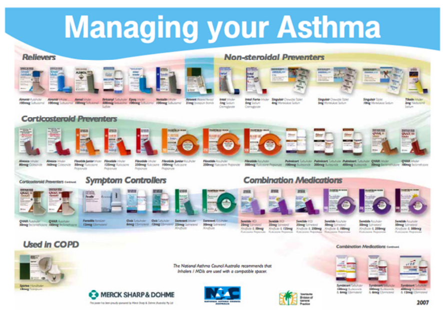
› First time device use 96%

Subsequent checking of technique?

› By the pharmacist 3%

› By another Health care professional 11%

THE PRODUCTS



Appendix 3.07: QUIP lecture slides

OUR FOCUS

› Pressurised Metered Dose Inhalers (pMDI)

› Dry Powder Inhalers (DPI)

Press-activated devices

Metered Dose Inhaler

Breath-activated devices

Easi-Breathe

Autohaler

Multi-dose devices

Accuhaler/Diskus

Diskhaler

Turbuhaler

Single-dose devices

Aeroliser

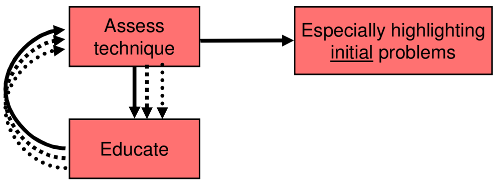
Handihaler

HOW DO WE CHECK TECHNIQUE ?

WHAT WE KNOW IS ESSENTIAL !

› Physical demonstration and verbal explanation

Inhaler technique intervention



WHAT CAN WE ACHIEVE?

› Through a simple intervention (<5 mins)…..

› Effective in improving inhaler technique
› Improved asthma outcomes
› BETTER CONTROL
› Better PEF variability, mean PEF, AQOL, perceived control
› Similar magnitude to that achieved with additional medication

Appendix 3.08: QUIP workshop slides

THE UNIVERSITY OF SYDNEY

Quality Use of Inhalers In Pharmacy Workshop

Saturday 27th February 2010
Faculty of Pharmacy
University of Sydney

Workshop Outcomes

You will:

1. Understand inhaler misuse and pharmacist's role
2. Be experts in AC, TH, pMDI use
3. Be confident patient educators
4. Be confident ITeM study investigators

Pressurised Metered Dose Inhaler

1. Remove cap
2. Shake inhaler well
3. Exhale air out of lungs
4. Hold inhaler upright
5. Put mouthpiece between teeth and seal with lips
6. Start to Inhale slowly *and* press canister firmly
7. Continue slow and deep inhalation
8. Hold breath for as long as is comfortable (aim for 10 seconds)
9. While still holding breath remove inhaler from mouth
10. Exhale away from mouthpiece
11. Replace cap

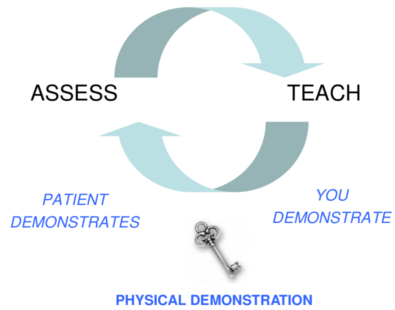
Turbuhaler

1. Unscrew and lift off cap
2. Hold inhaler upright
3. Rotate grip one way, then back until click is heard to load dose
4. Exhale air out of lungs
5. Exhale away from mouthpiece
6. Put mouthpiece between teeth and seal with lips
7. Inhale forcefully and deeply
8. Hold breath for as long as is comfortable (aim for 10 seconds)
9. While still holding breath remove inhaler from mouth
10. Exhale away from mouthpiece
11. Replace cap

Accuhaler

1. Open inhaler
2. Push lever back completely to load dose
3. Exhale air out of lungs
4. Exhale away from mouthpiece
5. Hold inhaler horizontally
6. Put mouthpiece between teeth and seal with lips
7. Inhale steadily and deeply
8. Hold breath for as long as is comfortable (aim for 10 seconds)
9. While still holding breath remove inhaler from mouth
10. Exhale away from mouthpiece
11. Close cover

Teaching Technique



Appendix 3.08: QUIP workshop slides

3Ps of Inhaler Technique

	pMDI	Turbuhaler	Accuhaler
Prepare	1 Cap 2 Shake 3 Exhale 4 Upright 5 Seal	1 Cap 2 **Upright** 3 Rotate 4 Exhale 5 Away 6 Seal	1 Open 2 **Lever** 3 Exhale 4 Away 5 Horizontal 6 Seal
Perform	6 Press & inhale 7 **Continue** 8 Hold breath	7 **Deep & forceful** 8 Hold breath	7 **Deep & steady** 8 Hold breath
Perfect	9 Remove inhaler 10 Exhale away 11 Cap	9 Remove inhaler 10 Exhale **away** 11 Cap	9 Remove inhaler 10 Exhale **away** 11 Cover

Recruitment Tips

- Display Poster
- Approach all possible participants
- Make a list from database
- Existing good working relationships
- Flags for next visit
- Emphasise study benefits…

ITeM Study Protocol

Recruit Patient

1. Invite patient to participate and explain the purpose of the study
2. Complete the **Eligibility for Study checklist** (F1)
3. Give out **Participant Information Statement** (F2)
4. Ask participant to sign the **Consent Form** (F3). Place in plastic sleeve.
5. Allow 2 weeks for recruiting

ITeM Study Protocol

Visit 1

1. Ask participant to complete the **Pharmacy Asthma Inhaler Device Use Survey Visit 1** (F4)
2. Complete the **Medication Profile** (F5) with the participant
3. Using the **Inhaler Technique Scoring Sheet Visit 1** (F6) assess participant inhaler technique. Give a score out of 11.
4. Correct technique if necessary as per workshop
5. Make appointment for the 4 week follow-up visit with participant

ITeM Study Protocol

Between Visit 1 and 2

Reminder phone call to participant for follow up visit

Pointers

- All paperwork back in folder for collection except…
- Only trained pharmacists to counsel
- Confidential storage of data
- Group email

Congratulations!

You now:

1. Understand inhaler misuse and pharmacist's role
2. Are experts in AC, TH, pMDI use
3. Are confident patient educators
4. Are confident ITeM study investigators

Appendix 3.09: Technique checklists for peer assessment

Inhaler Technique Score Sheet – Peer Assessment

PRESSURISED METERED DOSE INHALER

☐ 1. Remove cap
☐ 2. Shake inhaler well
☐ 3. Exhale air out of lungs
☐ 4. Hold inhaler upright
☐ 5. Put mouthpiece between teeth and seal with lips
☐ 6. Inhale slowly *and* press canister firmly
☐ 7. Continue slow and deep inhalation
☐ 8. Hold breath, aim for 10 seconds
☐ 9. While still holding breath remove inhaler from mouth
☐ 10. Exhale away from mouthpiece
☐ 11. Replace cap

SCORE: /11

TURBUHALER

☐ 1. Unscrew and lift off cap
☐ 2. Hold inhaler upright
☐ 3. Rotate grip one way, then back until click is heard
☐ 4. Exhale air out of lungs
☐ 5. Exhale away from mouthpiece
☐ 6. Put mouthpiece between teeth and seal with lips
☐ 7. Inhale forcefully and deeply
☐ 8. Hold breath, aim for 10 seconds
☐ 9. While still holding breath remove inhaler from mouth
☐ 10. Exhale away from mouthpiece
☐ 11. Replace cap

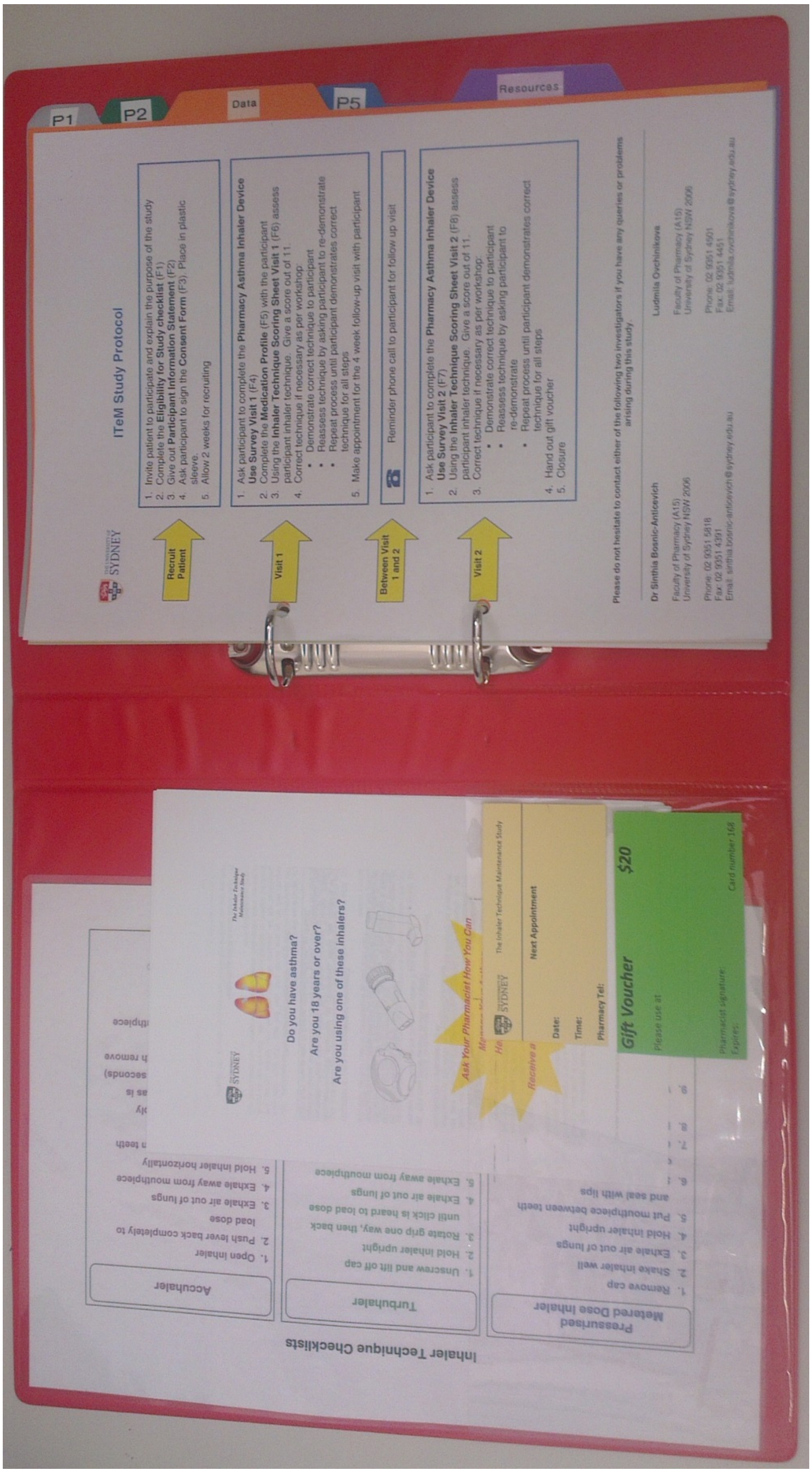
SCORE: /11

ACCUHALER

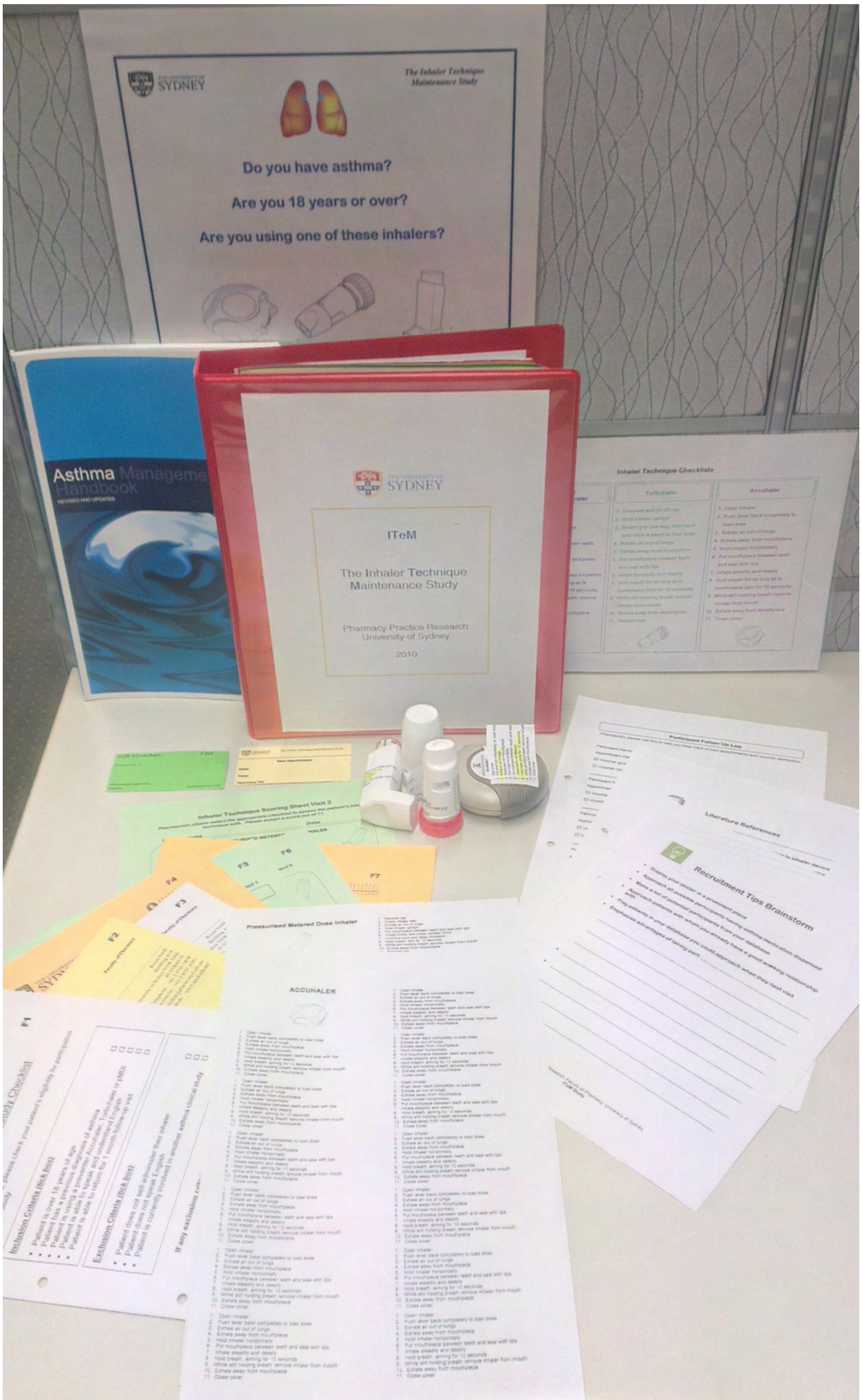
☐ 1. Open inhaler
☐ 2. Push lever back completely to load dose
☐ 3. Exhale air out of lungs
☐ 4. Exhale away from mouthpiece
☐ 5. Hold inhaler horizontally
☐ 6. Put mouthpiece between teeth and seal with lips
☐ 7. Inhale steadily and deeply
☐ 8. Hold breath, aiming for 10 seconds
☐ 9. While still holding breath remove inhaler from mouth
☐ 10. Exhale away from mouthpiece
☐ 11. Close cover

SCORE: /11

Appendix 3.10: ITeM study manual

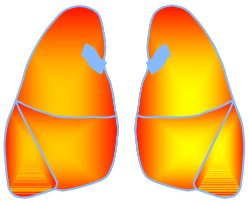


Appendix 3.10: ITeM study manual



THE UNIVERSITY OF SYDNEY

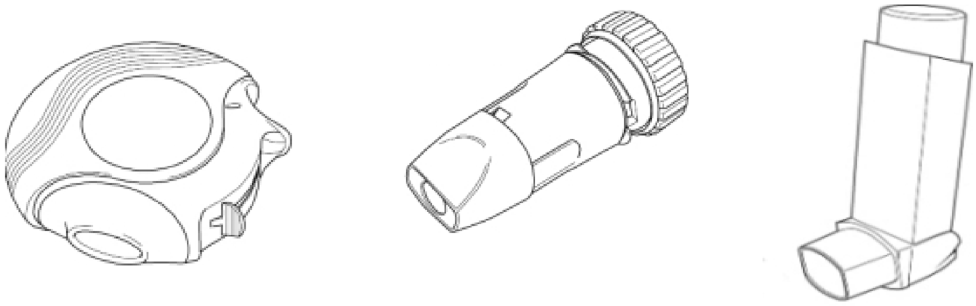
The Inhaler Technique Maintenance Study



Do you have asthma?

Are you 18 years or over?

Are you using one of these inhalers?



★

Ask Your Pharmacist How You Can

Manage Your Asthma,

Help Asthma Research

&

Receive a Gift Voucher for Your Time

A research project being conducted through the Faculty of Pharmacy, University of Sydney.

★Images from http://www.patient.co.uk/health/Inhalers-for-Asthma.htm accessed 13/1/10

Appendix 3.12: QUIP workshop certificate of completion

THE UNIVERSITY OF SYDNEY

This certificate is in recognition that

---

has successfully completed the workshop:

"Quality Use of Inhalers in Pharmacy"

Which was run at the

Faculty of Pharmacy, University of Sydney

on the 27/2/2010 and 1/3/2010

Dr Sinthia Bosnic-Anticevich

Senior Lecturer in Pharmacy Practice

Continuing
Professional Development
& Practice Improvement
Pharmaceutical Society of Australia

F2

THE UNIVERSITY OF SYDNEY

Faculty of

ABN 15 211 513 464

Sinthia Bosnic-Anticevich *BPharm(Hons), PhD*

Room N405
Building A15
University of Sydney NSW 2006
AUSTRALIA
Telephone: +61 2 9351 5818
Facsimile: +61 2 9351 4391
Email: sinthia@pharm.usyd.edu.au
Web: www.usyd.edu.au/

Pharmacy

PARTICIPANT INFORMATION STATEMENT
Research Project

Title: The Inhaler Technique Maintenance Study

(1) What is the study about?
You are invited to take part in a research study into the use of inhaler devices by people with asthma. The aim of this study is to investigate patterns of inhaler device use in people with asthma and the factors that can impact on this. It has been shown many people using inhaler devices have difficulty getting the exact technique correct and this may compromise their levels of asthma control.

(2) Who is carrying out the study?
The study is being conducted by Ms Ludmila Ovchinikova and will form the basis for the degree of Doctor of Philosophy at the University of Sydney under the supervision of Dr Sinthia Bosnic-Anticevich and Dr Lorraine Smith, all from the Faculty of Pharmacy.

(3) What does the study involve?
This study involves visiting your community pharmacy on two occasions. The second visit will be one month after your first visit. On both visits your pharmacist will be checking the way you use your inhaler device and providing training on optimal inhaler medication use. You will also be asked to provide some information about yourself; your asthma and medication use and fill out questionnaires.

(4) How much time will the study take?
Both the first and second visit should take approximately 15 - 20 minutes.

(5) Can I withdraw from the study?
Being in this study is completely voluntary - you are not under any obligation to consent and - if you do consent - you can withdraw at any time without affecting your relationship with the University of Sydney or your community pharmacy.

(6) Will anyone else know the results?
All aspects of the study, including results, will be strictly confidential and only the researchers will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

(7) Will the study benefit me?
Firstly, you may find improvements in the way you use your asthma inhaler device and this may lead to better levels of asthma control. Secondly, you will also receive a $20 gift voucher to spend in the pharmacy at the completion of the study in recognition of the costs incurred as a result of attending the 2 pharmacy visits.

(8) Can I tell other people about the study?
You are free to discuss the study with others if you so wish.

(9) What if I require further information?
When you have read this information, your pharmacist will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Dr Sinthia Bosnic-Anticevich on (02) 9351 5818 or Ludmila Ovchinikova on (02) 9351 4501.

(10) What if I have a complaint or concerns?

Any person with concerns or complaints about the conduct of a research study can contact the Deputy Manager, Human Ethics Administration, University of Sydney on (02) 8627 8176 (Telephone); (02) 8627 7177 (Facsimile) or human.ethics@usyd.edu.au (Email).

This information sheet is for you to keep

THE UNIVERSITY OF SYDNEY

F3

Faculty of Pharmacy

ABN 15 211 513 464

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Facsimile: +61 2 9351 4391
Email: sinthia@pharm.usyd.edu.au
Web: www.usyd.edu.au/

PARTICIPANT CONSENT FORM

I, ...[PRINT NAME], give consent to my participation in the research project

TITLE: **"The Inhaler Technique Maintenance Study"**

In giving my consent I acknowledge that:

1. The procedures required for the project and the time involved have been explained to me, and any questions I have about the project have been answered to my satisfaction.

2. I have read the Participant Information Statement and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s Dr Sinthia Bosnic-Anticevich, Dr Lorraine Smith and Ms Ludmila Ovchinikova of the Faculty of Pharmacy, The University of Sydney.

3. I understand that I can withdraw from the study at any time, without affecting my relationship with the researchers, the University of Sydney or my community pharmacy now or in the future.

4. I understand that my involvement is strictly confidential and no information about me will be used in any way that reveals my identity.

5. I understand that being in this study is completely voluntary – I am not under any obligation to consent.

6. I consent to:

i) Being checked on my inhaler technique by my pharmacist or the researcher ☐YES ☐NO

ii) Receiving inhaler device education from my pharmacist or the researcher ☐YES ☐NO

iii) Completing questionnaires relating to my asthma and medication use ☐YES ☐NO

iv) Participating in the 1 month follow-up ☐YES ☐NO

v) Receiving Feedback ☐YES ☐NO

If you answered YES to the "Receiving Feedback Question (v)", please provide your details i.e. mailing address, email address.

<u>Feedback Option</u>

Address: ______________________________

____

Email: ______________________________

Signed: ....

Name: ....

Date: ....

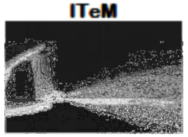
F4

THE UNIVERSITY OF SYDNEY

Pharmacy Asthma Inhaler Device Use Survey

The **I**nhaler **Te**chnique **M**aintenance Study

ITeM



Visit 1

Date Today	
Participant ID	

Thank you for participating in the Inhaler Technique Maintenance Study.

Please note that this study has been approved by the Sydney University Human Research Ethics Committee and all information you provide will be kept confidential and you will never be identified. Your name is requested in case that we might want to contact you again.

This survey has been designed for you to complete yourself, however if you have any questions do not hesitate to ask the pharmacist.

This survey should take approximately 10 minutes to complete.

Appendix 3.15: Patient visit 1 questionnaire_F4

Section 1: Personal Details

1. Family name ______________________

Given Name ______________________

2. Date of Birth __/__/____

3. Gender ☐ Male ☐ Female

4. Phone number ______________________

5. Email address ______________________

6. Postal address ______________________

____

__________ Postcode ________

7. Highest educational level (*Please tick one*)
- ☐ Primary
- ☐ Secondary
- ☐ TAFE
- ☐ University

Section 2: Medical History

8. How long have you been diagnosed with asthma? ______________________

9. Do you have any other medical conditions? ☐ Yes ☐ No

10. Do you have any other lung conditions besides asthma?
- ☐ No
- ☐ Yes, please specify ________

____

11. In the *past year* how many times have you been admitted to hospital or visited emergency due to your asthma?
- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ More than 3 times

12. In the *past year* how many times have you seen a health care professional about your asthma?
- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ Other, please specify ______________

Section 3: Asthma Control

13. Please tick the response that best describes how you have been during the ***past week***

a. On average, during the past week, how often were you ***woken by your asthma*** during the night?
- 0 ☐ Never
- 1 ☐ Hardly ever
- 2 ☐ A few times
- 3 ☐ Several times
- 4 ☐ Many times
- 5 ☐ A great many times
- 6 ☐ Unable to sleep because of asthma

Appendix 3.15: Patient visit 1 questionnaire_F4

b. On average, during the past week, how ***bad were your asthma symptoms when you woke*** up in the morning?

0 ☐ No symptoms
1 ☐ Very mild symptoms
2 ☐ Mild symptoms
3 ☐ Moderate symptoms
4 ☐ Quite severe symptoms
5 ☐ Severe symptoms
6 ☐ Very severe symptoms

c. In general, during the past week, how ***limited were you in your activities*** because of your asthma?

0 ☐ Not limited at all
1 ☐ Very slightly limited
2 ☐ Slightly limited
3 ☐ Moderately limited
4 ☐ Very limited
5 ☐ Extremely limited
6 ☐ Totally limited

d. In general, during the past week, how much ***shortness of breath*** did you experience because of your asthma?

0 ☐ None
1 ☐ A very little
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Quite a lot
5 ☐ A great deal
6 ☐ A very great deal

e. In general, during the past week, how much of the time did you ***wheeze***?

0 ☐ Not at all
1 ☐ Hardly any of the time
2 ☐ A little of the time
3 ☐ A moderate amount of the time
4 ☐ A lot of the time
5 ☐ Most of the time
6 ☐ All the time

f. On average, during the past week, how many ***puffs of short-acting bronchodilator*** (eg. Ventolin) have you used each day?

0 ☐ None
1 ☐ 1-2 puffs most days
2 ☐ 3-4 puffs most days
3 ☐ 5-8 puffs most days
4 ☐ 9-12 puffs most days
5 ☐ 13-16 puffs most days
6 ☐ More than 16 puffs most days

Section 4: Inhaler Technique Instruction

14. When were you taught the technique for using your ***Preventer*** inhaler (you may choose more than one)?

☐ When it was first prescribed
☐ Sometime after it was first prescribed
☐ Never
☐ Other, please specify _____

____

15. If applicable, how long ago did you **last** receive instruction on using your ***Preventer*** inhaler? ______________________________

16. When were you taught the technique for using your ***Reliever*** inhaler (you may choose more than one)?

☐ When it was first prescribed
☐ Sometime after it was first prescribed
☐ Never
☐ Other, please specify_____

____

17. If applicable, how long ago did you **last** receive instruction on using your ***Reliever*** inhaler? ______________________________

Appendix 3.15: Patient visit 1 questionnaire_F4

18. Who taught you about inhaler technique (you may choose more than one)?

☐ GP
☐ Lung specialist
☐ Pharmacist
☐ Nurse
☐ Other, please specify __________

____

☐ No one

19. How were you taught inhaler technique (you may choose more than one)?

☐ Written information or pamphlet
☐ Verbal explanation
☐ Physical demonstration
☐ Other, please specify __________

____

20. Has your inhaler technique ever been ***re-checked*** by a health care professional after it was first taught?

☐ No
☐ Yes, please specify how many times this has occurred

____

21. Have you ever shown somebody else how to use an inhaler device?

☐ Yes
☐ No

22. If you answered 'Yes' to the previous question, please specify:

a. Approximately how many times you did this

____

b. The last time you did this

____

Section 5: Preventer Inhaler Use

23. Many people find a way of using their ***Preventer*** inhaler which suits them. This may differ from the instructions on the label or from what the doctor had said. Here are some ways in which people have said they use their ***Preventer*** inhaler. For each statement, please tick the box which best applies to you.

Your own way of using your asthma medicine	**ALWAYS**	**OFTEN**	**SOME - TIMES**	**RARELY**	**NEVER**
I alter the dose of my preventer inhaler	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
I forget to use my preventer inhaler	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
I stop taking my preventer inhaler for a while	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
I decide to miss out on a dose of my preventer inhaler	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
I take less than instructed of my preventer inhaler	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

Appendix 3.15: Patient visit 1 questionnaire_F4

Section 6: Medication Beliefs

24. We would like to ask your personal views about the ***Preventer*** inhaler medication prescribed for your asthma. Below are statements other people have made about their ***Preventer*** medication. Please indicate the extent to which you agree or disagree with them by ticking the appropriate box. There are no right or wrong answers. We are interested in your personal views.

A. My health at present, depends on this medicine

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

B. Having to take this medicine worries me

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

C. My life would be impossible without this medicine

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

D. Without this medicine I would be very ill

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

E. I sometimes worry about long-term effects of this medicine

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

F. This medicine is a mystery to me

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

G. My health in the future will depend on this medicine

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

H. This medicine disrupts my life

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

I. I sometimes worry about becoming too dependent on this medicine

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

Appendix 3.15: Patient visit 1 questionnaire_F4

J. This medicine protects me from becoming worse

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

25. The following questions are about ***ANY*** inhaler device you may have used. Please indicate the extent to which you agree or disagree with the following statements by circling the appropriate position on the scale: 1 stands for *'strongly agree'* and 10 stands for *'strongly disagree'*

A. It is important to follow the correct steps every time I use my inhaler

Strongly Agree *Strongly Disagree*

1 2 3 4 5 6 7 8 9 10

B. My inhaler will work just as well if I follow *most* of the correct steps

Strongly Agree *Strongly Disagree*

1 2 3 4 5 6 7 8 9 10

C. The way that I use my inhaler will *not* affect my asthma

Strongly Agree *Strongly Disagree*

1 2 3 4 5 6 7 8 9 10

D. I am motivated to follow the correct steps when I use my inhaler

Strongly Agree *Strongly Disagree*

1 2 3 4 5 6 7 8 9 10

This is the end of the survey.
Thank you for your time!

Appendix 3.15: Patient visit 1 questionnaire_F4

F5

Medication Profile

Pharmacists please complete the following patient medication profile during Visit 1.

Patient name ________________________ **Date**______________

1. **Which type of *preventer* inhaler is the patient currently prescribed?**
- ☐ **Pressurised Metered Dose Inhaler**
- ☐ **Turbuhaler**
- ☐ **Accuhaler**

2. **In relation to the patient's preventer medication, please specify the:**

a. **Name**____________________

b. **Strength**____________________ **c.** **Dose:** ____ **puffs** ____**times per day**

3. **How many years and/or months has the patient used this particular inhaler device?**

____

4. **Please list any other types of inhaler devices the patient is currently using:**

____

____

____

5. **Is the patient currently taking any oral medication (e.g. *Montelukast or Zafirlukast*) for their asthma?**
- ☐ **No**
- ☐ **Yes, please specify**______________________________

6. **Is the patient currently taking any other regular medication (OTC or prescription) NOT for their asthma?**
- ☐ **No**
- ☐ **Yes, Please specify**______________________________

____

____

Please turn over for score sheet (F6)

F6

Inhaler Technique Scoring Sheet Visit 1

Pharmacists please select the appropriate checklist to assess the patient's inhaler technique with. Please assign a score out of 11.

PRESSURISED METERED DOSE INHALER

- ☐ 1. Remove cap
- ☐ 2. Shake inhaler well
- ☐ 3. Exhale air out of lungs
- ☐ 4. Hold inhaler upright
- ☐ 5. Put mouthpiece between teeth and seal with lips
- ☐ 6. Inhale slowly *and* press canister firmly
- ☐ 7. Continue slow and deep inhalation
- ☐ 8. Hold breath, aim for 10 seconds
- ☐ 9. While still holding breath remove inhaler from mouth
- ☐ 10. Exhale away from mouthpiece
- ☐ 11. Replace cap

SCORE: /11

TURBUHALER

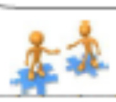
- ☐ 1. Unscrew and lift off cap
- ☐ 2. Hold inhaler upright
- ☐ 3. Rotate grip one way, then back until click is heard
- ☐ 4. Exhale air out of lungs
- ☐ 5. Exhale away from mouthpiece
- ☐ 6. Put mouthpiece between teeth and seal with lips
- ☐ 7. Inhale forcefully and deeply
- ☐ 8. Hold breath, aim for 10 seconds
- ☐ 9. While still holding breath remove inhaler from mouth
- ☐ 10. Exhale away from mouthpiece
- ☐ 11. Replace cap

SCORE: /11

ACCUHALER

- ☐ 1. Open inhaler
- ☐ 2. Push lever back completely to load dose
- ☐ 3. Exhale air out of lungs
- ☐ 4. Exhale away from mouthpiece
- ☐ 5. Hold inhaler horizontally
- ☐ 6. Put mouthpiece between teeth and seal with lips
- ☐ 7. Inhale steadily and deeply
- ☐ 8. Hold breath, aiming for 10 seconds
- ☐ 9. While still holding breath remove inhaler from mouth
- ☐ 10. Exhale away from mouthpiece
- ☐ 11. Close cover

SCORE: /11



Pharmacists, please make your follow-up appointment with the patient for 4 weeks time

Pharmacy Practice Research, Faculty of Pharmacy, University of Sydney Page 1 of 2

Pre-printed stickers for the Accuhaler™

ACCUHALER

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1. Open inhaler
2. Push lever back completely to load dose
3. Exhale air out of lungs
4. Exhale away from mouthpiece
5. Hold inhaler horizontally
6. Put mouthpiece between teeth and seal with lips
7. Inhale steadily and deeply
8. Hold breath, aiming for 10 seconds
9. While still holding breath remove inhaler from mouth
10. Exhale away from mouthpiece
11. Close cover

1. Open inhaler
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5. Hold inhaler horizontally
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11. Close cover

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9. While still holding breath remove inhaler from mouth
10. Exhale away from mouthpiece
11. Close cover

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3. Exhale air out of lungs
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5. Hold inhaler horizontally
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3. Exhale air out of lungs
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5. Hold inhaler horizontally
6. Put mouthpiece between teeth and seal with lips
7. Inhale steadily and deeply
8. Hold breath, aiming for 10 seconds
9. While still holding breath remove inhaler from mouth
10. Exhale away from mouthpiece
11. Close cover

Pre-printed stickers for the pMDI

Pressurised Metered Dose Inhaler

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1. Remove cap
2. Shake inhaler well
3. Exhale air out of lungs
4. Hold inhaler upright
5. Put mouthpiece between teeth and seal with lips
6. Inhale slowly and press canister firmly
7. Continue slow and deep inhalation
8. Hold breath, aim for 10 seconds
9. While still holding breath remove inhaler from mouth
10. Exhale away from mouthpiece
11. Replace cap

1. Remove cap
2. Shake inhaler well
3. Exhale air out of lungs
4. Hold inhaler upright
5. Put mouthpiece between teeth and seal with lips
6. Inhale slowly and press canister firmly
7. Continue slow and deep inhalation
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9. While still holding breath remove inhaler from mouth
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11. Replace cap

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7. Continue slow and deep inhalation
8. Hold breath, aim for 10 seconds
9. While still holding breath remove inhaler from mouth
10. Exhale away from mouthpiece
11. Replace cap

Appendix 3.18: Stickers affixed on patients' inhaler device

Pre-printed stickers for the Turbuhaler™

Turbuhaler

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1. Unscrew and lift off cap
2. Hold inhaler upright
3. Rotate grip one way, then back until click is heard
4. Exhale air out of lungs
5. Exhale away from mouthpiece
6. Put mouthpiece between teeth and seal with lips
7. Inhale forcefully and deeply
8. Hold breath, aim for 10 seconds
9. While still holding breath remove inhaler from mouth
10. Exhale away from mouthpiece
11. Replace cap

1. Unscrew and lift off cap
2. Hold inhaler upright
3. Rotate grip one way, then back until click is heard
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11. Replace cap

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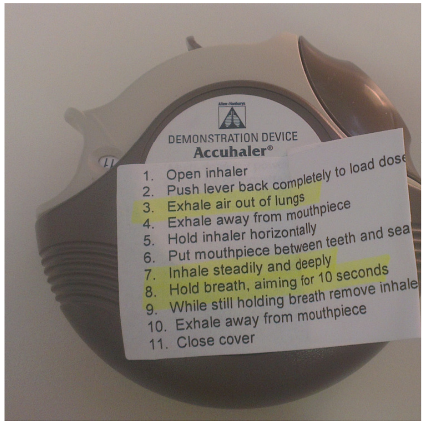
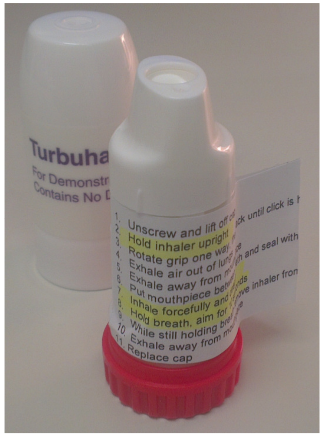
11. Replace cap

Appendix 3.18: Stickers affixed on patients' inhaler device

Inhaler technique stickers, as would appear, affixed on patients' inhaler device.





Appendix 3.18: Stickers affixed on patients' inhaler device

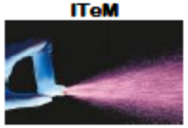
F7

THE UNIVERSITY OF SYDNEY

Pharmacy Asthma Inhaler Device Use Survey

The **I**nhaler **Te**chnique **M**aintenance Study

ITeM



Visit 2

Date Today	
Participant ID	

Thank you for participating in the Inhaler Technique Maintenance Study.

Please note that this study has been approved by the Sydney University Human Research Ethics Committee and all information you provide will be kept confidential and you will never be identified. Your name is requested in case that we might want to contact you again.

This survey has been designed for you to complete yourself, however if you have any questions do not hesitate to ask the pharmacist.

This survey should take approximately 10 minutes to complete.

Appendix 3.19: Patient visit 2 questionnaire_F7

Section 1: Personal Details

1. Family name ______________________

Given Name ______________________

Section 2: Asthma Control

2. Please tick the response that best describes how you have been during the ***past week***

a. On average, during the past week, how often were you ***woken by your asthma*** during the night?

0 ☐ Never
1 ☐ Hardly ever
2 ☐ A few times
3 ☐ Several times
4 ☐ Many times
5 ☐ A great many times
6 ☐ Unable to sleep because of asthma

b. On average, during the past week, how ***bad were your asthma symptoms when you woke*** up in the morning?

0 ☐ No symptoms
1 ☐ Very mild symptoms
2 ☐ Mild symptoms
3 ☐ Moderate symptoms
4 ☐ Quite severe symptoms
5 ☐ Severe symptoms
6 ☐ Very severe symptoms

c. In general, during the past week, how ***limited were you in your activities*** because of your asthma?

0 ☐ Not limited at all
1 ☐ Very slightly limited
2 ☐ Slightly limited
3 ☐ Moderately limited
4 ☐ Very limited
5 ☐ Extremely limited
6 ☐ Totally limited

d. In general, during the past week, how much ***shortness of breath*** did you experience because of your asthma?

0 ☐ None
1 ☐ A very little
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Quite a lot
5 ☐ A great deal
6 ☐ A very great deal

e. In general, during the past week, how much of the time did you ***wheeze***?

0 ☐ Not at all
1 ☐ Hardly any of the time
2 ☐ A little of the time
3 ☐ A moderate amount of the time
4 ☐ A lot of the time
5 ☐ Most of the time
6 ☐ All the time

f. On average, during the past week, how many ***puffs of short-acting bronchodilator*** (eg. Ventolin) have you used each day?

0 ☐ None
1 ☐ 1-2 puffs most days
2 ☐ 3-4 puffs most days
3 ☐ 5-8 puffs most days
4 ☐ 9-12 puffs most days
5 ☐ 13-16 puffs most days
6 ☐ More than 16 puffs most days

Appendix 3.19: Patient visit 2 questionnaire_F7

Section 3: Preventer Inhaler Use

3. Many people find a way of using their ***Preventer*** inhaler which suits them. This may differ from the instructions on the label or from what the doctor had said. Here are some ways in which people have said they use their ***Preventer*** inhaler. For each statement, please tick the box which best applies to you.

Your own way of using your asthma medicine	**ALWAYS**	**OFTEN**	**SOME - TIMES**	**RARELY**	**NEVER**
I alter the dose of my preventer inhaler	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
I forget to use my preventer inhaler	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
I stop taking my preventer inhaler for a while	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
I decide to miss out on a dose of my preventer inhaler	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
I take less than instructed of my preventer inhaler	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

Section 4: Medication Beliefs

4. We would like to ask your personal views about the ***Preventer*** inhaler medication prescribed for your asthma. Below are statements other people have made about their ***Preventer*** medication. Please indicate the extent to which you agree or disagree with them by ticking the appropriate box. There are no right or wrong answers. We are interested in your personal views.

A. My health at present, depends on this medicine

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

B. Having to take this medicine worries me

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

C. My life would be impossible without this medicine

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

D. Without this medicine I would be very ill

STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

Appendix 3.19: Patient visit 2 questionnaire_F7

E. I sometimes worry about long-term effects of this medicine

STRONGLY				STRONGLY
AGREE	AGREE	UNCERTAIN	DISAGREE	DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

F. This medicine is a mystery to me

STRONGLY				STRONGLY
AGREE	AGREE	UNCERTAIN	DISAGREE	DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

G. My health in the future will depend on this medicine

STRONGLY				STRONGLY
AGREE	AGREE	UNCERTAIN	DISAGREE	DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

H. This medicine disrupts my life

STRONGLY				STRONGLY
AGREE	AGREE	UNCERTAIN	DISAGREE	DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

I. I sometimes worry about becoming too dependent on this medicine

STRONGLY				STRONGLY
AGREE	AGREE	UNCERTAIN	DISAGREE	DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

J. This medicine protects me from becoming worse

STRONGLY				STRONGLY
AGREE	AGREE	UNCERTAIN	DISAGREE	DISAGREE
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

5. The following questions are about ***ANY*** inhaler device you may have used. Please indicate the extent to which you agree or disagree with the following statements by circling the appropriate position on the scale: 1 stands for *'strongly agree'* and 10 stands for *'strongly disagree'*

A. It is important to follow the correct steps every time I use my inhaler

Strongly Agree 1 2 3 4 5 6 7 8 9 10 ***Strongly Disagree***

B. My inhaler will work just as well if I follow ***most*** of the correct steps

Strongly Agree 1 2 3 4 5 6 7 8 9 10 ***Strongly Disagree***

C. The way that I use my inhaler will ***not*** affect my asthma

Strongly Agree 1 2 3 4 5 6 7 8 9 10 ***Strongly Disagree***

Appendix 3.19: Patient visit 2 questionnaire_F7

D. I am motivated to follow the correct steps when I use my inhaler

Strongly Agree ... ***Strongly Disagree***

1	2	3	4	5	6	7	8	9	10

This is the end of the survey.

Thank you for your ongoing participation.
Please collect your voucher from the pharmacist at the end of your visit as a token of our appreciation.

Appendix 3.19: Patient visit 2 questionnaire_F7

Appendix 3.20: Visit 2 patient technique checklist_F8

F8

Inhaler Technique Scoring Sheet Visit 2

Pharmacists please select the appropriate checklist to assess the patient's inhaler technique with. Please assign a score out of 11.

Patient name ______________________________ Date____________

PRESSURISED METERED DOSE INHALER

- ☐ 1. Remove cap
- ☐ 2. Shake inhaler well
- ☐ 3. Exhale air out of lungs
- ☐ 4. Hold inhaler upright
- ☐ 5. Put mouthpiece between teeth and seal with lips
- ☐ 6. Inhale slowly *and* press canister firmly
- ☐ 7. Continue slow and deep inhalation
- ☐ 8. Hold breath, aim for 10 seconds
- ☐ 9. While still holding breath remove inhaler from mouth
- ☐ 10. Exhale away from mouthpiece
- ☐ 11. Replace cap

SCORE: /11

TURBUHALER

- ☐ 1. Unscrew and lift off cap
- ☐ 2. Hold inhaler upright
- ☐ 3. Rotate grip one way, then back until click is heard
- ☐ 4. Exhale air out of lungs
- ☐ 5. Exhale away from mouthpiece
- ☐ 6. Put mouthpiece between teeth and seal with lips
- ☐ 7. Inhale forcefully and deeply
- ☐ 8. Hold breath, aim for 10 seconds
- ☐ 9. While still holding breath remove inhaler from mouth
- ☐ 10. Exhale away from mouthpiece
- ☐ 11. Replace cap

SCORE: /11

ACCUHALER

- ☐ 1. Open inhaler
- ☐ 2. Push lever back completely to load dose
- ☐ 3. Exhale air out of lungs
- ☐ 4. Exhale away from mouthpiece
- ☐ 5. Hold inhaler horizontally
- ☐ 6. Put mouthpiece between teeth and seal with lips
- ☐ 7. Inhale steadily and deeply
- ☐ 8. Hold breath, aiming for 10 seconds
- ☐ 9. While still holding breath remove inhaler from mouth
- ☐ 10. Exhale away from mouthpiece
- ☐ 11. Close cover

SCORE: /11

Email newsletter sent 25 March 2010

Hello Pharmacists,

Thank you for your feedback on your recruitment over the past week.

I do appreciate all your efforts and am heartened by the positive feedback you report that you are receiving from your patients. Like those who have been using their device for 10 years but you are the first person to actually *show* them how!

At this point in time we have not yet reached our target number of 150 patients - we are just over half way there. It is important that we meet this target for research purposes. As you know I am here to help in any way I can and I know as a group we can get there!

You'll find below tips for successful recruiting that other pharmacists have reported back to me.

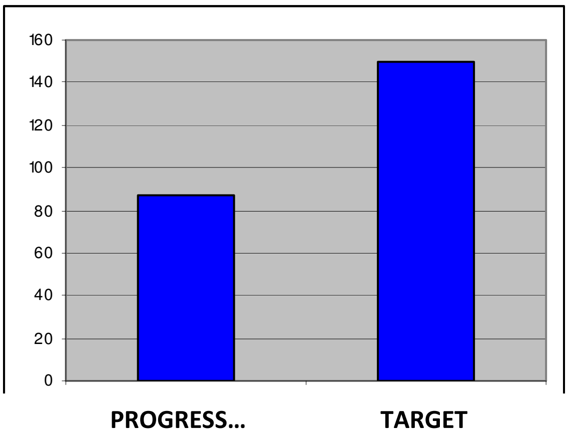
At this stage please continue to recruit patients without stressing about the timeframe. Let's assess the situation every few days to see how much further we have to go.

You will also be expecting some of your patients to start returning for Visit 2 in the coming week. Could you please give them reminder phone calls?

As always – happy investigating!

Ludmila

Recruitment progress at 25 March



Appendix 3.21: Newsletter to pharmacists

Recruitment tips from our fellow pharmacists:

Ask those who are purchasing Ventolin/Asmol if they are also on a preventer. If you have spare placebos, the patient can demonstrate on these straight away. Alternatively you could write an appointment for them to come back with their own preventer.

Empahsise how quick and simple the study really is – many pharmacists tell me that the survey takes less than 10min. In fact the patient should really know that you are providing a free service that you have undertaken specialised training for and there is everything for them to gain!

Discuss the study with your support staff/dispensary assistants and ask them to flag eligible patients.

Photocopy the study information and give it to potential patients to take home; on the sheet write down your availabilities at the pharmacy. This may take the pressure off of putting patients on the spot if that's what they feel.

Allow patients to fill out the survey at home if they wish as long as they bring it back.

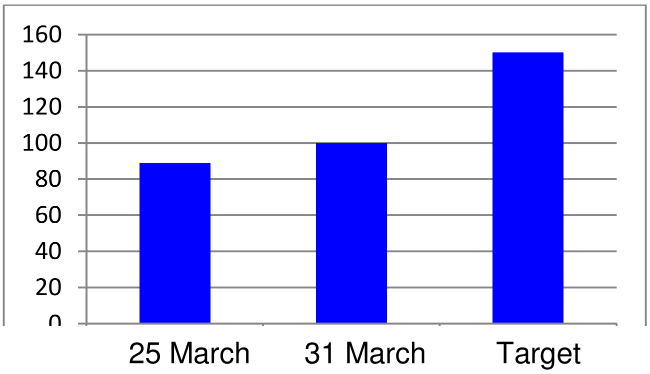
Work as a team – for those pharmacists who have a buddy in the same pharmacy that is also enrolled in the study, take advantage of this arrangement. E.g. you could refer patients to one another to get around timing/roster constraints.

Ask every patient who could be potentially eligible to take part

Email newsletter sent 7 April 2010

Hello Pharmacists,

As you can see we are making progress with recruitment, only a third of the way to go!



Thank you for all your very useful feedback about your own experiences with the study.

Thank you also to those pharmacists who are continuing to help to recruit beyond their own five patients - your contribution to our group goal is much appreciated.

Below is the feedback some of these pharmacists have given me on how they approached recruiting.

We welcome any further comments and tips you may want to share with everyone else.

I will be in touch about further progress - *we are getting there*!

For now I wish everyone a safe and happy Easter ☺

Ludmila

Ngaire Thewlis *Calman's Pharmacy Picnic Point*

- Emphasise the interaction will be quick
- Get patients to fill out the survey while waiting for their prescription - no extra time off the patient.
- Explain the study to your support staff and colleagues so they can help out in the process
- For patients who may be nervous about demonstrating technique, tell them the exercise is about improving the pharmacist's ability to teach inhaler use; it is not a test for them.

Alice and Badria *MediAdvice Pharmacy Glenmore Park*

- Talk positively about the study
- Tell patients the interaction is quick and simple
- If you are working with another study pharmacist, work together on your cases

Anderson Leong *Fullife Pharmacy Moorebank*

- Ask your regular customers to 'help you out' with conducting a study about their asthma
- Approach all patients who are getting a prescription dispensed for a preventer inhaler

Jenny Nguyen *Harrisons Pharmacy Broadway*

- State that your invitation is exclusive with the study limited to only 5 people
- Saying that it is research being conducted by the University of Sydney has helped
- State the research showing up to 90% of patients have incorrect technique → there are 11 steps to correct technique and it is often more difficult than assumed → incorrect use = wasting their money on medication.
- Actively look out for patients and approach all possible candidates

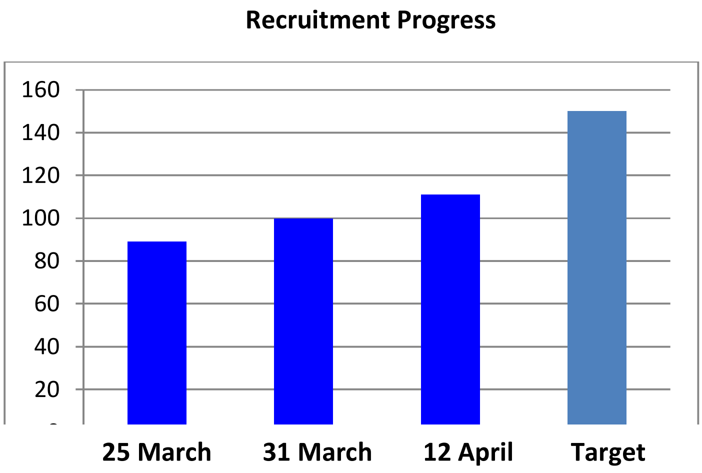
Email newsletter sent 12 April 2010

Hello Pharmacists,

Good news - based on your feedback over the past week we are getting closer to our target…

We do have a little bit more to go with the numbers and I anticipate that this won't take much longer – thanks for your continued efforts!

If anyone has more up to date numbers please let me know.



Most of you will also be expecting/having return visits from your patients.
Please give your patients a reminder phone call if you haven't already so it all runs smoothly for you.

It will be very interesting to see your findings at Visit 2 - it will help us answer our burning research question about inhaler technique maintenance!

Happy investigating ☺

Ludmila

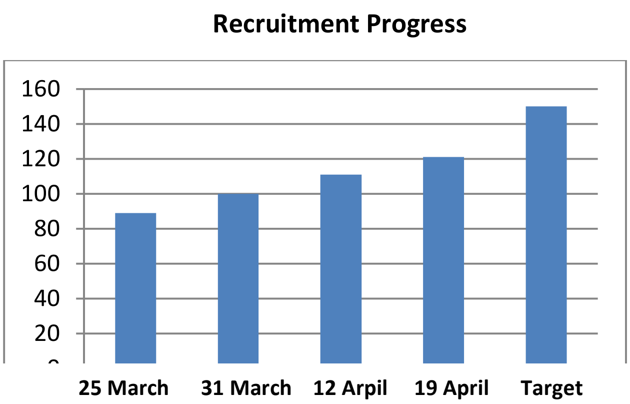
Email newsletter sent 19 April 2010

Hello Pharmacists,

As you can see form our recruitment chart below, you have continued to make progress, well done and keep up the good work!

Right now most of you will be in the midst of conducting Visit 2 with your patients.

☎ Give your patients a quick reminder call to help them remember their appointment with you.



If like other pharmacists, you find that you have extra patients that would like to participate in the study you are most welcome to enroll them at this stage. Just let me know and I'll supply the necessary documents.

In the meantime feel free to contact me with any feedback or issues you'd like to discuss.

Happy investigating ☺

Ludmila

Email newsletter sent 18 June 2010

Hello Pharmacists,

You will be happy to know that we are near completion with the data collection for the ITeM Study.

In wrapping up the study:

There are just a handful of patients left who need to come back for Visit 2. If you still have such patients please do contact them again to complete the study. As you would appreciate, this is important for us to reach our target numbers for data analyses.

I will be contacting and visiting you in the next two weeks for the final data audit and collection. Please have your folders ready for this.

If you need to fill out a tax invoice for reimbursement of vouchers, you can find the template for this in my email dated the 31/5. Simply fill out and email back.

In Thanks:

Thank you all for your participation in the ITeM Study and support with my research! It wouldn't have been possible without your contributions. *I hope your experience has been rewarding and that your patients benefit from taking part.*

In the meantime I will be setting out to analyse all the data you have collected… I'm sure there will be interesting findings! We'll be in touch to keep you informed.

Please feel free to contact me if there are any queries.

See you soon ☺

Ludmila

Appendix 3.22: Normality statistics for repeat measures variables

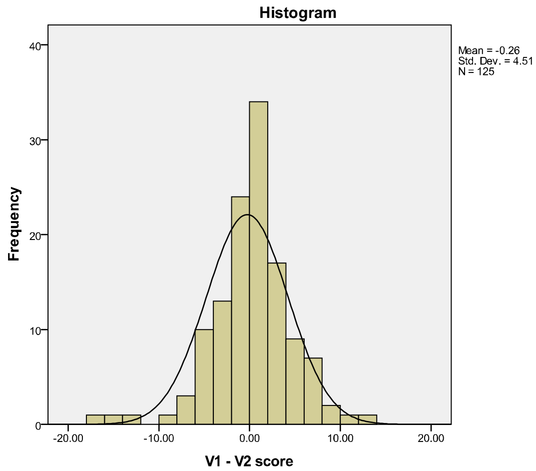
Testing for normality of sampling distributions:

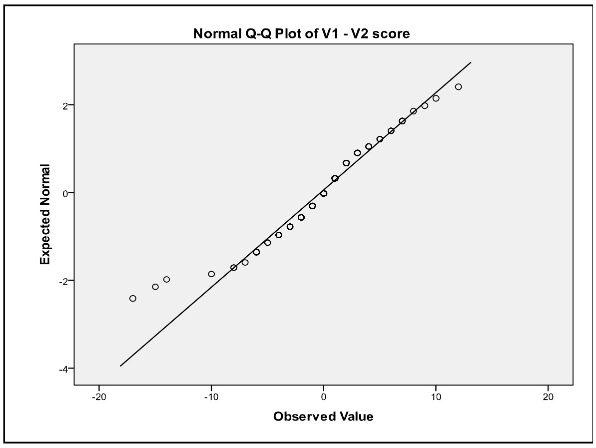
(With the dependent t-test we analyse the difference between scores because we are interested in the sampling distribution of these differences and not the raw data. To test for normality before a dependent t-test create a new variable by computing the difference between scores. Check if this new variable is normally distributed pg. 329)

Three new variables were created in SPSS:
1. **BMQ V1 – V2 scores** (difference in medication belief scores between visit 1 and 2)
2. **MARS V1 – V2 scores** (difference in adherence scores between visit 1 and 2)
3. **AC V1 –V2 scores** (difference in asthma control scores between visit 1 and 2)

Data were represented graphically and tested using the Kolmogorov-Smirnov and Shapiro-Wilk tests. All three data sets were found to be non-normally distributed.

1. BMQ V1 – V2 scores:





Skewness = -0.614 *(-ve indicating pile up on right side, tail pointing to lower scores)* Kurtosis = 2.202 *(+ve indicating pointy and heavy tailed). These should be 0 in normal distribution.*

Tests of Normality

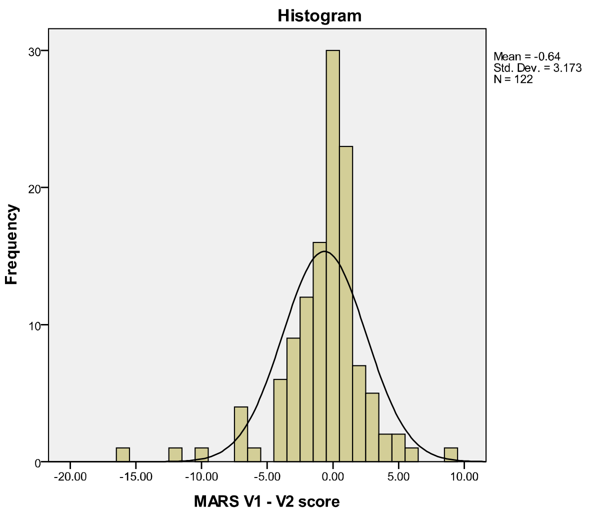
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
V1 - V2 score	.110	125	.001	.955	125	.000

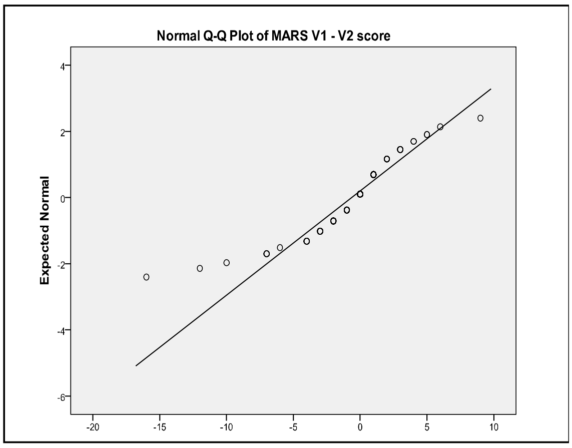
a. Test values are significant

The distribution for the BMQ V1-V2 scores, D(125) = 0.11, p< 0.05 is significantly not normal

Appendix 3.22: Normality statistics for repeat measures variables

2. MARS V1 – V2 scores





Skewness = - 0.138 *(-ve indicating pile up on right side, tail pointing to lower scores)* Kurtosis = 5.783 *(+ve indicating pointy and heavy tailed). These should be 0 in normal distribution*.

Tests of Normality

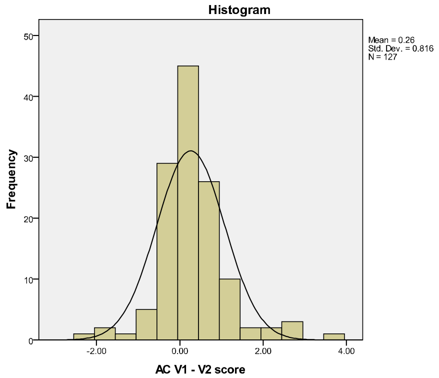
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
MARS V1 - V2 score	.168	122	.000	.876	122	.000

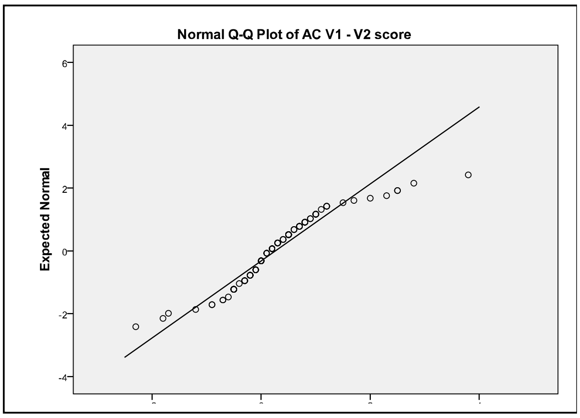
a. Lilliefors Significance Correction

The distribution for the MARS V1 – V2 scores, D(122) = 0.168, p<0.05, is significantly not normal

Appendix 3.22: Normality statistics for repeat measures variables

3. AC V1 –V2 scores





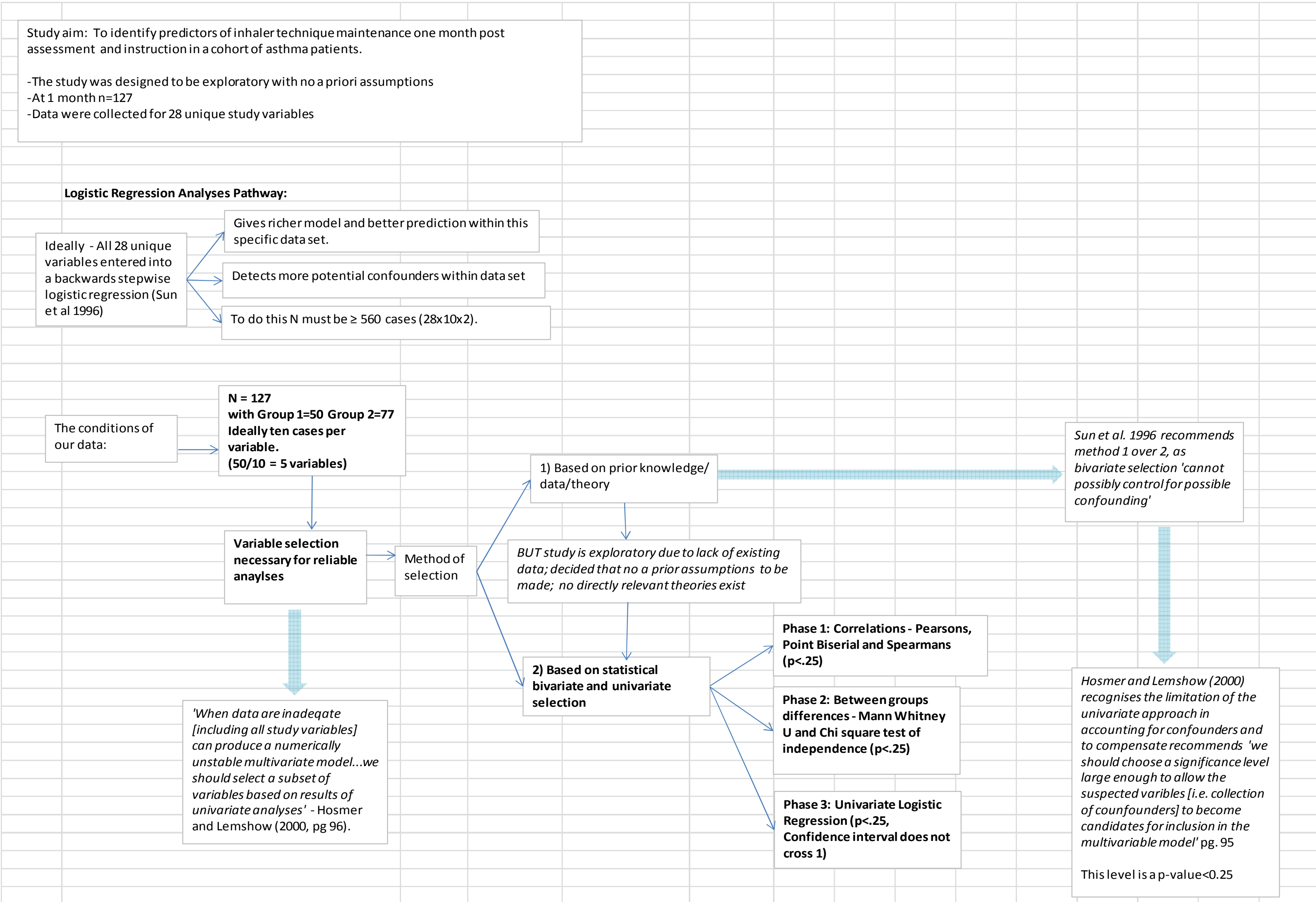
Skewness = 0.904 *(+ve indicating pile up on left side, tail pointing to higher scores)* Kurtosis = 4.030 *(+ve indicating pointy and heavy tailed). These should be 0 in normal distribution.*

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
AC V1 - V2 score	.125	127	.000	.911	127	.000

a. Lilliefors Significance Correction

The distribution for the AC V1 – V2 scores, D(127) = 0.125, p<0.05, is significantly not normal



Appendix 3.23: Rationale for statistical selection of independent variables

Appendix 3.24: Univariate logistic regression results

		Univariate Logistic Regression	
Variable	**Description**	**p value**	**95% Confidence Interval**
1a	[†,‡] **Critical technique errors at V1 (≥1 vs 0)**	**0.02**	**1.15-5.09**
1b	[†] **Technique score at V1 (3-11)**	**0.0005**	**1.15-1.73**
1c	[†] **Number of critical errors at V1**	**0.01**	**0.38-0.89**
2a	Preventer type (pMDI vs TH vs ACC)	0.09	0.90-5.23 (pMDI vs TH), 0.98-5.61 (pMDI vs ACC).
2b	[†] **Preventer type (pMDI vs DPI)**	**0.03**	**1.08-4.68**
3	Preventer duration (0-45 years)	0.13	0.92-1.01
4	Other devices (none vs same vs different)	0.06	0.17-1.62 (none vs same), 0.52-4.01 (none vs different).
5	Oral Asthma Medication (no vs yes)	0.85	0.18-4.01
6a	Other medication (None vs <5 vs ≥5)	0.31	0.61-3.02 (none vs <5), 0.78-6.45 (none vs ≥5).
6b	Other medication (no vs yes)	0.24	0.74-3.30
7a	Age (18 -88 years)	0.83	0.98-1.02
7b	Age (<60 vs ≥60)	0.65	0.41-1.74
8	Gender (male vs female)	0.59	0.37-1.77
9	Education (primary&secondary vs tafe&tertiary)	0.12	0.86-3.65
10	Asthma duration (0.08 - 81 years)	0.12	1.00-1.04
11	Other medical conditions (no vs yes)	0.39	0.35-1.52
12	Other lung conditions (no vs yes)	0.30	0.66-3.87
13	Hospitalisations (0 vs ≥1)	0.95	0.37-2.57
14a	HCP visits (0 - 52 times)	0.01	0.75-1.00
14b	HCP visits (0 vs 1 vs 2 vs 3 vs >3)	0.34	0.23-2.76 (0 vs 1), 0.21-2.29 (0 vs 2), 0.15-2.05 (0 vs 3) 0.95-1.08 (0 vs >3).
14c	HCP visits (0 vs ≥1)	0.26	0.20-1.57
15	When was preventer technique taught (Never vs 1st prx OR after vs 1st prx & after)	0.28	0.67-7.67 (never vs 1st prx Or after), 0.71-15.85 (never vs 1st prx & after).
16a	Last preventer instruction (0.003 - 43 years)	0.56	0.94-1.03
16b	Last preventer instruction (≤3 m vs >3m)	0.32	0.27-1.53
16c	Last preventer instruction (≤1 m vs >1m)	0.12	0.19-1.22
17	When was reliever technique taught (Never vs 1st prx OR after vs 1st prx & after)	0.42	0.67-6.95 (never vs 1st prx Or after), 0.39 - 7.15(never vs 1st prx & after).
18a	Last reliever instruction (0.001 - 60 years)	0.08	0.99-1.05
18b	Last reliever instruction (≤1 m vs >1m)	0.19	0.18-1.42
18c	Last reliever instruction (≤3 m vs >3m)	0.10	0.17-1.18
19	Mode of past technique instruction (No physical demo vs physical demo)	0.5	0.62-2.63

20a	Previous technique recheck (0-15 times)	0.28	0.85-1.59
20b	Previous technique recheck (no vs yes)	0.61	0.54-2.88
21a	Shown technique to others (0-100 times)	0.02	0.94-1.36
21b	Shown technique to others (0 vs once vs >once)	0.24	0.11-2.54 (0 vs once), 0.75-4.70 (0 vs > once).
21c	Shown technique to others (0 vs ≥once)	0.46	0.46-1.37
22	Last shown technique (0.003 - 30 years)	0.09	0.85-1.02
23a	V1 Asthma Control score (0-4.7)	0.09	0.50-1.06
23b	**[†]V1 Asthma Control (≥1.5 vs <1.5)**	**0.02**	**1.13-4.90**
24a	V1 Adherence score (6-25)	0.16	0.98-1.14
24b	V1 Adherence (≤21 vs >21)	0.60	0.59-2.51
25a	V1 Necessity score (7-25)	0.39	0.95-1.13
25b	V1 Necessity (<20 vs ≥20)	0.21	0.77-3.33
26a	V1 Concern score (5-24)	0.15	0.87-1.02
26b	V1 Concern (<20 vs ≥20)	0.09	0.79-13.94
26c	V1 Necessity Concerns Differential score (-10 to +20)	0.09	0.99-1.13
27	V1 Inhaler Technique Beliefs score (9-30)	0.72	0.95-1.08
28	**[†]V1 Motivation SCORE (1-10)**	**0.01**	**1.05-1.54**

[†] Variables where p<.25 and the confidence interval does not cross 1.

[‡] The dichotomised variable 'Visit 1 critical technique errors 'was chosen (over technique score or the number of critical errors at Visit 1) because:

1. Dichotomising Visit 1 technique scores (into <11 and 11) results in uneven groups increasing chances of overfitting (i.e. two groups of n=24 vs n=115).
2. Using raw visit 1 technique score is not ideal as the measurements do not fall on a continous scale i.e. the relative signifcance of of each step is not accounted for. This is similar for the 'number of critical errors'.

Further using Visit 2 critical errors as the outcome measure was considered, but this measurement results in uneven groups increasing the chance of overfitting data (i.e. two groups of n=103 vs n=24)

Diagnostic statistics conducted for outliers and influential cases (Field, 2009).

Diagnostic statistic	Description/and model goodness of fit criteria

Standardised Residuals	• The residual is the difference between the value predicted by the regression model and value observed in the data set. The smaller the residual the better he model fits the data. A residual for each observation in the data set is calculated, collectively referred to as residuals.
	• Residuals are standardised in order to define general cut-off values.
	• The purpose of the Standardised residual is to identify points that the model fits poorly
	• Values of standardised residuals indicating model is poor fit for data:
	  o If > 1% cases have values > 2.58, and
	  o If > 5% cases have values >1.96, and
	  o If any case has a value > 3.29

Cooks Distance	• An influence statistic used to identify points that exert a disproportionate influence on the model. • Any value > 1 may indicate an influential case
DFBeta	• An influence statistic used to identify points that exert a disproportionate influence on the model. • Any value > 1 may indicate an influential case.
Leverage	• An influence statistic used to identify points that exert a disproportionate influence on the model. • Average leverage is = (k+1)/N, where k is the number of predictors in model and N is the sample number. • Any value > 2 to 3 times the average leverage may indicate an influential case.

Assumptions tested for in the final logistic regression model generated to determine generalisability of model (Field, 2009, Bagley et al., 2001).

Assumption tested	Description and criteria for meeting assumption
Independence or errors	The cases of data are not related, i.e. each value of the outcome variable comes from a separate case.
Sufficient cases per independent variable	In logistic regression it is suggested that the number of the less common of the two possible outcomes (i.e. the smaller group of either the number of patients who did, or did not, maintain technique) divided by the number of predictor variables entered into the regression is ≥ 10.
Multicollinearity	• Multicollinearity describes a strong correlation between two or more predictor variables in a regression model. • Multicollinearity is undesirable and problematic for regression (it indicates unreliable regression coefficients, limits the amount of variance accounted for, makes it difficult to distinguish the important predictors). • The correlation matrix for predictor variables were scanned for high degree correlations (above 0.8) • Variance Inflation Factor (VIF) and Tolerance (1/VIF) statistics were examined to determine the degree of multicollinearity in the model generated. • VIF values > 10 is a cause for concern; an average VIF substantially > 1 indicates regression may be biased. • Tolerance values < 0.1 indicates a serious problem; tolerance < 0.2 indicates a potential problem.
Conformity with linear gradient for continuous variables	• Continuous variables in a logistic regression should conform with linearity of the logit. • To test for this assumption a logistic regression (forced entry method, all variables entered in as a single block) was performed with all of the qualifying variables as well as the *interaction terms of any continuous predictor variables and their logs i.e. predictor variable x Ln(predictor variable).* • A violation of the assumption of linearity of the logit is indicated by any interaction terms found to be significant after performing the regression.
Cross-validation	• Cross validation is when the accuracy of the regression model is assessed over different samples (Field, 2009). • A severe drop of the predictive power of the model when applied across a different sample means the model is not generalizable. • The adjusted R^2 value was examined. It indicates the loss in predictive value/ shrinkage if the model is applied to the sample population. • The adjusted R^2 was calculated using Stein's formula: adjusted $R^2 = 1 - [(n-1/n-k-1)(n-2/n-k-2)(n+1/n)]\ (1 - R^2)$, where R^2 is the unadjusted value, n is number of participants and k is number of predictors.

```
LOGISTIC REGRESSION VARIABLES TqSCOREv2DICH01
  /METHOD=BSTEP(LR) CRITerrorsV1Dichot PrvTypDICH01 ACV1dichot MotV1
  /CONTRAST (CRITerrorsV1Dichot)=Indicator(1)
  /CONTRAST (PrvTypDICH01)=Indicator(1)
  /CONTRAST (ACV1dichot)=Indicator(1)
  /SAVE=PRED PGROUP COOK LEVER DFBETA RESID LRESID SRESID ZRESID DEV
  /CASEWISE OUTLIER(2)
  /PRINT=GOODFIT CORR ITER(1) CI(95)
  /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

1.Logistic Regression

[DataSet1] C:\Documents and Settings\Pharm Prac\Desktop\ITeM RESULTS_11.11\PS AW DATA ENTRY\Data Sets\With outliers\ITeM data 10.11_Logits.sav

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	125	89.9
	Missing Cases	14	10.1
	Total	139	100.0
Unselected Cases		0	.0
Total		139	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
score<11/11	0
score=11/11	1

Categorical Variables Codings

		Frequency	Parameter coding (1)
AC V1 Poor/Good	Scores of 1.5 or higher	52	.000
	Scores less than 1.5	73	1.000
Preventer Type pMDI/DPI 01	pMDI	50	.000
	DPI	75	1.000
Critical error/s made or not V1	One or more critical errors	68	.000
	No critical errors	57	1.000

Block 0: Beginning Block

Iteration History[a,b,c]

Iteration		-2 Log likelihood	Coefficients: Constant
Step 0	1	168.254	.400
	2	168.253	.405
	3	168.253	.405

a. Constant is included in the model.

b. Initial -2 Log Likelihood: 168.253

c. Estimation terminated at iteration number 3 because parameter estimates changed by less than .001.

Classification Table[a,b]

Observed			Predicted: Technique Score V2 DICHOT 0,1 score<11/11	score=11/11
Step 0	Technique Score V2 DICHOT 0,1	score<11/11	0	50
		score=11/11	0	75
	Overall Percentage			

Classification Table[a,b]

Observed			Predicted: Percentage Correct
Step 0	Technique Score V2 DICHOT 0,1	score<11/11	.0
		score=11/11	100.0
	Overall Percentage		60.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	.405	.183	4.932	1	.026	1.500

Appendix 3.27: Logistic regression statistical output

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	CRITerrorsV1Dichot(1)	6.213	1	.013
		PrvTypDICH01(1)	5.000	1	.025
		ACV1dichot(1)	5.274	1	.022
		MotV1	6.677	1	.010
	Overall Statistics		17.822	4	.001

Block 1: Method = Backward Stepwise (Likelihood Ratio)

Iteration History[a,b,c,d]

Iteration		-2 Log likelihood	Coefficients		
			Constant	CRITerrors V1Dichot(1)	PrvTyp DICH01(1)
Step 1	1	149.879	-2.060	.561	.735
	2	149.475	-2.426	.654	.853
	3	149.474	-2.448	.659	.859
	4	149.474	-2.449	.659	.859
Step 2	1	152.321	-2.180		.843
	2	152.035	-2.535		.967
	3	152.034	-2.552		.972
	4	152.034	-2.552		.972

Iteration History[a,b,c,d]

Iteration		Coefficients	
		ACV1dichot(1)	MotV1
Step 1	1	.724	.152
	2	.847	.178
	3	.854	.179
	4	.854	.179
Step 2	1	.714	.187
	2	.818	.217
	3	.823	.218
	4	.823	.218

a. Method: Backward Stepwise (Likelihood Ratio)

b. Constant is included in the model.

c. Initial -2 Log Likelihood: 168.253

d. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	18.779	4	.001
	Block	18.779	4	.001
	Model	18.779	4	.001
Step 2[a]	Step	-2.561	1	.110
	Block	16.218	3	.001
	Model	16.218	3	.001

a. A negative Chi-squares value indicates that the Chi-squares value has decreased from the previous step.

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	149.474[a]	.139	.189
2	152.034[a]	.122	.164

a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

Hosmer and Lemeshow Test

Step	Chi-square	df	Sig.
1	8.776	7	.269
2	9.931	6	.128

Appendix 3.27: Logistic regression statistical output

Contingency Table for Hosmer and Lemeshow Test

		Technique Score V2 DICHOT 0,1 = score<11/11		Technique Score V2 DICHOT 0,1 = score=11/11		Total
		Observed	Expected	Observed	Expected	
Step 1	1	10	8.499	1	2.501	11
	2	7	8.243	6	4.757	13
	3	6	7.634	9	7.366	15
	4	5	4.091	4	4.909	9
	5	4	5.653	9	7.347	13
	6	4	5.242	13	11.758	17
	7	9	5.014	8	11.986	17
	8	3	2.886	9	9.114	12
	9	2	2.738	16	15.262	18
Step 2	1	12	9.565	1	3.435	13
	2	5	7.740	8	5.260	13
	3	5	5.333	5	4.667	10
	4	2	4.711	9	6.289	11
	5	8	6.995	10	11.005	18
	6	9	7.453	12	13.547	21
	7	5	3.161	8	9.839	13
	8	4	5.040	22	20.960	26

Classification Table[a]

Observed			Predicted: Technique Score V2 DICHOT 0,1	
			score<11/11	score=11/11
Step 1	Technique Score V2 DICHOT 0,1	score<11/11	20	30
		score=11/11	8	67
	Overall Percentage			
Step 2	Technique Score V2 DICHOT 0,1	score<11/11	21	29
		score=11/11	12	63
	Overall Percentage			

Classification Table[a]

Observed			Predicted: Percentage Correct
Step 1	Technique Score V2 DICHOT 0,1	score<11/11	40.0
		score=11/11	89.3
	Overall Percentage		69.6
Step 2	Technique Score V2 DICHOT 0,1	score<11/11	42.0
		score=11/11	84.0
	Overall Percentage		67.2

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	CRITerrorsV1Dichot(1)	.659	.414	2.532	1	.112	1.933
	PrvTypDICH01(1)	.859	.409	4.407	1	.036	2.361
	ACV1dichot(1)	.854	.405	4.438	1	.035	2.349
	MotV1	.179	.106	2.890	1	.089	1.197
	Constant	-2.449	.994	6.071	1	.014	.086
Step 2[a]	PrvTypDICH01(1)	.972	.400	5.907	1	.015	2.643
	ACV1dichot(1)	.823	.400	4.225	1	.040	2.277
	MotV1	.218	.102	4.538	1	.033	1.244
	Constant	-2.552	.986	6.703	1	.010	.078

Variables in the Equation

		95% C.I.for EXP(B)	
		Lower	Upper
Step 1[a]	CRITerrorsV1Dichot(1)	.858	4.354
	PrvTypDICH01(1)	1.059	5.264
	ACV1dichot(1)	1.061	5.199
	MotV1	.973	1.472
	Constant		
Step 2[a]	PrvTypDICH01(1)	1.207	5.788
	ACV1dichot(1)	1.039	4.990
	MotV1	1.018	1.521
	Constant		

a. Variable(s) entered on step 1: CRITerrorsV1Dichot, PrvTypDICH01, ACV1dichot, MotV1.

Appendix 3.27: Logistic regression statistical output

Correlation Matrix

		Constant	CRITerrors V1Dichot(1)	PrvTyp DICH01(1)	ACV1dichot(1)
Step 1	Constant	1.000	.044	-.337	-.169
	CRITerrorsV1Dichot(1)	.044	1.000	-.148	.077
	PrvTypDICH01(1)	-.337	-.148	1.000	.139
	ACV1dichot(1)	-.169	.077	.139	1.000
	MotV1	-.904	-.214	.103	-.110
Step 2	Constant				
	PrvTypDICH01(1)				
	ACV1dichot(1)				
	MotV1				

Correlation Matrix

		MotV1	Constant	PrvTyp DICH01(1)
Step 1	Constant	-.904		
	CRITerrorsV1Dichot(1)	-.214		
	PrvTypDICH01(1)	.103		
	ACV1dichot(1)	-.110		
	MotV1	1.000		
Step 2	Constant		1.000	-.333
	PrvTypDICH01(1)		-.333	1.000
	ACV1dichot(1)		-.168	.155
	MotV1		-.918	.076

Correlation Matrix

		ACV1dichot(1)	MotV1
Step 1	Constant		
	CRITerrorsV1Dichot(1)		
	PrvTypDICH01(1)		
	ACV1dichot(1)		
	MotV1		
Step 2	Constant	-.168	-.918
	PrvTypDICH01(1)	.155	.076
	ACV1dichot(1)	1.000	-.101
	MotV1	-.101	1.000

Model if Term Removed

Variable		Model Log Likelihood	Change in -2 Log Likelihood	df	Sig. of the Change
Step 1	CRITerrorsV1Dichot	-76.017	2.561	1	.110
	PrvTypDICH01	-76.981	4.487	1	.034
	ACV1dichot	-76.998	4.522	1	.033
	MotV1	-76.294	3.114	1	.078
Step 2	PrvTypDICH01	-79.064	6.093	1	.014
	ACV1dichot	-78.161	4.288	1	.038
	MotV1	-78.524	5.014	1	.025

Variables not in the Equation

			Score	df	Sig.
Step 2[a]	Variables	CRITerrorsV1Dichot(1)	2.565	1	.109
	Overall Statistics		2.565	1	.109

a. Variable(s) removed on step 2: CRITerrorsV1Dichot.

Casewise List [a]

a. The casewise plot is not produced because no outliers were found.

Appendix 3.27: Logistic regression statistical output

6.Logistic Regression

[DataSet1] C:\Documents and Settings\Pharm Prac\Desktop\ITeM RESULTS_12.11\PSAW DATA ENTRY\Data Sets\With outliers\ITeM data 10.11_Logits.sav

Classification Table[a,b]

Observed			Predicted	
			Technique Score V2 DICHOT 0,1	
			score<11/11	score=11/11
Step 0	Technique Score V2 DICHOT 0,1	score<11/11	0	50
		score=11/11	0	75
	Overall Percentage			

Classification Table[a,b]

Observed			Predicted
			Percentage Correct
Step 0	Technique Score V2 DICHOT 0,1	score<11/11	.0
		score=11/11	100.0
	Overall Percentage		60.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	.405	.183	4.932	1	.026	1.500

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	PrvTypDICH01(1)	5.000	1	.025
		MotV1	6.677	1	.010
		ACV1dichot(1)	5.274	1	.022
		CRITerrorsV1Dichot(1)	6.213	1	.013
		CRITerrorsV1Dichot(1) by PrvTypDICH01(1)	5.515	1	.019
		ACV1dichot(1) by CRITerrorsV1Dichot(1)	7.333	1	.007
		CRITerrorsV1Dichot(1) by MotV1	6.528	1	.011
		MotV1 by PrvTypDICH01 (1)	7.701	1	.006
		ACV1dichot(1) by PrvTypDICH01(1)	6.909	1	.009
		ACV1dichot(1) by MotV1	4.972	1	.026
	Overall Statistics		22.026	10	.015

Appendix 3.28: Interaction terms statistical output

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	125	89.9
	Missing Cases	14	10.1
	Total	139	100.0
Unselected Cases		0	.0
Total		139	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
score<11/11	0
score=11/11	1

Categorical Variables Codings

		Frequency	Parameter coding (1)
Critical error/s made or not V1	One or more critical errors	68	.000
	No critical errors	57	1.000
AC V1 Poor/Good	Scores of 1.5 or higher	52	.000
	Scores less than 1.5	73	1.000
Preventer Type pMDI/DPI 01	pMDI	50	.000
	DPI	75	1.000

Block 0: Beginning Block

Iteration History[a,b,c]

Iteration		-2 Log likelihood	Coefficients Constant
Step 0	1	168.254	.400
	2	168.253	.405
	3	168.253	.405

a. Constant is included in the model.

b. Initial -2 Log Likelihood: 168.253

c. Estimation terminated at iteration number 3 because parameter estimates changed by less than .001.

Appendix 3.28: Interaction terms statistical output

Block 1: Method = Backward Stepwise (Likelihood Ratio)

Iteration History[a,b,c,d,e]

Iteration		-2 Log likelihood	Coefficients								
			Constant	PrvTyp DICH01(1)	MotV1	ACV1dichot(1)	CRITerrors V1Dichot(1)	CRITerrors V1Dichot(1) by PrvTyp DICH01(1)	ACV1dichot(1) by CRITerrors V1Dichot(1)	CRITerrors V1Dichot(1) by MotV1	MotV1 by PrvTyp DICH01(1)
Step 1	1	145.184	-2.702	-.064	.218	4.197	2.240	-.416	.531	-.171	.125
	2	143.533	-4.507	.374	.408	5.885	3.547	-.301	.769	-.316	.080
	3	143.263	-5.800	.812	.542	6.953	4.368	-.267	.812	-.404	.035
	4	143.248	-6.202	.931	.583	7.293	4.638	-.261	.817	-.432	.023
	5	143.248	-6.229	.936	.586	7.318	4.659	-.261	.817	-.434	.022
	6	143.248	-6.230	.936	.586	7.318	4.659	-.261	.817	-.434	.022
Step 2	1	145.347	-3.216	.937	.283	3.989	1.613	-.223	.501	-.118	
	2	143.531	-4.964	1.116	.457	5.924	3.183	-.228	.759	-.284	
	3	143.266	-6.029	1.143	.566	7.006	4.235	-.239	.809	-.392	
	4	143.252	-6.353	1.143	.599	7.326	4.554	-.240	.815	-.425	
	5	143.252	-6.376	1.143	.601	7.349	4.577	-.240	.815	-.427	
	6	143.252	-6.376	1.143	.601	7.349	4.577	-.240	.815	-.427	
Step 3	1	145.411	-3.179	.863	.284	3.991	1.356		.514	-.106	
	2	143.602	-4.901	1.026	.455	5.878	2.912		.775	-.270	
	3	143.343	-5.951	1.045	.563	6.945	3.946		.827	-.378	
	4	143.329	-6.271	1.044	.596	7.261	4.261		.833	-.410	
	5	143.328	-6.293	1.044	.598	7.284	4.284		.833	-.413	
	6	143.328	-6.294	1.044	.598	7.284	4.284		.833	-.413	
Step 4	1	145.531	-3.094	.699	.284	3.833	1.449		.459	-.112	
	2	143.741	-4.765	.828	.452	5.689	3.032		.732	-.279	
	3	143.488	-5.795	.837	.558	6.744	4.068		.786	-.387	
	4	143.474	-6.111	.836	.590	7.058	4.382		.792	-.419	
	5	143.474	-6.134	.835	.593	7.081	4.405		.792	-.421	
	6	143.474	-6.134	.835	.593	7.081	4.405		.792	-.421	
Step 5	1	146.046	-3.063	.695	.267	3.730	1.363			-.074	
	2	144.476	-4.694	.818	.426	5.410	2.719			-.204	
	3	144.249	-5.674	.823	.526	6.365	3.649			-.298	
	4	144.237	-5.964	.821	.555	6.648	3.929			-.326	
	5	144.237	-5.983	.821	.557	6.667	3.948			-.328	
	6	144.237	-5.983	.821	.557	6.667	3.948			-.328	
Step 6	1	146.265	-2.951	.714	.254	3.714	.674				
	2	145.217	-4.083	.862	.359	5.010	.816				
	3	145.187	-4.348	.877	.385	5.297	.836				

Appendix 3.28: Interaction terms statistical output

Iteration History[a,b,c,d,e]

Iteration		Coefficients: ACV1dichot(1) by PrvTyp DICH01(1)	Coefficients: ACV1dichot(1) by MotV1
Step 1	1	-.313	-.391
	2	-.291	-.569
	3	-.322	-.678
	4	-.333	-.712
	5	-.334	-.714
	6	-.334	-.714
Step 2	1	-.243	-.372
	2	-.322	-.571
	3	-.340	-.682
	4	-.341	-.715
	5	-.341	-.717
	6	-.341	-.717
Step 3	1	-.266	-.371
	2	-.318	-.566
	3	-.331	-.676
	4	-.331	-.708
	5	-.331	-.711
	6	-.331	-.711
Step 4	1		-.369
	2		-.563
	3		-.673
	4		-.705
	5		-.707
	6		-.707
Step 5	1		-.335
	2		-.501
	3		-.598
	4		-.627
	5		-.629
	6		-.629
Step 6	1		-.335
	2		-.464
	3		-.493

Iteration History[a,b,c,d,e]

Iteration		-2 Log likelihood	Coefficients: Constant	PrvTyp DICH01(1)	MotV1	ACV1dichot(1)
Step 6	4	145.187	-4.360	.878	.386	5.310
	5	145.187	-4.360	.878	.386	5.310

Iteration History[a,b,c,d,e]

Iteration		Coefficients: CRITerrors V1Dichot(1)	CRITerrors V1Dichot(1) by PrvTyp DICH01(1)	ACV1dichot(1) by CRITerrors V1Dichot(1)	CRITerrors V1Dichot(1) by MotV1	MotV1 by PrvTyp DICH01(1)
Step 6	4	.836				
	5	.836				

Iteration History[a,b,c,d,e]

Iteration		Coefficients: ACV1dichot(1) by PrvTyp DICH01(1)	ACV1dichot(1) by MotV1
Step 6	4		-.494
	5		-.494

a. Method: Backward Stepwise (Likelihood Ratio)

b. Constant is included in the model.

c. Initial -2 Log Likelihood: 168.253

d. Estimation terminated at iteration number 6 because parameter estimates changed by less than .001.

e. Estimation terminated at iteration number 5 because parameter estimates changed by less than .001.

Appendix 3.28: Interaction terms statistical output

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	25.005	10	.005
	Block	25.005	10	.005
	Model	25.005	10	.005
Step 2[a]	Step	-.004	1	.949
	Block	25.001	9	.003
	Model	25.001	9	.003
Step 3[a]	Step	-.077	1	.782
	Block	24.924	8	.002
	Model	24.924	8	.002
Step 4[a]	Step	-.146	1	.703
	Block	24.779	7	.001
	Model	24.779	7	.001
Step 5[a]	Step	-.763	1	.382
	Block	24.016	6	.001
	Model	24.016	6	.001
Step 6[a]	Step	-.950	1	.330
	Block	23.066	5	.000
	Model	23.066	5	.000

a. A negative Chi-squares value indicates that the Chi-squares value has decreased from the previous step.

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	143.248[a]	.181	.245
2	143.252[a]	.181	.245
3	143.328[a]	.181	.244
4	143.474[a]	.180	.243
5	144.237[a]	.175	.236
6	145.187[b]	.169	.228

a. Estimation terminated at iteration number 6 because parameter estimates changed by less than .001.

b. Estimation terminated at iteration number 5 because parameter estimates changed by less than .001.

Hosmer and Lemeshow Test

Step	Chi-square	df	Sig.
1	6.117	7	.526
2	5.233	7	.632
3	5.303	7	.623
4	7.557	7	.373
5	8.599	7	.283
6	10.141	7	.181

Contingency Table for Hosmer and Lemeshow Test

		Technique Score V2 DICHOT 0,1 = score<11/11		Technique Score V2 DICHOT 0,1 = score=11/11		
		Observed	Expected	Observed	Expected	Total
Step 1	1	11	10.725	1	1.275	12
	2	10	8.547	5	6.453	15
	3	4	6.654	9	6.346	13
	4	5	6.273	11	9.727	16
	5	4	3.951	8	8.049	12
	6	3	3.430	8	7.570	11
	7	5	2.712	4	6.288	9
	8	4	3.668	9	9.332	13
	9	4	4.041	20	19.959	24
Step 2	1	11	10.728	1	1.272	12
	2	10	8.510	5	6.490	15
	3	4	6.653	9	6.347	13
	4	5	6.320	11	9.680	16
	5	4	3.949	8	8.051	12
	6	3	3.143	7	6.857	10
	7	5	3.008	5	6.992	10
	8	4	3.658	9	9.342	13
	9	4	4.031	20	19.969	24
Step 3	1	12	11.293	1	1.707	13
	2	6	6.752	6	5.248	12
	3	6	6.746	7	6.254	13
	4	4	4.435	6	5.565	10
	5	6	5.553	10	10.447	16
	6	3	4.572	11	9.428	14
	7	4	3.891	9	9.109	13
	8	6	3.170	5	7.830	11
	9	3	3.588	20	19.412	23

Appendix 3.28: Interaction terms statistical output

Contingency Table for Hosmer and Lemeshow Test

		Technique Score V2 DICHOT 0,1 = score<11/11		Technique Score V2 DICHOT 0,1 = score=11/11		
		Observed	Expected	Observed	Expected	Total
Step 4	1	12	11.217	1	1.783	13
	2	8	7.154	5	5.846	13
	3	5	7.186	9	6.814	14
	4	6	7.025	12	10.975	18
	5	2	4.135	10	7.865	12
	6	4	2.562	4	5.438	8
	7	4	3.747	8	8.253	12
	8	6	3.562	6	8.438	12
	9	3	3.412	20	19.588	23
Step 5	1	11	10.776	1	1.224	12
	2	9	7.822	5	6.178	14
	3	5	6.242	8	6.758	13
	4	6	7.493	12	10.507	18
	5	4	4.505	9	8.495	13
	6	2	3.693	10	8.307	12
	7	4	2.922	6	7.078	10
	8	6	2.735	5	8.265	11
	9	3	3.812	19	18.188	22
Step 6	1	12	10.961	1	2.039	13
	2	9	9.315	7	6.685	16
	3	6	6.357	7	6.643	13
	4	4	5.743	10	8.257	14
	5	4	4.778	10	9.222	14
	6	2	3.803	10	8.197	12
	7	5	3.168	6	7.832	11
	8	5	2.065	4	6.935	9
	9	3	3.810	20	19.190	23

Classification Table[a]

Observed			Predicted	
			Technique Score V2 DICHOT 0,1	
			score<11/11	score=11/11
Step 1	Technique Score V2 DICHOT 0,1	score<11/11	24	26
		score=11/11	14	61
	Overall Percentage			
Step 2	Technique Score V2 DICHOT 0,1	score<11/11	24	26
		score=11/11	14	61
	Overall Percentage			
Step 3	Technique Score V2 DICHOT 0,1	score<11/11	24	26
		score=11/11	14	61
	Overall Percentage			
Step 4	Technique Score V2 DICHOT 0,1	score<11/11	24	26
		score=11/11	14	61
	Overall Percentage			
Step 5	Technique Score V2 DICHOT 0,1	score<11/11	20	30
		score=11/11	6	69
	Overall Percentage			
Step 6	Technique Score V2 DICHOT 0,1	score<11/11	24	26
		score=11/11	13	62
	Overall Percentage			

Appendix 3.28: Interaction terms statistical output

Classification Table[a]

Observed			Predicted: Percentage Correct
Step 1	Technique Score V2 DICHOT 0,1	score<11/11	48.0
		score=11/11	81.3
	Overall Percentage		68.0
Step 2	Technique Score V2 DICHOT 0,1	score<11/11	48.0
		score=11/11	81.3
	Overall Percentage		68.0
Step 3	Technique Score V2 DICHOT 0,1	score<11/11	48.0
		score=11/11	81.3
	Overall Percentage		68.0
Step 4	Technique Score V2 DICHOT 0,1	score<11/11	48.0
		score=11/11	81.3
	Overall Percentage		68.0
Step 5	Technique Score V2 DICHOT 0,1	score<11/11	40.0
		score=11/11	92.0
	Overall Percentage		71.2
Step 6	Technique Score V2 DICHOT 0,1	score<11/11	48.0
		score=11/11	82.7
	Overall Percentage		68.8

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.
Step 1[a]	PrvTypDICH01(1)	.936	3.341	.079	1	.779
	MotV1	.586	.395	2.194	1	.139
	ACV1dichot(1)	7.318	3.474	4.436	1	.035
	CRITerrorsV1Dichot(1)	4.659	3.982	1.369	1	.242
	CRITerrorsV1Dichot(1) by PrvTypDICH01(1)	-.261	.926	.079	1	.778
	ACV1dichot(1) by CRITerrorsV1Dichot(1)	.817	.923	.785	1	.376
	CRITerrorsV1Dichot(1) by MotV1	-.434	.405	1.152	1	.283
	MotV1 by PrvTypDICH01 (1)	.022	.353	.004	1	.949
	ACV1dichot(1) by PrvTypDICH01(1)	-.334	.879	.144	1	.704
	ACV1dichot(1) by MotV1	-.714	.366	3.818	1	.051
	Constant	-6.230	3.766	2.736	1	.098
Step 2[a]	PrvTypDICH01(1)	1.143	.782	2.137	1	.144
	MotV1	.601	.310	3.761	1	.052
	ACV1dichot(1)	7.349	3.453	4.529	1	.033
	CRITerrorsV1Dichot(1)	4.577	3.760	1.482	1	.224
	CRITerrorsV1Dichot(1) by PrvTypDICH01(1)	-.240	.868	.077	1	.782
	ACV1dichot(1) by CRITerrorsV1Dichot(1)	.815	.922	.782	1	.377
	CRITerrorsV1Dichot(1) by MotV1	-.427	.389	1.209	1	.271
	ACV1dichot(1) by PrvTypDICH01(1)	-.341	.872	.153	1	.696
	ACV1dichot(1) by MotV1	-.717	.365	3.867	1	.049
	Constant	-6.376	3.002	4.511	1	.034

Appendix 3.28: Interaction terms statistical output

Variables in the Equation

		Exp(B)	95% C.I.for EXP(B) Lower	Upper
Step 1[a]	PrvTypDICH01(1)	2.550	.004	1778.629
	MotV1	1.796	.828	3.898
	ACV1dichot(1)	1506.638	1.663	1365347.911
	CRITerrorsV1Dichot(1)	105.545	.043	258947.620
	CRITerrorsV1Dichot(1) by PrvTypDICH01(1)	.770	.125	4.731
	ACV1dichot(1) by CRITerrorsV1Dichot(1)	2.264	.371	13.813
	CRITerrorsV1Dichot(1) by MotV1	.648	.293	1.432
	MotV1 by PrvTypDICH01 (1)	1.023	.512	2.044
	ACV1dichot(1) by PrvTypDICH01(1)	.716	.128	4.014
	ACV1dichot(1) by MotV1	.490	.239	1.002
	Constant	.002		
Step 2[a]	PrvTypDICH01(1)	3.135	.677	14.514
	MotV1	1.824	.994	3.350
	ACV1dichot(1)	1554.601	1.788	1351865.391
	CRITerrorsV1Dichot(1)	97.242	.061	154448.216
	CRITerrorsV1Dichot(1) by PrvTypDICH01(1)	.786	.144	4.308
	ACV1dichot(1) by CRITerrorsV1Dichot(1)	2.259	.371	13.755
	CRITerrorsV1Dichot(1) by MotV1	.652	.304	1.397
	ACV1dichot(1) by PrvTypDICH01(1)	.711	.129	3.927
	ACV1dichot(1) by MotV1	.488	.239	.998
	Constant	.002		

Variables in the Equation

		B	S.E.	Wald	df	Sig.
Step 3[a]	PrvTypDICH01(1)	1.044	.693	2.271	1	.132
	MotV1	.598	.310	3.727	1	.054
	ACV1dichot(1)	7.284	3.436	4.493	1	.034
	CRITerrorsV1Dichot(1)	4.284	3.617	1.403	1	.236
	ACV1dichot(1) by CRITerrorsV1Dichot(1)	.833	.920	.821	1	.365
	CRITerrorsV1Dichot(1) by MotV1	-.413	.386	1.144	1	.285
	ACV1dichot(1) by PrvTypDICH01(1)	-.331	.869	.145	1	.703
	ACV1dichot(1) by MotV1	-.711	.363	3.833	1	.050
	Constant	-6.294	2.984	4.448	1	.035
Step 4[a]	PrvTypDICH01(1)	.835	.420	3.952	1	.047
	MotV1	.593	.310	3.646	1	.056
	ACV1dichot(1)	7.081	3.414	4.300	1	.038
	CRITerrorsV1Dichot(1)	4.405	3.624	1.477	1	.224
	ACV1dichot(1) by CRITerrorsV1Dichot(1)	.792	.911	.756	1	.385
	CRITerrorsV1Dichot(1) by MotV1	-.421	.387	1.184	1	.277
	ACV1dichot(1) by MotV1	-.707	.365	3.747	1	.053
	Constant	-6.134	2.960	4.294	1	.038
Step 5[a]	PrvTypDICH01(1)	.821	.419	3.846	1	.050
	MotV1	.557	.303	3.374	1	.066
	ACV1dichot(1)	6.667	3.292	4.102	1	.043
	CRITerrorsV1Dichot(1)	3.948	3.509	1.266	1	.261
	CRITerrorsV1Dichot(1) by MotV1	-.328	.364	.814	1	.367
	ACV1dichot(1) by MotV1	-.629	.344	3.335	1	.068
	Constant	-5.983	2.918	4.205	1	.040
Step 6[a]	PrvTypDICH01(1)	.878	.414	4.501	1	.034
	MotV1	.386	.173	4.950	1	.026
	ACV1dichot(1)	5.310	2.441	4.731	1	.030
	CRITerrorsV1Dichot(1)	.836	.428	3.817	1	.051
	ACV1dichot(1) by MotV1	-.494	.263	3.527	1	.060
	Constant	-4.360	1.651	6.977	1	.008

Appendix 3.28: Interaction terms statistical output

Variables in the Equation

		Exp(B)	95% C.I.for EXP(B) Lower	Upper
Step 3[a]	PrvTypDICH01(1)	2.841	.731	11.044
	MotV1	1.819	.991	3.338
	ACV1dichot(1)	1456.661	1.731	1226038.752
	CRITerrorsV1Dichot(1)	72.544	.061	86959.614
	ACV1dichot(1) by CRITerrorsV1Dichot(1)	2.300	.379	13.946
	CRITerrorsV1Dichot(1) by MotV1	.662	.311	1.410
	ACV1dichot(1) by PrvTypDICH01(1)	.718	.131	3.943
	ACV1dichot(1) by MotV1	.491	.241	1.001
	Constant	.002		
Step 4[a]	PrvTypDICH01(1)	2.306	1.012	5.255
	MotV1	1.809	.984	3.324
	ACV1dichot(1)	1188.692	1.475	958170.523
	CRITerrorsV1Dichot(1)	81.857	.067	99588.577
	ACV1dichot(1) by CRITerrorsV1Dichot(1)	2.208	.370	13.174
	CRITerrorsV1Dichot(1) by MotV1	.656	.307	1.401
	ACV1dichot(1) by MotV1	.493	.241	1.009
	Constant	.002		
Step 5[a]	PrvTypDICH01(1)	2.273	1.000	5.162
	MotV1	1.746	.963	3.165
	ACV1dichot(1)	786.092	1.240	498368.455
	CRITerrorsV1Dichot(1)	51.836	.053	50327.696
	CRITerrorsV1Dichot(1) by MotV1	.720	.353	1.470
	ACV1dichot(1) by MotV1	.533	.272	1.047
	Constant	.003		
Step 6[a]	PrvTypDICH01(1)	2.405	1.069	5.411
	MotV1	1.471	1.047	2.066
	ACV1dichot(1)	202.260	1.691	24194.741
	CRITerrorsV1Dichot(1)	2.308	.997	5.340
	ACV1dichot(1) by MotV1	.610	.364	1.022
	Constant	.013		

a. Variable(s) entered on step 1: PrvTypDICH01, MotV1, ACV1dichot, CRITerrorsV1Dichot, CRITerrorsV1Dichot * PrvTypDICH01 , ACV1dichot * CRITerrorsV1Dichot , CRITerrorsV1Dichot * MotV1 , MotV1 * PrvTypDICH01 , ACV1dichot * PrvTypDICH01 , ACV1dichot * MotV1 .

Model if Term Removed

Variable		Model Log Likelihood	Change in -2 Log Likelihood	df	Sig. of the Change
Step 1	PrvTypDICH01	-71.664	.080	1	.777
	MotV1	-73.552	3.856	1	.050
	ACV1dichot	-75.372	7.496	1	.006
	CRITerrorsV1Dichot	-72.433	1.617	1	.203
	CRITerrorsV1Dichot * PrvTypDICH01	-71.664	.079	1	.778
	ACV1dichot * CRITerrorsV1Dichot	-72.020	.793	1	.373
	CRITerrorsV1Dichot * MotV1	-72.298	1.349	1	.245
	MotV1 * PrvTypDICH01	-71.626	.004	1	.949
	ACV1dichot * PrvTypDICH01	-71.696	.145	1	.704
	ACV1dichot * MotV1	-74.620	5.993	1	.014
Step 2	PrvTypDICH01	-72.731	2.211	1	.137
	MotV1	-75.850	8.448	1	.004
	ACV1dichot	-75.374	7.497	1	.006
	CRITerrorsV1Dichot	-72.512	1.773	1	.183
	CRITerrorsV1Dichot * PrvTypDICH01	-71.664	.077	1	.782
	ACV1dichot * CRITerrorsV1Dichot	-72.021	.790	1	.374
	CRITerrorsV1Dichot * MotV1	-72.339	1.426	1	.232
	ACV1dichot * PrvTypDICH01	-71.703	.154	1	.695
	ACV1dichot * MotV1	-74.626	6.001	1	.014
Step 3	PrvTypDICH01	-72.830	2.332	1	.127
	MotV1	-75.866	8.404	1	.004
	ACV1dichot	-75.381	7.434	1	.006
	CRITerrorsV1Dichot	-72.530	1.731	1	.188
	ACV1dichot * CRITerrorsV1Dichot	-72.079	.830	1	.362
	CRITerrorsV1Dichot * MotV1	-72.342	1.355	1	.244
	ACV1dichot * PrvTypDICH01	-71.737	.146	1	.703
	ACV1dichot * MotV1	-74.637	5.946	1	.015

Appendix 3.28: Interaction terms statistical output

Model if Term Removed

Variable		Model Log Likelihood	Change in -2 Log Likelihood	df	Sig. of the Change
Step 4	PrvTypDICH01	-73.742	4.009	1	.045
	MotV1	-75.894	8.313	1	.004
	ACV1dichot	-75.437	7.399	1	.007
	CRITerrorsV1Dichot	-72.655	1.835	1	.176
	ACV1dichot * CRITerrorsV1Dichot	-72.119	.763	1	.382
	CRITerrorsV1Dichot * MotV1	-72.442	1.409	1	.235
	ACV1dichot * MotV1	-74.661	5.847	1	.016
Step 5	PrvTypDICH01	-74.066	3.894	1	.048
	MotV1	-75.925	7.612	1	.006
	ACV1dichot	-75.573	6.908	1	.009
	CRITerrorsV1Dichot	-72.895	1.553	1	.213
	CRITerrorsV1Dichot * MotV1	-72.594	.950	1	.330
	ACV1dichot * MotV1	-74.679	5.120	1	.024
Step 6	PrvTypDICH01	-74.881	4.575	1	.032
	MotV1	-76.101	7.014	1	.008
	ACV1dichot	-75.600	6.013	1	.014
	CRITerrorsV1Dichot	-74.539	3.891	1	.049
	ACV1dichot * MotV1	-74.737	4.287	1	.038

Casewise List[a]

a. The casewise plot is not produced because no outliers were found.

```
SAVE OUTFILE='C:\Documents and Settings\Pharm Prac\Desktop\ITeM RESULTS
\PSAW DATA '+
    'ENTRY\Data Sets\With outliers\ITeM data 10.11_Logits.sav'
 /COMPRESSED.
```

Variables not in the Equation

			Score	df	Sig.
Step 2[a]	Variables	MotV1 by PrvTypDICH01(1)	.004	1	.949
	Overall Statistics		.004	1	.949
Step 3[b]	Variables	CRITerrorsV1Dichot(1) by PrvTypDICH01(1)	.077	1	.782
		MotV1 by PrvTypDICH01(1)	.001	1	.970
	Overall Statistics		.081	2	.960
Step 4[c]	Variables	CRITerrorsV1Dichot(1) by PrvTypDICH01(1)	.069	1	.793
		MotV1 by PrvTypDICH01(1)	.000	1	.987
		ACV1dichot(1) by PrvTypDICH01(1)	.145	1	.703
	Overall Statistics		.225	3	.973
Step 5[d]	Variables	CRITerrorsV1Dichot(1) by PrvTypDICH01(1)	.114	1	.736
		ACV1dichot(1) by CRITerrorsV1Dichot(1)	.759	1	.384
		MotV1 by PrvTypDICH01(1)	.003	1	.956
		ACV1dichot(1) by PrvTypDICH01(1)	.079	1	.779
	Overall Statistics		.977	4	.913
Step 6[e]	Variables	CRITerrorsV1Dichot(1) by PrvTypDICH01(1)	.020	1	.887
		ACV1dichot(1) by CRITerrorsV1Dichot(1)	.304	1	.582
		CRITerrorsV1Dichot(1) by MotV1	.874	1	.350
		MotV1 by PrvTypDICH01(1)	.073	1	.787
		ACV1dichot(1) by PrvTypDICH01(1)	.137	1	.711
	Overall Statistics		1.812	5	.875

a. Variable(s) removed on step 2: MotV1 * PrvTypDICH01 .

b. Variable(s) removed on step 3: CRITerrorsV1Dichot * PrvTypDICH01 .

c. Variable(s) removed on step 4: ACV1dichot * PrvTypDICH01 .

d. Variable(s) removed on step 5: ACV1dichot * CRITerrorsV1Dichot .

e. Variable(s) removed on step 6: CRITerrorsV1Dichot * MotV1 .

Appendix 3.28: Interaction terms statistical output

Appendix 3.29: Diagnostic statistics results

Results for diagnostic statistics conducted to examine goodness of fit of model/for outliers and influential cases.

Diagnostic statistic	Goodness of fit criteria	Results
Standardised Residuals	Values of standardised residuals indicating model is poor fit for data: • If > 1% cases have values > 2.58, and • If > 5% cases have values >1.96, and • If any case has a value > 3.29 (Field, 2009)	No values were > 1.96 therefore this statistic did not identify any points which the model fits poorly.
Cooks Distance	Any value > 1 may indicate an influential case.	No values were > 1; therefore this statistic did not identify any points that exerted a disproportionate influence on the model.
DFBeta	Any value > 1 may indicate an influential case (Field, 2009) (Field pg. 218)	No values were > 1; therefore this statistic did not identify any points that exerted a disproportionate influence on the model.
Leverage	Any value > 2 to 3 times the average leverage may indicate an influential case.	• Expected leverage = K+1/N = 4+1/125 = 0.04. • Two influential cases with values > 2x0.04 = 0.08 were identified. • Leverage = 0.17 for case 16. Suspected reason: patient did not complete visit 2, therefore missing values. • Leverage = 0.18 for case 135. Suspected reason: outlier case i.e. patient maintained correct technique, had good asthma control, used a DPI, but scored low for motivation.

Results for assumptions tested to determine the generalisability of the logistic regression model.

Assumption tested	Criteria	Results
Independence or errors	Each value of the outcome variable comes from a separate case.	All 125 cases used in the logistic regression were unique.
Sufficient cases per independent variable	N (the number of the smaller group of either patients who did, or did not, maintain technique)/ (number of predictor variables entered into the regression) ≥ 10.	- N = 50 (number of patients not maintaining correct technique); 4 predictor variables were entered in to the regression. - 50/4 = 12.5, indicating sufficient cases per independent variable.
Multicollinearity	- Correlations between predictor variables should not be > 0.8. - VIF values > 10 is a cause for concern; an average VIF substantially > 1 indicates regression may be biased. - Tolerance values < 0.1 indicate a serious problem; tolerance < 0.2 indicates a potential problem.	- No correlations between were > 0.8 - No VIF value > 10 - Average VIF = 1.08, which is not substantially greater than 1. - No tolerance values were < 0.2 (all tolerance values > 0.90). - These tests indicate that the assumption for no multicollinearity was met.
Conformity with linear gradient for continuous variables	If interaction terms for continuous variables are significant after performing the regression, the assumption of linerarity of the logit is violated.	- One continuous predictor variable was entered into the regression, motivation. - A forced entry logistic regression was conducted with the following independent variables: inhaler technique, device type, asthma control, motivation, and *Ln(motivation) x motivation*. - The interaction term was not significant in the regression model produced (p=0.93). - The assumption for linearity of the logit was met.
Cross-validation	- The adjusted R^2 value indicates the loss in predictive value/ shrinkage if the model is applied to the sample population. - The adjusted R^2 is calculated: adjusted R^2 = 1 – [(n-1/n-k-1)(n-2/n-k-2)(n+1/n)] (1 – R^2), where R^2 is the unadjusted value, n is number of participants and k is number of predictors.	- Adjusted R^2=0.1127 (given n=125, k=3, R^2=0.1622) - Thus the predictive power of the model is calculated to shrink to 11.27%, from 16.22%, if applied to the sample population.

Appendix 3.31: Factors correlated with baseline Motivation

This table shows the baseline factors significantly correlated with baseline motivation (Pearson's R, $p<0.05$).

	Motivation
Motivation	1
Inhaler Technique Beliefs	0.28
Preventer necessity beliefs	0.20
Preventer concerns beliefs	-0.02
Preventer Adherence	0.31
Inhaler Technique	0.26
Age	0.31
Multiple medications	0.25
Asthma duration	0.17

THE UNIVERSITY OF SYDNEY

Faculty of Pharmacy

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Letter of Invitation

Dear___________________________

Mid last year you participated in the Inhaler Technique Maintenance Study at your local pharmacy. You would have demonstrated the use of your inhaler device and also filled out some questionnaires.

We would like to thank you for your contribution to our research and also invite you to take part in a telephone interview with the researcher (Ludmila Ovchinikova) on your views about your asthma and asthma medication. Your personal opinions on the subject are very important to us.

If you wish to take part, the researcher will conduct a telephone interview with you, at a time convenient for you. You may freely voice any opinions you have about your asthma and asthma medications. The interview will be audio-taped and will take between 15-30 minutes, depending on how much you wish to say.

Your participation is voluntary and anything you disclose will be kept strictly confidential. Further study information will be provided upon request or if you decide to take part.

The researcher will be contacting you via telephone in one week's time regarding your decision.

If you are keen to take part please feel free to contact us so we can schedule an interview time. Also please do not hesitate to contact us if you have any further questions.

Yours faithfully,

Ludmila Ovchinikova and

Dr Sinthia Bosnic-Anticevich

11 March 2011

Contact Information:

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Appendix 4.02: Interview guide, version 8/final.

Patient:

Date:

Time:

Interview Guide

- Thank you

- Interview about: experience with asthma and inhaler medication

- Feel free to express your opinions

- Some questions may seem repetitive – make sure I get exact meaning of what you're saying and not misinterpreting anything.

- Interview will be tape recorded

- Everything you say to me will be kept confidential

- Feel free to ask questions at any time during the interview

- Before we start – are you comfortable? We can pause at any time during the interview if you need, just let me know.

Asthma

1. Could you tell me about your experience with asthma?

Identity: how has your asthma developed or changed over time? Has your asthma always been like this?

Cause: What's caused your asthma?

Consequences: What is life like with asthma?

Duration: Have you always had asthma?

Cure: How can you get cured of asthma?

*** How severe would you rate your asthma? Always like this?**
*** Any particularly bad/scary experiences with asthma?**

Asthma Control

1. What does it mean to have well controlled asthma? (belief)

2. How would you describe your level of asthma control? /
How well under control is your asthma? Always?
Why? signs?

3. How *confident* do you feel that your asthma will always be well controlled?
Why? (self-efficacy)

4. How *important* is it to you for your asthma to be maintained at a well-controlled

level? (value)
- Why?
*(**Asthma control is** about what your asthma is like on a day to day basis; in terms of, for instance - how bad your symptoms were when you woke in the morning, how short of breath you felt recently, how much you've wheezed recently, how much Ventolin you've used recently, if you've been woken up by asthma at night time and if you've found it more difficult to do your usual activities e.g. you may have missed work.*
So basically it's how smoothly or not smoothly your day to day life is running because of your asthma.
So does this make sense to you?)

Self-management/ treatment strategies

1. What sort of things do you do to get your asthma better?
Why do you do these things? (motivation & autonomy for s/management)

2. How do you know that what you're doing is working? (Feedback)

3. How capable do you feel about always being able to do the things you need to to manage your asthma? (self efficacy)

4. Are there things that make it hard to manage your asthma they way you would like to?

Medications

- Clarify asthma medicines

1. Could you tell me about the medications that you are taking for your asthma…

- what does it do for your asthma?

- How is it different to Reliever

- How do you know it's working? (Feedback)

2. Is there anything at all that *concerns* you about using your _______(prv)?

- What about in the past?

- *Experienced anything* (else) that *concerns* you? e.g. SEs

3. How *necessary* is it for you to have the ___________(prv) in your life? Is this true for all of the time?

4. Many people find a way to take their _________ (prv) that suits them, different to what was prescribed…
– *How are you taking you're taking* your____(prv)? Why?

5. How do you feel about your asthma treatment? Keeping on top of it?

**** When it comes to your asthma medication, in your opinion, *what are the most important things that you need to be doing when you are taking them?*****

- What about the way that you use your inhaler? (autonomy – values technique, sees the purpose?)

‘The way you use your inhaler’

1. How do you find it to physically use your inhaler devices?

2. Do you know why your (preventer inhaler) come with those nitty gritty instructions for using them?

3. Do you think the way that you use your inhaler (e.g. if you miss a step here and there) makes a difference your overall asthma?
How? (Importance or lack of)

4. Do you think it’s worth the effort to remember all the steps? (Importance or lack of)

5. So how willingly are you to follow the exact steps every single time you use your inhaler? Why? (direct motivation for technique)

6. How *confident or capable* do you feel about sticking to *all* of the steps every time you use your (prv)?
What makes you say that?

Maintaining correct technique

Relate to patient’s own scores:

1. I noticed on our records that a lot of people came back at visit 2, after being shown by the pharmacist the correct technique, still with a few errors.

- Why do you think this is the case?

- What can we do to eliminate recurrent errors?

- What sort of things would help you stick to correct inhaler technique?

2. I noticed that like the a lot of people you missed out on a couple of steps with your inhaler technique when you came back the 2nd time, can you remember why this happened?

HCPs

1. Tell me, which health care professionals have you seen in the past or do you still see for your asthma?

- How *often* would you see them? Who do you see most regularly?

2. How *helpful or supportive* do you actually find them?

- What about with inhaler use; how have they helped you here?
- Was this as a result of being in the study or did it happen at other times?

3. (Besides what you have already mentioned) What (other) *benefits* do you think you get when you visit your (health care professional)?

- patient confidence, motivation

Responsibility:

1. Who do you think is responsible for making sure your asthma is well managed?/ Technique stays correct

---

*** Written information for you to keep**
*** Consent form to sign and return in reply paid envelope included**
→ Confirm address

Portia Richmond

From:	Sinthia Bosnic-Anticevich
Sent:	Tuesday, 12 October 2010 9:28 AM
To:	Portia Richmond
Cc:	Lorraine Smith; Ludmila Ovchivnikova
Subject:	Re: HREC No. 12226 Improving inhaler technique maintenance - developing novel ways to optimise inhaler instruction for asthma patients
Attachments:	Participant Letter_Phase_II_V2.docx

Dear Portia,

Please find letter as requested attached, for your records.

Kind regards

Sinthia

APPROVED
13/10/10

DR SINTHIA BOSNIC-ANTICEVICH | Senior Lecturer
Faculty of Pharmacy

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CRICOS 00026A

On 30/09/10 3:49 PM, "Portia Richmond" <portia.richmond@sydney.edu.au> wrote:

Dear Dr Bosnic-Anticevich

Approval of your Request for Modification dated 20 September 2010 was deferred by the Human Research Ethics Committee Executive, subject to provision of the following:

- Please provide a letter to be sent to participants to explain the reasons for the new request.

Please email the letter as soon as possible to enable approval.

Regards
PORTIA RICHMOND | Ethics Administration Officer
Office of Ethics Administration
THE UNIVERSITY OF SYDNEY
Jane Foss Russell Building G02 | The University of Sydney | NSW | 2006
T +61 2 8627 8171 | F +61 2 8627 8177
E portia.richmond@sydney.edu.au <mailto:portia.richmond@sydney.edu.au> | W http://www.usyd.edu.au/ethics/ <http://www.usyd.edu.au/ethics/>
CRICOS 00026A

Appendix: 4.04: Qualitative study themes and how Maintainers and Non-maintainers responded.

Qualitative study themes; how Maintainers and Non-maintainers responded.

- *Themes identified in the qualitative study (relating to patient attitudes/beliefs, feelings and experiences regarding inhaler technique and device use; asthma, health and quality of life; asthma self-management; and social and therapeutic relationships) that may influence patient motivation to maintain correct inhaler technique.*
- *Listed under each theme are those patients (identified by their interview number and initials) who reported that particular theme.*
- *Patients who were Non-maintainers (those with less motivation to maintain correct technique) are underlined. Maintainers (patients with more motivation to maintain correct technique) are not underlined.*

Themes related to inhaler technique and device use	
Perceived importance of correct technique:	〉 **High importance:** 10:DD, 1:PS, 11:SM, 12:KK, 4:DR, 3:RL, 6:LN, 9:BB, 8:RH, 2:JH, 5:LJ, 18:FE, 19:PF, 20:PL, 14:MC, 15:LF 〉 **Importance dependent on symptom presence – greater importance when symptoms present:** 13:CH, 17:JC 〉 **Low importance:** 7:GW 〉 **Technique maintenance perceived as a matter of habit:** 12:KK, 3:RL, 9:BB, 8:RH, 4:DR, 17:JC, 18:FE, 15:LF, 14:MC, 20:PL, 13:CH 〉 **Perceived improved technique associated with improved asthma symptoms:** 4:DD, 1:PS, 11:SM, 12:KK, 3:RL, 4:DR, 13:CH, 17:JC, 19:PF
Perceived ease/difficulty with inhaler device use:	〉 **Device/s perceived to be easy to use:** 10:DD, 1:PS, 11:SM, 3:RL, 4:DR, 6:LN, 8:RH, 9:BB, 2:JH,7:GW, 13:CH, 15:LF, 20:PL 〉 **Use of multiple types of devices; not perceived to increase difficulty to practise correct technique; DPIs and pMDIs perceived equally easy to use:** 10:DD, 1:PS, 12:KK, 3:RL, 4:DR, 8:RH, 9:BB, 6:LN 〉 **pMDI perceived to be more difficult to use than DPI (and using both devices):** 17:JC 〉 **pMDI perceived to be difficult to use (using only pMDIs):** 14:MC, 19:PF
Perceived confidence with maintaining correct technique:	〉 **High confidence:** 1:PS, 3:RL, 4:DR, 6:LN, 8:RH, 9:BB, 10:DD, 11:SM, 12:KK, 2:JH, 7:GW, 5:LJ, 13:CH, 15:LF, 18:FE, 20:PL, 17:JC
Perceived responsibility for correct technique maintenance:	〉 **Predominantly personal or shared (with HCP) responsibility:** 11:SM, 3:RL, 12:KK, 6:LN, 9:BB, 8:RH, 2:JH, 15:LF 〉 **Minimal personal responsibility; responsibility attributed to external agents (e.g. HCPs):** 7:GW, 5:LJ, 17:JC, 20:PL

Appendix: 4.04: Qualitative study themes and how Maintainers and Non-maintainers responded.

Themes related to asthma, health and quality of life	
Concept of asthma and acceptance of diagnosis	〉 **Asthma related to symptom experience:** 10:DD, 1:PS, 11:SM, 12:KK, 3:RL, 4:DR, 6:LN, 8:RH, 9:BB, 2:JH, 5:LJ, 7:GW, 13:CH, 14:MC, 15:LF, 16:VT, 19:PF, 20:PL 〉 **Diagnosis of asthma was denied in the past or currently:** 11:SM, 1:PS, 18:FE, 19:PF
Duration of asthma	〉 **Chronic:** 12:KK, 5:LJ, 14:MC 〉 **Episodic:** 10:DD, 11:SM, 9:BB, 4:DR, 2:JH, 7:GW, 16:VT, 18:FE, 20:PL
Cause of asthma	〉 **Genetic:** 4:DR, 5:LJ 〉 **Cigarette smoking**: 10:DD, 1:PS 〉 **Stress and trauma**: 10:DD 〉 **Allergens**: 2:JH 〉 **Medication (B-blocker) side effect**: 11:SM 〉 **Unknown**: 9:BB, 3:RL, 6:LN
Importance of asthma control, health and quality of life.	〉 **Good asthma control believed important for health and quality of life:** 10:DD, 1:PS, 11:SM, 12:KK,3:RL, 4:DR, 8:RH, 6:LN, 9:BB, 2:JH, 7:GW, 5:LJ, 18:FE, 20:PL, 13:CH, 14:MC, 15:LF, 16:VT, 17:JC, 19:PF 〉 **Health highly valued:** 1:PS, 12:KK, 10:DD, 11:SM, 6:LN, 8:RH, 2:JH
Perceived threat of asthma and	〉 **High threat to quality of life and/or mortality; turning point experiences:** 10:DD, 9:BB, 3:RL, 8:RH, 12:KK, 4:DR, 6:LN, 1:PS, 2:JH, 19:PF, 20:PL, 5:LJ, 13:CH 〉 **Minimal threat to quality of life and health:** 7:GW, 15:LF, 16:VT, 14:MC, 20:PL
Memorable experiences of past asthma exacerbations	〉 **Severe asthma exacerbations experienced in past:** 4:DR, 1:PS,8:RH, 9:BB, 3:RL, 10:DD, 6:LN, 11:SM, 12:KK, 5:LJ, 2:JH, 14:MC, 15:LF, 17:JC, 18:FE, 19:PF, 20:PL 〉 **Severe asthma exacerbations never experienced:** 7:GW, 16:VT 〉 **Severe asthma exacerbations experienced for the first time at time of interview:** 13:CH
Witnessing	〉 **Witnessing severe asthma symptoms in others reinforces high perceived threat:**

Appendix: 4.04: Qualitative study themes and how Maintainers and Non-maintainers responded.

asthma in others	6:LN, 5:LJ 〉 **Witnessing severe asthma symptoms in others reinforces low perceived threat:** 10:DD, 11:SM, 7:GW, 16:VT
Themes related to asthma self-management	
Attitude and approach to self-management	〉 **Preventative attitude/approaches (via medication or lifestyle strategies):** 4:DR, 3:RL, 9:BB, 1:PS, 12:KK, 6:LN, 8:RH, 2:JH, 5:LJ, 14;MC, 15:LF, 17:JC, 19:PF 〉 **Reactive, symptom based use of preventer:** 11:SM, 10:DD, 7:GW, 20:PL, 13:CH, 16:VT, 18:FE
Attitude toward medication in general	〉 **Beneficial to take whatever medication is necessary to stay well:** 12:KK, 11:SM, 5:LJ 〉 **Medication should be avoided:** 1:PS, 11:SM, 10:DD, 2:JH, 19:PF, 20:PL, 18:FE
Attitude toward preventer medication	〉 **High necessity – asthma control achieved via medication:** 11:SM, 12:KK, 3:RL, 4:DR, 6:LN, 8:RH, 1:PS, 9:BB, 5:LJ, 14:MC, 15:LF, 17:JC, 19:PF, 20:PL 〉 **Low necessity – asthma control primarily achieved via lifestyle means (fitness, allergy avoidance, quitting smoking):** 10:DD, 2:JH, 13:CH, 18:FE 〉 **Benefits perceived (asthma symptoms improved):** 11:SM, 12:KK, 3:RL, 4:DR, 6:LN, 8:RH, 9:BB, 1:PS, 17:JC, 15:LF, 19:PF, 20:PL 〉 **No or inconsistent benefits perceived:** 2:JH, 7:GW, 5:LJ, 13:CH, 18:FE 〉 **Immediate uncomfortable physical sensation felt after DPI use:** 2:JH, 15:LF 〉 **Side effects experienced with ICS (e.g. oral thrush, sore throat):** 10:DD, 1:PS, 5:LJ, 15:LF, 18:FE 〉 **No side effects with ICS:** 11:SM, 12:KK, 3:RL, 4:DR, 6:LN, 8:RH, 9:BB, 2:JH, 7:GW, 13:CH, 14:MC, 19:PF, 20:PL 〉 **No concerns:** 11:SM, 12:KK, 3:RL, 4:DR, 8:RH, 7:GW, 13:CH 〉 **Current and/or past concerns:** 6:LN, 10:DD, 1:PS, 2:JH, 5:LJ, 17:JC, 18:FE, 14:MC
Influence of comorbidities on asthma self-management	〉 **Co-morbid respiratory conditions boosted motivation to maintain lung health:** 1:PS, 4:DR, 6:LN, 11:SM, 3:RL, 8:RH, 9:BB, 12:KK, 14:MC, 19:PF 〉 **Co-morbidities (e.g. hypertension and diabetes) were prioritised over asthma:** 4:DR, 10:DD, 11:SM,

Appendix: 4.04: Qualitative study themes and how Maintainers and Non-maintainers responded.

	<u>7:GW, 16:VT, 18:FE, 20:PL</u> 〉 **Co-morbidities (e.g. HF, ABPA, depression) increased difficulty to self-manage asthma:** <u>13:CH, 5:LJ</u>
Social and personal barriers to good self-management	〉 **Medication costs perceived to be too high (due to non-pbs listing, poly-pharmacy):** 1:PS, <u>5:LJ</u> 〉 **Trauma (loss of job, divorce, death of loved ones):** 10:DD, <u>5:LJ, 13:CH, 16:VT, 20:PL</u>
Perceived confidence with self-management	〉 **High (based on effectiveness of past self-management, availability of effective medication treatment and health care professional support):** 10:DD, 1:PS, 6:LN, 11:SM, 4:DR, 9:BB, 12:KK, 3:RL, <u>2:JH, 20:PL, 14:MC, 15:LF, 18:FE</u> 〉 **Low or ambivalent :** <u>7:GW, 5:LJ, 13:CH, 19:PF</u>
Perceived responsibility for self-management	〉 **Predominantly personal or shared (with HCP) responsibility:** 1:PS, 12:KK, 3:RL, 4:DR, 6:LN, 9:BB, 8:RH, <u>2:JH, 14:MC, 15:LF, 16:VT, 17:JC, 18:FE, 19:PF, 20:PL</u> 〉 **Minimal personal responsibility; responsibility attributed to external agents (e.g. HCPs):** <u>5:LJ, 13:CH</u>
	Themes related to social and therapeutic relationships
Perceived satisfaction, trust and rapport with HCPs	〉 **High (with all HCPs):** 10:DD, 1:PS, 11:SM, 12:KK, 3:RL, 4:DR, 6:LN, 8:RH, <u>2:JH, 14:MC, 16:VT, 18:FE, 19:PF</u> 〉 **Low (with one or more HCP):** <u>13:CH, 20:PL, 5:LJ</u> 〉 **Mixed (varied between HCPs):** <u>15:LF, 17:JC</u> 〉 **Indifferent:** <u>7:GW</u>
Perceived support from significant others	〉 **Family identified as a source of support in asthma management:** 12:KK, 4:DR, 6:LN <u>14:MC, 17:JC, 18:FE</u> 〉 **Desire to reduce burden of ill health on family identified as a source of motivation to maintain well controlled asthma:** 12:KK, 4:DR, 6:LN, <u>13:CH</u> 〉 **Friends and colleagues identified as a source of support in asthma management:** 10:DD, 12:KK, <u>14:MC</u> 〉 **Lack of perceived support from family and friends in asthma management:** <u>5:LJ, 13:CH, 19:PF</u>

Appendix 4.05: Individual patient responses on core study themes and the interrelatedness of core study themes.

The interconnected themes characterising patients with higher (initials) and lower (<u>initials, underlined</u>) motivation for inhaler technique maintenance.