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Inhaler devices: Do patients have a preference and does it make a difference?

A thesis submitted for the degree of Master of Philosophy

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Abstract

The aim of this study was to assess participants perceptions and preferences for inhaler devices; and the relationship of inhaler technique to the decision making process . A mixed-methods approach including a semi-structured interview, Patient Satisfaction and Preference Questionnaire (PASAPQ) and inhalation technique assessment were employed. A total of 25 participants with at least one inhaler were recruited. The interviews analyzed qualitatively. In addition, each participant received a score for PASAPQ in regards to satisfaction with performance, satisfaction with convenience and overall satisfaction. Participants' inhalation technique was assessed. Two matrices were generated to identify any patterns of association between participants perception from qualitative interviews, with participants satisfaction and preference (PASAPQ) with regards to correct and incorrect use of inhalers.

Triangulation of data revealed that there did not appear to be a relationship between patient satisfaction with inhaler device, preference, inhalation technique and level of choice in decision-making. There are other factors influencing patient opinions of inhaler devices rather than physical features of inhalers including the level of asthma control, effectiveness of medication in relieving asthma symptoms and length of time of use of inhalers. Participants did not differentiate the device from medication and this affected not only their perception about inhaler devices but also their perception about inhalation technique. This research further highlights the lack of understanding of the relevant role of inhaler devices in asthma management.

Table of Contents

Introduction 1

1.1. Prevalence of Asthma 1

1.2. Asthma management 1

1.3.2. Preventer medications 5

1.4. Medication delivery in asthma 8

1.5. Poor inhalation technique 11

1.6. Possible reasons for poor technique 12

1.6.1. The role of the device 12

1.6.2. The role of health care professionals 13

1.6.3. The role of the patient 13

1.7. Patients and treatment decision making 14

1.8. Inhalers and patient satisfaction 16

1.9. Inhaler devices selection 16

1.10. Patient preference 16

1.11. Significance 21

1.12. Aim and Objectives 21

Material and Methods 22

2.1. Overall design 22

2.2. Participant recruitment 22

2.3. Sample Size 23

2.4. Data collection 23

2.4.1. Qualitative data 23

2.4.2. Patient Satisfaction and Preference Questionnaire (PASAPQ) 25

2.4.3. Inhalation Technique assessment 26

2.5. Analysis of data 29

`

2.5.1. Qualitative analysis 29
2.5.2. PASAPQ analysis 29
2.5.3. Inhalation technique assessment 30
2.5.4. Convergence/Triangulation of data 30
Results 32
3.1. Demographic information 32
3.2. Qualitative interviews 33
3.3. Inhalation technique 45
3.4. PASAPQ 46
3.5. Triangulation 47
Discussion 55
References 62
Appendices 62

`

List of Tables

Table 1: Short acting beta-2 agonists 4
Table 2: Recommended daily dosage of inhaled glucocorticoids 6
Table 3: Recommended daily dosage of long acting beta-2 agonists 7
Table 4: Inhalation technique steps..... 9
Table 5: Summary of studies about patient preference and inhaler devices 18
Table 6 : Semi-structured interview guide..... 24
Table 7: Relevant Patient Satisfaction and Preference Questionnaire domains 26
Table 8: Inhaler technique assessment checklist for Accuhaler® 27
Table 9: Inhaler technique assessment checklist for Turbuhaler® 27
Table 10: Inhaler technique assessment checklist for Pressurised Metered Dose Inhaler 28
Table 11: Inhaler technique assessment checklist for Pressurised Metered Dose Inhaler with Spacer 28
Table 12: Inhaler technique assessment checklist for Autohaler® 29
Table 13: Subjects demographic information (Total =25) 32
Table 14: Proportion of participants demonstrating correct technique 45
Table 15: Patient Satisfaction and Preference Questionnaire (PASAPQ) score for satisfaction with performance, convenience and overall satisfaction for each device 46
Table 16: Mean PASAPQ scores for performance, convenience and overall satisfaction in regards to correct use of inhaler and incorrect use of inhaler 47
Table 17: Matrix A of triangulation for participant with correct technique relating to score from PASAPQ and qualitative feedback..... 49
Table 18: Matrix B of triangulation for participants with incorrect technique relating to scores from PASAPQ and qualitative feedback..... 50

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Introduction

1.1. Prevalence of Asthma

Asthma as a chronic inflammatory disease has a major impact on the lives of people with the condition. It affects different age groups and associates with poor quality of life (1) and life expectancy. Three hundred million people worldwide have been affected by asthma with the average range of 1-18% in different countries. It has been accounted for 250000 annual deaths in all over the world (2). The number of people affected by asthma has increased in recent decades due to the impact of western lifestyle, industrialization and urbanization (3), air pollution and higher usage of antibiotics (4).

In Australia with one of the highest prevalence of asthma, 2.2 million people (14-16% of children and 10-12% of adults) have been affected. In 2004-2005, $606 million of the Federal budget was spent on asthma; with the higher asthma-related costs being associated with the expenditure on prescription pharmaceuticals (1).

1.2. Asthma management

When it comes to the management of asthma, although medicines are considered the cornerstone, effective asthma control often consists of a multifaceted approach (3). Asthma management consists of various strategies to achieve and maintain control of the disease (2). A number of management guidelines have been developed, which identify and describe the key elements to optimal asthma management (5). These include guidelines for the diagnosis of asthma, the development of asthma management plans, including the need to optimise lung

function, decrease symptoms, avoid exposure to trigger factors, appropriate medication, written self-management plans and regular asthma review (3).

It is worth noting that Asthma Management Guidelines stress the importance of not only the appropriate and correct use of medicines but also the need for patients to be able to effectively self-manage their medication through the use of Asthma Action Plans. Asthma Action Plans are personalized written asthma self-management plans, which are written by the medical practitioner, and outline the way in which patients should modify their medication regimen, based on their asthma symptoms (1). The importance in Asthma Action Plans lies in the contribution of patients in self management of asthma to increase the adherence and optimise treatment cost. This is associated with patient better understanding to deal with asthma exacerbation by adjusting doses of controller and reliever medications (6).

One thing, however, that guidelines do not address are the hidden barriers to asthma control. In particular, those associated with the type of inhaler device used, this being shown to be a vital consideration in medication selection (6). Patients with various preferences and perceptions will master better inhalation techniques for a certain device rather than others (7). Regardless of the actual drug, a device plays a significant role in treatment result in long term. Selecting an inhaler for a patient should be tailored based on their needs of medication as well as their ability to use the device.

Unfortunately, despite the availability of management guidelines, asthma still remains a poorly controlled condition. This has been attributed to sub-optimal management of asthma, including the difficulty of implementing guidelines into practice (5) the lack of time for health care professionals to employ them (8) as

well as patients' attitude and medication use (adherence and inhalation technique) (5).Patients negative attitude towards asthma medication may impact on patient willingness to use medication appropriately (7).

1.3. Medications

Medications play a fundamental role in asthma management. The overall aim of medication therapy in asthma is to optimise asthma control with the lowest effective doses of medication. While there is no cure for asthma, this is the ultimate aim of medication management. Although a variety of medications in a range of dosing devices are available to either relieve symptoms or control the disease; it remains that inhalation therapy is the preferred route of administration. For the optimal management of asthma, medication administration through inhalation is preferred due to it enabling greater effectiveness and fewer side effects than delivery of medication via oral and parental route (2, 9, 10).

When it comes to the classification of asthma medications, they are categorized into three main categories of relievers, preventers and symptom controllers. Relievers, including short acting beta agonists and Ipratropium bromide are recommended on an as needed basis to relieve the symptoms. Preventers mainly contain inhaled corticosteroids and are recommended on a regular basis to prevent exacerbation and control the disease. Occasionally oral corticosteroids are recommended to treat severe asthma exacerbations. Symptom controllers are long acting beta agonists being recommended to use as an adjunct therapy with corticosteroids to control asthma symptoms (3, 4). A stepwise therapy is recommended for controlling asthma symptoms with dose adjustment of therapies based on asthma severity and exacerbation (4).

1.3.1. Reliever medication

Fast acting beta-2 agonists are used to relieve acute asthma bronchospasm as their fast onset of action make them treatment of choice in acute exacerbation of asthma as well as in the prevention of exercise induced asthma . These agents cause relaxation of the bronchial smooth muscle (6). They are administered via inhalation, however can result in side effects consistent with beta-2 adrenoreceptor stimulation such as restlessness and tremor, even in recommended doses (3, 6).

Table 1 is the summary of different short acting beta-2 agonists available in the Australian market through various devices and recommended dosage for adult and children.

Despite their significant role in therapy, over reliance on rapid acting beta agonists leads to ignorance of asthma exacerbation and necessity of preventive measures (11). As a result, recommended usage is as needed basis on the lowest possible dosage. Frequency of administration is an indicator of asthma exacerbation and necessitates preventive therapy initiation (3, 12).

Table 1: Short acting beta-2 agonists (6)

Medication	*Device*	*Brand*	*Adult and children dose*
Salbutamol	pMDI	Ventolin®	100-200 mcg as required every 3-6 hours
Salbutamol	Autohaler®	Airomir®	100-200 mcg as required every 3-6 hours
Terbutaline	Turbuhaler®	Bricanyl®	500 mcg as required every 3-6 hours

1.3.2. Preventer medications

Of particular interest in the medication management of asthma, is the use of the preventer class of asthma medications. They are of particular importance in the management of asthma and successful asthma management is highly reliant on these medications. There are several drug classes within the preventer domain.

1.3.2.1 Inhaled Glucocorticoids

Glucocorticoids in general and inhaled glucocorticoids in particular, are the mainstay in achieving asthma control and preventing breakthrough exacerbations (13, 14). Inhaled glucocorticoids inhibit inflammation in the airways (4, 15) and with regular use have been shown to reduce asthma mortality by improving lung function (16), reducing the frequency and severity of asthma exacerbations (3, 17) and preventing irreversible airway limitation in susceptible patients (5). Variety of glucocorticoids are available through different delivery devices (3, 6, 15, 16). Table 2 summarizes the range of inhaled glucocorticoids currently available on the Australian market, the devices in which they are available and recommended dose range for adults and children.

The main side effects of inhaled glucocorticoids are local adverse effects, including oropharyngeal candidiasis and hoarse voice, which can be prevented through the correct use of the inhalers and by mouth rinsing after inhalation. At higher doses, (>500 mcg/day for Beclometasone dipripionate and > 800 mcg/day for Budesonide) long term treatment can result in systemic absorption (6) and an increased risk of osteoporosis, adrenal suppression, cataract, glaucoma and bruising highlighting the need for appropriate medication use.

Table 2: Recommended daily dosage of inhaled glucocorticoids (6)

Medication	*Device*	*Brand*	*Adult dose*	*Children ≥ 5 years old dose*
Beclomethasone dipropionate–HFA	pMDI Autohaler®	Qvar®	50-200 mcg BD	50 mcg BD
Budesonide	Turbuhaler®	Pulmicort®	400-2400 mcg/day	200-800 mcg/day
Fluticasone propionate	pMDI Accuhaler®	Flixotide®	100-500 mcg BD	50-250 mcg BD
Ciclesonide	pMDI	Alvesco®	80-320 mcg/day	N/A

1.3.2.2. Leukotriene receptor antagonists

Leukotriene antagonists are anti-inflammatory agents, available in oral form only. Currently, there is only one available on the Australian market (montelukast, Singulair®). Generally less effective than small doses of inhaled corticosteroids in reduction of bronchial inflammation and improvement of lung function, their role in treatment is limited to treatment of aspirin-sensitive asthma and prevention of exercise induced asthma. They are recommended as add on therapy to inhaled corticosteroids (ICS) when long acting beta-2 agonists (LABA) are not effective or tolerated (13, 16).

1.3.2.3. Theophylline

Theophylline, available in oral form only, is an anti-inflammatory agent and bronchial muscle relaxant is employed in controlling asthma symptoms. Due to a narrow therapeutic index and side effects, it is no longer recommended as a first line therapy in asthma patients (3, 5). It is recommended as add on therapy when ICS are not effective alone after treatment failure of LABA and leukotriene antagonists (3, 16).

1.3.3. Symptom relievers

1.3.3.1 Long acting beta-2 agonists

Due to the concerns associated with the use of high dose corticosteroids, inhaled long acting beta-2 agonists (LABA), used in combination with ICS have been shown to be effective when used with corticosteroids in reducing nocturnal symptoms, improving lung function and reduction of reliever measures thereby avoiding the need to increased ICS doses (12, 17). Table 3 summaries the range of ICS + LABA products currently available on the Australian market, the devices in which they are available and recommended dose range for adults and children. It should be noted that these products include both an ICS and a LABA, hence are known as combination products. The advantage of the combination products over drug administrator through one inhaler rather than two is increased adherence to treatment as Haughney et al, (2007) has shown that patients prefer to use fewer inhalers and lowest dose of inhaled corticosteroid (13). Therefore, combination inhalers can increase adherence to treatment while allowing for the lowest effective daily dosage of corticosteroids to be administered (12).

Table 3: Recommended daily dosage of long acting beta-2 agonists (6)

Medication	*Device*	*Brand*	*Adult dose*	*Children > 4 years old*
Budesonide and Formoterol	Turbuhaler®	Symbicort®	1-2 inhalation BD and prn as reliever	N/A
Fluticasone and Salmetrol	pMDI	Seretide®	Two inhalation BD	Two inhalation BD of 50 mcg
Fluticasone and Salmetrol	Accuhaler®	Seretide®	One inhalation BD	One inhalation BD of 100 mcg

1.4. Medication delivery in asthma

While several different types of medications are commonly used in the medication management of asthma, a vast majority of them are available through inhalation devices. The concept of direct medication delivery to the lungs allows rapid onset of action (18) and high local concentration (19) with smaller dose and better efficacy with relatively lower adverse effect, which maximises patient adherence to therapy (19, 20). The significant role of an efficient inhaler in treatment process (20) has led to introduction of several inhaler devices to the market with the most commonly used in the treatment of asthma are the pressurised metered dose inhalers (pMDIs) and the dry powder inhalers (DPIs) (21). This significantly changes the management of asthma as patients are required to engage with their medication in a different way. Knowledge and skills were required to not only know which medication to use, but also how to physically administer medication via an inhaler device. That is, several steps are required to be performed correctly to ensure of optimum drug delivery. Various operation of each inhaler necessitates different inhalation maneuver to maximise the lung deposition of medications (22). In general, preparation of the inhaler, exhalation and inhalation maneuver and actuation and post actuation steps are required for all inhalers (23). Table 4 summarises the inhalation technique steps for each device type.

Table 4: Inhalation technique steps

Pressurised Metered Dose Inhaler
1. Remove mouthpiece cover and shake well. 2. Exhale all air out of lungs. 3. Keep head upright, lift chin slightly. 4. Mouthpiece between teeth and seal with lips. 5. Inhale slowly and press canister early. 6. Continue slow and deep inhalation. 7. Hold breath for as long as is comfortable (aim for 10 seconds). 8. Breathe out normally, away from the inhaler. 9. Replace cap.
Pressurised Metered Dose Inhaler+ Spacer
<u>Single Breath Technique Method</u> 1. Assemble the spacer. 2. Remove mouthpiece cover of inhaler, shake and insert into spacer. 3. Exhale all air out of lungs. 4. Keep head upright, lift chin slightly. 5. Spacer mouthpiece between teeth and seal with lips. 6. Press canister and inhale slowly and deeply from spacer. 7. Hold breath for as long as is comfortable (aim for 10 seconds). 8. Breathe out normally.
Pressurised Metered Dose Inhaler+ Spacer
<u>Multiple Breath Technique Method</u> 1. Assemble the spacer. 2. Remove mouthpiece cover of inhaler, shake and insert into spacer. 3. Exhale all air out of lungs. 4. Keep head upright, lift chin slightly. 5. Spacer mouthpiece between teeth and seal with lips. 6. Breathe in and out of spacer, then press canister. 7. Continue to breathe normally through spacer for a few breaths.

Autohaler®
1. Remove inhaler cap and shake well. 2. Raise lever up to prepare device. 3. Exhale all air out of lungs. 4. Keep head upright, lift chin slightly. 5. Place mouthpiece between teeth and seal with lips. 6. Inhale slowly and deeply. 7. Hold breath for as long as comfortable (aim for 10 seconds). 8. Breathe out normally away from inhaler. 9. Push lever down and replace cap.
Turbuhaler®
1. Unscrew and remove the cap from the inhaler. 2. Keep inhaler upright. 3. Rotate grip one way, then back, to load dose. 4. Exhale all air out of lungs. 5. Exhale away from the mouthpiece. 6. Keep head upright, lift chin slightly. 7. Place mouthpiece between teeth and seal with lips. 8. Inhale forcefully and deeply. 9. Pause, then breathe out normally. 10. Exhale away from the inhaler. 11. Replace cap.
Accuhaler®
1. Open Inhaler. 2. Push lever back completely to load dose. 3. Exhale all air out of lungs. 4. Exhale away from the mouthpiece. 5. Hold inhaler horizontally. 6. Place mouthpiece between teeth and seal with lips. 7. Inhale slowly and deeply. 8. Hold breath for as long as is comfortable (aim for 10 seconds). 9. Exhale away from the inhaler. 10. Close Inhaler.

1.5. Poor inhalation technique

These inhaler devices are used to deliver a range of medications in the treatment of asthma and in terms of their use, all have their advantages and disadvantages however, the one most common feature of inhaler device is the extent to which patients use them incorrectly. Up to 94% (24-28) of patients do not use their inhalers correctly and even after education, require further follow-up education to ensure that they maintain correct technique over time (29-31).

Pressurised Metered Dose Inhalers are the most prescribed devices (32) used for the delivery of reliever medication and while they have the advantages of being cost-effective (33) and portable, their correct use require the co-ordination of a breathing maneuver and activation of the device, which is problematic for most patients (32, 34-36). UP to 96% (21, 33, 37) of patients do not use their pMDIs correctly where co-ordination of actuation and inhalation is the major error made by patients. They generally prime the device too early or too late which effects drug delivery to the lungs (38). In addition, despite the common belief about necessity of rapid and forceful inhalation with pMDIs, slow and deep inhalation is required to minimize the oropharyngeal delivery of medication (29) and increase the peripheral deposition (38). Moreover, the majority of patients fail to hold their breath after inhaling a dose which is necessary for best drug delivery (38). In summary, due to different natural breathing pattern of patients, pMDIs are recommended devices for patient with slower pattern of breathing(29).

On the other hand, the main advantage of DPIs is that they are breath actuated, thereby do not require co-ordination and match the patients with fast inhalation, while still remaining highly portable (33). In Australia, the most commonly used DPIs in the management of asthma are the Turbuhaler® and Accuhaler® .However, once again, despite the fact that co-ordination is not required, DPIs inhaler

technique continues to be problematic (7, 39) with up to 94% of patients failing to demonstrate correct inhaler technique (26).Technique maintenance is once again a problem with DPI use (30, 31) . The concern is that major errors are made with handling a device and obviously with DPIs patients play a significant role in preparing a dose and making it ready for inhalation(38). In addition, fast and deep inhalation is required to deliver the dose to lungs which is problematic in patient with insufficient inspiratory flow, children and elderly (29, 32, 33).

The implications of incorrect inhaler technique are significant with poorer asthma control, lung function, quality of life and perceived control of asthma being linked to poor inhaler technique (30). Therefore, the success of inhalation therapy is extremely dependent of correct use of inhalers for optimal drug delivery. Incorrect use of inhalers contributed to patients' belief that the medication is not useful for their symptoms and lead to non adherence (7, 22).

1.6. Possible reasons for poor technique

Undoubtedly correct technique is an integral part of asthma control. Despite availability of various inhalers, if handled incorrectly, there is no difference amongst different inhalers in effectiveness of treatment (40). There has been much research attempting to understand the reasons for poor technique and the ways in which inhaler technique can be improved and maintained over time. Research shows that some of the potential reasons for poor inhaler technique are linked to the device, the patient and the health care professional (37).

1.6.1. The role of the device

There are different classifications for devices based on generation of aerosol, particle size, formulation, whether they are single dose or multi dose inhalers. Various inhalers require mastering different skills to achieve the optimal effect of

medication (34) which may be a limitation for younger patients and elderly. Some devices are easier to use than others for some patients due to various technique steps. Therefore, device selection is important and healthcare professionals need to be aware of this when prescribing inhalers.

1.6.2. The role of health care professionals

Health care professionals also play an important role in patient achievement of correct technique although they presented difficulties in mastering technique due to lots of different devices in the market (22, 33, 34, 41). It has been suggested most critical errors occurs when patients are not provided with optimal training (42) or they use more than one type of inhaler (18). Verbal instructions along with physical demonstration and written instruction (22, 39) is deemed to be the most effective way for patient training, that is step by step demonstration of correct technique from health care professionals alongside verbal instruction to achieve optimal technique (36, 39). By following this process of education, almost all patients are able to develop the appropriate skills. However, initial training is not enough as following training, 39% of patients do not maintain correct technique (43). Therefore, the initial training should be followed by regular reviewing and re-education to ensure that correct technique is maintained over time (33, 36).

1.6.3. The role of the patient

Patients as the actual inhaler users play a significant role in mastering correct technique. Patient related factors are categorized as person's attitude and behaviour and physical features of inhalers.

1.6.3.1. Physical feature of inhalers

Physical features of inhalers have a major effect on achieved technique (26). There are several factors which may influence patient mastering correct technique such

as age (35), the natural pattern of breathing, incorrect handling of a device. For instance, insufficient inspiratory flow limited the administration of DPIs in elderly and children (29) or the patient's natural pattern of breathing does not meet the criteria for specific inhaler to be employed. Some patients inhale too fast or too slow as a result unable to use pMDI and DPIs respectively (29).

1.6.3.2. Patients' attitude and behavior

Patients' attitude towards medication, adherence and preference for inhalers is another feature suggested playing a crucial role in correct inhalation technique achievement (44). Patients' non adherence to treatment is highly influenced by their beliefs about medication. Although patient rarely differentiate between actual drug and inhaler device in terms of outcome, those with positive attitudes and preference toward their therapy show better adherence to treatment (45-47) and better technique (44, 45). To meet patient needs in achieving appropriate technique, physician's choice should be tailored based on patient preference and needs. In this way, shared treatment decision making is one of the recommended strategies.

1.7. Patients and treatment decision making

Shared Treatment Decision Making (STDM) is the process of finalizing the treatment where patient preference recognized and took into account by physician and both patient and physician achieve agreement on the ultimate result (48, 49). It is well established in the literature that patients' adherence to treatment regimen is highly influenced by their active participation in treatment decision-making (50-52). Taking into account patient's opinion in choosing the medication may lead to not only satisfaction with treatment but also better adherence to therapy and successful therapeutic outcome (53). Physicians play a

fundamental role in addressing patient preference and perception to build up a good relationship and achieve treatment goals (54).

Preference of involvement in the treatment decision making is influenced by age, level of education (55), severity of disease, characteristic of health professional (56), trust (57) and previous experience with disease where passive role is more preferred by older and less educated people (55, 56). Asthma as lifelong condition necessitates more involvement in decision-making to increase compliance with therapy.

While patient active participation in decision-making has been shown to result in positive outcomes, still a number of patients prefer to rely on physician decision where 43.7% of asthma patient presented preference for the passive role in decision- making due to lack of consultation time, lack of knowledge, severity of disease and physician unwillingness to accept patient opinion (56). Several studies explored treatment decision-making in asthma management presented various results with regards to the extent and type of participation patient prefer. Small and colleagues, (2010) investigated the effect of patient- physician partnership on level of asthma control and quality of life. The results revealed a positive link between patient-physician participation and it's effect on asthma management in long term, however emphasized the importance of patient education to be able to involve in decision-making (58). Adam et al, (2001) finding was inconsistent with the hypothesis of shared decision-making when patient preferred a passive role in the process, while retaining some degree of involvement (56). In addition, Gibson et al, (1995) found asthma patients would like to be informed about their condition, however prefer to rely on physician's decision-making to manage asthma exacerbation (59).

1.8. Inhalers and patient satisfaction

Patient satisfaction of their medications particularly in chronic diseases has been found to be very important in terms of the success of medication treatment. Increased patient satisfaction and positive perceptions of medication have been linked with increased adherence to medication and patient outcomes (60-63). That is, when patients are satisfied, they comply with treatment regimens which lead to optimal control of disease (53) and better clinical outcomes (64, 65).

1.9. Inhaler devices selection

Given the complexity associated with patient and the use of inhalers, the importance of marrying the right inhaler to the patient cannot be underestimated. Asthma guidelines have pinpointed variety of features to be taken into account when it comes to inhaler sections. First of all, the availability of therapeutics agent needs to be established. Then a series of additional physical and cognitive aspects need to be considered. Patient ability to use a device is one of the significant factors to be considered when choosing a device for a patient. Inhaler device should be matched to patient ability in employing a device as well as breathing pattern (29). For example, pMDIs are easier to use for patient with slow inhalation and DPIs match with fast inhalations. Portability and small size, metered dose counter and cost-effectiveness are another factors can be considered when choosing amongst different inhalers (18, 35). However patient preference is the most significant factor deemed to effect acceptance of the device and success of the treatment (18).

1.10. Patient preference

Therefore, taking into account patient preference will be associated with better technique, more adherence and success of treatment. Small et al, (2011) evaluated and measured the relation between preference for inhaler devices and

treatment outcome. The positive asthma control along with improved quality of life was proven after administration of preferred inhalers (66).

While patient preference has not been directly explored with regards to inhaler devices, but rather medication management, there have been several studies that have reported on patient preference for different inhaler devices used in clinical trials. These clinical trials have not focused on patient preference but do give us insight into some of the factors, which are important with regards to patient preferences. Knowledge gap in terms of patient attitude and perception of inhalers necessitates more studies to explore patient acceptance of the devices. Majority of studies simply employed questionnaire to explore patient preference while qualitative methods are most appropriate for such endeavors.

Table 5 summarises the results from these studies. Clearly, there are factors on a variety of different levels, which influence the patient's preference for one device over another. When it comes to patient preference and how it relates to satisfaction, there is no data linking the two. Further, there is no evidence to show how patient preference and patient satisfaction relate to inhaler technique. We can hypothesis that if patients have a preference and are able to choose their inhaler, they might be more likely to use it correctly and continue to do so.

Table 5: Summary of studies about patient preference and inhaler devices

Study Year	*Devices used*	*Factors influencing preference*			*Preferred device*
		Operational use	Convenience	Oral sensation	
2004 (53)	Turbuhaler® pMDI	• Ease of learning to use • Ease of holding and operating • Ease of knowing when to replace • Ease of cleaning • Comfort with mouthpiece • Experience coordination problems • Rating of accompanying instruction • Knowledge of how to use the device	• Size • Shape • Durability Weight	• Unpleasant taste • Irritation in the mouth • Feel of medication in the airway	Turbuhaler®
2003 (67)	Diskus® pMDI	• Ease of use • Easier to be taught • Easier to Know how many doses are left • Ease of cleaning	• Convenient to carry • Durability	N/A	Diskus®

Study Year	*Devices used*	*Factors influencing preference*			*Preferred device*
		Operational use	**Convenience**	**Oral sensation**	
2009 (68)	Turbuhaler® Respimat® SMI	• Overall feeling of inhaling • Inhaled dose goes to lungs • Amount of medication left • Works reliably • Ease of inhaling a dose • Using the inhaler • Speed medicine comes out	• Instruction for use • Size • Durability • Ease of cleaning • Ease of holding during the use • Convenience of carrying	N/A	Respimat® SMI
1998 (69)	Diskus® Turbuhaler®	• Instruction leaflet • Ease of holding • Overall perceived ease of use • Ease of use in acute exacerbation • Counting mechanism • Ability to use medicine quickly • Large amount of dosage • Ease of use of cap • Overall preference	• Shape of mouthpiece • Ease of carrying around • Hygiene of the device • Susceptibility to moisture Size • Weight • Overall attractiveness	• Tasting the medicine	Turbuhaler®

Study	*Devices used*	*Factors influencing preference*			*Preferred device*
Year		**Operational use**	**Convenience**	**Oral sensation**	
1997 (70)	Diskus® Diskhaler®	• Easy to load • Easy to hold and operate • Easy to tell number of doses left	• Convenient to carry • Durability • Easy to clean	N/A	Diskus®

1.11. Significance

Although it is increasingly taken for granted that patients' opinions on treatment are widely sought (65, 71, 72), little is known about patient preference for inhaler devices and its relationship with inhalation technique. The knowledge gap regarding inhaler device selection, patient preference and inhaler technique should be addressed in future studies (22). The result of this kind of studies will deepen our understanding about patient thought of inhalation systems in respiratory treatment, also the particular aspects of inhaler device use that are important for the patient will be identified. This will have broader implications for prescribing of inhaler devices and contribute to the inhaler device development in the future.

1.12. Aim and Objectives

The overall aim of this research was to explore the potential relationship between patient choice and patient experiences of inhaler use.

The objectives of this study are:

1) Explore the attitudes, perceptions and preferences of people with asthma regarding inhaler devices.

2) Explore patient's experience with choosing their inhaler devices.

3) Explore the relationship between inhaler technique and the attitudes, perception and preference of people with asthma regarding inhaler devices**.**

We hypothesize that taking into account the patient preference and attitude toward inhaler devices will lead to acceptance of the device and better technique. That is when patient are given a choice in selecting an inhaler and prescribed the preferred device; they will demonstrate better technique which improves the ultimate treatment outcome.

Material and Methods

2.1. Overall design

In order to gain a deeper understanding of the relationship between inhaler technique, patient satisfaction, preference and role of decision-making with regards to inhalers, this study took the form of a mixed methods design. Data collected through qualitative interview, a quantitative survey and assessment of inhaler technique was triangulated. This research was approved by the University of Sydney, Human Research Ethics Committee.

2.2. Participant recruitment

In order to be eligible for study potential participants were required to be at least 18 years old, diagnosed with asthma and currently using at least one inhaler device for their asthma treatment. Subjects who were unable to speak English, were unable to self-complete the questionnaire or did not self-administer their inhaler were excluded from study.

Participants were recruited through a convenience sample of community pharmacies that have expressed an interest to participate in research. Participating pharmacies displayed study advertisements in their pharmacy, inviting potential participants to register an interest with their pharmacists. In addition, potential participants who presented a prescription for asthma medication were approached by their pharmacist and invited to participate. All potential participants were referred to the researcher who then explained the study and organised a time to conduct the study.. All participants signed informed consent prior to enrolling in the study.

Following enrolment, a face-to -face interview was conducted with the participant in the pharmacy. All interviews were conducted by one researcher (LJ). Following the completion of the interview, participants completed the Patient Satisfaction and Preference questionnaire (PASAPQ) (73). Participants were then asked to demonstrate to the researcher (LJ) how they would usually use their inhaler. This allowed the researcher to assess their inhaler technique, based on device-specific inhaler checklists (described below).

All participants who completed the study were offered a $30 gift voucher to be spent inside the pharmacy as compensation for any inconvenience.

2.3. Sample Size

As qualitative approach was the main approach of this project, therefore a sample size was based on the sample required to reach saturation of data and until the generation of data did not result in the identification of any new concepts. This occurred within 20 interviews however, data collection continued up to 25 interviews.

2.4. Data collection

2.4.1. Qualitative data

A semi-structured interview guide was developed with the aim of exploring the participant's attitudes, perceptions and preferences for their inhalers. The semi-structured interview guide was developed based on the published literature. Prior to development of questions a widespread literature review carried out to address all criteria of asthma inhalers and patient point of view regarding their asthma in general and inhalers in particular (64, 74, 75). The interviewee's own vocabularies utilized in order to find out new areas without imposing any assumptions (76).

After completion of a series of initial interviews some of the questions refined to ensure all the targeted domains have been covered in interviews. This was likely to occur as little is known about patients' perception for their inhalers. A summary of the key topics addressed and final questions developed and utilized is included in Table 6.

Table 6 :Semi-structured interview guide

Topic	*Primary questions*	*Clarification*
1. Background: Understanding of patient experience and perception of inhalers and asthma management .	How is your asthma treated? What is your opinion about your asthma management?	Could you take me through the medication you are taking for your asthma? What was your treatment when you were first diagnosed? How many different devices have you used for your asthma? How well do you feel your medications are controlling your asthma? Have you ever been admitted to the hospital because of asthma or a complication of asthma? If yes what do you think was the main reason for?
2. Confidence with inhaler and inhalation technique.	How confident are you in using your inhaler?	Who has shown you how to use your inhaler in past? How helpful was it? How do you evaluate your inhalation technique?
3. Perception about their role in treatment decision- making.	What is the process for deciding on which inhaler you will need for your asthma?	How much are you involved in decisions about your treatment? Has this involvement changed over the time? Have you ever given a choice in selecting an inhaler? Would this be important for you? Why? Describe the kind of the role you would like to have had?

Topic	*Primary questions*	*Clarification*
4. Overall views on inhaler.	What are your overall thoughts about your inhaler?	What do you like or dislike about your inhaler? Have you ever thought of changing the inhaler?
5. Reasons for satisfaction.	What do you like most about your inhaler?	What do you like/dislike about your inhaler? Have you ever thought of changing your inhaler? How difficult/easy is it to use?
6. Reasons for dissatisfaction.	What are your greatest concerns about your inhaler?	What makes you to feel you have difficulty with your inhaler? What do you like about the operation of your inhaler? Have you ever had difficulty to operate your inhaler during attack?
7. Identification of an ideal inhaler and the specific elements that make it ideal.	How would you describe your ideal inhaler?	What aspects of an inhaler are most important to you and why?

2.4.2. Patient Satisfaction and Preference Questionnaire (PASAPQ)

The Patient Satisfaction and Preference Questionnaire (PASAPQ) is a validated instrument which measures patient perception and preference for inhaler devices (Table 7) (73). It is validated for 5 domains (satisfaction with performance, satisfaction with convenience, overall satisfaction, preference for device and willingness to continue to use a device). The preference sub-scale in this questionnaire was primarily designed to measure patient preference when two inhalers are compared. It clearly states: Which inhaler do you prefer? a) Inhaler one b) Inhaler two c) No preference. This study was aimed to gain an understanding of patients' opinion for asthma inhalers rather than comparing inhalers. Therefore not all participants were using more than one inhaler. For the purposes of this research, only the former three domains are relevant. As a result, only these three

were used in this research. The 3 domains are covered in 14 items of the PASAPQ and relate to the following three sub-domains: satisfaction with performance (7 items), satisfaction with convenience (6 items) and overall satisfaction (1 item). For each item within the three sub-domains, a 7 point Likert type response scale is utilized (68, 73). It is designed for self-administration.

Table 7: Relevant Patient Satisfaction and Preference Questionnaire domains (73)

Domain		Question	Description	Scoring
Total score	**Performance domain**	Q1	Overall feeling of inhaling	All items scored on a 7-point Likert scale: 1= Very dissatisfied 2=Dissatisfied 3=Somewhat dissatisfied 4=Neither satisfied nor dissatisfied 5=Somewhat satisfied 6=Satisfied 7=Very satisfied
		Q2	Inhaled dose goes to lungs	
		Q3	Amount of medication left	
		Q4	Works reliably	
		Q5	Ease of inhaling a dose	
		Q10	Using the inhaler	
		Q11	Speed medication comes out	
	Convenience domain	Q6	Instruction for use	
		Q7	Size of the inhaler	
		Q8	Durability of the inhaler	
		Q9	Ease of cleaning inhaler	
		Q12	Ease of holding during use	
		Q13	Convenience of carrying	
		Q14	Overall satisfaction	

2.4.3. Inhalation Technique assessment

Inhaler technique checklists were utilized to assess inhaler technique (Tables 8 – 12). These checklists were developed from manufacturer developed written

inhaler devices instructions through an Australian Research Council grant LP 0882737.

Participants were asked to demonstrate how they would usually use their inhaler. This technique was compared to the items (steps) listed in the checklist. A participant was assessed as having "correct" technique only if they were able to perform all steps listed in the checklist correctly. Tables 8 to 12 are samples of the checklist used.

Table 8: Inhaler technique assessment checklist for Accuhaler®

Accuhaler®
1. Open Inhaler.
2. Push lever back completely to load dose.
3. Exhale all air out of lungs.
4. Exhale away from the mouthpiece.
5. Hold inhaler horizontally.
6. Place mouthpiece between teeth and seal with lips.
7. Inhale slowly and deeply.
8. Hold breath for as long as is comfortable (aim for 10 seconds).
9. Exhale away from the inhaler.
10. Close Inhaler.

Table 9: Inhaler technique assessment checklist for Turbuhaler®

Turbuhaler®
1. Unscrew and remove the cap from the inhaler.
2. Keep inhaler upright.
3. Rotate grip one way, then back, to load dose.
4. Exhale all air out of lungs.
5. Exhale away from the mouthpiece.
6. Keep head upright, lift chin slightly.
7. Place mouthpiece between teeth and seal with lips.
8. Inhale forcefully and deeply.
9. Pause, then breathe out normally.
10. Exhale away from the inhaler.
11. Replace cap.

Table 10: Inhaler technique assessment checklist for Pressurised Metered Dose Inhaler

Pressurised Metered Dose Inhaler
1. Remove mouthpiece cover and shake well.
2. Exhale all air out of lungs.
3. Keep head upright, lift chin slightly.
4. Mouthpiece between teeth and seal with lips.
5. Inhale slowly and press canister early.
6. Continue slow and deep inhalation.
7. Hold breath for as long as is comfortable (aim for 10 seconds).
8. Breathe out normally, away from the inhaler.
9. Replace cap.

Table 11: Inhaler technique assessment checklist for Pressurised Metered Dose Inhaler with Spacer

Pressurised Metered Dose Inhaler + Spacer
Single Breath Technique Method
1. Assemble the spacer.
2. Remove mouthpiece cover of inhaler, shake and insert into spacer.
3. Exhale all air out of lungs.
4. Keep head upright, lift chin slightly.
5. Spacer mouthpiece between teeth and seal with lips.
6. Press canister and inhale slowly and deeply from spacer.
7. Hold breath for as long as is comfortable (aim for 10 seconds).
8. Breathe out normally.
Multiple Breath Technique Method
1. Assemble the spacer.
2. Remove mouthpiece cover of inhaler, shake and insert into spacer.
3. Exhale all air out of lungs.
4. Keep head upright, lift chin slightly.
5. Spacer mouthpiece between teeth and seal with lips.
6. Breathe in and out of spacer, then press canister.
7. Continue to breathe normally through spacer for a few breaths.

Table 12: Inhaler technique assessment checklist for Autohaler®

Autohaler®
1. Remove inhaler cap and shake well. 2. Raise lever up to prepare device. 3. Exhale all air out of lungs. 4. Keep head upright, lift chin slightly. 5. Place mouthpiece between teeth and seal with lips. 6. Inhale slowly and deeply. 7. Hold breath for as long as comfortable (aim for 10 seconds). 8. Breathe out normally away from inhaler. 9. Push lever down and replace cap.

2.5. Analysis of data

2.5.1. Qualitative analysis

Analysis performed by two researchers independently and agreement on results achieved prior to finalisation of themes and concepts.

Interviews were audio recorded and transcribed verbatim. Analysis involved content analysis of the transcripts to identify emerging themes and concepts. The reduction of mass of data into categories carried out by means of coding. Open coding was the first step in putting data in categories and subcategories and generates initial labels. Then further coding initial labels and themes reviewed which led to emergence of new concepts and themes and finally the overall analysis organised to measure the core concept (77).

2.5.2. PASAPQ analysis

Each participant received a total score for the sub-domains of satisfaction with performance, satisfaction with convenience and overall satisfaction.

For the “satisfaction with performance” score, the value of each of the 7 performance questions was added. As these questions were based on a 7-point Likert scale, each participant obtained a value between 7 and 49.
For the “satisfaction with convenience” score, the value to each of the 6 performance questions was added. As these questions were based on a 7-point Likert scale, each participant obtained a value between 6 and 42.
For the “overall satisfaction” score, as there was only one question addressing this domain, participants received a value between 1 and 7.

PASAPQ scores were analysed descriptively. Based on the findings of Kozma et al (73) a difference of 3 to 4 points is required to observe a small difference and 8 to 10 points to observe a medium difference in the convenience and performance domains. In the current study, a difference of 8 to 10 points was adopted to represent a significant difference in the convenience and performance domains respectively.

2.5.3. Inhalation technique assessment

For each inhaler, participants were evaluated as having either correct (performed all steps correctly) or incorrect (did not perform all steps correctly) technique. In addition, to identify whether participants were able to use their inhalers correctly, they received an “inhaler technique score”. This corresponded to the number of steps performed correctly.

2.5.4. Convergence/Triangulation of data

In order to describe any pattern of association between participants point of view from qualitative interview with inhalation technique result and PASAPQ scores, data relating to correct use of inhaler and incorrect use of inhaler, satisfaction with performance, satisfaction with convenience and overall satisfaction were

triangulated with qualitative responses (exploring preference, and decision-making). This was achieved by mapping this data in a matrix. The matrix was then qualitatively explored to identify characteristics which could indicate a relationship between inhaler technique, satisfaction, preference and decision-making.

Results

3.1. Demographic information

Twenty five participants completed the study. A total of 4 different types of inhalers were used overall (participants including pMDI, Turbuhaler®, Accuhaler® and Autohaler®). The most commonly used devices were the pMDI, Turbuhaler® and Accuhaler® with 92%, 32% and 20% of participants using each of these respectively. The average number of years of asthma duration was 24.12(±10.4) years. Table 13 is a summary of demographic data.

Table 13: Subjects demographic information (Total =25)

Age (years), mean (SD) Range	43.08 (15.5) 21-79 (years)
Female, n (%)	19 (76)
Highest level of education, n (%) Secondary school Diploma or TAFE degrees University undergraduate Postgraduate degrees	 7 (28) 8 (32) 4 (16) 6 (24)
Duration of asthma (years), mean (±SD) Range	24.12 (±10.4) 2-40 (years)
Duration of pMDI use (years), mean (±SD) Range	20.45 (±11) 2-36 (years)
Duration of Turbuhaler® use (years), mean (±SD) Range	11.06 (±12.1) 0.5-36 (years)
Duration of Accuhaler® use (years), mean (±SD) Range	12.20 (±8.9) 3-23 (years)
Duration of Autohaler® use (years) (±SD) Range	10 (n=1) N/A (n=1)

3.2. Qualitative interviews

The following themes emerged: Asthma inhalers and expectations, inhaler preference, characteristics of an ideal inhaler, Perceived effectiveness of inhalers, inhalers and patient decision-making

Asthma inhalers and expectations

When it came into inhalers as delivery devices, a majority of participants could not distinguish between inhaler devices and actual medication in the devices. Inhalers from their point of view were part of the treatment process regardless of the type of device. It was very difficult to realize the concept of effectiveness from their viewpoint whether it is related to device or drug itself. Lack of clear understanding of inhalers as mechanical delivery devices was noticeable. In addition, effectiveness of medication in relieving asthma symptoms was considered as a sign of good inhalation technique. They did not consider that the way in which they used their inhaler was an issue here.

Examples of participants' responses:

> "*I like my inhaler, yeah that's fine. It works very well." (*pMDI*)*(Participant 14)

> "*I think my technique is pretty good. Because I have just known that, all of my bests for certain amount of time and it's quite good. I think my technique is fine. The Ventolin® fixes me up every time in a minute*." (Participant 18)

> "*I am getting results and for me the result is this, my asthma decline, my breathing is easier and also if I have got some sort of congestion, it releases the congestion and actually clears my lungs...because it works, my technique must be good*."(Participant 13)

Participants presented various perceptions and opinions in regards to their inhaler devices and asthma management. Presented perceptions covered their feeling and

expectations of inhaler as delivery devices of asthma medication, which was closely linked, to their perceptions of their asthma.

Participants commonly reported being dependent on their inhalers, and the discomforted/concern felt being without them when they were needed. In reflecting this participants mentioned their desire to be free of asthma and not needing to carry their inhalers with them. This rendered the inhalers as a burden. They did not distinguish this with regards to the different inhalers.

Examples of participants' responses:

> *"I would not be without it; I am very dependent on it. I would not go anywhere. I go anywhere and I do not have it, I will be a bit nervous".* (Participant 22)

> "*I just feel like one day they are not going to help me. That always worries me. You know like they are helping me now but are they always going to help me that is my biggest worry, you know." (Participant 16)*

> "*My greatest concern is that I have to use it for rest of my life."* (Participant 7)

> *"I do not think I like much about it. I suppose if I didn't have exertion asthma, I would not use it but it is there, a necessity."* (Participant 18)

When talking about their inhalers it was clear that actual medication-related factors were influencing patient's opinion of asthma inhalers. For example, prior experience of side effects of asthma medication and reported ineffectiveness of a particular medication, affected overall thoughts about their devices. This was contrasted with their "experience" with particular "devices" in that long-term use of a particular device resulted in satisfaction with the device and perceptions of ease of use.

Examples of participants' responses:

> *"I have been trying different things and then I end up using this one. Before I had Pulmicort®. It was not good either. They all have something that I get anxiety reactions."* (Participant 23)

> "*I have used it all my life so very comfortable with it. I know how to use it*." (Participants 25)

Another remarkable point-of-view was participants' lack of interest for new inhalers. Although some presented dissatisfaction with some aspects of their inhalers, such as a lack of counter for the metered dose inhaler, they lacked knowledge and information about alternate inhalers, therefore did not consider them as options for treatment. For others effectiveness of inhaler in relieving asthma symptoms was adequate to convince them that they did not need to change inhalers.

Examples of participants' responses:

> *"You can feel the benefit of it which is important. So I really don't want to change it, you know. If I am getting comfort and relief from that, I think that is the main thing."* (Participant 24)

> *"I wouldn't know what to change it to. That is the thing; I have only been given the information I have. I have just used what I have had, the same sort of inhalers for these years and it has worked very well so I have never thought about changing or what options are available."* (Participant 14)

> "*I don't know what else is available."* (Participant 6)

Inhaler Preference

Participants with various inhalers presented diverse perceptions and expectations of their inhalers based on perceived performance and convenience of use.

All participants wanted a device that was easy to use and majority expressed satisfaction with the ease of use of their inhalers. Some devices were perceived to

be easier to use than others. Users of pMDIs perceived that they were easy to use, while for some of those using the pMDIs as well as DPIs they felt use was confusing and complicated. Participants reported that loading the dose was the most troublesome and confusing step with the DPIs.

Examples of participants' response:

> "*I twisted it once and if I am not thinking what I am doing or I go away, I think oh have I loaded it? I never know whether I loaded it or not and I can be doing this and I don't know whether I am wasting it and it is expensive very expensive so I don't look at the counter you know. I guess it is just a kind of thing I have to pay more attention at the time".* (Turbuhaler®)(Participant 22)

> *"I sometimes just forget which way I have turned it to activate it. You have to suck really hard to try to make sure you get the gas or whatever is inside which I found a bit irritating."*(Turbuhaler®)(Participant 14)

> *"I did not want to take the other one, what it called the puffer inhaler yeah I didn't really like to take that one and I just found it really too hard to use it permanently. It may work for a couple of seconds but then I struggle to breathe again so I found it very difficult to use. It wasn't effective."* (pMDI)(Participant 8)

> "*It is very simple. You just puff it and breath it in so it's pretty simple which is what I like* (pMDI)." (Participant 14)

In addition, some participants expressed concerns about the difficulty of inhaling a dose from a DPI when you had difficulty breathing properly during an attack.

Examples of participants' response:

> *"Sometimes tough if you are suffering from asthma, you can't take a deep breath to inhale really deeply. With a good inhaler you have get a take a normal breath and it just goes in."* (Turbuhaler®)(Participant 20)

> *"I found that a little bit more pain to use it. Having to suck in because my breath control isn't that great but using the puffers*

> *are pretty straightforward, it's always helped." (*Turbuhaler®*)* (Participant 14)

An aspect that was important to participants was the ability to identify how much drug was left in the device once use commenced. Participants particularly liked the dose counter on dry powder inhalers while pressurised metered dose inhalers specifically Ventolin® still does not have a counter. Lack of dose counter was one of the main concerns due to shortage of medication in emergency events.

Examples of participants' response:

> *"I can see the numbers that how many I have left. In that way I know that I can go and get a new one."* (Accuhaler®) (Participant 23)

> "*I quite like the way that some of them now have the little numbers on it, so I know when it runs out instead of keep trying, when you realize that there is actually nothing left into it."* (pMDI) (Participant 17)

> *"I don't like Ventolin® not being able to complete tell them when it runs out. But that getting down to little half things, dose counter would be better*". (Participant 3)

Another important feature was convenience: portability and size. Participants felt that the smaller size inhalers are linked to improved compliance to medication due to the convenience of carrying inhaler in handbag or pocket. However, what was convenient for one participant was not necessarily the case for others. For example, although for some the inhalers were considered bulky and difficult to fit in a pocket or handbag, others found them portable and easy to carry around.

Examples of participants' response:

> *"They are small, easy to take with me. I put them in my hand bag yeah."* (pMDI, Turbuhaler®)(Participant 10)
> *"It is easy to carry around. I travel quite a bit for work so it is not a big thing to carry around."* (Turbuhaler®)(Participant 25)
>
> "*Size is all right. It is just always in my pocket here so yeah pretty much just like, it is just something you have it. It is just there.*" (pMDI) (Participant 20)
>
> "*Maybe the size, which is when I am going out if I need it, I have a big bag. When I need to go out with a smaller handbag I tend to leave it at home just because of the size*" (Accuhaler®). (Participant 9)
>
> "*The size at the Seretide® is probably is bigger than I would have liked."* (Accuhaler®)(Participant 3)
>
> *"It is bulky fit not into your pocket when you go for a walk. That is you get to bring your bag if you have a small bag or whatever. That is down side to it. I am not sure they could do anything smaller or slimmer, I don't know but if they could do it the same thing in the smaller container."* (pMDI)(Participant 22)
>
> *"The only thing I guess could be smaller because these days when you wear I suppose skinny jeans and things like that; it is just big it's never got the small".* (pMDI)(Participant 18)

In addition, participants have the same opinion concerning their inhalers to be hygienic to use. Inhalers are used on a daily basis and carried in handbags and pockets. Participants recognized that dust can build up in mouthpiece and it may aggravate asthma while inhaling a dose. Cleaning inhalers on a regular basis was found inconvenient by consumers and they presented dissatisfaction about inhalers hygiene in general and pMDIs in particular. While DPIs are preferred in terms of hygiene, they raised concern of how pMDIs lids came off easily and dust could build up in the nozzle.

Examples of participants' response:

> "*What I dislike is when I thrown them in my bag and something get caught in them and I go to use it and it goes to my lung… Things can go down inside it or if I lost the cap on the end, lots of funny things end up from my handbag in there then end up down in my lungs."* (pMDI) (Participant 17)

> "*Turbuhaler® is more contained than the pump in terms of if you have a pump in your backpack or your pocket or wherever, can get dirt inside. The mechanism those that Turbuhaler® is quite contained and clean ... I guess if you got dust in your inhaler, it's one of the triggers for asthma then perhaps it's important".* (Participant 6)

> *"What do I like most about it is just the fact that it has got the mouthpiece covered up. I quite like that so this is sort of thing not really you think, but the hygiene fact to it. That would be the positive thing."* (Accuhaler®)(Participant 13)

Additionally participants noted the cost of asthma medications, specifically preventers. They were found to be expensive.

Examples of participants' response:

> *"I never know whether I loaded it or not and I can be doing this and I don't know whether I am wasting it and it is expensive very expensive."* (Turbuhaler®)(Participant 22)

> *"Seretide®, it's a bit expensive I mean the government subsidized it so it's $32 or $34.20 now so it's a bit on the expensive side… You can just get that one [Ventolin®] whenever you want it is out of script. That's really handy but with Seretide® you have to go to doctor and get a script which is annoying cause he charges for it, so it's a bit expensive."*(Participant 7)

Characteristics of an ideal inhaler

Some participants had never thought about what they wanted in an ideal inhaler while others had clear opinions. Characteristic of an ideal inhaler from their point of view was a reflection of preferred features of inhaler devices, whether their own inhalers meets the preference or not. These opinions were based on performance and convenience. Due to the importance of compliance to inhalers as daily medication, ease of use was the dominant feature of a preferred inhaler. Ease of use was particularly important during emergency treatment. Participants reported that ease of use make an inhaler quick enough to relieve the asthma attack. In addition, the dose counter was another advantage to an inhaler to overcome the concern of

running out the medication. Majority believed that a dose counter should be an integral part of an inhaler.

Examples of participants' response:

> *"Easy to use... compliance because you have something you have to take it, particularly the steroid ones. So it's the compliance things. If it is too hard, you do not take it and also just trying to remember to take it, linking that to something you do like brushing your teeth."* (Participant 13)

> *"Gauge on the Ventolin® would be a big advantage ... I wouldn't like to be caught up without having something in the inhaler. Because I do not know whether you are asthmatic, but its worse feeling when you cannot breathe. Even to get one puff is something when you can feel that, it is giving you some relief so I would like the one show it."* (Participant 24)

Getting feedback after correct use was the preferred aspect of some of inhaler. The idea of being able to monitor the delivery of the medication was raised and discussed. That is, participants expressed a preference for an inhaler that shows you the delivery of the medication to the lungs.

Example of participants' response:

> *"If there was a way of monitoring the delivery of medication that wouldn't be a bad feature to have as well, just in terms of making ensuring.... For the people who have to monitor their asthma very carefully, method of monitoring the delivery of the medication would be useful to have as well." (Participant 25)*

With regards to convenience, the majority of participants were agreed that the significance of portability and small size of an inhaler and how it would affect the compliance. In addition, ease of cleaning and the hygiene of an inhaler were emphasized as an important feature.

Examples of participants' response:

> *"It would be lighter and smaller, the portability reasons."* (Participant 1)

> *"Keep it clean so nothing would get it on top of it."* (Participant 12)

Perceived effectiveness of inhalers

Majority of participants were confident about their inhalation technique and found inhalers very easy to use. Their confidence was related to the effectiveness of the medication rather than any objective measure of whether they could use them correctly. Participants believed their effective asthma control is the best indicator of good inhalation technique.

Examples of participants' response:

> *"I am getting results and for me the result is the asthma declines, my breathing is easier and also if I have got some sort of congestion, it releases the congestion and actually enables me to clear the lungs... because it works my technique must be good."* (Participant 13)

> *"Whether I am getting the full dose I am not sure but certainly in terms of its effects, it seems to work well and I do not have an*

> *asthma attack for a long time so I have got no reason to doubt that I am not doing it correctly."* (Turbuhaler®)(Participant 25)

In addition, the fact that many of the participants had used their inhalers for a long time made them confident that they were using them correctly.

Examples of participants' response:

> *"Confident. I have been using them in all my life so it's like blinking."*(Participant 20)

> *"It is something I have used probably for about 10 years so yes very confident. My technique is effective."* (Participant 12)

History of technique training, perceived ease of use, feeling taste of medication and doctors' satisfaction of technique were all various reasons associated to patient confidence of technique. Majority of participants had received training from their doctor and emphasized the significance of proper training with an educated person.

Examples of participants' response:

> *"I use it in the right way. The way the doctor showed me."* (Participant 23)

> *"It is pretty much; I mean it's not like a science. Is it? Yeah open your mouth and put your head back and take a couple of puffs and pretty much, if I can do it, anyone can do it."* (Participant 20)

> *"I did it in front of the doctor and the doctor showed me. He wanted to see how I take it, to see if I am in bad condition, and he said that you are doing in the right way. He was happy so I was happy."* (Participant 16)

> *"Doctors have never complained. I don't see it is coming back out of my mouth when I use it or is coming out of the top of puffer so I assume its ok."* (Participant 17)

> *"I usually get the taste. I can taste the medication ... Yeah it has a certain taste."* (Participant 11)

> *"Helpful [doctor demonstration] because probably you wouldn't ever read the instruction. My dad had the same, had Symbicort® as well, he clicked it once and expected it to work and complained how it didn't work and I told him you have to click it twice and the third time it works so I am glad yeah I am glad that he told me."* (Participant 8)

Only three participants expressed uncertainty about their inhaler technique although they found asthma treatment effective.

Examples of participants' response:

> *"I am not sure if I am using them in the right way but yeah it is working."* (Participant 9)

> *"I don't mind using the inhalers. I can manage it pretty well. I prefer using the spacer because I don't think I'll be comfortable just using inhaler by itself with my technique, so that's why I use it with the spacer."* (Participant 7)

Inhalers and patient decision-making

Almost none of the participants had been informed about the possibility of being involved in treatment decision-making. They did not express dissatisfaction with this. No involvement in decision-making was not their concern when the outcome of good asthma control was fulfilling. A strong relationship with their doctor which was based on trust was adequate to build up satisfaction with the doctor's decision. In addition, health care professionals' education had convinced them to use their knowledge in management of their health condition.

Examples of participants' response:

> *"No, I have always got the one doctor says, the doctor says take that I will take that. I don't take away from that because I trust them after years."* (Participant 21)

> *"I was just thinking, I would take the advice of my doctor because he has an educated opinion."* (Participant 18)

Participants thought that treatment decision-making was influenced by the necessity for good asthma control, based on patient asthma history rather than considerations of the device. Participants felt that the final goal of asthma treatment was asthma control and did not think that inhaler device selection played any significant role in that. In some cases development of side effects to specific ingredients were thought to lead to changes in the treatment regimen but still not with any consideration of the actual inhaler device or inhaler technique.

Examples of participants' response:

> *"The sort of the device I use is not that important to me, it is the effect has on me and the management of my condition is more important than how it is administered."* (Participant 25)

> *"It is not about the method of delivery for me. It's about delivery. It's about what medication does."* (Participant 13)

On the other hand, a minority of participants mentioned amendment to therapy or preference for a specific inhaler due to lack of proper technique.

Examples of participants' response:

> *"Ventolin®, I just wasn't getting any benefit from it because I couldn't take it, I couldn't breathing at the right time and I found it really uncomfortable to use and they told me Symbicort® they give to children so I told Ok I'll try that one and because it is very mild and it's just exercise induced asthma then I don't need anything stronger."* (Participant 8)

When it came to decision-making, a minority of participants expressed a preference for being involved in treatment decision-making. Most were content with the prescribers' recommendations.

Examples of participants' response:

> *"Prefer to do what I like than what they like."* (Participant 3)

> *"That would be good, if they said to me which one do I prefer I go for the puffer just one click done. With other ones you got a maneuver it with your hands. Why is that? Why I am not able to saying that?"* (Participant 22)

3.3. Inhalation technique

Participants were on various inhalers for their asthma treatment. Some participants used their pMDI with a spacer with single breath technique and multiple breath technique. A number of some participants used more than 1 device. A maximum of 3 devices was used by one individual. Table 14 summarizes the number of participants using each device and the proportion of participants demonstrating correct technique for each device.

Table 14: Proportion of participants demonstrating correct technique

Device	Number of participants using this inhaler	Proportion demonstrating correct technique (%)
pMDI	22	9
pMDI+ Spacer single breath technique	3	33
pMDI+ Spacer multiple breath technique	1	0
Turbuhaler®	8	0
Accuhaler®	5	40
Autohaler®	1	0

Note: Amongst the 25 participants a total of 40 inhalers were used. Proportion relates to proportion of participants using a particular device.

3.4. PASAPQ

Mean (±SD) PASAPQ scores for satisfaction with performance, satisfaction with convenience and overall satisfaction were 41.43 (±6.2), 34.67 (±4.9) and 6 (±0.8) respectively.

Table 15 is a summary of the mean scores for PASAPQ score for satisfaction with performance, satisfaction with convenience and overall satisfaction in regards to different devices. Only one participant had Autohaler®, as a result the mean score was not calculated for Autohaler®.

Table 15: Patient Satisfaction and Preference Questionnaire (PASAPQ) score for satisfaction with performance, convenience and overall satisfaction for each device

PASAPQ scores	pMDI (n=23)	Turbuhaler®(n=8)	Accuhaler® (n=5)
	Mean(SD)	Mean(SD)	Mean(SD)
Satisfaction with performance scores[a]	41.84(±5.4)	40.25 (±6.4)	40.2 (±9.8)
Satisfaction with convenience scores[b]	34.39 (±4.8)	36.50 (±4.1)	31.8 (±5.9)
Overall satisfaction with inhaler[c]	6.13 (±0.8)	6.12 (±0.9)	5.60 (±1.1)

[a]For satisfaction with performance score, minimum is 7 and maximum is 49. Scores ≥ 35 indicates at least "somewhat satisfied".
[b]For satisfaction with convenience score, minimum is 6 and maximum is 42. Scores ≥ 30 indicates at least "somewhat satisfied".
[c]For overall satisfaction score, minimum is 1 and maximum is 7. Scores ≥ 5 indicates at least "somewhat satisfied".

3.5. Triangulation

Table 16 summarizes the mean (±SD) score for satisfaction with performance, satisfaction with convenience and overall satisfaction relating to correct use of inhaler and incorrect use of inhaler.

Table 16: Mean PASAPQ scores for performance, convenience and overall satisfaction in regards to correct use of inhaler and incorrect use of inhaler

Inhalation technique result	Satisfaction with Performance[a]	Satisfaction with Convenience[b]	Overall Satisfaction[c]
	Mean (±SD)	Mean (±SD)	Mean (±SD)
Correct	40.00 (±7.7)	31.50 (±4.9)	6.00(±0.8)
Incorrect	41.60 (±6.1)	35.12(±4.8)	6.09 (±0.9)

[a]For satisfaction with performance score, minimum is 7 and maximum is 49. Scores over 35 indicates at least "somewhat satisfied".
[b]For satisfaction with convenience score, minimum is 6 and maximum is 42. Scores over 30 indicates at least "somewhat satisfied".
[c]For overall satisfaction score, minimum is 1 and maximum is 7. Scores over 5 indicates at least "somewhat satisfied".

Matrix A (Table 17) represents the data relating to satisfaction with performance, satisfaction with convenience and overall satisfaction from PASAPQ triangulated with qualitative responses (exploring preference, and decision-making) for participants with correct inhalation technique.

Matrix B (Table 18) represents the data relating to satisfaction with performance, satisfaction with convenience and overall satisfaction from PASAPQ triangulated with qualitative responses (exploring preference, and decision-making) for participants with incorrect inhalation technique.

Triangulation of data did not uncover a relationship between inhaler tehcnique, saitsfaction, perception of inhaler devices and or the opportunity for participants to have a choice in device selection. However there appeared to be an association

with correct inhaler technique and participants who were more aware of their asthma and expressed motivation to achieve optimal control. This trend was seen through the relative qualitative data when separated for the particpatns with correct versus incorrect technique. PASAPQ scores and qualitative feedback relating to satisfation were consistent.

Table 17: Matrix A of triangulation for participant with correct technique relating to score from PASAPQ and qualitative feedback

Participant	*Inhalation technique*	*PASAPQ score*			*Qualitative feedback*
		Operation	*Convenience*	*Overall satisfaction*	
P4	Correct (MDIand MDI+ Spacer)	41	34	6	•Effectiveness of medication leads to satisfaction with inhalers •Satisfaction with asthma management and satisfaction with inhalers •Some level of choice •Asthma control was important
P13	Correct (MDI)	40	29	6	•Confidence about technique because of effectiveness of medication •Asthma control more important than type of inhaler •No involvement in treatment decision making
	Correct (Accuhaler®)	30	26	5	
P21[a]	Correct (Accuhaler®)	49	37	7	•Overall dissatisfaction with asthma and medication lead to dissatisfaction with inhalers •Concern of taking medication and having asthma •Confidence about technique because of effectiveness of medication •Could not distinguish device from medication •No involvement in treatment decision making

[a]Participant had 2 different inhaler and demonstrated correct technique for one of them and incorrect technique for other one.

Table 18: Matrix B of triangulation for participants with incorrect technique relating to scores from PASAPQ and qualitative feedback

Participant	*Inhalation technique*	*PASAPQ score*			*Qualitative feedback*
		Operation	*Convenience*	*Overall satisfaction*	
P1	Incorrect (MDI)	33	28	6	•Overall satisfaction with inhalers •Long term usage leads to satisfaction •Confidence of technique
P2	Incorrect (MDI)	44	32	5	•Overall satisfaction with inhalers •Confidence of technique
P3	Incorrect (MDI)	31	29	6	•Effectiveness leads to satisfaction with inhalers •Effectiveness of medication leads to confidence of technique •Satisfaction with ease of use •Confidence of technique
	Incorrect (Accuhaler®)	29	25	4	
P5	Incorrect (MDI)	35	40	7	• Effectiveness of medication leads to confidence with technique •Difficult operation is a reason of dissatisfaction with device •Actual medication influences overall opinion of inhalers •Confident of technique with Autohaler®
	Incorrect (Autohaler®)	48	41	7	
P6	Incorrect (MDI)	45	33	6	•Could not distinguish device from medication •Confidence with technique •Actual medication influences overall opinion of inhalers •Satisfaction with convenience of Turbuhaler® •No involvement in treatment decision making
	Incorrect (Turbuhaler®)	45	40	7	

Participant	*Inhalation technique*	*PASAPQ score*			*Qualitative feedback*
		Operation	*Convenience*	*Overall satisfaction*	
P7	Incorrect (MDI+ Spacer)	40	28	4	•Not confident of technique without spacer •Overall dissatisfaction of having asthma and necessity of using inhalers •Dissatisfaction with convenience of device •Actual medication influences overall opinion of device •No involvement of treatment decision making
P8	Incorrect (Turbuhaler®)	47	39	7	•Effectiveness of medication leads to satisfaction with inhaler •Effectiveness of medication leads to confidence with technique •Satisfaction with inhaler because of easy performance •Some level of involvement in treatment decision making
P9	Incorrect (MDI)	49	32	6	•Not very confident about technique •Effectiveness of medication leads to some level of confidence about technique •No involvement in treatment decision making
	Incorrect (Accuhaler®)	48	34	6	
P10	Incorrect (MDI)	41	36	6	•Effectiveness of medication leads to satisfaction with inhaler •Could not distinguish medication from device •Dissatisfaction with operation of Turbuhaler® /Non confident about technique •Confidence of technique with MDI® because of ease of use
	Incorrect (Turbuhaler®)	28	28	6	

Participant	*Inhalation technique*	*PASAPQ score*			*Qualitative feedback*
		Operation	*Convenience*	*Overall satisfaction*	
P11	Incorrect (MDI)	33	29	5	•Long term usage leads to confidence about technique •Could not distinguish device from medication •Effectiveness is the most important inhaler feature •Effectiveness of medication leads to satisfaction with inhaler
	Incorrect (Turbuhaler®)	40	33	6	
P12	Incorrect (MDI)	46	39	7	•Long term usage leads to confidence about technique •Satisfied with operation of inhaler
P14	Incorrect (MDI)	47	38	7	•Effectiveness of medication and long term usage lead to satisfaction with inhaler •Long term usage leads to confidence about technique •Effectiveness of medication leads to confidence about technique •Satisfaction with operation leads to confidence about technique •Could not distinguish device from medication
P15	Incorrect (MDI)	45	39	6	•Long term usage leads to satisfaction •Effectiveness of medication leads to confidence about technique •Overall satisfaction with inhalers •Could not distinguish medication from device
P16	Incorrect (MDI and MDI+ Spacer)	38	35	6	•Confidence about inhalation technique •Effectiveness of medication leads to satisfaction with inhaler •Satisfaction with operation leads to satisfaction with inhaler

Participant	*Inhalation technique*	*PASAPQ score*			*Qualitative feedback*
		Operation	*Convenience*	*Overall satisfaction*	
P17	Incorrect (MDI)	42	37	6	•Confidence about inhalation technique because of doctor's satisfaction with technique •Could not distinguish device from medication
P18	Incorrect (MDI)	36	25	5	•Overall dissatisfaction of having asthma effects the opinion of inhalers •Effectiveness of medication and long term usage lead to confidence about technique
P19	Incorrect (MDI)	49	42	7	•Long term usage leads to confidence about technique •Could not distinguish medication from device •Long term usage leads to satisfaction with inhaler •Satisfaction with inhalers because of satisfaction with performance
	Incorrect (Turbuhaler®)	37	40	6	
P20	Incorrect (MDI)	49	39	7	•Effectiveness of medication and long term usage lead to confidence about technique •Could not distinguish device from medication •Overall satisfaction with inhalers
P21[a]	Incorrect (MDI)	45	39	7	•Overall dissatisfaction with asthma and medication lead to dissatisfaction with inhalers •Confidence about technique because of effectiveness of medication •Could not distinguish device from medication

Participant	*Inhalation technique*	*PASAPQ score*			*Qualitative feedback*
		Operation	*Convenience*	*Overall satisfaction*	
P22	Incorrect (MDI)	46	31	7	• • Long term usage leads to satisfaction with inhaler •Satisfaction with inhaler because of ease of use
	Incorrect (Turbuhaler®)	46	36	7	
P23	Incorrect (MDI)	41	40	7	•Could not distinguish device from medication •Confidence about technique because of effectiveness of medication •Satisfaction/dissatisfaction with medication influences opinion of device
	Incorrect (Turbuhaler®)	36	37	4	
	Incorrect (Accuhaler®)	45	37	6	
P24	Incorrect (MDI and MDI+ Spacer)	46	37	6	•Confidence about technique because of effectiveness of medication
P25	Incorrect (Turbuhaler®)	43	39	6	•Effectiveness of medication leads to confidence about technique •Effectiveness of medication leads to satisfaction with inhaler

*Participant had 2 different inhaler and demonstrated correct technique for one of them and incorrect technique for other one.

Discussion

In this study we aimed to investigate the relationship between inhaler technique, patient satisfaction, preference and role of decision making with regards to inhalers. We found that, similar to other studies, a high proportion of participants did not use their inhalers correctly (24-28). We identified no relation between inhaler technique and patient perception and satisfaction with asthma inhalers or participant's views on being actively involved in decision making i.e. having a choice in device selection. Rather, we found that device use, selection and preference were not considered in isolation by participants and were intrinsically linked to medication effectiveness, overall views about asthma management and belief that their health care providers could make decisions about medications for them. That is, other factors, unrelated to the device were influencing patient opinions of their inhalers.

In an attempt to identify a relationship between inhaler technique, satisfaction with inhaler and attitudes and perceptions, a mixed method approach was taken. Although a number of studies have explored patient satisfaction with inhaler devices, a majority has taken a quantitative approach (53, 67-70). These have failed to add understanding to the relationship between patient's satisfaction with devices, the notion of having a choice in selection of devices and how this might relate to their ability to use the inhalers correctly. If we are to address the issue of inhaler misuse (i.e. technique), then it is important to understand whether patient selection may make a difference. Triangulation of qualitative and quantitative data was able to explore this potential relationship.

Despite the common academic belief that inhalers as delivery devices are important in clinical effectiveness of medication, participants did not associate treatment efficacy with inhaler devices. From the participants' perspective, the physical characteristics or features of an inhaler were not considered. Inhaler devices were not distinguished from the specific medications that they delivered and any opinions on then were collectively considered with regards to the participants' perceptions of the effectiveness of their treatment in relieving and controlling asthma symptoms. That is, participants' approaches towards their inhalers were intrinsically linked to their perceptions of asthma control and the side effects they experienced when using their medications. In that way, it can be said that asthma control and side effects, rather than inhaler characteristics were linked to satisfaction with inhalers. In fact, when participants were specifically asked to reflect on the features that they considered important in an inhaler, a number of them admitted they have never thought about it. This suggested that overall, inhaler devices themselves were insignificant when considering the use of medications in asthma management.

In this study participants were burdened by the chronic nature of their asthma and the necessity of using inhalers in such a "dependent" and long-term way. An overwhelming majority of participant believed that having asthma meant that they were at risk of developing a dependency on their medications/inhalers. Participants expressed dissatisfaction with inhalers because of dissatisfaction with having asthma more generally. From the responses of participants in this study, it seems that for patients, inhaler devices as physical delivery systems play a minor role in their overall satisfaction with treatment. While on probing some mentioned the physical feature of the inhalers, overall satisfaction with inhaler devices was related, once again to the perceived effectiveness of asthma therapy and relief of asthma symptoms. One of the main inhaler-related factors which influenced their

satisfaction and confidence about inhalation technique was in fact, the length of time that they had been using the inhaler. This emergent information is perhaps controversial. It is highlighted in the literature that using inhaler for a long time enhances the chance of incorrect technique because with no technique reinforcement patients' competency declines (24, 78, 79). Therefore, reassessment and reinforcement of inhalation technique is essential after the initial training and during therapy since studies shown patient will begin to demonstrate incorrect technique during time (80). It is significant to reinforce patients' technique to ensure of retaining the correct technique (43). Participants did not report on ever receiving inhaler device education as a follow-up.

When it come to confidence with inhaler devices, in addition to length of time of inhaler use, effectiveness of medication was viewed as a measure of correct use, as was the recount of having received instructions on use by the doctor. If a participant perceived that their inhaler was effective, they were confident in their ability to use it. Confidence based on the aforementioned criteria was somewhat misguided as despite the overwhelming confidence that participants felt they had with regards to their ability to use their inhalers, 88% of then did not. The mismatch of confidence with use and actual use of inhalers is not novel. This research is consistent with previous findings, which have shown that patients, who reported that their inhalers were easy to use, made major errors in inhalation technique (81). This mismatch highlights the focus on medication effectiveness and a lack of understanding of the fundamental aspects of medication use contributing to clinical outcomes. Participants did not consider that even if effective, with improved technique they may be able to decrease the dose of medication and reduce potential sides.

In this study we could not find any relationship between inhalation technique and satisfaction with inhalers; however the group with correct technique did differ to those who were not using their inhalers correctly. Those with correct inhaler technique clearly displayed a greater awareness of their asthma control and were clearly motivated to optimise it. The concept of motivation has previously been linked to inhaler technique in a recent study which indicated that patients who are motivated are more likely to demonstrate maintenance of correct technique over time (43).

This study explored the level of choice and involvement of the participants in device selection. As expected, a majority of participants had not experienced any level of involvement in treatment decision-making, although it is highly recognized in literature that patient involvement in decision-making is important (50-52, 82). Lack of knowledge, insufficient physician time, reliance on a trusted physician to make decision and educated decision were the main reasons of non-involvement in this study. Despite the proposed association between having a choice and satisfaction with inhalers, a majority of the participants expressed satisfaction with their current passive role in asthma management and their inhalers and were content to rely on physicians' decision to control their asthma. It can be hypothesis that in our study, the lack of desire for greater decision-making power is related to the level of knowledge of the participants. Reviewing the published literature, generally there are a limited number of studies which have specifically explored the level of asthma patient involvement in treatment decision-making and their expectation. Carees et al, (2002) employed a qualitative approach to explore the level of involvement in asthma treatment processes and patient perception (57). A collaborative role was the most preferred role amongst participants, which was followed by passive role. Research has shown that the main barriers to shared decision-making are trust in health professionals, patient level of knowledge (55),

lifelong nature of asthma and severity of the condition (57). Similar to our findings, in another study by Carees et al, (2005) the importance of patient and health care professionals' education for collaboration in treatment process is emphasized when the passive role was the preferred role by 40% of participants, followed by 36% preferring a collaborative approach and only 24% an active role (83).

In exploring patient perception about their inhalers, as expected, the results relating to patient satisfaction were consistent between the data collected through interviews and the Patient Satisfaction and Preference Questionnaire (PASAPQ). A majority of participants reported satisfaction with their inhalers. Consistent with the literature, ease of use was the most important feature of an inhaler regardless of the type of the device. Participants associated easy to use with their inhaler as being associated with better handling of the device, effectiveness in controlling symptoms and satisfaction and fulfillment with therapy. These factors were not related to actual ability to use their inhalers, hence it can be argued that while ease of use was important from the participants perspective, they did not have the knowledge to objectively evaluate if their perceived ease related to correct use. This is further exemplified in participants' responses to particular devices. Participants reported pMDIs as being easy to use, even though it is well established that coordination of actuation and inhalation is one the most challenging steps, being done incorrectly by majority of patients (35, 36). In terms of DPIs, despite the satisfaction with ease of use, a number of participants were confused about performance of their device in general and loading the dose in particular. In fact, participants were unsure about correct administration of DPIs because they could not feel anything coming out of inhaler. In our study some of participants found DPIs complicated and confusing to use and expressed preference for their old fashion pMDIs because they could not feel it after inhalation. This is consistent with other published research, which has shown that patients perceive DPI more

difficult to use (78, 84). In addition, other physical features of inhalers including metered dose counter, portability and hygiene of use were important from the participant's point of view. Participants were particularly aware of the dose counter expressing concern about running out of medication in emergency situations as a result of there being no dose counter on the device. From their perspective, the ideal inhaler would have a dose counter to ensure patients were aware of the remaining doses available. In several studies comparing various inhalers in a range of domains of convenience and performance, ease of use, hygiene, metered dose counter, portability and clear leaflet instruction were reported to be the most important inhaler features (85-87).

In summary, this study suggests that, in contrast to current evidence relating to patient preference, there is no relationship between patient perception, satisfaction or decision-making power relating to inhaler devices and patient's ability to use their devices correctly. The fact that participants could not differentiate the device from medication most certainly influenced their ultimate perception about inhalers. There are several other factors affecting not only patient opinion about asthma inhalers but also their perception about their inhalation technique and they are not necessarily related to the device. We found participants' inhalation technique scores and their perceptions relating to their inhalation technique do not match in a majority of cases and certainly, satisfaction is not related to better inhaler technique. In fact, it appears that those participants who are more aware, knowledgeable or motivated to achieve good asthma control, are more likely to have correct inhaler technique. In addition, participant's involvement in treatment decision-making is currently not on patient's radar for asthma management or medication selection. It does not appear to be feasible in reality, potentially due to the patient's lack of understanding of the role of inhalers, physician lack of time and the high level of trust that participant had for their

healthcare professionals, thereby removing the need for decision-making power. There is no indication that giving patients a choice in device selection alone will make any difference to the way they perceive their inhalers or their ability to use them correctly. However, investing time in explaining the technical importance of device use and the impact on the deposition of medication in the airways may improve understanding and help articulate the role of inhalers in asthma management and the importance of correct technique. The development of inhaler technique interventions, which include explanations of the technical importance of inhaler use, not only the consequences of misuse, should be developed and tested in the future.

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Appendices

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Participant Information Statement

Full Project Title:

Inhaler Devices: Patient Preference and Technique

This Participant Information Statement is 4 pages long. Please make sure you have all the pages.

1. Your Consent

You are invited to take part in a research project entitled "Inhaler Devices: Patient Preference and Technique" in which we seek to identify patient views about their inhalers.

This Participant Information contains detailed information about the research project to help you decide whether or not you would like to take part in it. Please feel free to ask us any questions you might have.

If you would like to participate in this project, you will be asked to sign the Consent Form, indicating that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Participant Information and Consent Form to keep as a record.

2. Purpose and Background

For most people with asthma and other respiratory conditions, inhaler devices are used on a regular basis. Although there is a range of inhaler devices available, consumers often find them a challenge to use. The purpose of this project is to explore the attitudes, perception and preference of people with asthma regarding inhaler devices. By understanding the view of consumers we will be able to identify the things that are important to them and how this relates to the use of these inhalers.

This study is being conducted by Ms Lia Jahedi ,a Mphil student at the Faculty of Pharmacy at the University of Sydney to obtain her Master's degree under supervision of Dr.Sinthia Bosnic-Anticevich and Dr.Bandana Siani and Professor Hak-Kim Chan from the Faculty of Pharmacy at the University of Sydney .

3. Procedures and time duration

Participation in this project will involve:

- Filling out a 'Patient Satisfaction and Preference Questionnaire' (PASAPQ) which contains 16 questions. These questionnaires take about 10 minutes to finish. You are allowed to take the questionnaire home and finish them later if you need more time. We will give you a stamped self-addressed envelope so that you can mail them back to us.
- Showing us how you would usually use your inhaler.
- Telling us about your inhalers in a 15-20 minute face-to-face or telephone interview with the researcher (Ms.Lia Jahedi).The interview will be

conducted at the pharmacy or asthma clinic and will be tape recorded with your permission.

4. Possible Benefits and Risks

There are no risks associated with participating in this study and if you choose not to participate, there will be no long-term of short-term consequences associated with the care you receive. The primary

benefit would be your contribution to the field of research into inhaler devices. This research may help to inform manufacturers of inhaler devices in the development of more user-friendly devices. You will also receive feedback on ways in which you can optimise the use of your inhaler through any modifications of your inhaler technique.

5. Reimbursement for your costs

You will receive a $30 gift card for the time associated with participation in this project.

6. Privacy, Confidentiality and Disclosure of Information

All aspects of the study including the results will be strictly confidential. All records will be de-identified and research data will not be able to be linked to any individual. Data will be stored in a locked secure area and only those persons identified above will have access to these records. No information revealing any personal information such as your name, address or telephone number will leave *the Faculty of Pharmacy at the Sydney University*.

Information gathered in this research study may be published or presented in public forums, however your name and other identifying information will not be used or revealed. Despite efforts to keep your personal information confidential,

absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law.

7. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. You may stop interview at any time or change your mind while filling out the questionnaire, if you do not wish to continue, the audio recording will be erased and the information provided will not be included in the study.

8. Further Information or Any Problems

If you require further information or if you have any problems concerning this project you can contact the researcher (Ms Lia Jahedi) to answer your question and for more discussion .If you would like to know more at any stage, please feel free to contact

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9. Other Issues

Any person with concerns or complaints about the conduct of a research study can contact The Manager, Human Ethics Administration, University of Sydney on +61 2 8627 8176 (Telephone); +61 2 8627 8177 (Facsimile) or ro.humanethics@sydney.edu.au (Email).

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Participant Consent Form

I ..... give consent to my participation in the research project entitled 'patient preference and asthma inhalers'.

By signing this consent I acknowledge that:

- I have read the information and consent forms and have had my questions answered by them in a language I understand. The risks and benefits have been explained to me.
- I believe that I have not been unduly influenced by any study team member to participate in the research study by any statements or implied statements. Any relationship (such as employer, supervisor or family member) I may have with the study team has not affected my decision to participate.
- I understand that I will be given a copy of this consent form after signing it.
- I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

- I understand that information regarding my personal identity will be kept confidential and no information about me will be used in any way that reveals my identity.

- I understand that I can stop the interview at any time if I do not wish to continue. The audio recording will be erased and the information provided will not be included in the study. I consent to

i) Audio taping YES ☐ NO ☐
ii) Receiving written transcripts YES ☐ NO ☐

If you answered YES to the" Receiving the transcript for my interview questions (ii)", please provide your details i.e. mailing address, email address.

Address.....

.....

.....

Email.....

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

Participant's name ……

Signature..... Date.....

Declaration by researcher: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's name …… Date…….

Signature..... Date.....

THE UNIVERSITY OF SYDNEY

Do you have Asthma?

Do you use an inhaler for your asthma or lung condition?

Would you like to help make them better?

Ask your pharmacist about our research.

We are interested in getting feedback from consumers about their inhalers and how they could be improved also you will receive a gift voucher for your time.

For further information please contact:

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