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The role of the community pharmacist in optimising patients' inhaler use in asthma management

Doctor of Philosophy

2013

Kathleen Niamh Buckley

TRINITY COLLEGE
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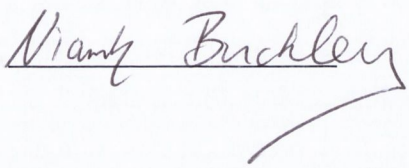
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Declaration

This thesis has not previously been submitted as an exercise for a degree at this or any other University.

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Acknowledgements

I would like to take this opportunity to thank Trinity College Dublin for funding my research through the Postgraduate Ussher Fellowship. I would like to express my sincere gratitude to my supervisor, Assistant Professor Sheila Ryder, School of Pharmacy, for her unfailing support and invaluable help and advice throughout the project. I would also like to thank the Asthma Society of Ireland for allowing me to collaborate with them on the Demonstration Project, for providing me with equipment for the Brief Intervention and for their support and help. Sincere thanks to all of the community pharmacists and patients who participated in the community pharmacist-led intervention on inhaler technique. The intervention was completely reliant on their goodwill and enthusiasm without which it would not have been possible. I would like to thank the Health Service Executive Primary Care Reimbursement Services scheme for providing me with access to data extracted from the pharmacy claims database. Sincere thanks also to Associate Professor Dr. Kathleen Bennett, Department of Pharmacology and Therapeutics, for facilitating access to the pharmacy claims database and for her invaluable assistance in extracting the relevant data.

I would like to thank my parents for their continuous support and encouragement throughout my research, and without whom I would not be where I am today. Finally, I would like to thank my partner, Bryan Ronayne, and my friends for their unfailing belief in me and their consistent encouragement over the years.

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Abbreviations

6-MWD	Six minute walking distance
ABP	Asthma Bother Profile
ACT	Asthma Control Test
ADSS	Asthma Disease Severity Scale
AE	Adverse effect
AH	Autohaler
AIA	Aspirin-induced asthma
AIRI	Asthma Insights and Reality in Ireland (study)
AIRE	Asthma Insights and Reality in Europe (study)
AIS	Asthma Impact Survey
ALIS	Asthma Life Impact Scale
AOMS	Asthma Outcomes Monitoring System
AQ20	Asthma Questionnaire 20 items
AQ30	Asthma Questionnaire 30 items
AQLQ(S)-J	Standardised Asthma Quality of Life Questionnaire, by E.F. Juniper
AQLQ-J	Asthma Quality of Life Questionnaire, by E.F. Juniper
AQLQ-MKs	Asthma Quality of Life Questionnaire, by G.B. Marks
ASI	Asthma Impact Survey
ATAQ	Asthma Therapy Assessment Questionnaire™;
ATC	Anatomical Therapeutic Chemical classification (system)
AZ	Aerolizer
BAI	Breath-actuated inhaler
BH	Breezhaler
BI	Brief Intervention
BN	Benosid-N-inhaler
BTS/SIGN	British Thoracic Society/Scottish Intercollegiate guidelines network
CH	Clickhaler
CH-5	Current health survey
CI	Confidence interval
CKAQ	Control, knowledge and adherence questionnaire
COPD	Chronic obstructive pulmonary disease
CPCF	Community pharmacy contractual framework
CPD	Cost per dose
CQ	Consumer asthma knowledge questionnaire
CRQ	Chronic respiratory disease questionnaire
CWR	Collaborative working relationship
CY	Cyclohaler
DH	Diskhaler
DPI	Dry powder inhaler
DRR	Dose-response ratio
DS	Diskus
DS-5	Disease severity survey
EB	Easi-breathe inhaler
ECRHS	European Community Respiratory Health Survey
ED	Emergency department
EH	Easyhaler
EQ-5D	European quality of life - 5 dimensions
FEF_{25-75}	Forced Expiratory Flow from 25%-75% of vital capacity
FEV1% predicted	Forced Expiratory Volume in one second % predicted;
FVC% predicted	Forced vital capacity % predicted
GAP II	Asthma General Awareness and Perceptions II (survey)
GAPP	Global Asthma Physician and Patient (survey)
GINA	Global Initiative for Asthma

GMS	General Medical Services
GP	General practitioner
HAD	Hospital anxiety and depression scale
HCP	Health-care professional
HD	Handihaler
HFA	Hydrofluoroalkane
HRQL	Health-related quality of life
HSE	Health Service Executive
HUI	Health Utilities Index
ICC	Interclass correlation coefficient
ICGP	Irish College of General Practitioners
ICS	Inhaled corticosteroid
II	Inhaler Ingelheim
INSPIRE	The International Asthma Patient Insight Research
ITG-ASF	Integrated Therapeutics Group Asthma Short Form
IQR	Interquartile range
JH	Jethaler
KR-20	Kuder-Richardson formula 20
LWAQ	Living with Asthma Questionnaire
MAQ20	Modified Asthma Questionnaire 20 items
MAQLQ-Mks	Modified Asthma Quality of Life Questionnaire, by G.B. Marks
MCS	Mental component summary
MID	Minimum clinically important difference
MIMIC	Multiple Indicators/Multiple Causes health index
Mini-AQLQ	Mini Asthma Quality of Life Questionnaire, by E.F. Juniper
MMAS	Morisky Medication Adherence Scale
MRC RSQ	Medical Research Council Respiratory Symptoms Questionnaire
ms-LWAQ	Modified Living with Asthma Questionnaire
NAEPP	National Asthma Education and Prevention Programme
NAP	National Asthma Programme
NCPE	National Centre for Pharmacoeconomics
NHLBI	National Heart Blood and Lung Institute
NHP	Nottingham Health Profile
NHS	National Health Service
NRT	Nicotine replacement therapy
NS	Not significant
NSAID	Non-steroidal anti-inflammatory (medicines)
NZ	Novolizer
OTC	Over-the-counter
P	Pearson's product moment correlation coefficient
PC_{20}	Airway responsiveness to methacholine
PCRS	Primary Care Reimbursement Service
PCS	Physical component summary
$PD_{20}FEV_1$	Dose of methacholine required to produce a 20% fall in FEV_1
PEFR	Peak expiratory flow rate
PFM	Peak flow meter
PGWB	The Psychological and General Well-Being scale
PIL	Patient information leaflet
PL	Pulvinal inhaler
pMDI	Pressurised metered dose inhaler
PMR	Patient medication record
PSI	Pharmaceutical Society of Ireland
QAM-CP	Questionnaire on asthma management for community pharmacists
QAM-GP	Questionnaire on asthma management for general practitioners
QAM-PN	Questionnaire on asthma management for practice nurses
QOL	Quality of life
R^2	Proportion of variance shared between the 2 variables

R03A	ATC code for inhaled adrenergics for obstructive airway diseases
R03B	ATC code for other inhaled drugs for obstructive airway diseases
RGHS	Rand General Health Survey
RH	Rotahaler
RT	Respiratory therapist
R_X	Prescription
S	Spearman's rank order correlation coefficient
SABA	Short-acting β-agonist
SD	Standard deviation
SE	Standard error
SEM	Standard error of measurement
SF-12	Medical Outcomes Survey short-form 12
SF-36	Medical Outcomes Survey short-form 36
SGRQ	St. George's respiratory questionnaire
SIP	Sickness impact profile
SMART	Symbicort Maintenance and Reliever Therapy
SP	Spinhaler
STAI	Speilberger state and trait anxiety inventory
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
TH	Turbohaler
WHO	World Health Organisation
WHS	World Health Survey

Summary

The Asthma Insights and Reality in Ireland survey revealed that only 8% of those surveyed had controlled asthma, as defined by evidence-based guidelines.

A detailed analysis of patients' abilities to use their inhalation devices in the real-life setting and the effects of various educational interventions on inhaler technique determined the primary objective of this project, which was to investigate the role of the community pharmacist in optimising patients' inhaler use. Prior to the design and implementation of a community pharmacist-led educational intervention it was essential to determine the opinions of the health-care professionals on the current state of asthma care in the primary care setting in Ireland, and to investigate if there were certain areas, considered important in asthma management, which were being neglected. The Asthma Society of Ireland and the Irish College of General Practitioners collaborated on the Demonstration Project, a project designed to investigate the barriers and facilitators to the implementation of best-practice asthma guidelines in primary care. The role of the pharmacist in asthma management was investigated prior to and after the commencement of the Demonstration Project. However, it became evident that community pharmacists had only limited involvement in this project and their role was poorly defined. Consequently, a community pharmacist-led educational intervention on inhaler technique was designed. It was considered essential to evaluate the impact of this intervention on all aspects of a patient's health status; therefore, prior to implementing the intervention a quality of life instrument with good psychometric properties was determined.

The nationwide surveys of health-care professionals on asthma management in the primary care setting revealed that both community pharmacists and nurses believe that asthma management among the majority of their patients is sub-optimal. However, GPs have a more optimistic and possibly unrealistic view of their patients, possibly due to infrequent consultations, poor communication or inadequate assessment methods, and this view is not in accordance with the published literature. Both pharmacists and practice nurses have a narrow perception of their roles in asthma management and the majority of asthma care appears to be considered the remit of the GP. However, the majority of GPs do not appear to be providing their patients with guideline-concordant care. In addition, there appears to limited communication and collaboration between these health-care professionals. Evaluating the role of the community pharmacist in asthma management before and after the commencement of the Demonstration Project revealed that pharmacists appear to infrequently assess and reinforce their patients' inhaler technique

and rarely counsel their patients on the importance of the peak flow meter. In addition, pharmacists appeared to have minimal involvement in the Demonstration Project, most likely due to the limited communication between them and the participating GPs and/or practice nurses and due to the lack of a clearly defined role for pharmacists in the project. The review of asthma-specific quality of life instruments ensured that the most relevant and valid instrument was used to detect any changes in quality of life in community pharmacist-led educational intervention on inhaler technique. This inhaler technique intervention revealed three issues. Firstly, time is a significant barrier to the provision of a specialised asthma service in community pharmacy, particularly in the absence of reimbursement. In addition, patient recruitment to, and persistence with, a free cognitive service is difficult, most likely due to a lack of awareness of the level of asthma control that is achievable. Secondly, a large proportion of asthma patients enrolled in the study had sub-optimal asthma control, poor quality of life, poor medication adherence, a lack of knowledge about many aspects of asthma and its treatments and poor inhaler technique. Finally, despite the time limitations and difficulties with patient recruitment, the provision of training on inhaler technique by the participating pharmacists resulted in a significant improvement in patients' inhaler technique scores at the follow-up consultations. This translated into significant improvements in asthma control and quality of life.

The pharmacoeconomic evaluation of R03A (inhaled adrenergics for obstructive airway diseases) and R03B (other inhaled drugs for obstructive airway diseases) medicines, licensed for asthma, dispensed over an identified 12 month period revealed that considerable savings in annual medicine expenditure could be achieved if beclometasone and salbutamol delivered by pressurised metered-dose inhalers were recommended as the first line treatments for asthma. In addition, the results revealed that average adherence with preventative asthma medications was poor and a substantial proportion of participants had excessive reliever medication usage, indicative of uncontrolled asthma. However, paediatric patients appeared to have significantly better adherence and significantly less excessive reliever usage than adult patients.

In conclusion, it is evident that the current system of asthma care, where each profession is operating in isolation and the burden of care is the responsibility of the GP, is not viable. To improve asthma care, each health-care professional should be familiar with the evidence-based asthma guidelines and collaborate with each other to provide the patient with team-based guideline-concordant asthma care. This project has demonstrated that community pharmacists can play a vital role in asthma care by successfully educating patients on inhaler technique resulting in improvements in their asthma control and quality of life.

1. Introduction

1.1. Introduction

The Global Strategy for Asthma Management and Prevention produced by the Global Initiative for Asthma (GINA) states that with the appropriate treatment asthma patients should live normal lives, experience minimal symptoms, have little or no need for rescue medications, experience no exacerbations and have normal lung function[1]. Inhalation is the preferred route of administration for asthma medications. As the medications are delivered directly to the site of action, they have a rapid onset of action, smaller doses are needed and they have a better safety to efficacy ratio than systemic therapies[1].

The inhalation devices for therapeutic drug delivery in asthma can be broadly divided into two categories: pressurised metered dose inhalers (pMDIs) and dry powder inhalers (DPIs). The inhalation techniques needed to ensure effective pulmonary drug deposition for both device types differ greatly. pMDIs require coordination between canister actuation and inhalation. Poor coordination results in a significant reduction in pulmonary drug deposition compared to deposition following good coordination[2,3]. In addition, lung deposition is greater when the inhalation rate to total lung capacity is slow than when a fast inspiration is used[3]. Conversely, DPIs are formulated as drug alone or mixed with an inactive excipient and so require a deep and reasonably forceful inhalation to facilitate the de-aggregation of these large particles into a respirable fraction[4]. Furthermore, patients should not exhale into DPIs after loading as the moisture could affect the de-aggregation of drug particles and/or displace the loaded dose[5].

A number of studies have investigated the existence of a relationship between incorrect inhaler technique and sub-optimal asthma control. Giraud and colleagues[6] and Coelho and colleagues[7] reported that patients with inadequate inhaler technique demonstrated significantly higher (≥ 1.5, worse) scores on the Asthma Control Questionnaire[8] than patients with adequate technique. Similarly, Melani and colleagues[9] reported that patients who performed at least one critical inhalation error were at a significantly greater risk of unscheduled emergency department (ED) visits and hospitalisations for asthma. Furthermore, Giraud and Roche[10] demonstrated that incorrect corticosteroid pMDI technique was strongly associated with asthma instability. Consequently, it is imperative that patients are using their inhalers correctly to ensure they are receiving the optimum benefits from their inhaled medications. The primary objective of this project was to investigate the role of the community pharmacist in optimising patients' inhaler use.

Consequently, it was essential to determine what is already known about adult and paediatric patients' abilities to use their inhalers correctly in real life, and whether or not educational interventions to improve inhaler technique are successful for all types of inhalation devices.

1.2. Search strategy for identifying observational and interventional studies on inhaler technique

Primary and secondary sources were used in the search for relevant articles. CENTRAL, MEDLINE and EMBASE electronic databases were searched using the following keywords 'ability', 'mishandling', 'errors', 'incorrect use' and 'technique' in conjunction with the keyword 'inhaler'. The searches were limited to articles published from 1990 to 2012 and available in the English language. The abstracts of all of the articles produced by these searches were assessed for preliminary eligibility prior to the retrieval of the full articles. Each of the full articles retrieved was subsequently considered for inclusion according to a pre-determined set of criteria outlined in 1.2.1 below. In addition, a search of secondary sources was conducted. This involved scanning all of the cited references from the articles identified in the search of electronic databases. The abstracts and full text articles considered potentially relevant were subsequently obtained and assessed for inclusion as discussed above.

1.2.1. Criteria for considering studies for inclusion

1.2.1.1. Types of studies

Observational studies were considered for inclusion only when patients were simply observed and assessed using their own inhalation devices (or a placebo of the same device) and no intervention was conducted. Studies in which patients were naive to the use of the device being studied were not included in the review of observational studies, but they were eligible for inclusion in the review of educational intervention studies. When an educational intervention was investigated, only prospective randomised studies were considered. Studies could be double, single or unblinded and of crossover or parallel group design.

1.2.1.2. Types of participants

Adult and paediatric studies were included. In the review of observational studies, only those that recruited patients with a clinical diagnosis of asthma or chronic obstructive

pulmonary disease (COPD) were eligible for inclusion. However, a diagnosis of asthma/COPD was not a prerequisite for studies on educational interventions. Studies conducted in primary care, secondary care (inpatient and ED) and residential care settings were considered. For observational studies on inhaler technique, only studies in which the patients were observed using their 'usual inhaler(s)' were included. .

1.2.1.3. Types of interventions (other than observational studies)

Studies were considered if the main objective of the study was to educate patients on the correct use of their inhalation devices.

1.2.1.4. Types of outcome measures

Studies were considered for inclusion if they included an objective measurement of inhaler technique, details of which were provided in the article. In addition, eligible studies needed to include inhaler technique checklists and scores/measurements that were differentiated according to inhaler type and an unambiguous definition of 'good'/'poor' technique (if relevant) was defined in the article.

1.3. Observational studies on inhaler technique in adults

1.3.1. Issues in study design and methodology

1.3.1.1. Characteristics of study population and study method

Thirty-seven studies[6,7,9,11-44] relating to adults were identified. However, the *characteristics of study population* varied greatly between the studies. The total number of participants included in each study ranged from 20 patients[14] to 3,811 patients[11]. The sample size is one factor that is important when considering the precision of a study[45]. A smaller study is more likely to generate less precise outcomes, often characterised by the presence of greater standard deviations[45]. Sample size and the number of study centres can affect the external validity of a study. Smaller, single centre studies may produce outcomes with reduced generalisability to a more universal population, than a larger multi-centric studies[45]. Eighteen[6,9,11,12,18-21,23,25,29,30,33,34,39-41,43,44] of the thirty-seven studies were multi-centric studies but the number of centres in each study varied from 2 - 3[20,23,25,30,33,40,44] to 575[11]. However, in many instances, little information was provided about the methods used to select these sites[12,18,20,21,23,25,30,33,34,40,41,44]. The different sites were chosen by random selection in only one study[11] and only two studies[9,29] indicated that the sites were chosen in an attempt to provide data from a wide range of geographical locations and

settings. Thus, the use of >1 setting may not have greatly increased the applicability and representativeness of many of the multi-centric studies as there was no published evidence that the settings used were geographically and demographically diverse.

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement is a series of recommendations developed to enhance the reporting of observational research[46]. It recommends that the eligibility criteria used in the sample selection process, in addition to the source and the selection procedure should be reported to facilitate the understanding of the applicability of the results[47]. Only one study[11] failed to outline the inclusion/exclusion criteria used in the sample selection, but considerable variation was observed in the inclusion/exclusion criteria employed by the authors in the remaining studies. Most authors specified that only adult patients were eligible[6,7,12-14,16,22,24,25,27,30-32,36,43,44], but some also included paediatric patients in the sample and failed to differentiate between the two groups when presenting the results[9,15,17-21,23,33,38,40-42]. Some studies limited participation to elderly patients only[26,35] and other studies failed to include any age limitation in the eligibility criteria[28,29,34,37,39]. Sizeable differences were also observed in another key criterion, the minimum period during which patients had been using the inhaler(s) under investigation prior to the study. Some studies did not make any reference to duration of inhaler use in the eligibility criteria[13,15], others included patients who were currently using/prescribed the inhaler(s) of interest[6,16-19,24-30,34-36,38,39,43], while others specified a minimum period of use that varied from ≥ 1 month to ≥ 1 year[7,9,12,14,20-23,31-33,37,40-42]. A number of studies attempted to mimic a 'real life' situation where the reinforcement of correct inhaler technique, after the initial prescription and dispensing, is often infrequent[43,48]. In these studies, participation was restricted to patients who had not received education on inhaler technique in the week[23] or month[21] preceding the study while others only permitted patients to participate if they had not received technique training from personnel in the clinic in which the study was set[13,16].

The source of the study sample was identified in most studies and was limited by a fixed available sample in the majority of cases. The sources included patients attending an appointment at a GP surgery/outpatient clinic within the specified study period[9,11,12,16,17,20,22,23,39,40,42], patients of an identified GP/clinic[7,13,15,18,21,25,29,32,33,37,44], inpatients in hospital within the identified study period[27,30,35,36], patients getting prescriptions filled at a community pharmacy within the pre-determined duration of the study[6,41,43], and patients attending the ED within the study period[24,28]. The procedures used for selecting the patient sample varied greatly. Random variation, leading to a lack of precision in the study's outcomes, can occur in a number of ways in observational studies, one of which is the method used in sample selection[45]. Selection bias may occur

as a result of the measures used in the selection of the study sample[49]. Sampling bias is an example of selection bias and it can arise when researchers select the study participants because of convenience, cost or preference instead of representativeness[50], thus limiting the reliability of the results[51]. The use of random sampling is recommended to effectively prevent such selection bias[52]. Random sampling of participants was only used in one study[26], convenience sampling was used in three studies[24,27,28], patients were recruited consecutively in six studies[6,9,11,12,19,43], all eligible patients, within the fixed available sample, were invited to participate in five studies[17,18,22,33,35] and in one study GPs chose patients who they considered to be 'willing or capable' of participating[37]. However, in the majority of studies[7,14-16,20,21,23,25,29-32,34,36,38-42,44], it is unclear whether or not all eligible patients within the pre-determined available sample were invited to participate or whether a particular sampling method was used in their selection. The lack of clarity in sample selection in the majority of studies and the absence of random sampling in all but one study indicates that sampling bias may be present in many of the studies, thus possibly reducing the reliability of the study findings[51].

Response bias is another example of selection bias that can arise when participating patients differ characteristically from those who decline participation and which can subsequently affect a study's reliability[47,49]. It is recommended that detailed and transparent information be provided on the numbers of potentially eligible participants, confirmed eligible participants, those invited to participate, those included in the study and those who completed the study in full. The provision of this information allows assessment of the representativeness of the study outcomes to the target population and the possible introduction of bias[47]. Only ten of the thirty-seven studies reviewed provided any information on participant recruitment and the level of detail provided varied greatly between the studies. Five studies[20,22,33,42,43] provided data on the numbers of patients who were invited to participate and the subsequent number who consented but only Savage and Goodyer[33] provided any details on the characteristics of both the eligible and consenting participants. Five studies[18,25,26,30,37] provided a comprehensive description of participant recruitment detailing the total number of eligible patients, those excluded, those invited and the final number of participants. Four[18,25,30,37] of the five studies also provided information on the reasons for exclusion and for declining to participate, but only Hesselink and colleagues[18] compared the characteristics of the participants and those who were excluded.

The types of inhalation devices under investigation varied greatly. The pMDI technique was assessed most frequently followed by the Turbohaler® (TH) technique; thirty-two[6,7,9,11-18,20-31,33-36,38-40,43,44] and sixteen studies[9,11-13,16,18,19,22,23,31,32,34,37,39,41,42] respectively

assessed patients' ability to use these devices correctly. The Easi-breathe® (EB) and Pulvinal® (PL) techniques were under investigation least often, both devices were each only assessed in one study[6,7]. The number of different inhalation techniques being assessed in each study varied from one device technique in thirteen studies[14,15,17,20,21,24,28,29,32,33,40,43,44] to seven techniques in two studies[16,31]. However, in studies where > 1 device technique was assessed, the proportion of observations for each device under investigation was frequently unbalanced[6,7,9,12,13,16,18,19,22,23,25-27,30,31,34,35,37-39], thus possibly reducing the precision of the studies' outcomes.

Information bias can arise due to an error in the measurement of study outcomes[53]. Interviewer or observer bias is a form of information bias that can occur from persistent discrepancies in obtaining, recording or interpreting data from participants[47,54], thus, it is important to analyse the characteristics of those evaluating the participants' inhaler technique, any training they received prior to the study and any efforts made to ensure consistency in outcome measurements. The characteristics of the assessors differed greatly from study to study. The patients' own general practitioners (GPs) conducted the assessments in three studies[11,18,39]. Physicians, medical students and/or respiratory therapists (RTs) also conducted technique assessments in three studies[26,28,38], only the RTs in the study conducted by Johnson and Robart[38] conducted assessments on patients under their usual care. Pharmacists, pharmacy student researchers or senior Doctor of Pharmacy students evaluated inhaler technique in eight studies[6,14,17,23,41-44]. Only the pharmacists in the studies conducted by both Giraud and colleagues[6] and Basheti and colleagues[41] were working in the community and thus, were likely to be familiar with and caring for some, if not all, of the patients they assessed. A nurse practitioner evaluated inhaler technique in the study conducted by Kumana and colleagues[15] and a clinical nurse specialist assessed patients in the study carried out by Abley[35]. Neither of these health-care professionals appeared to be involved in the participants' respiratory care. Lung function technicians evaluated inhaler technique in two studies[22,31]; these technicians do not usually have a cohort of patients under their care or have regular interactions with patients. Members of the investigative team, or research assistants conducted the technique assessments in a large number of studies[9,12,13,16,20,24,25,27,29,30,32,33,36,37,40] Finally, clinical research monitors conducted the assessments in one study[21], assessors who were 'not doctors or medical workers' evaluated the participants in another study[34], and in one study the assessors were only referred to as 'observers' and no further information on their characteristics was provided[19]. It is evident that in at least six studies, inhaler technique assessments were conducted by health-care professionals involved in the participants' respiratory care. Consequently, it is possible that these assessors may, consciously or subconsciously, have overestimated correct inhalation technique among

their patients[11]. The researchers themselves and/or members of their team frequently conducted the technique assessments. In cases where they were aware of the study hypothesis under investigation they may have, intentionally or otherwise, gathered data selectively, thus introducing observer bias[55]. However, despite this potential for the introduction of bias, there was no evidence of observer blinding in eleven[13,16,20,24,25,27,29,30,32,36,40] of these studies. Two studies conducted by Melani and colleagues[9,12] blinded the technique evaluators to the results of participant-completed questionnaires containing information on duration of inhaler use, perceived ease of handling, asthma control, technique education *etc.* but they were still aware of the study hypothesis. Only Savage and Goodyer[33] and Verver *et al.*[37] blinded the investigators when evaluating technique. However, they were blinded to the type of educational interventions on inhaler technique provided to the participants so the blinding is not relevant in this section.

Extensive and thorough observer training and detailed instructions can help in the reduction of observer bias[49]. Indeed, it is well documented that many health-care professionals are limited in their knowledge of inhaler technique[29,56-58], thus necessitating training prior to inhaler technique assessment. In nine of the thirty-seven studies there was no reference to any training provided to the technique evaluators[11,16,18,19,26,35,38,39,42] and in a further ten studies the authors stated that the evaluators were trained but no description of the training was provided[7,9,12,15,17,22,25,30,31,34]. However, an account of the training provided was documented in eleven studies[6,13,14,21,23,28,29,32,41,43,44]. Education on inhaler technique and assessment formed the basis of the training provided in most cases. In the remaining seven studies the technique evaluations were all conducted by the chief investigators themselves[20,24,27,33,36,37,40].

As thirty[6,7,9,11-14,16,18,20-23,25,26,28-34,36-41,43,44] of the thirty-seven studies used more than one evaluator to assess participants' inhaler technique and this assessment is subjective in its nature, methods to ensure inter-rater reliability are needed to reduce possible information bias. However, only ten studies attempted to ensure repeatability between the technique evaluators and the methods used varied. In two studies[28,44] the interviewers were supervised for the first number of patients, regular meetings both before and during the study were used in another study[12],and in one study[41] a principal investigator confirmed the assessors evaluations for a proportion of the study sample. The kappa value for inter-observer percentage agreement was calculated for all or a proportion of participants' assessments in three studies[21,32,33], and in one study[43] the assessors compared their independent evaluations of a patient sample prior to study commencement. Finally, in two

studies[13,37], the technique demonstrations were recorded and viewed repeatability or by two independent observers to ensure reliability.

Information bias can also arise when data on the study outcomes is collected using systematically different methods[54]. In the assessment of inhaler technique there are no validated technique checklists, nor is there a global consensus on what constitutes 'correct technique'. Consequently, considerable variation may be observed within a study on the number of steps included in the checklist and the definition of 'correct technique' for each device type. Due to the systematic differences in measuring inhaler technique between devices, the outcomes may be biased in favour of one device over another. Only three studies[39,41,42] that investigated inhaler technique in >1 device used inhaler technique checklists with an equal number of steps per device. All of the other nineteen studies[6,7,9,11-13,16,18,19,22,23,25-27,30,31,34,35,38] that investigated multiple inhalers, and differentiated the results according to device type, used technique checklists that differed in the number of steps under assessment and/or the number of critical errors for each inhaler type. As a result, there is an increased potential for participants to perform at least one error or at least one critical error using inhalers where a greater number of steps are included in the technique assessment and thus bias may be introduced into the study outcomes.

1.3.1.2. Outcome measures

Considerable variation was observed between studies in both the instruments used in the inhaler technique assessments and the definitions of 'correct technique'. As discussed above, thirty-two studies[6,7,9,11-18,20-31,33-36,38-40,43,44] assessed participants' inhaler technique using a pMDI. However, due to the absence of validated inhaler technique checklists the number of steps included in the studies' pMDI checklists varied from four steps[39] to twelve steps[35]. The step *remove the cap* was omitted in ten studies[11,17,20-22,27,31,36,43,44]. It was unclear if this step was included under 'adequate preparation' in one study[39]. The steps *remove the cap* and *shake the inhaler* were combined into one step in four studies[24,25,29,40] and these two steps were combined with the step *breathe out gently* in the study conducted by Lee and colleagues[34]. The eight steps common to most studies were *(1) remove cap, (2) shake inhaler, (3) breathe out gently, (4) hold the inhaler upright, (5) position the mouthpiece correctly, (6) coordinate actuation and inhalation, (7) continue inspiration after actuation,* and *(8) hold breath for 5-10 seconds*. Additional steps included *head slightly tilted/upright*[13,15,17,22,31,43,44], *only one actuation per inhalation*[9,11,12,14,15,20,21,29], and *wait 30 seconds - 1 minute before second inhalation*[14,15,17,20,24,27-29,34,35,38,44]. Twelve[6,7,9,11-13,16,18,22,23,31,34] of the thirty-two studies that evaluated pMDI technique defined

critical errors, which if committed would substantially reduce the amount of drug available for delivery to the lungs. Once again, extensive variations were observed between the studies. The number of critical errors defined in each study ranged from one[7] to eight[6]. All of the studies were in agreement that failure to coordinate pMDI actuation with inhalation was considered a critical error. However, a total of thirteen additional critical errors were identified, five of which were only considered critical errors by one study each[6,11,16].

Ten studies[7,12,13,26,27,30,35,36,38,39] included the pressurised metered-dose inhaler with spacer (pMDI+S) in the technique assessments. As with the pMDI alone, the number of steps included in the technique evaluation ranged from four[39] to sixteen[35] steps. Only one[13] of the studies used the multiple breath technique, the remainder assessed the single breath technique. Considerable variation was observed in the technique steps evaluated and the only step included in all ten studies was *shake the inhaler.* Critical errors were identified in three studies[7,12,13] (one additional study[26] listed 'major errors' but did not identify the steps that were not applicable to each device). Coelho and colleagues[7] only identified one critical error, *coordination of actuation and inhalation,* but according to the GINA guidelines[1], using a spacer with a pMDI reduces the need for coordination of actuation and inhalation, thus questioning the validity of this critical error.

Autohaler® (AH) technique was assessed in three studies[6,11,31], EB technique in one study[6] and breath-actuated inhaler (BAI) technique in general in one study[26]. The number of AH technique steps ranged from five to nine steps and the only steps common to all three studies were *(1) Raise lever to vertical position, (2) Breathe out gently before inhalation* and *(3) Hold breathe after inhalation.* The number of critical errors identified varied from two to ten errors and the only one described in all three studies was in failing to *raise the lever to the vertical position.*

TH technique was assessed in sixteen studies[9,11-13,16,18,19,22,23,31,32,34,37,39,41,42], but the number of technique steps being evaluated varied from four[39] to fourteen[32]. The seven steps common to most studies were *(1) Hold inhaler upright, (2) Twist grip forwards and backwards until a 'click' is heard', (3) Breathe out gently, (4) Place mouthpiece between lips, (5) Inhale deeply and forcefully, (6) Hold breath for 5 - 10 seconds, (7) Breathe out gently away from mouthpiece.* Seven studies[11,12,22,31,32,41,42] also included the step *exhale away from mouthpiece,* in addition to step (3). Critical errors were identified by eleven studies[9,11-13,16,18,19,22,23,31,34] and they varied in number from two[13] to six[9] but the three errors most commonly identified were *hold inhaler upright, twist grip forwards and backwards until a 'click' is heard',* and *inhale deeply and forcefully.*

Eleven investigative teams[9,11-13,19,23,25,30,34,41,42] evaluated Diskus® (DS) technique and the number of technique steps assessed ranged from six[11,34] to ten[12,30]. Five steps were common in most studies and these were *(1) Slide lever away until it clicks/load dose, (2) Breathe out gently, (3) Place mouthpiece between lips, (4) Inhale deeply and forcefully, (5) Hold breath for 5 - 10 seconds.* Seven studies[9,11-13,19,23,34] specified critical errors and the two errors identified by all but one[11] of the studies were *failure to load the dose correctly* and *failure to inspire with sufficient effort.* Five additional critical errors were also identified.

Aerolizer® (AZ) technique (± Handihaler® [HD] technique) was assessed in six studies[7,9,11,12,19,23] but two[19,23] of these studies only evaluated essential steps. The number of critical errors identified in each study varied from three[7] to six[9] and a total of nine different errors were described overall. The three critical errors most commonly included were *(1) Insert capsule, (2) Press and release the two buttons to pierce the capsule,* and *(3) Inhale deeply and forcefully.*

Rotahaler® (RH) technique was evaluated in six studies[16,18,22,31,37,39],one[18] of which combined RH and Spinhaler® (SP) technique, as they are often considered comparable. Three[16,37,39] of the seven studies used non-specific technique checklists that could be applied to any DPI. The remaining three studies[18,22,31] (two of which were led by van der Palen) identified the same three critical errors *(1) Hold inhaler upright, (2) Rotate grip until 'click' is heard'* and *(3) Inhale forcefully and deeply.*

The Diskhaler® (DH), Cyclohaler® (CY) and Inhaler Ingelheim® (II) are no longer listed on the GINA website (www.ginasthma.org) and personal communication with the relevant pharmaceutical companies revealed that they are no longer widely commercially available. Thus, these inhaler devices have been omitted from the discussion.

The primary outcome measures, employed in each of the studies to present the results, varied considerably. Nineteen studies[6,11,14,20,21,27-29,32,34-41,43,44] determined the number/percentage of patients who performed all of the inhaler technique steps correctly, according to device type, and thirteen studies[6,9,11-13,16,18,19,22,23,26,34,42] presented data on the number/percentage of patients who did not perform any critical errors, for each device. The mean technique score per device was provided in eight studies[14,17,22,24,29,32,41,44] and the mean technique score for essential technique steps only was also presented in one[22] of these studies. Twenty-four studies[6,7,9,11-16,20,22,24,25,27,28,31-38,40] provided data on the percentage of patients who performed each technique step correctly differentiated according to device type, and two[20,40] of these studies also differentiated the results

according to age range. Two additional studies[18,23] provided this information for technique steps they considered essential for pulmonary drug delivery. The percentage of patients scoring zero to the maximum score per device type was presented in five studies[17,21,37,40,44] and one study[25] provided information on standardised technique scores per device. One study[30] considered correct inhaler technique as ≥ 75% of steps performed correctly and so presented the results in this format. Hilton and colleagues[39] assessed inhaler technique using four general technique steps and inadequate technique was defined as obtaining a score of 0-2 out a maximum score of four. The mean number of errors per inhaler device were provided in two studies[36,37] and one study[16] presented data on the mean number of critical and non-critical errors. Finally, two studies[7,33] provided information on the percentage of patients with unsatisfactory/poor, adequate/fair, or good technique but only one[7] of the studies defined the three categories. The results obtained by the study participants, classified according to inhaler device type, are outlined in Table 1.1 at the end of the discussion.

1.3.1.3. Funding source

The presence of a funding source(s) and the contribution or influence of the source(s) on the study should be provided so that the reader is aware of any potential conflicts of interest that may have influenced the study design, methodology, outcomes or publication[47]. Thirteen[6,9,11,14,20,21,25,29-32,34,41] of the thirty-seven studies included in this review were funded completely or in part by a pharmaceutical company and/or one or more of the authors received honoraria from or were employed by a pharmaceutical company. However, only one[9] of these studies detailed the role of the funding source. Furthermore, additional studies or their authors may also have received financial support from pharmaceutical companies as fifteen of the remaining studies have not provided a conflict of interest statement or stated whether or not funding was provided from any source. The prevalence of conflict of interest statements has increased over the past decade. In a review of 1396 high impact journals across all scientific disciplines in 1997, Krimsky and Rothenberg[59] found that only 16% had conflict of interest policies. However, in 2008, Blum and colleagues[60] found that 89% of 256 medical journals reviewed had conflict of interest policies, but only 54% required that each author sign a conflict of interest statement. As this review includes studies published from 1990 onwards, it is possible that a proportion of the earlier studies were published in journals that did not have conflict of interest policies at the time of submission/publication. Lexchin and colleagues[61], Bekelman and colleagues[62] and more recently Sismondo[63] conducted systematic reviews on the impact of pharmaceutical industry funding on biomedical

research. All three studies concluded that studies funded by pharmaceutical industries are significantly more likely to produce outcomes favouring the industries' interests[61-63].

1.3.2. Adults' ability to use a pressurised metered-dose inhaler

Failure to shake the pMDI prior to actuation, unsuccessful coordination of inhaler actuation and inhalation, and failure to continue breathing in slowly and deeply after dose actuation have each been shown to significantly reduce pulmonary drug deposition[2,3,64]. In addition, these three steps were most frequently identified as essential steps in the reviewed studies. Furthermore, due to the variation in the number and content of pMDI technique steps included in the study checklists when assessing inhaler technique it was not feasible to perform a reasonable evaluation of patients' skill in using their pMDIs based on their ability to complete all technique steps correctly. Consequently, in order to determine patients' ability to use their pMDIs *adequately*, their capacity to perform the three aforementioned critical steps was evaluated. The percentage of patients who failed to shake their pMDI prior to use ranged from 2%[38] to 50%[35]. However, of the twenty-three studies[7,9,11-16,18,20,22-29,31,33,35,38,40] who provided data on patients' ability to perform this step correctly, fifteen [7,12-15,18,20,23-25,27-29,31,38,40] stated that ≤ 30% of patients studied performed this step incorrectly. The proportion of patients who did not coordinate inhaler actuation and inhalation ranged from 4%[15] to 71%[33]. In this instance, considerable variation was observed in the results obtained, with twelve[7,9,11,14,15,18,20,25,26,31,34,38] of the twenty-six studies stating that ≤ 30% of participants incorrectly performed this step while the remaining fourteen [6,12,13,16,21-24,27-29,33,35,40] calculated that 31%- 71% made an error on performing this step. The percentage of patients who failed to continue inhaling slowly and deeply after dose actuation ranged from 9%[31] to 51%[27]. Seventeen studies provided data on this step and fourteen[6,11-16,22,25,27-29,35,38] of these indicated that 20-40% of patients performed this step incorrectly. The remaining three studies[9,18,31] that provided data on this step reported that 9-12.5% of participating patients committed an error performing this step.

The considerable variation observed in results obtained may be explained in part by a number of factors. Firstly, five of the studies were funded completely or in part by pharmaceutical companies, all of whom manufacture DPIs or BAIs, the more expensive alternatives to the pMDI. As discussed above, research[61-63] has demonstrated that studies funded by pharmaceutical industries are significantly more likely to produce outcomes that benefit these industries. This may partly explain the large percentages of participants who failed to coordinate inhaler actuation and inspiration in four of these five studies, these were as follows: 25%[14], 25.5%[11], 28%[31], 37%[6] and 43%[29].

Seven of the studies evaluating pMDI technique and providing data on essential technique steps had small pMDI samples of 20 - 40 participants, thus possibly reducing the external validity of the results obtained[45]. Four of these studies reported large percentages of participants failing to coordinate inhaler actuation with inhalation, the results obtained were 25%[14], 52%[22], 72%[13] and 75%[35] (result for coordination and continuing to inhale after dose actuation). Conversely, three of these studies reported small percentage results of 5%[7] or 10%[18 26] for this essential step.

A number of studies investigated the existence of any determinants of or factors associated with incorrect technique. Rootmensen and colleagues[13] and Melani and colleagues (2004)[12] reported the existence of a positive correlation between incorrect inhalation technique and the absence of instruction from a health-care professional. Rootmensen and colleagues[13] observed that 31% of all participants had never received education on inhaler technique. Thus, this may be a contributory factor to their observation that 72% of participants failed to coordinate inhaler actuation and inhalation. Similarly Melani and colleagues[12] reported that 82% of pMDI users had received some form of instruction from a health-care professional at first prescription but 48% never had their technique checked after the initial prescription. They observed that 34% of participants failed to coordinate actuation and inhalation, and 40% failed to continue a slow inhalation after dose actuation.

Giraud and colleagues[6] determined that a significantly greater percentage of patients who had received previous education on inhaler technique from a health-care professional had optimal technique than those who had not received any education. They also observed that a significantly greater percentage of patients who had demonstrated their inhaler technique to the health-care professional during technique training had optimal technique than those who had observed a technique demonstration by a health-care professional but had not demonstrated technique themselves. Only 35% of all participants had demonstrated their technique to a health-care professional. The percentage of participants who failed to coordinate dose actuation with inhalation was 37%. Melani and colleagues (2011)[9] determined that patients who had received inhaler technique education had a lower risk of performing critical inhalation errors than those who had not. Furthermore, those who had their inhaler technique checked at least once at a follow-up visit had a lower risk of critical errors than those who had not. Two-thirds of all participants reported receiving inhaler technique training from a health-care professional but 35% of those never had their technique checked after the initial training.

Coelho and colleagues[7] recruited participants who had been attending the ProAR referral clinic for longer than one year. The ProAR clinic is part of the Bahia State Asthma and Allergic Rhinitis Control Program. This programme involves a multidisciplinary team dedicated to providing inhaler technique training. Coelho and colleagues[7] observed that only 5% of study participants failed to coordinate dose actuation and inhalation. Similarly, Lee and colleagues[34] recruited participants who regularly attended special asthma and allergy clinics in university hospitals and had been instructed on correct inhaler technique. They reported that only 18% of participants failed to coordinate dose actuation and inhalation. Conversely, Khassawneh and colleagues[23] reported that 67% of participants failed to coordinate actuation with inhalation. Interestingly, none of the three pulmonary clinics that the participants attended had a 'dedicated person to provide inhaler technique education'. This may have contributed to the poor technique score.

Older age was another factor that showed a positive correlation with incorrect inhaler technique in four studies[9,12,13,34]. Indeed Abley[35] investigated pMDI technique in elderly patients ≥ 70 years and reported that 75% failed to coordinate dose actuation and inhalation and failed to continue inhaling slowly after actuation. However, the study sample was very small so this study may lack external validity. Savage and Goodyer[33] reported that 57% of their study sample was > 50 years and 27% was > 65 years. Therefore, the older age of participants may have contributed to their observation that 71% of those studied failed to coordinate dose actuation and inhalation. A detailed description of patients' abilities to complete each of the inhaler technique steps is outlined in Table 1.2 at the end of the discussion.

1.3.3. Adults' ability to use a pressurised metered-dose inhaler with spacer

Only three[7,12,13] of the studies who assessed the inhaler technique of participants using a pMDI+S identified critical errors that would significantly reduce pulmonary drug deposition and considerable variation was observed in the errors that were identified. As discussed in 1.3.2 above failure to shake the pMDI prior to use significantly reduces pulmonary drug delivery[64] and this step is obviously still essential when using a spacer attachment. In addition, it is essential to correctly attach the spacer device to the pMDI mouthpiece prior to use, and to inhale slowly and deeply within seconds of actuating the inhaler, as a delay of > 5 seconds can cause a reduction of ~60% in the respirable drug fraction[65]. The percentage of patients who failed to shake the inhaler prior to use ranged from 4%[38] - 67%[35]. However, two of the studies[26,35] were conducted on elderly patients (≥ 70 years) and the mean age in another study[27] was 67.6 years. The percentages of patients who

failed to perform this step correctly in these three studies ranged from 34%-67%. As discussed in 1.3.2 above, older age is a determinant of incorrect technique. 0[26,38] - 22%[35] were unable to assemble the pMDI and spacer device, but again only the study by Abley[35] stated that > 10% made an error in performing this step. Only four studies provided data on the percentage of patients who 'inhaled slowly and deeply' and only one of these assessed patients on the time lag between inhaler actuation and inhalation, therefore the evaluation is confined to 'inhaling slowly and deeply'. The percentage of patients who performed this step incorrectly ranged from 11%[38] - 75%[12]. Considerable variation was observed between all four studies. Melani and colleagues[12] observed that 75% of participants performed this step incorrectly. As discussed above, a positive association was observed between older age and inadequate inhaler technique in this study where ~55% of the participants were ≥ 60 years. A detailed description of patients' abilities to complete each of the inhaler technique steps is outlined in Table 1.3 at the end of the discussion.

1.3.4. Adults' ability to use a breath-actuated inhaler

Only four studies [6,11,26,31] assessed patients' ability to use a BAI and as only one of these assessed the EB[6] and one[26] assessed BAIs as a group without specifying the device types it was not possible to conduct a fair evaluation on these devices. However, a detailed description of participants' abilities to perform each of the inhaler technique steps is outlined in Table 1.4 at the end of the discussion.

1.3.5. Adults' ability to use the Turbohaler®

The critical errors most commonly identified for the TH in the included studies were failure to hold the inhaler upright (tolerance ±45°), failure to rotate the grip forwards and backwards until a 'click' is heard, and failure to inhale reasonably forcefully and deeply. As the TH is a multi-dose DPI, prior to inhalation, each dose must be correctly loaded from the reservoir into a series of holes in the dosing disk by rotating the grip correctly[66]. However, if the inhaler is not held in the upright position during loading the dose will not load correctly[5]. Unlike pMDIs, DPIs do not contain a propellant, but are formulated as drug alone or mixed with an inactive excipient. In order to de-aggregate agglomerates of drug particles or particles of drug and excipient to fine particles < 5μm for pulmonary distribution the patient must inhale deeply and forcefully[67]. The percentage of patients who did not hold the inhaler upright during loading ranged from 0.6%[34] - 100%[42]. Eleven studies[9,11-13,18,22,23,31,32,34,42] provided data on this step and eight of them ranged from ~20%-30%. The remaining three[13,34,42] studies reported percentages that were

considerably lower or higher than this percentage range. Lee and colleagues[34] reported that 0.6% of participants failed to 'remove the cap and hold the device properly'. As discussed in 1.3.2, the participants in this study regular attended specialised asthma and allergy clinics and were all educated on inhaler technique, a factor that has been correlated with correct technique. In addition, this study is part funded by AstraZeneca, the pharmaceutical company that manufactures Turbohaler devices. Conversely, Rootmensen and colleagues[13] reported that 77% of participants did not hold the inhaler in the upright position during loading. The mean age of participants in this study was 61 years and 31% had never received inhaler technique education, two factors that have been correlated with incorrect technique. Basheti and colleagues[42] observed that 100% of participants in Jordan failed to keep the inhaler upright. 25% of the participants stated that they had not received any inhaler training in the past 12 months and only 30% stated that the education that they received included verbal instructions and a physical demonstration. Both of these factors may have contributed to this result.

Ten studies[9,11-13,18,22,23,31,32,34] provided data on percentages of participants who incorrectly loaded the dose and a range of 0%[22] - 24%[23] was observed. However, the study conducted by Khassawneh and colleagues[23] was the only study that reported that > 20% of participants performed this step incorrectly. As discussed in 1.3.2 the lack of dedicated training personnel to provide technique education may be a contributory factor in this instance. Nine studies[9,11,12,18,22,23,31,32,34,42] reported the proportion of participants who failed to inhale forcefully and deeply and this varied from 2%[18,31] - 33%[32], but only two studies found that > 20% of participants performed this step incorrectly. A comprehensive description of participants' abilities to use DPIs is outlined in Table 1.5 at the end of the discussion.

1.3.6. Adults' ability to use the Diskus®

The DS is also a multi-dose DPI and thus, like the TH, prior to inhalation the dose must be loaded and inhalation must be deep and reasonably forceful to de-aggregate the drug particle agglomerates. Correct dose loading by sliding the lever back completely and inhaling deeply and forcefully were the two steps most frequently identified in the relevant studies as critical to pulmonary drug deposition. The percentage of patients who failed to load the dose correctly ranged from 0%[42] - 20%[34]. Eight studies[9,11-13,23,25,34,41,42] provided data on this technique step but only one study[34] found that > 10% of patients studied performed the step incorrectly. The proportion of patients who did not inhale deeply and forcefully when assessed varied from 4%[23] - 28%[9]. Six studies provided individualised

data on this step, but only two[9,12] of them found that > 20% of patients studied failed to perform this step correctly.

1.3.7. Adults' ability to use the Aerolizer®

The AZ is a single dose capsule-based DPI, therefore a capsule must be loaded into the inhaler prior to use, then primed by piercing the capsule and, like all DPIs, a deep and reasonably forceful inhalation is needed to allow adequate dispersion of the drug agglomerates[67]. These three steps were those most frequently identified as critical by the relevant included studies. Five studies[7,9,11,12,23] provided data on the percentages of participants who incorrectly preformed at least one of the three essential steps. The percentage of participants who failed to insert a dosage capsule prior to use ranged from 0.7%[7,11] - 9%[9]. Failure to pierce the capsule by pressing the two lateral buttons was observed in 2%[12] - 14.5%[23] of instances and 5[23] - 24%[9] of patients failed to inhale deeply and forcefully.

1.3.8. Adults' ability to use the Rotahaler®/Spinhaler®

Both the RH and SP are single dose DPIs, therefore they require capsule loading while the inhaler is held vertically (tolerance of ± 45°), otherwise after opening the capsule the drug particles may be retained in the opening at the back of the inhaler. The capsule must be primed before use by rotating the barrel backwards and forwards, and like all DPIs, a deep and reasonably forceful inhalation is essential. These three steps were those most frequently identified as essential, but only two [22,31] of the six studies that assessed RH/SP technique differentiated the results according to device type. The percentage of patients who failed to hold the inhaler vertically on loading ranged from 32%[22] - 37%[31]. Failure to prime the capsule prior to inhalation was observed in 2%[31] - 4%[22] of instances and the percentage of participants who failed to inhale deeply and forcefully varied from 0.5%[18] - 10%[22].

1.4. Observational studies on inhaler technique in children

1.4.1. Issues in study design and methodology

1.4.1.1. Characteristics of study population and study method

Twelve studies[68-79] were included in this section of the review. As observed above in 1.3.1.11.the *characteristics of the study population* varied considerably between the studies. The sample size varied from 26[68] - 530[69] participants. Ten of the studies were conducted in a single site, one study[69] did not clarify whether the study was single or multi-centre and one study[70] was conducted in five sites. The method used to select the five study sites was not provided and the five sites chosen were all paediatric practices in non-urban areas of North Carolina. As discussed above, multi-centric studies can have greater generalisability than single centre studies, but the absence of geographical diversity among the sites in this study implies that this is unlikely in this case[45].

To determine the applicability of the results the inclusion criteria used to select study participants, the source of the study sample and the methods used to select the participants should be reported[47]. Considerable variation was observed in the eligibility criteria reported in the included studies. All twelve studies specified asthma as an inclusion criterion, but one study[71] specified 'physician diagnosed asthma' and another study[72] stated that asthma was diagnosed by a paediatric pulmonologist. Chan and colleagues[73] only included patients with 'persistent asthma', whereas Sleath and colleagues[70] stated that patients with mild, moderate or persistent asthma were eligible. Hagmolen of ten Have and colleagues[69] stipulated that eligible patients were those with at least two prescriptions for a short-acting β-agonist (SABA) or inhaled corticosteroids (ICS) in the year preceding the study. Furthermore, Walia and colleagues[71] only included patients who were not experiencing symptoms of an asthma exacerbation, whereas Scarfone and colleagues[74] specified that eligible patients were those experiencing an asthma exacerbation at the time of the study. For three studies the only reported inclusion criterion (other than asthma) was attendance at the specified asthma clinic for a follow-up visit[75] or as a newly referred patient[68,76]. Six studies did not specify any age range in their inclusion criteria other than using the term 'children/paediatric patients, whereas the remaining six indicated the age range of eligible patients. The age ranges specified were all different: < 5 years[77], 2-18 years[68], > 4 years[78], 6-17 years[73], 7-17 years[69] and 8-16 years[70]. Additional inclusion criteria included English-speaking children[70], children whose asthma medications were administered by their

parents/caregivers[77], children who were not under the care of a paediatrician[69], children who did not suffer from cystic fibrosis or congenital heart disease[74] *etc.*

The source of the study sample was identified in all twelve studies and in each case it was limited by a fixed available sample. The sources included patients attending an outpatient pulmonary clinic within the specified study period[71,72,75,79], patients attending a paediatric asthma compliance and technique clinic within a particular time frame[68,78], patients attending a pulmonary clinic for the first time[76,77], patients of identified general practices or general paediatric practices[69,70,73] and patients presenting at a hospital ED within the study period[74]. As discussed above, random sampling is the method recommended to prevent selection bias[52]. However, the methods used to select the study participants from the fixed available sample were not clearly specified in six studies[71-73,76,77,79]. It is possible that all the eligible patients were included in at least some of these studies but this is not stated definitively. All eligible patients were invited to participate in four studies[68-70,78], one study[75] recruited patients consecutively and another study[74] used convenience sampling.

In order to determine the applicability of the study outcomes to the target population and to assess the possible introduction of response bias each study should provide detailed information on the numbers of potentially eligible participants, confirmed eligible participants, those invited to participate, those included in the study and those who completed the study in full. However, seven studies[71-73,75-77,79] did not provide any of this information. Three studies[68,69,74] provided information on the number of potentially eligible patients, those confirmed eligible and those who consented to participate. The percentage of eligible participants who agreed to participate was provided in one study[70], the number of participants excluded due to incomplete data was provided in another study[78].

As the GINA guidelines[1] state that the recommended route of administration for inhaled medications in children ≤ six years is the pMDI+S it is unsurprising that nine[69-77] of the twelve studies investigated the participants' ability to use the pMDI+S. The pMDI used alone is evaluated in six studies[68-70,72,74,78], DPI technique is assessed in five studies[69,70,75,76,79], but in three[69,75,76] of these studies the results of DPI technique evaluations are presented as a group not differentiated according to device type. The number of device types evaluated in each study also varied. Five studies[68,71,73,77,78] only investigated one type of device, five studies[72,74-76,79] evaluated the inhaler technique of two types of device, one study[69] included three device types and one study[70] assessed four device types. However, in studies where > 1 device type was under evaluation, the

proportion of observations for each device were unbalanced in all but one study[79], thus possibly reducing the precision of these studies.

As discussed in 1.3.1.1, the characteristics of the assessors, any training that they received and any efforts made to ensure consistency must be evaluated to determine the possible existence of observer/interviewer bias, a form of information bias[47]. The characteristics of the assessors were quite varied. Nurses or nurse educators assessed inhaler technique in two studies[71,77], research assistants, 'observers', trained technicians or the investigators themselves conducted the evaluations in a number of studies[68,70,72,74,79] and RTs performed the assessments in one study[78]. In one study[73] the assessments were performed by a nurse or a pharmacist asthma educator or a case manager and in another study[69] physicians conducted the evaluations. In two studies[75,76] the assessments were conducted by two of the study authors who were consultant paediatric pulmonologists. In studies where members of the investigative team conducted the assessments and in studies where the assessors were involved in the participants' respiratory care, it is possible that, consciously or sub-consciously, the data may have been gathered selectively, thus introducing observer bias[11,55].

Extensive training can limit the occurrence of observer bias[49]. However, two studies[69,78] did not provide information about any training provided to the technique assessors and five studies[68,71,72,77,79] stated that the assessors were trained but did not provide any details of the training. In two studies[75,76] the chief investigators conducted the evaluations and in the remaining three studies[70,73,74] the assessors were trained on correct inhaler technique and assessment.

As use of observers to assess inhaler technique is subjective in nature, it is necessary to implement procedures to ensure inter-rater reliability. However, only two studies[70,74] provided any information on the procedures implemented to ensure consistency between assessors. In one[74] of these studies periodic meetings were held over the course of the study to reinforce the correct technique among the assessors. In the second study[70], recordings of children performing inhaler technique using a variety of devices with varying mistakes were provided to the assessors to score independently. They were then provided with feedback and the recordings were reviewed until concordance in scoring was achieved among all the assessors.

1.4.1.2. Outcome measures

Due to the absence of validated inhaler technique checklists considerable variation was observed between the technique checklists used to assess inhaler technique. The pMDI+S technique was assessed in nine studies and the number of technique steps in checklists used varied from three steps[75] to nine steps[73]. Four steps were common to the majority of the studies and these were: *(1) Shake the inhaler, (2) Fit the inhaler to the spacer device, (3) Put mouthpiece between teeth and close lips to form a tight seal* OR *Apply mask to patient's face covering nose and mouth with as tight a seal as possible, (4) Take ≥ 4 slow deep breaths* OR *Take a slow deep breath within 2-3 seconds of actuation and hold breath.* However, the additional technique steps included differed greatly from study to study: For example, three studies[75-77] included the step *Ensure the spacer valve is moving during inhalation,* the step *Wait at least 30 seconds before next inhalation* was included in two studies[70,72], one study[74] included the step *Ensure a minimum ration of inhalations to each actuation of 5:1,* and the step *Sit upright or stand* was included in another study[69]. Kamps and colleagues[75] only assessed essential technique steps but the first step in the checklist consisted of three steps combined *i.e.* Shake the inhaler, fit the inhaler to the spacer device and activate the inhaler. Walia and colleagues[71] also combined a number of technique steps *e.g.* the step *Fit the inhaler to the spacer device* was combined with the step *Hold the inhaler upright.* Combining two or more distinct steps into one step in the technique checklist is likely to reduce the precision of the instrument and renders it more difficult to determine exactly which step(s) patients are having most difficulty mastering. Five studies[69,71,72,75,76] identified essential technique steps, which if incorrectly performed would substantially reduce the pulmonary drug deposition. There was no essential step common to all five studies but four studies identified at least one of the following two steps as essential: *(1) Shake the inhaler, (2) Fit the inhaler to the spacer device.*

Six studies evaluated participants' ability to use the pMDI without a spacer attachment. The number of technique steps included in the inhaler checklists ranged from six steps[74] to eleven steps[69]. Five steps were common to all six studies and these were as follows: *(1) Shake the inhaler, (2) Breathe out gently, (3) Coordinate actuation and inhalation, (4) Continue inhaling slowly and deeply,* and *(5) Hold breath.* In addition, only one[74] of the six studies did not include the steps *Remove cap, Hold the inhaler upright* and *Form a tight seal around the mouthpiece* OR *Hold inhaler directly in front of the open mouth.* Additional steps incorporated in the technique checklists included *(1) Keep head slightly tilted[69], (2) Actuate pMDI once only[72], (3) Wait at least 30 seconds before next dose[70,72], (4) Ensure 1:1 ratio of inhalation to actuation[74], (5) Exhale, repeat steps as directed after 1*

minute[68,78]. Four[68,70,72,78] of the six studies combined two distinct technique steps into one step at least once in the checklist which, as discussed above, is likely to result in a less precise technique checklist. Only two studies[69,72] identified essential technique steps and the four steps common to both studies were *(1) Remove cap, (2) Shake inhaler, (3) Coordinate actuation and inhalation* and, *(4) Continue inhaling slowly and deeply.*

Five studies assessed participants' ability to use a DPI, but as only two of the studies used device specific checklists a general DPI checklist relevant to all DPIs will be discussed. The number of technique steps ranged from three steps[75] to nine steps[69]. The three steps common to all studies were: *(1) Load the dose correctly, (2) Place mouthpiece between lips and form a tight seal,* and *(3) Inhale deeply and forcefully.* Kamps and colleagues[75] only included these three essential steps in the inhaler technique checklist. A further two steps were included in the remaining four studies: *(1) Breathe out gently* and *(2) Hold breath for ~10 seconds.* The additional steps in the technique checklists included: *(1) Hold DPI in correct position during loading*[69,70,79], *(2) Keep head slightly tilted*[69,79], *(3) Close the DPI after use*[70]. Four[69,75,76,79] of the studies identified essential technique steps and the two steps identified by all four studies were *(1) Load the dose correctly* and *(2) Inhale deeply and forcefully.*

Considerable variation was observed in the primary outcome measures, employed in each of the studies to present the results. Three studies[73,78,79] determined the mean inhaler technique score and one[79] of these studies determined the mean DPI technique score for participants who only used a DPI and for those who also used a pMDI. Six studies[68,69,72,74,77] determined the number/percentage of patients who performed all of the inhaler technique steps correctly, five studies[69,71,72,75,76] established the percentage of patients who performed all the essential steps correctly and six studies[68-72,77] provided data on the percentage of patients who performed each technique step correctly. One study[73] determined the percentage of patients who obtained a mean percentage technique score of < 70% as this was considered inadequate for drug delivery and one study[77] established the percentage of patients who had difficulty accepting the face mask. The results obtained by the study participants, classified according to inhaler device type, are outlined in Table 1.6 at the end of the discussion.

1.4.1.3. Funding source

The presence of a funding source(s) and the contribution or influence of the source(s) on the study should be provided to facilitate awareness of any potential conflicts of interest that may have influenced the study design, methodology, outcomes or publication[47].

However, six studies[71,72,74-77] did not provide a conflict of interest statement or indicate whether or not any the study was supported by and funding source. Three studies[68,69,78] were funded by pharmaceutical manufacturers, two studies[70,73] were funded by sources other than the pharmaceutical industry and one study[79] declared that no conflict of interest, grant or sponsorship existed. As discussed above, the prevalence of conflict of interest statements in peer reviewed journals has increased in recent years[60]. However, as four[74-77] of the six studies without conflict of interest statements were published from 2000-2002 it is possible that a proportion of them were published in journals that did not have conflict of interest policies at the time of submission/publication.

1.4.2. Children's ability to use a pressurised metered-dose inhaler with spacer

Due to the considerable variation observed in the content of the inhaler technique checklists used to assess participants' ability to use the pMDI+S, an evaluation of participants' skill in using their pMDIs based on their ability to complete *all* technique steps correctly was not considered reasonable or viable. The two technique steps most frequently identified by the reviewed studies as essential for pulmonary drug delivery were *(1) Shake the inhaler before use* and *(2) Fit the inhaler to the spacer device correctly.* As discussed above, failure to shake the pMDI prior to use significantly reduces drug deposition in the lungs[64]. A third step considered necessary for pulmonary drug delivery, that was only identified in two[69,72] of the five studies that specified essential technique steps, is the need to inhale slowly and deeply within seconds of actuating the inhaler, as a delay of > 5 seconds can cause a reduction of ~60% in the respirable drug fraction[65]. Consequently, the evaluation of participants' ability to use the pMDI+S was based on their skills in performing these essential steps, when these data w were provided by the studies.

Seven[69-72,75-77] of the nine studies provided data on at least one of the essential steps. The percentage of participants who failed to shake the pMDI prior to use ranged from 10%[71] - 58%[70]. However, only one[70] of the studies that provided data on this step reported that > 30% of the participants failed to perform this step. 0%[69,72,77] - 4%[70,71] failed to correctly connect the pMDI to the spacer device. Kamps and colleagues[75] combined the following three steps into one step in the technique checklist: *(1) Shake the inhaler before use, (2) Attach the pMDI to the spacer device* and *(3) Activate the canister.* They observed that 20% of participants failed to perform this step correctly. Finally, the percentage of participants who failed to inhale slowly and deeply within seconds of actuating the inhaler ranged from 0%[72] - 30.5%[71]. The disparity observed in the results

may be explained in part by the sources of the population samples. Walia and colleagues[71] and Deerojanawong and colleagues[72] recruited participants from those who regularly attended a pulmonary clinic where inhaler technique was routinely evaluated and reinforced. In contrast, Sleath and colleagues[70] recruited participants from one of five general practices where it was observed that patients were infrequently asked to demonstrate inhaler technique. Kamps and colleagues[75] observed that participants who had received reinforcement of inhaler technique at least once after the initial instruction had significantly better inhaler technique scores to those whose technique was never reinforced. In addition, Chan and colleagues[73] recruited participants from a 'closed population in a medical system' that has undergone 10 years of intensive efforts to improve the delivery of asthma care to the paediatric population. They observed a mean inhaler technique score of 86% in patients using the pMDI+S only and 90% in those using the pMDI+S and a DPI. Consequently, in order to use the pMDI+S correctly paediatric patients require repeated reinforcement of correct technique after their initial training. Without repeated education, it is unlikely that many pMDI+S users will correctly perform the steps essential for pulmonary drug delivery[75,80]. Table 1.8, available at the end of the discussion, provides a detailed description of participants' abilities to perform each of the inhaler technique steps.

1.4.3. Children's ability to use a pressurised metered-dose inhaler

Only two paediatric studies identified inhaler technique steps essential to pulmonary drug delivery. However, the essential technique steps most frequently identified in the adult studies were *(1) Shake the inhaler before use, (2) Coordinate inhaler actuation and inhalation* and *(3) Continue slow and deep inhalation after actuation.* Failure to perform these essential steps correctly has been shown to significantly reduce pulmonary drug deposition[2,3,64]. Four[68-70,72] of the six studies provided data on at least two of these three essential steps. The percentage of participants who failed to shake the pMDI prior to use varied considerably. The results obtained by each of the four studies are as follows: 0%[72], 27%[68], 45%[69] and 56%[70]. Extensive variation was also observed in the percentage of participants incorrectly coordinating inhaler actuation with inhalation. The percentages reported by each of the four studies were: 16%[70], 41%[72], 50%[69] and 65%[68]. Finally, the percentages of participants who failed in continue a slow and deep inhalation after dose actuation were 35%[69], 36%[70] and 58%[68]. Foland and colleagues[68] reported the highest percentages of patients failing to coordinate actuation and inhalation and failing to continues a slow inhalation after dose actuation. It is important to note that this study had a small study sample of 26 participants so it may have questionable validity. In addition, it was funded by GlaxoSmithKline, Merck & Co. and AstraZeneca, three pharmaceutical

industries that manufacture DPIs, thus aspects of this study may have been influenced in some way. In contrast, Sleath and colleagues[70] received funding from the National Institutes of Health (*i.e.* not funded by the pharmaceutical industry) and they reported the lowest percentage of patients with poor coordination. Deerojanawong and colleagues[72] observed that a significantly greater proportion of participants > 10 years had correct pMDI technique than those ≤ 10 years. Similarly, Sleath and colleagues[70] observed that older participants were significantly more likely to perform more of the pMDI technique steps correctly than younger children were. The age range of the participants in one study was 7-17 years[69], in another study the age range was 8-16 years[70] and in another study 85% of the participants were ≤ 12 years[68]. Thus, it is possible that the poor pMDI technique performances observed may be attributed in part to younger participants who may be better suited to the pMDI+S where the need for coordinating actuation and inhalation is reduced. A detailed description of participants' abilities to perform each of the inhaler technique steps is outlined in Table 1.7 at the end of the discussion.

1.4.4. Children's ability to use dry powder inhalers

The two DPI technique steps most frequently identified by the included studies as essential for pulmonary drug deposition were *(1) Correct dose loading* and *(2) Inhale deeply and forcefully.* Four[69,70,75,76] of the five studies provided data on at least one of the two essential steps. The percentages of participants who failed to load the dose correctly were 2%[69], 24%[76] and 31%[70]. Variations were also observed in the percentages of participants who failed to inhale deeply and forcefully. The percentages reported by each of the four studies were 8%[69], 14%[75], 16%[70] and 24%[76]. It is important to note that the study conducted by Hagmolen of ten Have and colleagues[69] was funded by GlaxoSmithKline a pharmaceutical company that manufactures the DS a type of DPI and studies[61-63] have shown that trials funded by pharmaceutical industries are significantly more likely to produce outcomes favouring the industries. Alotaibi and colleagues[79] evaluated the mean DPI technique score among participants who only used a DPI device and among those who used a DPI and a pMDI. The mean technique score observed among those only using a DPI device was 86% and a score of 62% was recorded for those using a DPI and a pMDI. The difference between the two groups was statistically significant. Conversely, Chan and colleagues[73] observed that the mean pMDI technique score was not significantly different between paediatric patients who only used a pMDI and those who used a pMDI and a DPI. A detailed description of participants' abilities to perform each of the inhaler technique steps is outlined in Table 1.9 at the end of the discussion

1.5. Interventional studies on inhaler technique in adults

1.5.1. Issues in study design and methodology

1.5.1.1. Characteristics of study population

Eighteen studies[14,33,37,41,43,81-93] were included in this section, but as discussed in 1.3.1.11 above, considerable variation was observed in the *characteristics of the study population*. In comparative research, the sample size should be carefully considered to ensure that the study has sufficient statistical power or sensitivity to detect a statistically significant difference when such a difference truly exists[94,95]. Consequently, the authors should provide information on how the sample size was determined. However, only eight of the eighteen studies provided evidence of formal size calculations. One[87] of these studies stated that the sample size had been calculated prospectively but only provided retrospective calculations using the results of the study, which is considered of little merit as the confidence intervals are then used to indicate the appropriate power[96]. Five parameters are conventionally used to calculate the sample size: type I error, statistical power, expected treatment effect/minimum expected difference, estimated measurement variability, and whether the statistical analysis will be one- or two-tailed[94]. However, none of the remaining seven studies[14,33,41,43,90-92] provided information on all five of these parameters.

The eligibility criteria used in the selection of study participants should be comprehensively described to allow for the evaluation of the study's applicability and relevance to a particular population or setting[95]. All eighteen studies provided the inclusion/exclusion criteria used in participant selection, but as in 1.3.1.1 above, considerable variation was observed in the criteria employed. Ten studies included adult participants only, but of these, two studies[83,86] specified that participants had to be ≥ 40 years, one[93] deemed adults > 50 years to be eligible, one[90] included adults > 65 years and one study[91] only included 'elderly' patients. One study[81] included adult and child participants, five studies[33,37,41,84,92] recruited adolescents and adults for participation and two studies[82,87] did not specify the age range of the eligible participants. Eligible participants' inhaler experience also varied between studies. Seven studies[81-84,86,89,93] (one[93] of these studies recruited two different groups of participants) dictated that eligible patients were inexperienced in using the inhaler device under investigation but were currently using other inhalation devices. Four studies[90-93] stated that eligible participants were naive in the use of all inhalation devices, while five studies[33,37,41,43,85] included patients who currently using the test device and/or had been using the device for ≥ 1

month. In two[14,87] of the remaining three studies, participants' experiences with the devices under investigation were unclear and in the third study[88] ~30% had never before used any of the devices under evaluation.

Information on the study setting(s) should also be described in detail as this also influences the study's applicability and generalisability[95]. Three studies[82,86,92] provided no discernible information on the study setting or the setting from which the participants were recruited. Two studies[33,37] were based in the general practice setting and the patients were recruited from the practice registers, while two studies[41,43] were set in community pharmacies and the participants were recruited from those presenting in the pharmacies. Five studies were set in a hospital outpatient clinic and the participants were recruited from those attending the clinic[81,84,85,87] and from local advertising[83], and one study[89] was set in and recruited patients from the Klinik Bad Reichenhall, a specialist clinic for those with respiratory diseases or musculoskeletal problems. Three studies[14,90,91] were conducted in hospitals using hospital inpatients as participants, two of which recruited patients from acute elderly care wards[90,91]. One study[88] was set in a respiratory function laboratory and patients were referred to the laboratory from within the hospital or from a GP surgery. The final study[93] recruited patients from two separate settings, an outpatient chest clinic and a panel of health community resident people over 50 years in the North East of England.

As observed in 1.3.1.1 above, considerable variation was observed in the types of inhalation devices under investigation. The TH was the inhalation device most frequently included in the interventional studies; it was evaluated in ten studies[14,41,81,84,85,88-92]. It was followed closely by the DS[41,81,82,84,88,92,93] and the pMDI[33,43,83,85,87,88], which were investigated in seven studies and six studies respectively. Three studies each investigated the AH[87-89], DH[14,85,90] and HD[83,86,93] technique. The EB and the pMDI+S were both assessed in the same two studies[88,91]. The CH[82,88] and the EH[82,92] were also investigated in two studies each. The study conducted by Schulte and colleagues[82] was the only study that investigated CY, Jethaler® (JH), Novolizer® (NZ) and Benosid-N-inhaler® (BN) technique. Similarly, the Breezhaler (BH)[86] and RH[85] were only investigated in one study each. In addition, the number of device types under investigation in each study varied. The majority of studies compared participants' inhalation technique using two device types, but two studies[91,92] investigated three inhalation devices, one study[85] employed four device types and two studies[82 88]assessed inhalation technique using seven different inhalation devices.

1.5.1.2. Characteristics of study method

The intervention conducted should be described in detail to facilitate its replication and comparisons between studies[95]. For non-pharmacological studies, such as those employing an educational intervention, qualitative and quantitative data should be reported by the authors[97]. Qualitative data required include the provision of information on the contents of the educational session, the personnel involved in delivery, any instruments used in the session *etc*[97]. Quantitative data include the provision of information on the number and duration of each educational session, the timing of the sessions, lag period between educational session and assessment *etc*[97]. Extensive variation was observed in the reporting of both qualitative and quantitative data by the included studies. The information provided on the contents of the educational session(s) was frequently insufficiently detailed to facilitate replication. A number of studies[37,81,82,90-92] stated that the patients were instructed on the use of the device but failed to include the manner in which these instructions was provided, *e.g.* verbal instructions only, and/or use of a physical demonstration of technique. Limited information was also provided on the personnel who conducted the educational interventions; in fact, two studies[88,92] provided no information about the personnel who educated the participants on inhaler technique. In many instances[82,83,86,89,90,93], members of the investigative team provided inhaler technique education, but in all but one study[82] no information was provided on their professional qualifications or any training on inhaler technique provided to them. The instruments used in the educational sessions were identified in most studies, but in a number of studies[37,84,85,88,90,93] it was unclear whether patients were trained/assessed using placebo inhalers or those containing active ingredients. All of the included studies specified the number of educational sessions provided to each patient, but information on the duration of each session was infrequently provided. Nine studies[33,37,81-84,86,88,89] did not provide any indication of the average duration of an education session, three studies[14,87,92] stated that training continued until the patient's technique was considered correct and two studies[41,43] reported that education was repeated until technique was correct or for a maximum of three times. The remaining four studies[85,90,91,93] provided specific information on the average duration of a session provided to at least one of the patient groups in the study. Not all studies included a lag period between the provision of education and assessment but all those that did reported the length of the lag period.

Due to the complexities involved in executing non-pharmacological studies, particularly in multi-centre studies, it is recommended that the authors have a protocol for standardising the intervention across the various educational personnel and study centres[97]. A description of any standardisation procedures should be published to facilitate study

replication. All of the studies included in this section of the review provided a description of the study protocol used for the educational sessions. The educational interventions were further standardised in a number of studies by training the personnel involved in the provision of education or conducting assessments. However, a description of the education provided was only reported in six[14,37,41,43,82,91] of the nine studies who stated that the personnel had been trained. Inhaler technique checklists used for assessment were also provided in all studies to aid in the standardising of technique assessments. However, as more than one person conducted the inhaler assessments in sixteen of the eighteen studies, and this form of assessment is subjective in nature, additional standardisation protocols would be needed to ensure consistent technique evaluation across all patients. However, ten[14,81-83,85-90] of the remaining sixteen studies did not report using any protocols to ensure the standardisation of participant assessments. The procedures employed in the remaining studies varied extensively. In one study[43] the two assessors independently evaluated a pilot sample of participants to ensure consistent assessment and in another study[91] a pilot sample was assessed jointly by the two evaluators to ensure consistency. In the study conducted by Basheti and colleagues[41] one of the authors assessed the technique of half of the participants and compared the results with those obtained by the pharmacists who were conducting the assessments in the study. In two studies[37,92] the assessments were videotaped and assessed by two evaluators. In one of these studies[92], the assessments obtained from the videotapes were compared with those obtained 'live' and any disagreements were resolved by two clinicians. In the second study[37], if the two evaluators disagreed when assessing the videotape, the tape was viewed repeatedly until consensus was reached. Finally, in the study conducted by Savage and Goodyer[33], the assessments were videotaped and evaluated by one assessor. To ensure consistency a purposive sample of twelve participants, pre- and post-education, representing good and poor technique were assessed again and the level of agreement between the two sets (pre- and post-education) was evaluated.

Randomisation is the preferred method for assigning participants to treatment groups[95]. When correctly implemented it has a number of advantages over other methods of group assignment, the most important being the elimination of selection bias in the assignment of treatments[98]. Successful randomisation is dependent on two aspects: the generation of an unpredictable allocation sequence and the concealment of that sequence from the researchers recruiting and engaging study participants[99]. One of the criteria for inclusion in this review was the presence of randomisation in the study design, but only six[33,41,43,81,91,93] of the studies referred to the method used to generate the random allocation sequence and one[93] of these used a non-random alternation method. The other

five studies used a computer-generated list, computer-generated random group allocation or random number tables. However, no information was provided by any of the studies on the personnel who generated the random allocation sequence, the protocol used to implement the sequence, or any steps taken to conceal the allocation sequence from the investigators until participants were assigned to groups[95]. The lack of information on the two crucial aspects of randomisation, the generation of the random sequence and concealment, in the majority of the studies, may imply that randomisation was frequently unsuccessfully implemented. Consequently, selection bias may have been introduced into these studies[95].

Wood and colleagues[100] provided empirical evidence that lack of blinding in trials with subjective outcomes was associated with biased estimates of treatment effect. Blinding refers to concealing information about the allocated intervention from study participants, outcome assessors, caregivers or any personnel who may potentially be influenced by this information[100]. Unblinded outcome assessors or data collectors may differentially assess outcomes. Unblinded participants or healthcare providers may respond differently than usual if they are aware of their treatment assignment[100,101]. However, despite the importance of blinding as a safeguard against bias, only seven[14,33,37,41,43,83,87] of the included studies blinded any of the study personnel. Three[33,37,87] of these studies blinded the outcome assessors to the participants' treatment assignment, two studies[14,43] blinded the patients to focus of the study, one study[41] used a 'sham' intervention so personnel in the control group were unaware of their 'control' status and one study[83] blinded the patients to the fact that one of their 'take-home' inhalers contained active drug and the other was a placebo device.

In addition to the methodological issues, extensive variations were also observed in the educational interventions employed in the included studies. In one study[84], the only education provided was the provision of the device instruction leaflets. Steier and colleagues[89] trained patients on the 'optimal inhalation manoeuvre' using the Inhalation Manager, in addition to providing them with device instruction leaflets and technique demonstrations. Franks and Briggs[93] only trained their patients on the preparation of the inhaler devices not on the inhalation manoeuvres necessary. Basheti and colleagues[41] used a unique 'Show and Tell' training technique combined with novel inhaler technique reminder labels. A number of studies[14,81,82,86,91,92] used a two-stage educational intervention whereby they provided patients with the device instruction leaflets in the first stage and in the second stage the provided them with individual technique instruction. One study[87], provided one group of patients with the device instruction leaflet only and the other patient group received individual device instruction and they were provided with the

instruction leaflet to take home. Three additional studies investigated the effects of different educational interventions on their patient groups. Savage and Goodyer[33] provided one patient group with the PIL only and the other group was provided with the same information using a multimedia touchscreen computer. Van der Palen and colleagues[85] investigated three different educational methods; individual technique education, group education and the use of a technique videotape for home viewing. Bosnic-Anticevich and colleagues[43] provided one patient group with individual verbal instructions and the PIL and the second group received physical technique demonstrations in conjunction with individual verbal instructions and the PIL.

1.5.1.3. Outcome measures

The results of each study should include the flow of participants through each stage of the study[95]. The number of participants who were assessed for eligibility, randomly allocated to each group, received the specified intervention and was assessed for the primary outcome should be specified. In addition, the number of participants, if any, who were lost to follow-up or were excluded, together with the reasons should be provided[95]. If all participants are not included in the analysis flawed conclusions can be drawn and imbalanced exclusions between groups may indicate possible bias[102]. In addition, knowledge about the loss of participants to follow-up allows one to estimate the potential efficacy of the intervention in ideal circumstances[95]. In non-pharmacological studies, information should also be provided on the number of study centres and the distribution of the participants across the study centres. The generalisability and relevance of the study outcomes can be determined with this information[97]. Only four[33,37,41,43] of the included studies provided information on the number of participants assessed for study eligibility and one[41] of these studies only provided this information for the pharmacists providing inhaler technique education and not those receiving the intervention. The total number of participants who underwent randomisation was reported in all eighteen studies. In studies without a crossover element, where all patients received each inhalation device in a randomised order, the number of patients receiving each specified intervention was reported. A number of studies[81,82,84,88,89] were completed in a single day so no loss to follow-up occurred and two studies[37,93] reported that all patients completed the study. Three[41,83,85] of the remaining studies reported the numbers of participants lost to follow-up but did not provide the reason for the loss and two[87,90] further studies did not make any reference to the participants who did not complete the study but the numbers of participants included in the primary outcome analyses differed from the number of participants randomised initially. Seven studies were conducted in or recruited

participants from more than one location, but three[41,43,92] of these studies did not report the total number of participants recruited in each study centre.

As discussed in 1.3.1.2 above, there are currently no validated inhaler technique checklists, therefore considerable variation was observed among the checklists used in the included studies. The number of steps included in the TH checklists varied from five steps[90,91] to ten steps[84]. However, excluding the two studies with five step TH checklists, the following six steps were common to the majority of the remaining eight studies[14,41,81,84-86,88,89]: *(1) Hold inhaler in the upright position, (2) Twist grip forwards and backwards until a 'click' is heard, (3) Breathe out gently, (4) Put mouthpiece between lips to form a tight seal, (5) Inhale deeply and forcefully, (6) Hold breath for 5-10 seconds.* Neither of the two studies[90,91] with five-item checklists included the step *inhale deeply and forcefully,* an essential step for the de-aggregation of drug or drug/excipient agglomerates into fine particles necessary for pulmonary deposition[67], instead they checked for 'hand-breath coordination'. Only four studies[84,85,88,89] identified essential steps, which, if incorrectly performed, would substantially reduce pulmonary drug delivery. The step common to all four was *Twist grip forwards and backwards until a 'click' is heard.* Three additional steps common to at least three of the four studies were, *(1) Remove cap, (2) Hold inhaler in the upright position* and *(3) Inhale deeply and forcefully.*

DS technique was evaluated in seven studies but one study[93] only investigated preparing and loading the inhaler not the inhalation manoeuvre. In the remaining six studies and the number of checklist items ranged from five steps[81] to twelve steps[82]. Three steps were included in the checklists for all six studies and these were *(1) Slide lever until it clicks, (2) Put mouthpiece between lips to form a tight seal* and *(3) Inhale deeply and forcefully.* Three studies[82,84,88] identified essential steps but the only step common to all three was *slide lever until it clicks.* The steps *open the inhaler* and *inhale deeply and forcefully* were identified by two[82,84] of the three studies.

Six studies[33,43,83,85,87,88] investigated pMDI technique and the number of steps included in the checklists varied from six steps[88] to twelve steps[83]. Three steps were common to all six studies, these were *(1) Shake inhaler, (2) Coordinate actuation and inhalation* and *(3) Continue inhaling slowly and deeply.* However step (2) and step (3) were combined into a single step in two[33,88] of the six studies. Only two studies[85,88] identified critical errors and the one error common to both was failure to coordinate actuation with inhalation.

The EB and AH techniques were evaluated in two[88,91] and three studies[87-89] respectively. Five items were included in the EB checklist in one study and the second study had a six-

item checklist. The studies both included the following steps *(1) Priming the device, (2) Coordinate hand-breath action,* and *(3) Hold breath for 10 seconds*. However, despite the inclusion of the step *coordinating actuation and inspiration* in both studies the EB inhaler is a breath-activated device thus reducing the need for such coordination as drug delivery is activated by inspiratory flow[103]. The number of steps included in the AH checklists ranged from seven[88] to nine[87,89] steps. The three steps common to all three studies were *(1) Remove the cap, (2) Push the lever upwards,* and *(3) Put mouthpiece between lips to form a tight seal.*

The HD technique was investigated in three studies[83,86,93] but the study conducted by Franks and Briggs[93] did not investigate the inhalation manoeuvre. The remaining two studies included twelve and eighteen steps respectively in the technique checklists. The steps were common to both studies were *opening the device, inserting the capsule, piercing the capsule, the inhalation manoeuvre, repeating the inhalation to ensure the capsule was emptied and discarding the capsule.* The additional steps included in the eighteen-item checklist were frequently due to splitting one technique step into two separate steps for increased specificity.

The pMDI+S technique was investigated in two studies, both studies[88,91] used five-item checklists and four steps were common to both studies. These were *priming the device, exhaling to residual volume, coordinating inhalation and device actuation* and *holding breath after inhalation.* Two studies also evaluated EH technique and the number of technique steps used in the checklists were twelve steps[82] and eight steps[92] respectively. Seven of the eight steps identified by Ronmark and colleagues[92] were also included in the study by Schulte and colleagues[82]. Similarly, CH technique was assessed in two studies using a five-item[88] and a twelve-item[82] checklist respectively. All of the steps included in the five-item checklist were also present in the twelve-item checklist but they were frequently divided into two separate steps for greater clarity. The BN, CY, JH and NZ were all assessed in one study[82] as was the BH[86] , and the RH[85]. The results obtained by the study participants, classified according to inhaler device type, are outlined in Table 1.10 at the end of the discussion.

In addition to the absence of validated technique checklists, there were also differences in the methods used to score inhalation techniques. The most common method was to assess whether each step was correctly or incorrectly performed and assign a score of one for each correct step and a score of 0 for each incorrect step. However, Steier and colleagues[89] assigned an overall score of 0 to the technique result if an essential step was incorrectly performed. The studies conducted by Jones and colleagues[91] and Diggory and

colleagues[90] used an alternative scoring method whereby every step that was performed 'poorly' was assigned a score of 0, a 'moderately correct' step was assigned a score of 1 and a 'perfect' step was assigned a score of 2. Similarly, Ronmark and colleagues[92] assigned a 0 to any 'incorrect' step, a step 'not completely correct' was assigned a 1 and a correct step was assigned a 2. However, 'overall correct use' was considered only if no step was incorrect and no more than two steps were 'not completely correct'. Lenney and colleagues[88] used a grading system where the pre-specified technique faults determined the resultant grade. 'A' denoted good drug delivery, 'B' denoted partial drug delivery and 'C' denoted little or no drug delivery.

Extensive differences were observed in determining the results of the primary outcomes and the choice of primary outcome measures used to present the results. Firstly, the timing of the technique assessments was wide-ranging. In studies using participants inexperienced in the used of the test inhalers, four studies[81,82,84,89,92] conducted the initial assessments immediately after the provision of the device instruction leaflets, two studies[14,86] performed the initial evaluations thirty minutes after providing participants with device instruction leaflets and one[86] of these studies allowed patients to practice their technique in this thirty minute period. Five studies[83,88,90,91,93] conducted the first technique assessments immediately after the educational intervention *e.g.* verbal instructions and/or placebo demonstration. Rydman and colleagues[87] divided participants into two groups, group one were assessed initially following the provision of device instruction leaflets and group two were evaluated after receiving individual technique instructions. In studies with second/additional assessments the timing of the assessments in studies using inhaler-naive participants also showed considerable variation. Three studies[14,81,89] conducted the second assessments immediately post education and one study[82] conducted the assessments after a lag period of thirty minutes. The lag periods between the educational interventions and the second assessments in the remaining eight studies[14,83,86,87,90-93] varied from 6 hours to 8-20 weeks. Only three[90,91,93] of these studies did not provide patients with the test inhaler to use at least once daily in the lag period. In studies where the participants were experienced in using the test inhalers, the initial assessments in all of these studies were conducted prior to the provision of any additional education. The second/subsequent assessments were conducted immediately after the educational interventions in one study[33], after a lag period in three studies[37,41,85] that ranged from 2 weeks to 22 weeks, and one study[43] evaluated technique immediately after the provision of education and after lag periods of four weeks and eight weeks.

As observed in 1.3.1.2 above, the range of primary outcome measures used to present the results of the interventions was extensive. Ten studies[14,37,41,43,81,83,84,87,89,90] determined

the percentage of participants who performed all of the inhaler technique steps correctly. Eight studies[33,37,84-86,90-92] reported the percentage of patients performing each individual technique step correctly or the mean technique score for each step. The percentage technique score or mean score was calculated in eleven studies[14,41,43,81,82,84-86,89-91]. The percentage of participants with ≥ 1 critical error was determined in five studies[82,84-86,89] and the percentage technique score for essential steps only was provided in one study[85]. Franks and Briggs[93] determined the number of critical and non-critical errors and the mean time needed for each participant to complete three correct consecutive technique manoeuvres. Savage and Goodyer[33] determined the percentage of patients with 'good', 'adequate' and 'poor' technique but they did not define these technique classifications. As discussed in this section above, Lenney and colleagues[88] determined the percentage of patients who obtained a grade of 'A', 'B' or 'C' where the pre-specified technique faults determined the resultant grade.

1.5.1.4. Funding source

Authors should report the sources of funding for the study, the degree of involvement of the study sponsor and any influence they exerted over the study design, execution, analysis or reporting[95]. As discussed in detail in 1.3.1.3 above, a number of reviews have concluded that studies funded by pharmaceutical industries are significantly more likely to produce outcomes favouring the industries' interests[61-63]. Six[43,81,83,88,89,91] of the eighteen studies did not report their sources of funding, but and at least one author in three [81,83,89] of the six studies was employed by a pharmaceutical company, thus implying a possible bias in favour of that company's interests. Three studies[33,37,41] were not funded by pharmaceutical companies and one study[90] stated that the study received no funding. However, one author in the study conducted by Basheti and colleagues[41] was on the advisory boards for two pharmaceutical companies and her employer received funding and honoraria from a number of pharmaceutical companies. The remaining eight studies[14,82,84-87,92,93] were all funded, at least in part, by a pharmaceutical company who manufactured one of the inhalation devices under investigation in the study. Furthermore, at least one author in three[82,86,92] of these eight studies was employed by the funding pharmaceutical company.

1.5.2. Patients' ability to use a pressurised metered-dose inhaler following an educational intervention

In 1.3.2 above, it was possible to evaluate patients' ability to use a pMDI by assessing their ability to perform the steps considered essential for pulmonary drug delivery.

However, only one study[85] provided data on the percentage of participants correctly performing each pMDI technique step so this form of evaluation was not possible in this instance. The studies revealed that the type of educational intervention used to educate patients on pMDI technique might influence their ability to learn the correct technique. Dahl and colleagues[83] reported that all participants (both pMDI-naive and experienced) who were 'instructed and trained' on pMDI technique were all able to demonstrate correct use within three attempts. Similarly, Bosnic-Anticevich and colleagues[43] found that only 1 pMDI-experienced patient at each clinic visit could not demonstrate correct technique after written and verbal instructions and a placebo demonstration of technique. However, 24% (6/25), 25% (4/16), and 50% (3/6) of participants at visits one, two and three respectively, who were educated using written and verbal instructions only, were unable to demonstrate correct pMDI technique despite three instructions. Savage and Goodyer[33] reported that only 11% of pMDI-experienced participants who received the pMDI patient information leaflet (PIL) and no further education demonstrated an improvement in inhaler technique whereas 44% of those who were educated using a multimedia touchscreen computer to demonstrate inhaler technique demonstrated an improved inhaler technique score. However, the global technique ratings of 'poor', 'adequate' and 'good' used in this study were not defined, thus possibly limiting the applicability of these findings.

Lenney and colleagues[88] reported that, immediately following the educational intervention, 79% of patients had optimal pMDI technique. However, 'some' (exact proportion not defined) of the participants in this study were referred to the clinic due to a difficulty using their current inhalers and 55% of the participants were using a pMDI at the time of the study. Thus, it is possible that the participants included in this study were not representative of the general population of pMDI users but rather were biased towards those with established difficulty using their pMDIs.

Dahl and colleagues[83] discovered that, despite observing that all participants could use their pMDIs correctly after the educational intervention, following four weeks use 44% of all participants demonstrated ≥ 1 technique error. Conversely, van der Palen[85] and colleagues reported a pre-educational intervention mean technique score of 65% and 76% of experienced participants performed ≥ 1 critical error. An average of 22 weeks after the educational interventions (individual, group or videotaped instructions) the mean technique score was 93% and 10% of participants demonstrated ≥ 1 critical error. However, the participants were provided with their inhaler technique checklist to take home and any errors they committed were highlighted. This may have provided them with a reminder of the correct technique in the intervening weeks prior to technique assessment. Rydman and colleagues[87] reported that 62% of experienced participants

demonstrated ≥ 1 technique error prior to the educational intervention. However, 8-20 weeks after inhaler technique training 28% demonstrated ≥ 1 technique error. Bosnic-Anticevich and colleagues[43] discovered that the mean inhaler technique score prior to implementation of the educational intervention was 62.5%. Following written and verbal instructions in conjunction with placebo demonstrations the mean technique score was significantly higher than the baseline score at each subsequent visit ($p < 0.05$), but technique declined slightly between three and six months when no additional education was provided.

1.5.3. Patients' ability to use the Turbohaler® following an educational intervention

Four studies[14,81,89,92] that assessed the ability of TH-naive participants to learn the TH technique employed two different educational interventions, the provision of written inhaler technique instructions *e.g.* PIL and individual training provided by a researcher or health-care professional. In all four studies, a greater number of participants were able to demonstrate correctly the TH technique following individual training than following the provision of written technique instructions. However, van der Palen and colleagues[84] reported that 74% of participants performed all essential items correctly following the provision of the PIL.

The assessment of TH technique on inhaler naive participants, immediately following individual training provided by a researcher or health-care professional, revealed mean inhaler technique scores ranging from 81% - 95%[14,81,89-91] and 62% - 87%[14,81,88,89] of participants with optimal technique/all technique steps demonstrated correctly. As discussed in 1.5.1.3 above, Jones and colleagues[91] and Diggory and colleagues[90] used an alternative scoring method whereby each step was assigned a score of 0-2 depending on its execution. Both studies investigated naive participants' ability to learn the TH technique and immediately following the educational interventions the mean technique scores observed were 81%[91] and 87.4%[90] respectively, but caution must be exercised when interpreting these scores due to the alternative scoring method employed. Participants with TH experience were also assessed in two studies[41,85], initially prior to any education and again after a lag period. Prior to the educational intervention, the mean technique score observed by van der Palen and colleagues[85] was 69% and 61% demonstrated TH technique without any critical errors. After an average of 22 weeks following the educational intervention, the mean technique score reported was 86% and 77% of participants demonstrated TH technique without performing any critical errors. As discussed in 1.5.2, retention of correct technique may have been aided by the provision of

highlighted checklists. Basheti and colleagues[104] reported that 8.7% of participants demonstrated all TH technique steps correctly prior to any education and this rose to 85% after two educational sessions and a lag period of one month. However, a small decline in technique scores was observed between three and six months due to the absence of educational sessions in that period.

1.5.4. Patients' ability to use the Diskus® following an educational intervention

As observed in 1.5.3 above, three studies assessed inexperienced participants' abilities to learn the DS technique by first providing them with written technique instructions only and then providing them with individual DS technique training. Serra-Battles and colleagues[81] recorded a mean technique score of 70% following the provision and written instructions only, and Schulte and colleagues[82] reported a mean technique score of 87%. Following individual technique training, these mean scores increased to 93% and 96% respectively. Similarly, Ronmark and colleagues[92] reported that 43% of participants demonstrated 'overall correct use' (see *outcome measures* above) after the provision of written instructions only but this increased to 89% following two individual technique training sessions and four weeks practice with the DS. Conversely, van der Palen and colleagues[84] provided inexperienced participants with the DS PIL only and they reported that 92% demonstrated DS technique without any critical errors and the mean technique score obtained was 93%. Lenney and colleagues[88] provided DS-naive patients with individual technique education only and assessed their performance immediately afterwards. They reported that 90% of participants had optimal technique. Franks and Briggs[93] investigated inexperienced patients' abilities to prepare, load and close the DS only. Immediately following individual DS training 82.5% performed no critical errors. Basheti and colleagues[104] assessed experienced participants' ability to use the DS prior to education and found that 10% performed all the technique steps correctly. Following two educational sessions and a one-month lag period, this increased to 96% of participants.

1.5.5. Patients' ability to use the Easi-breathe®/Autohaler® following an educational intervention

Two studies assessed inexperienced participants' ability to learn the EB technique. Immediately following individual technique training Lenney and colleagues[88] reported that 91% of participants had optimal technique and Jones and colleagues[91] recorded a mean technique score of 82.5%. However, as previously discussed both of these studies assessed participants' ability to coordinate actuation and inspiration despite the fact that

the EB is a breath-activated device and so does not necessitate such coordination for optimal drug delivery[103].

Two studies investigated the effects of two different educational interventions on inexperienced participants' ability to learn the AH technique. Rydman and colleagues[87] discovered that 83% of participants performed all technique steps correctly immediately following the provision of written technique instructions (Group 1) and 96% of participants made no technique errors immediately following verbal instructions, technique demonstration and the provision of written instructions (Group 2). However, 8-20 weeks later, during which time patients were instructed to use the AH as their reliever inhaler, 82% of participants in Group 1 made no technique errors and 68% of participants in Group 2 performed all technique steps correctly. This result is contrary to findings obtained with other inhalation devices. A possible explanation may be that Group 1 patients provided with written instructions only may have used these instructions as a reminder/refresher of correct technique over the course of the lag period whereas Group 2 patients had no such reminders. Steier and colleagues[89] reported that, immediately following the provision of written instructions only 49% of participants made no technique errors, but subsequently, immediately following individual technique education 78% of participants performed all the technique steps correctly. Finally, Lenney and colleagues[88] reported that 91% of participants had optimal AH technique immediately following individual technique training.

1.5.6. Patients' ability to use the Handihaler® following an educational intervention

Dahl and colleagues[83] reported that, following individual training all inexperienced participants could demonstrate HD technique correctly within three attempts. Four weeks later, with daily HD use, 24% of participants demonstrated ≥ 1 error. Chapman and colleagues[86] found that following the provision of written instructions only with thirty minutes practice time the mean technique score obtained was 91% and 70% performed no critical errors. Seven days after the provision of individual technique training during which time patients were instructed to use the HD daily, the mean technique score was 94% and 81% performed all the essential steps correctly. As discussed in 1.5.4, Franks and Briggs[93] only evaluated participants' abilities to prepare, load and close the devices under investigation. They reported that immediately following individual technique training twenty-two critical errors were observed among forty participants. Two days later 50% of participants performed at least one critical error. However, this was a comparison study

between the DS and the HD and was funded by GlaxoSmithKline who manufacture the DS but not the HD so the results should be interpreted with caution.

1.5.7. Patients' ability to use the Clickhaler® following an educational intervention

Schulte and colleagues[82] evaluated inexperienced participants' Clickhaler (CH) technique immediately after the provision of written technique instructions and thirty minutes after providing individual technique instructions. The mean technique score following written instructions only was 88% and this rose to 93% following individual technique education. Lenney and colleagues[88] discovered that 90% of inexperienced participants had optimal CH technique immediately following individual technique training.

1.5.8. Patients' ability to use the Easyhaler® following an educational intervention

Schulte and colleagues[82] also included the Easyhaler® (EH) in the study described in 1.5.7 above. They reported that immediately after the provision of written technique instructions the mean technique score recorded was 84% and this increased to 91% following the provision of individual technique training. Ronmark and colleagues[92] reported that 45% of participants demonstrated 'overall correct use' after the provision of written instructions only and this increased to 89% following two individual technique training sessions, four weeks practice with the DS, and a two week lag period between the last education session and the technique assessments. However, issues with the scoring method used in this study must be considered and are discussed in 1.5.1.3 above.

1.5.9. Patients' ability to use a pressurised metered-dose inhaler with spacer following an educational intervention

Immediately following the provision of individual technique training Lenney and colleagues[88] reported that 87% of participants had optimal technique and Jones and colleagues[91] recorded a mean technique score of 64%. In the study by Jones and colleagues[91] this mean technique score dropped to 49% after a lag period of six hours, but after an additional five-minute training session and a further lag of 18 hours the mean technique score recorded was 60%. However, the participants in this study were all ≥ 75 years and, as discussed previously in 1.3.2 older age is associated with inadequate

technique. The scoring method discussed in 1.5.1.3 above must also be considered when evaluating this study.

1.5.10. Patients' ability to use the Breezhaler®, Benosid-N-inhaler®, Cyclohaler®, Jethaler®, Novolizer® and Rotahaler® following an educational intervention

The BN, CY, JH and NZ were all investigated by Schulte and colleagues[82] but only thirty-six participants were assessed on their ability to learn these inhalation techniques, thus it is not possible to perform a definitive evaluation a patient's ability to learn these techniques. Similarly, only one study[86] of eighty-two participants investigated patients' ability to learn the BH technique and one study[85] of fifty-one participants evaluated patients' ability to learn the RH technique. Therefore, no conclusions could be drawn on these techniques either.

Table 1.1: Results of the adult observational studies classified according to inhalation device

Study	Inhaler devices	% ≥ 1 critical error	% ≥ 1 error	Mean % technique score
Molimard *et al.*[11]	AZ (769)	12%	54%	NP
	AH (728)	11%	55%	
	DS (894)	11%	49%	
	pMDI (552)	28%	76%	
	TH (868)	32%	54%	
Melani *et al.*[12]	AZ (524)	17%	NP	NP
	DS (475)	24%		
	pMDI (866)	24%		
	pMDI+S (190)	3%		
	TH(524)	23%		
Rootmensen *et al.*[13]	CY (20)	45%	NP	NP
	DH (24)	21%		
	DS (41)	15%		
	pMDI (32)	81%		
	pMDI+S (36)	47%		
	TH (51)	18%		
Nimmo *et al.*[14]	pMDI (20)	NP	65%	83%

Study	Inhaler devices	% ≥ 1 critical error	% ≥ 1 error	Mean % technique score
Van Beerendonk *et al.*[16]	DH (94)	52%	NP	NP
	II (45)	80%		
	pMDI (56)	55%		
	RH (92)	73%		
Al-Hassan *et al.*[17]	pMDI (100)	NP	NP	36%
Hesselink *et al.*[18]	CY/II (76)	11%	NP	NP
	DH (130)	4%		
	pMDI (40)	30%		
	RH/SP (210)	37%		
	TH (102)	31%		
Weishammer *et al.*[19]	AZ (22)	9%	NP	NP
	DS (86)	27%		
	HD (32)	53%		
	TH (109)	35%		
Pinto Pereira *et al.*[20]	pMDI (331)	NP	59%	NP
Larsen *et al.*[21]	pMDI (501)	NP	78%	NP
Van der Palen *et al.*[22]	DH (27)	4%	NP	82%
	pMDI (25)	76%		65%
	RH (68)	~43%		73%
	TH (32)	~36%		70%

Study	Inhaler devices	% ≥ 1 critical error	% ≥ 1 error	Mean % technique score
Khassawneh *et al.*[23]	AZ (83)	17%	NP	NP
	DS (103)	7%		
	pMDI (193)	75%		
	TH (146)	43%		
Richards *et al.*[24]	pMDI (115)	NP	NP	56%
Melani *et al.*[9]	AZ/HD (587)	35%	NP	NP
	DS (467)	35%		
	pMDI (843)	12%		
	TH (361)	44%		
Ho *et al.*[26]	BAI (18)	28%	NP	NP
	pMDI (39)	18%		
	pMDI+S (34)	3%		
Giraud *et al.*[6]	AH (250)	NP	23%	NP
	EB (33)		18%	
	pMDI (444)		26%	
Shrestha *et al.*[28]	pMDI (125)	NP	79%	NP
Plaza *et al.*[29]	pMDI (746)	NP	91%	NP
Epstein *et al.*[32]	TH	NP	89%	78%
Verver *et al.*[37]	Undifferentiated DPIs	NP	94%	NP

Study	Inhaler devices	% ≥ 1 critical error	% ≥ 1 error	Mean % technique score
Lee *et al.*[34]	DS (145)	6%	37%	NP
	pMDI (137)	23%	63%	
	TH (78)	13%	51%	
Abley[35]	pMDI (16)	NP	81%	NP
	pMDI+S (9)		88%	
Thompson *et al.*[36]	pMDI (41)	NP	82%	NP
Johnson *et al.*[38]	pMDI (126)	NP	82%	NP
	pMDI+S (46)		24%	
Hilton *et al.*[39]	DH (26)	NP	46%	NP
	pMDI (262)		55%	
	pMDI+S (36)		42%	
	RH (62)		50%	
	TH (23)		22%	
Tan *et al.*[40]	pMDI (156)	NP	93%	NP
Basheti *et al.*[41]	DS (54)	NP	13%	66%
	TH (43)		7%	61%
Bosnic-Anticevich *et al.*[43]	pMDI	NP	94%	NP
Erickson *et al.*[44]	pMDI	NP	94%	63%
Song *et al.*[27]	pMDI	NP	95%	NP
Basheti *et al.*[42]	DS (51)	20%	NP	NP
	TH (40)	100%		

NP: Data not provided in identified study

*Table 1.2 Percentage of **adult** patients **failing to perform** each pMDI technique step correctly in each identified study*

Study	pMDI Technique Steps								
	Remove cap	Shake inhaler	Breathe out gently	Hold inhaler upright	(i) Form tight seal around mouthpiece OR (ii) Hold inhaler directly in front of open mouth*	Coordinate actuation and inhalation	Continue inhaling slowly and deeply	Hold breath	Breathe out slowly
Molimard *et al.*[11] (552)	NP	33.5%	30.4%	NP	NP	25.5%	37.2%	31%	NP
Melani *et al.*[12] (866)	0.2%	20.3%	32.5%	7.3%	(i) and (ii): 0%	33.9%	40.1%	33.8%	NP
Rootmensen *et al.*[13] (32)	0%	16%	59%	3%	(i) only: 3%	72%	31%	50%	13%
Nimmo *et al.*[14] (20)	0%	10%	15%	0%	(i) or (ii): 0%	25%	40%	25%	20%
Kumana *et al.*[15] (74)	1%	26%	NP	3%	(i) or (ii): 31%	4%	27%	70%	NP
Hesselink *et al.*[18] (40)	NP	15%	NP	NP	NP	10%	12.5%	NP	NP

Study	pMDI Technique Steps								
	Remove cap	Shake inhaler	Breathe out gently	Hold inhaler upright	(i) Form tight seal around mouthpiece OR (ii) Hold inhaler directly in front of open mouth*	Coordinate actuation and inhalation	Continue inhaling slowly and deeply	Hold breath	Breathe out slowly
Pinto Pereira *et al.*[20] (324)	NP	7%	31%	NP	NP	23%	NP	16%	11%
Coelho *et al.*[7] (38)	0%	24%	55%	0%	(ii) only: 84%	5%	NP	34%	11%
Van der Palen *et al.*[22] (25)	NP	40%	60%	0%	(i) only: 32%	52%	32%	56%	NP
Khassawneh *et al.*[23] (193)	3.1%	42.5%	NP	NP	NP	67.4%	NP	NP	NP
Richards *et al.*[24] (115)	19%		75%	0%	(i) and (ii): 16%	46%	NP	67.1%	NP
Roy *et al.*[25] (107)	16%		50%	3%	(i) only: 17%	20%	30%	41%	NP

Study	pMDI Technique Steps								
	Remove cap	Shake inhaler	Breathe out gently	Hold inhaler upright	(i) Form tight seal around mouthpiece OR (ii) Hold inhaler directly in front of open mouth*	Coordinate actuation and inhalation	Continue inhaling slowly and deeply	Hold breath	Breathe out slowly
Melani *et al.*[9] (843)	0.15%	37%	50%	9%	(i) and (ii): 0.7%	23%	10%	53%	NP
Ho *et al.*[26] (39)	7.7%	35.9%	NP	0%	NP	10.3%	NP	53.8%	NP
Giraud *et al.*[6] (443)	5.6%	NP	41.3%	13.5%	(i) only: 19.2%	36.6%	22%	47.6%	NP
Song *et al.*[27] (2P) (42)	NP	26.2%	NP	26.2%	NP	44.1%	51.2%	71.4%	NP
Shrestha *et al.*[28] (125)	3%	15%	46%	NP	NP	34%	30%	37%	NP
Tan *et al.*[40] (156)	11%		46%	NP	(i) only: 31%	42%		68%	NP
Plaza *et al.*[29] (746)	20%		42%	NP	(i) only: 12%	43%	32%	56%	NP

Study	pMDI Technique Steps								
	Remove cap	Shake inhaler	Breathe out gently	Hold inhaler upright	(i) Form tight seal around mouthpiece OR (ii) Hold inhaler directly in front of open mouth*	Coordinate actuation and inhalation	Continue inhaling slowly and deeply	Hold breath	Breathe out slowly
Johnson *et al.*[38] (126)	2%	2%	56%	5%	(ii) only:67%	10%	30%	46%	NP
Savage *et al.*[33] (100)	NP	41%	NP	NP	NP	71%	73%	NP	NP
Lee *et al.*[34] (137)	And hold inhaler upright*: 25%		72%	*	NP	18%	NP%	19%	NP
Abley[35] (16)	19%	50%	50%	6%	(i) only: 38%	75%		56%	50%
Van der Palen *et al.*[31] (~89)	NP	14%	28%	0%	(i) only 7%	28%	9%	15%	NP

NP: Data not provided in identified study; 2P: Results provided are based on each subject taking 2 puffs of the inhaler. The numbers in parentheses refer to the numbers of participants assessed on pMDI technique. Where columns are merged, the result provided in the study included both steps combined

*Table 1.3 Percentage of **adult** patients **failing to perform** each pMDI + spacer technique step correctly in each identified study*

Study	pMDI+S Technique Steps									
	Remove cover of inhaler	Shake inhaler	Fit inhaler to spacer	Breathe out gently	Hold pMDI upright	Position mouthpiece correctly	Actuate inhaler once	Take ≥ 3 slow deep breaths	Take slow deep breath in within 2-3s	Hold breath
Melani *et al.*[12] (190)	0.5%	23%	10%	47%	5%	0.5%	18%	n/a	75%	79%
Rootmensen *et al.*[13] (36)	NP	25%	3%	NP	NP	0%	25%	33%	n/a	n/a
Abley[35] (9)	33%	67%	22%	56%	22%	22%	22%	n/a	56%	78%
Song *et al.*[27] (2P) (16)	NP	34%	NP	NP	13%	NP	25%	n/a	66%	63%
Ho *et al.*[26] (34)	0%	35%	0%	NP	0%	NP	9%	n/a	3%	68%
Coelho *et al.*[7] (142)	2%	25%	8%	50%	4%	25%	NP	n/a	9%	25%
Johnson *et al.*[38] (46)	0%	4%	NP	4%	4%	NP	0%	n/a	11%	13%

2P: Results provided are based on each subject taking 2 puffs of the inhaler. The numbers in parentheses refer to the numbers of participants assessed on pMDI+S technique.

*Table 1.4 Percentage of **adult** patients **failing to perform** each breath-activated technique step correctly in each identified study*

Study	Inhaler device	BAI Technique Steps								
		Shake inhaler	Remove cap	Hold inhaler upright	Push lever up	Breathe out gently	Position mouthpiece correctly	Breathe in steadily	Keep inhaling after 'puff'/'click	Breath hold
Molimard et al.[11]	AH (728)	n/a	NP	NP	6%	22%	5%		37%	30%
Giraud et al.[6]	AH (251)	n/a	10%	19%	21%	41%	22%	45%	NP	52%
	EB (33)	NP	9%	24%	n/a	46%	21%	52%	NP	61%
Ho et al.[26]	BAIs (18)	6%	6%	6%	17%	NP	NP	6%	NP	33%
Van der Palen et al.[31]	AH (n unknown)	25%	NP	0%	0%	25%	0%	0%	50%	0%

The numbers in parentheses refer to the numbers of participants assessed on BAI technique.

*Table 1.5 Percentage of **adult** patients **failing to perform** each DPI technique step correctly in each identified study*

Study	Inhaler device	DPI Technique Steps								
		Remove cover	Position inhaler correctly[a]	Insert capsule	Load dose[b]	Breathe out gently	Position mouthpiece correctly	Inhale deeply & forcefully	Hold breath	Breathe out gently
Molimard *et al.*[11]	AZ (769)	NP	NP	1%	4%	33%	NP	NP	28%	NP
	DS (894)	NP	7%	n/a	3%	30%	NP	NP	26%	NP
	TH (868)	NP	18%	n/a	15%	30%	NP	NP	25%	NP
Melani *et al.*[12]	AZ (230)	0%	42%	NP	2%	24%	1%	12%	15%	NP
	DS (475)	2%	NP	n/a	6%	24%	2%	22%	29%	NP
	TH (524)	0.2%	28%	n/a	8%	24%	1%	17%	24%	NP
Rootmensen *et al.*[13]	DH (24)	NP	0%	n/a	21%	63%	8%	0%	58%	8%
	DS (41)	NP	NP	n/a	5%	61%	0%	10%	51%	10%
	SD (20)	NP	NP	19%	35%	70%	15%	0%	80%	10%
	TH (51)	NP	77%	n/a	14%	75%	0%	6%	38%	2%
Hesselink *et al.*[18]	DH (130)	NP	NP	n/a	3%	NP	NP	2%	NP	NP
	CY/II (76)	NP	9%	NP	1%	NP	NP	0%	NP	NP
	RH/SP (210)	NP	34%	NP	3%	NP	NP	0.5%	NP	NP
	TH (102)	NP	29%	n/a	2%	NP	NP	2%	NP	NP

Study	Inhaler device	DPI Technique Steps								
		Remove cover	Position inhaler correctly[a]	Insert capsule	Load dose[b]	Breathe out gently	Position mouthpiece correctly	Inhale deeply & forcefully	Hold breath	Breathe out gently
Van der Palen *et al.*[22]	DH (27)	NP	NP	n/a	4%	44%	4%	0%	37%	11%
	RH (68)	NP	37%	4%	0%	66%	21%	10%	54%	21%
	TH (32)	NP	31%	n/a	0%	66%	28%	6%	41%	16%
Khassawneh *et al.*[23]	AZ (83)	2%	NP	6%	15%	NP	NP	5%	NP	NP
	DS (103)	0%	NP	n/a	7%	NP	NP	4%	NP	NP
	TH (146)	1%	25%	n/a	24%	NP	NP	14%	NP	NP
Roy *et al.*[25]	Non-specified DPIs	NP	13%	n/a	6%	68%	2%	19%	NP	53%
Melani *et al.*[9]	AZ/HD (587)	0%	NP	9%	3%	19%	5%	26%	25%	19%
	DS (467)	0.65%	NP	n/a	7%	22%	5%	29%	32%	21%
	TH (361)	0%	23%	n/a	14%	14%	4%	22%	28%	11%

Study	Inhaler device	DPI Technique Steps								
		Remove cover	Position inhaler correctly[a]	Insert capsule	Load dose[b]	Breathe out gently	Position mouthpiece correctly	Inhale deeply & forcefully	Hold breath	Breathe out gently
Epstein *et al.*[32]	TH (62)	0%	29%	n/a	8%	49%	0%	31%	45%	10%
Lee *et al.*[34]	DS (145)	2%		n/a	20%	76%	NP	11%	18%	NP
	TH (78)	1%		n/a	5%	73%	NP	13%	16%	NP
Coelho *et al.*[7]	AZ (446)	0%	5%	0.7%	5%	55%	6%	6%	43%	43%
	PL (59)	2%	4%	n/a	7%	59%	14%	39%	39%	26%
Van der Palen *et al.*[31]	CY (~7)	0%	0%	0%	0%	40%	0%	0%	30%	10%
	DH(~110)	NP	NP	n/a	2%	28%	7%	9%	26%	2%
	RH (~98)	NP	32%	2%	2%	53%	4%	7%	34%	8%
	TH (~63)	NP	29%	n/a	2%	38%	2%	2%	17%	2%
Verver *et al.*[37]	DPIs not differentiated, (n = 48)	NP	10%	6%		60%	0%	10%	71%	6%

[a] *'Position inhaler correctly' refers to the upright position for AZ/HD on loading, to upright with tolerance of ±45° for TH on loading, to upright when inserting capsule for CY, PL and RH/SP, to upright for Pulvinal on loading, to horizontal position for DS on inhalation and to horizontal position for DH on piercing blister and inhalation.*

[b] *'Load dose' refers to piercing /splitting the capsule for AZ/HD, RH/SP and CY, for DS it refers to sliding the lever away until it clicks, for DH it refers to piercing the blister, for PL it refers to twisting the body of the inhaler anti-clockwise until it clicks, and for TH it refers to twisting grip forward and backward until it clicks.*

In any instances where the results for one particular technique step are presented separately as two consecutive technique steps, the average value for both steps combined is presented in the table above. If the results of two consecutive inhalations are presented separately in the study, the results of the first puff are presented in the table.

The numbers in parentheses refer to the numbers of participants assessed on the specified inhalation devices.

*Table 1.6: Results of the **paediatric** observational studies classified according to inhalation device*

Study	Inhaler devices	% ≥ 1 critical error	% ≥ 1 error	Mean % technique score
Walia *et al.*[71]	pMDI+S (213)	12%	NP	NP
Hagmolen *et al.*[69]	CY(17)	12%	DPIs : 81%	NP
	DH (157)	10%		
	DS (60)	5%		
	TH(59)	19%		
	pMDI (65)	78%	pMDI: 94%	
	pMDI+S (230)	23%	pMDI+S: 51%	
Chan *et al.*[73]	pMDI+S (117)	NP	NP	88%
Kamps *et al.*[75]	DPIs (92)	82%	NP	NP
	pMDI+S (108)	76%		
Deerojanawong *et al.*[72]	pMDI (42)	50%	74%	NP
	pMDI+S (51)	39%	53%	
Marguet *et al.*[77]	pMDI+S (94)	NP	42%	NP
Kamps *et al.*[76]	DPIs (17)	71%	NP	NP
	pMDI+S (49)	33%		
Sleath *et al.*[70]	DS (105)	NP	78%	NP
	pMDI (270)		92%	
	pMDI+S (69)		80%	
	TH (45)		84%	

Study	Inhaler devices	% ≥ 1 critical error	% ≥ 1 error	Mean % technique score
Scarfone *et al.*[74]	pMDI (73)	NP	75%	NP
	pMDI+S (135)		76%	
Foland *et al.*[68]	pMDI (26)	NP	88%	NP
Minai et al.[78]	pMDI (45)	NP	NP	55%
Alotaibi *et al.*[79]	DS±pMDI (40)	NP	NP	DS alone: 83%; DS + pMDI: 62%
	TH±pMDI (28)			TH alone: 87% TH + pMDI: 61%

The numbers in parentheses refer to the numbers of participants assessed on the specified inhalation devices.

*Table 1.7 Percentage of **paediatric** patients **failing to perform** each pMDI technique step correctly in each identified study*

Study	pMDI Technique Steps								
	Remove cap	**Shake inhaler**	**Breathe out gently**	**Hold inhaler upright**	**(i) Form tight seal around mouthpiece OR (ii) Hold inhaler directly in front of open mouth***	**Coordinate actuation and inhalation**	**Continue inhaling slowly and deeply**	**Hold breath**	**Breathe out slowly**
Hagmolen of ten Have *et al.*[69] (65)	1%	45%	70%	4%	(i) only: 4%	50%	35%	45%	14%
Deerojana wong *et al.*[72] (42)	0%		28%	0%	(i) and (ii): 0%	40.5%	NP	22%	NP
Sleath et al.[70] (270)	3%	56%	64%	16% [(i) and (ii)]		16%	36%	67%	NP
Foland et al.[68] (26)	And hold inhaler upright*: 8%	27%	73%	*	(i) and (ii): 12%	65%	58%	54%	NP

The numbers in parentheses refer to the numbers of participants assessed on the specified inhalation device.

*Table 1.8 Percentage of **paediatric** patients **failing to perform** each pMDI + spacer technique step correctly in each identified study*

Study	pMDI+S Technique Steps									
	Remove cover of inhaler	**Shake inhaler**	**Fit inhaler to spacer**	**Breathe out gently**	**Hold pMDI upright**	**Position mouthpiece correctly**	**Actuate inhaler once**	**Take ≥ 3 slow deep breaths**	**Take slow deep breath in within 2-3s**	**Hold breath**
Hagmolen of ten Have *et al.*[69] (230)	NP	28%	100%	NP	NP	99%	20%	14%	n/a	n/a
Sleath *et al.*[70] (69)	NP	NP	5%	58%	19%		10%	n/a	16%	54%
Walia *et al.*[71](138)	4%	7%	And hold pMDI upright: 3%	And position mouthpiece correctly: 4%			NP	30%	n/a	n/a
Deerojanawong *et al.*[72] (51)	NP	16%	0%	NP	0%	0%	19%	0%	n/a	n/a

The numbers in parentheses refer to the numbers of participants assessed on the specified inhalation devices.

*Table 1.9 Percentage of **paediatric** patients **failing to perform** each DPI technique step correctly in each identified study*

Study	Inhaler device	DPI Technique Steps								
		Remove cover	Position inhaler correctly[a]	Insert capsule	Load dose[b]	Breathe out gently	Position mouthpiece correctly	Inhale deeply & forcefully	Hold breath	Breathe out gently
Sleath *et al.*[70]	DS (105)	1%	NP	n/a	27%	60%	1%	11%	58%	NP
	TH (45)	36%	*	n/a	31%	And correct inhaler positioning: *71%	0%	12%	59%	NP

The numbers in parentheses refer to the numbers of participants assessed on the specified inhalation devices.

*Table 1.10: Results of the **interventional studies** classified according to inhalation device*

Study	Inhaler devices	Education	Lag period	Mean technique score (%)							% Performing all steps correctly	
Serra-Battles *et al.*[81] (169)	DS, TH	PIL	None	DS: 70%			TH: 69%				DS: 34%,	TH: 18%
		Physician education	None	DS: 93%,			TH: 90%				DS: 72%;	TH: 62%
Schulte *et al.*[82] (72)	CH, CY, DS, JH, BN, EH, NZ	PIL	None	CH: 88%	CY: 79%	DS: 87%	JH: 82%	BN: 86%	EH: 84%	NZ: 80%	NP	
		Investigator education	30 min	CH: 93%	CY: 93%	DS: 96%	JH: 93%	BN: 91%	EH: 91%	NZ: 92%	NP	
Nimmo *et al.*[14] (20)	DH, TH	PIL	30 min	DH: 68%			TH: 69%				DH: 32%	TH: 6%
		Demo & VI	None	DH: 93%			TH: 95%				DH: 68%	TH: 81%
			3 days using inhaler	DH: 88%			TH: 94%				DH: 54%	TH: 64%
Dahl *et al.*[83] (151)	HD, pMDI	Demo % VI	None	NP							HD: 60%	pMDI: 55%
			4 weeks using both inhalers	NP							HD: 76%	pMDI: 56%
Van der Palen *et al.*[84] (50)	DS, TH	PIL	None	DS: 93%			TH: 92%				DS: 50%	TH: 46%

Study	Inhaler devices	Education	Lag period	Mean technique score (%)		% Performing all steps correctly						
Chapman *et al.*[86] (82)	BH, HD	PIL & practice	None	BH: 92%	HD: 91%	NP						
		Demo & VI	7 days using inhaler	BH: 94%	HD: 94%	NP						
Rydman *et al.*[87] (68)	AH	PIL	None	NP		83%						
			8-20 wks using AH	NP		82%						
		Demo & VI	None	NP		96%						
			8-20 wks using AH with PIL	NP		68%						
	pMDI	Demo &VI	8-20 wks	NP		72%						
Lenney *et al.*[88] (100)	AH, CH, DS, EB, pMDI+S, TH	Demo &VI	None	NP		AH: 91%	CH: 90%	DS: 90%	EB: 91%	pMDI: 79%	pMDI+S: 87%	TH: 87%
Steier *et al.*[89] (200)	AH, TH	PIL	None	AH: 73%	TH: 48%	AH:49%				TH: 28%		
		Demo, VI & practice	None	AH: 92%	TH: 87%	AH: 78%				TH: 65%		

Study	Inhaler devices	Education	Lag period	Mean technique score (%)				% Performing all steps correctly	
Verver *et al.*[37] (48)	Undifferentiated DPIs (83% used RH)	Practice assistant instruction	2 weeks	NP				20%	
Van der Palen *et al.*[85] (152)	DH, pMDI, RH, TH	Demo & VI or Group training or Videotape training	Mean: 22 weeks	DH: 95%	pMDI: 93%	RH: 91%	TH: 86%	NP	
Bosnic-Anticevich *et al.* [43] (52)	pMDI	PIL % VI	None	100%				NP	
			4 weeks	~63%					
			8 weeks	~81%					
		Demo, VI & PIL	None	100%				NP	
			4 weeks	~88%					
			8 weeks	~88%					
Basheti *et al.*[41] (97)	DS, TH	Demo & VI, 'technique reminder labels'	1 month	DS: 92%		TH: 90%		NP	
			1 month	DS: 96%		TH: 93%		NP	
			1 month	DS: 100%		TH: 97%		NP	
			3 months	DS: 96%		TH: 92%		DS: 79%	TH: 50%

Study	Inhaler devices	Education	Lag period	Mean technique score (%)			% Performing all steps correctly	
Diggory *et al.*[90] (48)	DH, TH	Individual training	None	DH: 71%		TH: 87%	DH: 26%	TH: 57%
			24 hrs	DH: 54%		TH: 83%	DH: 13%	TH: 47%
Jones *et al.*[91] (102)	EB, pMDI+S, TH	PIL & VI	None	EB: 83%	pMDI+S: 64%	TH: 81%	NP	
			6 hours	EB: 72%	pMDI+S: 49%	TH: 71%		
			18 hours	EB: 75%	pMDI+S: 60%	TH: 78%		

The numbers in parentheses refer to the numbers of participants assessed on the specified inhalation devices.

1.6. Conclusion

1.6.1. Observational studies on inhaler technique

Analysis of both adult and paediatric observational studies on inhaler technique revealed that a large proportion of the studies were of questionable quality or the reporting was not sufficiently detailed to perform a critical appraisal. It is likely that many of the included studies introduced selection bias in the form of sampling bias and/or response bias. Information bias may also have occurred in various studies due to the apparently limited attempts to ensure inter-rater reliability, and the possible introduction of observer/interviewer bias. Furthermore, a large proportion of the studies were funded completely or in part by the pharmaceutical industry and this may have influenced aspects of the study design or publication of the results. The absence of validated inhaler technique checklists introduced considerable heterogeneity in both the number of technique steps assessed and the content of these steps. In addition, the definition of 'correct technique' and the outcome measures used to present the results varied greatly from study to study. Consequently, performing a balanced evaluation of participants' abilities to use their inhalers in the real life setting was challenging.

Among adult patients, pMDI technique was assessed more frequently than that of any other device and the results obtained varied considerably. However, the high percentage errors in essential steps were frequently observed in studies funded by rival pharmaceutical companies, studies on elderly participants or those > 60 years, and studies lacking external validity due to small sample sizes. Conversely, younger adult patients, those who had been educated by a health-care professional on inhaler technique and particularly those whose technique had been reinforced at least once had low instances of critical errors. Overall, it is evident from the results that at least 20-30% of adult patients have difficulty performing inhaler technique steps essential to pulmonary drug delivery irrespective of device type. There does not appear to be any one inhaler device that is superior to another with respect to a patient's ability to use it correctly given sufficient training.

The number of observational studies on inhaler technique in paediatric patients was significantly smaller than the number of available adult studies so less conclusive deductions are possible. Similarly to adults, paediatric patients require initial inhaler technique training from a health-care professional and repeated reinforcement to ensure that they can use the pMDI+S correctly. In the absence of such education, the percentage of critical errors rises significantly. It appears that older patients (> 10 years)

perform significantly fewer critical errors in pMDI technique than their younger counterparts do. Thus, pMDIs should be reserved for use in children at least older than 10 years. DPIs were frequently assessed as a group; therefore, it is not possible to determine the paediatric patients' abilities to use individual DPIs. It would appear that they are a viable alternative to the pMDI for older patients but further research is needed in this area.

1.6.2. Interventional studies on inhaler technique

A considerable number of the interventional studies had deficiencies in reporting and many of them appeared to be poorly designed, thus possibly producing biased results. It is likely that many of the studies were insufficiently powered to detect statistically significant results. Furthermore, the randomisation procedure, a crucial aspect in study design to prevent selection bias, was infrequently reported suggesting that it was not successfully implemented, at least in a proportion of studies. Blinding of participants and/or technique assessors occurred infrequently despite the fact that the assessment of inhaler technique by observers is subjective in nature and thus susceptible to the introduction of bias. In addition, few studies appeared to implement a procedure that would facilitate the standardisation of technique assessments and ensure inter-rater reliability. In addition, eleven of the eighteen included studies were funded completely or partly by the pharmaceutical industry and/or at least one of the authors was employed by the industry. Considerable heterogeneity was also observed between the studies. The studies differed in the participants' previous experiences with the inhalers under investigation, the nature of the educational interventions implemented, the content of the inhaler technique checklists used in the assessments, the scoring methods used in the technique assessments, the timing of the assessments and the outcome measures used to present the results. As a result, it was difficult to determine the benefits of educational interventions on participants' abilities to correctly perform inhaler techniques using a variety of inhalation devices.

Educational interventions on pMDI technique revealed that most, if not all, adult patients can learn the correct inhaler technique if they are provided with education that includes verbal instructions reinforced with a demonstration of correct technique. Provision of the PIL alone does not appear to be sufficient for most patients. However, patients' ability to retain the correct technique over time varied. Therefore, the majority of patients require a reinforcement of the correct technique and/or the provision of a memory aid such as a checklist with the technique errors highlighted to maintain the correct technique. Only two studies investigated patients' ability to learn the pMDI+S technique and the EB technique

and in both cases, one of these studies only included patients ≥ 75 years so further research is needed in this area.

The majority of studies evaluating the effects of educational interventions on patients' abilities to learn DPI techniques revealed that the vast majority of patients could learn the correct DPI technique. In addition, the provision of individual technique education by a trained professional appears superior to providing the patient with written instructions alone. Few studies investigated patients' retention of the correct DPI technique over time, but the limited research available shows that the correct technique is likely to decline over time (> 3 months) if not reinforced.

In conclusion, a significant proportion of inhaler users (pMDI/DPI) are performing critical technique errors that are preventing or significantly reducing pulmonary drug deposition. As a result, it likely that patients are not benefitting sufficiently from their inhaled medications and this may lead to sub-optimal asthma control. However, the vast majority of patients can learn to use all of the available inhalation devices if they are provided with verbal instructions augmented with a physical technique demonstration, provided, of course, that they have both the physical and cognitive ability to do so. To maintain the correct technique over time, inhaler technique instructions must be reinforced at regular intervals. Community pharmacists are uniquely positioned to provide technique reinforcement as they have more frequent contact with asthma patients than other health-care professionals in primary care to due to patients' need for monthly prescription refills.

1.6.3. Objectives of the research project.

Numerous observational and interventional studies on asthma patients and their healthcare professionals have been conducted to date. However, a detailed analysis of the literature revealed that the vast majority of the available studies were conducted in developed countries other than Ireland. Asthma care in Ireland differs from many countries, both in Europe and worldwide, due to the current absence of an Irish national asthma programme. In addition, the majority of Irish healthcare services are operated on a cost sharing basis with high user fees for the majority of the population, whereas the healthcare systems in much of Europe and worldwide either offer full coverage for healthcare services and/or operate cost sharing strategies with considerably lower user fees[105]. The combination of these two issues indicates that asthma patients and healthcare professionals involved in asthma care in Ireland represent two unique populations necessitating in-depth research and investigation as the available asthma studies may not always be relevant or applicable.

1.6.3.1. National asthma programmes

At present asthma care in Ireland is not provided as part of a national integrated chronic disease programme. In 2009, asthma was one of a number of chronic disease programmes established under the Health Service Executive (HSE) Quality and Clinical Care Directorate and it was included in the HSE National Service Plan 2010[106] with the aim of developing and implementing a national asthma programme. However, this programme is still under development.

Considerable research on asthma management has been conducted in Australia led by researchers such as Armour, Basheti, Bosnic-Anticevich and Saini. However, asthma care in Australia differs considerably from asthma care in Ireland. In 1999, the Australian government recognised asthma as a National Health Priority Area and provided considerable funding for the implementation of the National Asthma Strategy 1999, an integrated programme for asthma care. The goals of the National Asthma Strategy were (1) 'to reduce asthma mortality and morbidity, (2) to identify and reduce risk factors for asthma, and (3) to achieve planned and shared responsibility for asthma'[107]. Furthermore, following a review of both the National Asthma Strategy 1999 and the National Asthma Action Plan of the Department of Health and Ageing, the National Asthma Strategy 2006-2008 was developed to facilitate the continued collaboration of stakeholders and healthcare professionals to improve asthma care in Australia[108]. National public health policies have informed a number of state-level initiatives such as the Asthma Model of Care published by the Department of Health in Western Australia in 2008 and updated in

2012[109]. As a result, Australian-based studies on asthma may not be relevant to Ireland due to the considerable differences between the approaches to asthma care in the two countries.

North America was the setting for numerous studies on asthma care. However, similarly to Australia, asthma care has been the focus of a public health strategy in America since 1989, when the National Asthma Education and Prevention Program (NAEPP) was established to address asthma morbidity and mortality[110]. Indeed, goals for improving asthma care have been included in the U.S. Public Health Service 'Healthy People' reports since 2000. The 'Healthy People' reports set national health-related goals with target periods of 10 years with the aim of promoting action among public health and private sectors to meet the goals and to facilitate the provision of indicators to monitor progress[111]. The NAEPP has developed and distributed guidelines for asthma diagnosis and management and produced a number of accompanying documents for healthcare professionals and patients. In 2000 the U.S. Department of Health and Human Services published 'Action against Asthma: A Strategic Plan'[112] and the President's Task Force on Environmental Health Risks and Safety Risks to Children published 'Asthma and the Environment: A Strategy to Protect Children'[113]. These reports were developed to provide a strategy to meet the goals and objectives of the Healthy People 2010 report by prioritising key areas for investment. In addition, there are numerous government-approved asthma resources available on the Centres for Disease Control and Prevention and the National Institutes for Health websites. It is evident, therefore, that studies conducted in North America may not be applicable to Ireland.

Within Europe, significant differences also exist between the asthma care available in Ireland and that offered in both France and Finland particularly. In both of these countries, asthma has been officially recognised as a public health priority by their respective government health departments for some time. In France, a national asthma programme was initiated from 2002-2005 with five objectives that encompassed improving the quality of asthma care, improving occupational asthma care and detection, developing patient education, developing information on asthma for patients and the general public, and establishing a surveillance system on epidemiological and economic aspects of asthma[114]. A national asthma programme was undertaken in Finland from 1994 to 2004 and the primary objective of the programme was to reduce the overall burden of asthma on both patients and society. Stepwise educational sessions were organised to ensure that all healthcare professionals involved in asthma care had up-to-date knowledge on the best practice guidelines and a network of local asthma coordinators was established in each healthcare centre. In 1997, the programme was enlarged to include the Pharmacy

Programme and in 2002, the Childhood Asthma mini-Programme was launched[115]. Once again, the research studies on asthma conducted in both of these countries may not be relevant to Ireland due to the differences in the organisation and delivery of asthma care.

1.6.3.2. Healthcare systems

The healthcare system in Ireland differs significantly from many of the systems in operation in Europe and worldwide. In Ireland, to date (2013), there is no statutory insurance-based health system. The Irish healthcare system can broadly be divided into two categories; those who are issued with a medical card (Category I) and those who are not (Category II). In 2010, 36% of the Irish adult population were in possession of a medical card[116]. There are three main categories under which a person over 16 years of age and ordinarily resident in the state can qualify for a medical card: (1) means testing, where a single person/family has an income that is below a specified financial threshold, (2) undue hardship, where a person's income exceeds the specified financial threshold but the HSE deems that the financial burden of medical expenses or other exceptional circumstances would cause undue hardship, and (3) automatic, those who are automatically entitled to a medical card due to EU entitlement or under certain government schemes. From 2001-2008 all persons over 70 years of age were automatically entitled to a medical card, but from 2009 automatic entitlement was removed and means testing was applied. Medical card entitlements include free GP care, certain dental, aural and ophthalmic care, free inpatient and outpatient care in public hospitals and the supply of approved prescription medicines subject to a co-payment of €1.50 per dispensed item up to a maximum of €19.50 per month per person/family. In 2005, a new type of medical card was introduced, the GP visit card. Eligibility for this card is also means tested but the income threshold is higher than that for a full medical card. The GP visit card entitles a person to free GP care only [117].

People in Category II comprise 64% of the Irish population[116]. These people must pay the full price of each GP visit and the cost of a visit can range from €40-€65[118]. Individuals in Category II are entitled to public hospital care subject to statutory charges of €75 per night up to maximum of €750 per year for inpatient care and €100 fee for all self-referred outpatient procedures including attendance at the ED. Everyone in Category II is eligible for a Drug Payment Scheme (DPS) card. This card ensures that an individual/family has to pay a maximum of €144 a month for approved prescribed drugs. The Long Term Illness (LTI Scheme and the High-Tech Scheme are two additional schemes which provide public cover for medications/appliances related to specified long-term illnesses (excluding asthma) and high-technology medicines respectively.

A project funded by the European Commission 'HealthBASKET - Health Benefits and Service Costs across Europe' identifies 'benefit baskets' for a range of European countries[119]. This 'benefit basket' framework provides a useful means for comparing Ireland's healthcare system with the healthcare systems in a selection of European countries (UK, France, Germany, Sweden and Denmark), Canada and Australia. The 'benefit basket' is characterised by three dimensions[120]: (1) 'breadth': the extent of the covered population, (2) 'depth': the number and type of services covered, and (3) 'height': the extent to which the costs of the services are covered. Services or goods that necessitate a copayment of 100% are not considered part of the 'benefit basket'[120]. This comparison will focus on the 'breath' and 'height' of the healthcare systems' primary care and prescription medicine coverage as these are the areas most relevant to this research project. GP care is free at the point of use for everyone with no copayments in the UK, Canada, and Denmark[121-123]. In Australia, the majority of GP services are free if the GP is prepared to bulk-bill the government health insurance scheme 'Medicare Australia'. Alternatively the GP can charge the patient a higher fee and the patient can claim an 85% rebate on the fee from 'Medicare Australia'[124]. In France, the system of reimbursement is complex and there is variation in the degree of reimbursement. For the average person, he/she must pay for the GP visit at the point of care (this includes a €1 non-reimbursable copayment) and then claim reimbursement from the national health insurance fund. The reimbursement rate is 70% for patients who attend the GP with whom he/she is registered. However, there are two relevant types of exemption where the patient does not have to make the initial direct GP payment: (1) exemption linked to health status where the patient suffers from one of 30 specified long-term illnesses, (2) exemption linked to the patient *e.g.* disabled children, pensioners *etc.* In addition, complementary coverage of private health insurance is offered to all persons below a specified income threshold, thus exempting them from copayments[125]. In Germany, patients must pay a copayment of €10 for the first physician's visit per quarter and when other physicians are seen within the same quarter without referral. There are a number of exemptions to copayments: children under 18 years, pregnant women, once more than 2% of the gross household income per annum has been spent on copayments or 1% of the gross household income for a person with a serious chronic illness (defined)[126]. In Sweden, there is direct out-of-pocket charge of €11-€22 for attending a GP. The charge is set by the county council. However, the national ceiling for out-of-pocket outpatient charges is set at €122 for a 12-month period. Children under 20 years of age are exempt from out-of-pocket charges in most county councils[127].

In England, all prescribed medicines included in the National Health Service (NHS) formulary, recommended by the National Institute for Health and Care Excellence, are

subject to a flat fee per item of £7.20, payable by the patient, irrespective of the number of items or the cost of the prescription. However, there are widespread exemptions and, as a result, ~50% of the population are exempt from charges. In addition, patients who require a large number of prescription items can buy 3 month or 12 month prescription pre-payment certificates, which for a fixed cost of £29.10 (3 month) or £104 (12 month) allow one to obtain an unlimited number of items without further payment within that fixed period[121]. This prescription fee was abolished in Scotland in 2011 and in Wales in 2007, so there is no charge for obtaining any prescribed medicine, included in the NHS Drug Tariff (excluding those in section XVIIIA, which are not reimbursable) in these countries[128,129]. In Sweden, the patient has to pay the full cost for prescribed drugs up to €122. Once this threshold has been reached the subsidy increases up to 100%. The maximum copayment for prescription drugs in a 12-month period is €244. Patients under 20 years are exempt from prescription copayments in most county councils[127]. In Australia[124], prescription medicines are subsidised under the Pharmaceutical Benefits Scheme for general beneficiaries (general public) and concessional beneficiaries (pensioners or those with other entitlement cards). General beneficiaries pay a copayment of AUS$36.10 (~€25) and concessional beneficiaries pay a copayment of AUS$5.90 (~€4) per prescription. However, on reaching a defined threshold for patient/family, general beneficiaries pay the concessional rate for further prescriptions and concessional beneficiaries receive further prescriptions free of charge. The 2013 thresholds for general beneficiaries and concessional beneficiaries were AUS$1390.60 (~€970) and AUS$354 (~€245) respectively. In Canada, the cost of prescription drugs to the patient is determined by provincial and territorial drug plans, which vary in terms of breadth and depth of coverage, but most frequently provide cover for elderly people, those with some specified chronic illnesses and residents on social assistance[122]. In France, prescription medicines are graded according to their therapeutic value and the seriousness of the condition and this determines the degree of reimbursement that the patient can claim from the national health insurance. Medicines are divided into three grades that are eligible for different levels of reimbursement: (1) major or considerable value= 65% reimbursement, (2) moderate value = 35% reimbursement, (3) low value but justifying reimbursement = 15% reimbursement. The majority of prescription medicines are reimbursed at the 65% rate[125]. In Germany, patients must pay a copayment of 10% on prescription medicines with a minimum payment of €5 per prescription and a maximum payment of €10. In addition, they must pay a copayment of the difference between the price of the drug and the reference drug price where applicable, but few drugs now exceed the reference price[126]. In Denmark, out-of pocket payments and reimbursement depends on an individual's prescription medication costs in a year. If a person's prescription medicines cost does not exceed €116 he/she is not eligible for

reimbursement. For medication costs of €116-189, patients receive a refund of 50%, for costs of €189-408 they receive a refund of 75% and patients whose drug costs exceed €408 in a year receive a refund of 85% of the cost. Children under 18 years receive a refund of 60% of their medication costs up to €189, 75% of their medication costs up to €408 and 85% of their costs thereafter. Chronically ill patients with permanent or high medicine utilisation levels can apply for 100% reimbursement for any yearly medication costs exceeding €477. Pensioners and those on low income can apply for financial assistance.

It is evident that the breadth and height of the Irish healthcare system is distinctly different from each of the healthcare systems discussed above. For the majority of the Irish population, GP care is outside the 'benefit basket' as a GP visit necessitates a 100% copayment. In contrast, the breadth of public coverage for GP care in the countries discussed above extends to the entire population and GP care is either free at the point of use, subject to a small charge (with ceiling limitations), or eligible for significant reimbursement. Comparing the cost of prescription medicines to the patient between countries is more complex, but once again, the majority of the Irish population pay considerably more than most, if not all, of the countries discussed above. The maximum expenditure on prescription medicines per year for the average Irish adult is €1728 (DPS). In contrast, prescription medicines are free in Scotland and Wales, the maximum yearly expenditure in England is £104 and €244 in Sweden. In Denmark and France patients receive considerable reimbursements on their drug costs and these range from 60%-85%. In Germany, the maximum copayment on a prescription is €10. Prescription costs in Canada are unclear and vary according to province and territory. Australia appears to be the only country in which the drug costs to the patient approach those paid by Irish patients and even then, once the average person has paid ~€970 over a 12 month period for the medicines, they pay a reduced fee of ~€4 for all remaining prescriptions in that year. Consequently, it is apparent that the majority of the Irish population pay significantly more for GP care and prescription medicines than any of the countries outlined above.

The fact that the majority of the Irish population must pay 100% of their GP fees has considerable influences on patient behaviour within the healthcare system. The 'Eurobarameter on Health and Long-term Care in the European Union' (EU), conducted in the twenty-seven EU member states in 2007, revealed that an EU average of 11% found the services of family doctors to be 'not (very) affordable'. However, the Irish average was considerably higher at 33%, the fourth highest among all twenty-seven countries[130]. Nolan and Smith[131] investigated GP utilisation among patients with differential GP coverage. They discovered that medical card holders were significantly more likely to

attend their GP at least once per year than those without a medical card, controlling for a range of demographic, socio-economic and health factors. O'Reilly and colleagues[132] investigated the effects of the GP consultation fee on the health-seeking behaviour in Ireland and Northern Ireland (in Northern Ireland, GP consultations are free at the point of use). They discovered that only 1.8% of patients in Northern Ireland had a medical problem but did not attend a GP in the previous year compared to 18.9% of patients in Ireland (~4% of patients with a medical card and 26% of patients without a medical card).

1.6.3.3. Research project

This research project was prompted by the proposed Demonstration Project, a collaborative project between the Asthma Society of Ireland (ASI) and the Irish College of General Practitioners (ICGP), designed to investigate the barriers and facilitators to the implementation of best practice asthma guidelines in primary care. A detailed analysis of patients' abilities to use their inhalation devices in the real-life setting and the effects of various educational interventions on inhaler technique determined the primary objective of this project, which was to investigate the role of the community pharmacist in optimising patients' inhaler use. However, prior to the design and implementation of any educational intervention it was essential to investigate the opinions of the healthcare professionals on the current state of asthma care in the primary care setting in Ireland. The Demonstration Project was initiated in October 2009. It was a coordinated approach between GPs and practice nurses, and community pharmacists had a supporting role. The intention was to interface with the Demonstration Project, gathering appropriate baseline data and monitoring these parameters longitudinally, in order to evaluate the impact of the project on asthma management in the community setting. In addition, the role of the pharmacist in asthma management before and after the initiation of the project was investigated. However, it became evident that community pharmacists had only limited involvement in this project and their role was poorly defined. Consequently, a community pharmacist-led educational intervention on inhaler technique was designed. It was considered essential to evaluate the impact of this intervention on all aspects of a patient's health status; therefore, prior to implementing the intervention it was necessary to determine the most appropriate quality of life instrument with good psychometric properties. Finally, through the detailed analysis of data on prescription dispensings of R03A and R03B medicines for a 12-month period, the total quantities and costs of all inhaled medications licensed for asthma were investigated. R is the ATC code for respiratory drugs, R03 is the code for obstructive airways diseases drugs, R03A is the code for 'adrenergics, inhalants' and R03B is the code for 'other drugs or obstructive airways diseases, inhalants'. The data were analysed to investigate what changes, if any, could be made to reduce annual medicine expenditure. In addition, the information obtained was used to determine

patients' mean adherence to preventative asthma medication and to investigate the prevalence of excessive reliever medication usage. In summary, the objectives of this research project are:

1) *To determine the opinions of health-care professionals on the current state of asthma care in the primary care setting in Ireland (Chapter 2).*
2) *To evaluate the role of community pharmacists in asthma management before and after the commencement of the Demonstration Project (Chapter 3).*
3) *To review the available asthma-specific quality of life instruments and determine the most appropriate instrument for use in a community pharmacy-based intervention (Chapter 4).*
4) *To design, implement and evaluate a community pharmacy-based educational intervention on inhaler technique (Chapter 5).*
5) *To conduct a pharmacoeconomic evaluation of R03A and R03B medicines licensed for asthma and to determine the level of adherence to these medications (Chapter 6).*

2. Survey of health-care professionals on asthma care in the primary care setting

2.1. Introduction

The first questionnaire developed was the 'Questionnaire on Asthma Management for Community Pharmacists' (QAM-CP) and it was developed for a number of reasons: Firstly, to determine the opinions of community pharmacists about the current level of asthma management among their asthma patients in terms of inhalation technique, asthma control, medication compliance and overall understanding of the disease. In addition, items were included to explore the level of counselling that pharmacists carry out regularly on their asthma patients and to investigate if there are certain areas, considered important in asthma management, which are being neglected. As patient counselling is considered so important in asthma management[1], questions were also included to examine the factors that influence pharmacists 'ability to counsel their patients. In order to obtain the maximum benefit from treatment in the primary care setting it is essential that there are appropriate communication links between the health-care professionals to ensure continuity of care for the patient. Therefore, one section of the QAM-CP was dedicated to investigating the current state of communication between pharmacists and both GPs and practice nurses in the community setting.

As discussed in 1.6.3.1 and 1.6.3.2, asthma care in Ireland is not delivered as part of a national integrated programme and so pharmacists' professional role in asthma management is not explicitly defined. In addition, the presence of considerable GP fees of €45-€60 per patient visit[118] have been shown to considerably reduce the frequency with which non-medical card patients attend their GP[131]. In contrast, consultations with a pharmacist are free and no appointment is required. As a result, it is likely that for at least a proportion of asthma patients in Ireland, the pharmacist is the healthcare professional with whom they have most contact. Consequently, the views of the pharmacists on the asthma management of their patients and their asthma interventions with their patients were considered imperative when determining the current state of asthma care in the primary care setting in Ireland.

The final section of the QAM-CP was dedicated to a proposed nationwide asthma programme. From October 2009 - August 2010 the ASI in collaboration with the ICGP designed and implemented the Demonstration Project, a pilot programme designed to investigate the barriers and facilitators to the implementation of a national asthma

programme. Items were included to determine pharmacists' opinions about the proposed project and to investigate any potential barriers and desirable features related to its implementation. It was hoped that these opinions would be considered if/when a nationwide programme on asthma management was developed.

Following the successful development and administration of the QAM-CP, two additional questionnaires were developed: the 'Questionnaire on Asthma Management for General Practitioners' (QAM-GP) and the 'Questionnaire on Asthma Management for Practice Nurses' (QAM-PN). These questionnaires were developed for similar reasons; primarily to explore the views of GPs and practice nurses about the current state of asthma management among their patients, and to investigate the frequency and content of the counselling conducted by these health-care professionals with their asthma patients. In addition, the surveys were designed to facilitate a comparison of the responses provided by community pharmacists, GPs and practice nurses and to explore any similarities or differences that might arise from the results. To date, there do not appear to be any other studies on asthma that have compared the views and asthma interventions of the three groups of healthcare professionals involved in asthma care in the primary care setting.

2.2. Methods

2.2.1. Questionnaire format: QAM-CP

The QAM-CP was a 39-item questionnaire divided into six subsections and it is available in Appendix 3. It consisted of two A4 pages printed on both sides. The questionnaire was printed on pink paper as it has been shown that brightly coloured paper elicits a greater response rate than white paper[133]. Furthermore, a brightly coloured document would be conspicuous amidst the post received in the pharmacy daily.

2.2.2. Questionnaire format: QAM-GP and QAM-PN

The QAM-GP and QAM-PN were 25- and 24-item questionnaires respectively, and both questionnaires were divided into four subsections. They both consisted of one A4 page printed on both sides. The QAM-GP and the QAM-PN were shortened versions of the QAM-CP. The QAM-PN was identical in content to the QAM-GP with two exceptions outlined in 2.2.4 below. The QAM-GP was printed on pink paper and the QAM-PN was printed on yellow paper to facilitate their distinction from each other. The QAM-GP is available in Appendix 6 and the QAM-PN is available in Appendix 7.

2.2.3. Questionnaire content: QAM-CP

As mentioned, the questionnaire was subdivided into six sections: (A) Baseline Characteristics, (B) Opinions on current asthma treatment/management, (C) Interactions with asthma patients, (D) Factors influencing pharmacists' interventions with asthma patients, (E) Communication with other health-care professionals and (F) Proposed national asthma project.

Prior to the administration of the questionnaire nationwide, the QAM-CP was informally piloted. It was sent to four community pharmacists who had been working in the primary care setting for an average of four years. They were asked to analyse the questionnaire and identify any ambiguities or items that required further clarification. Any suggestions were discussed and amendments made as required.

2.2.3.1. Baseline characteristics

This subsection consisted of ten items, four of which related to the demographic characteristics of the respondent community pharmacist: the respondent's sex, age, professional status and number of years in community pharmacy practice. It also included four items on the characteristics of the community pharmacy where the respondent currently worked: the county location, the regional location of the pharmacy within the county, the type of pharmacy *e.g.* independently owned/chain pharmacy, and the dispensing software in use. The classification system used to determine the type of pharmacy was decided following an online search of the number of pharmacy units operating within a single pharmacy group in Ireland across a range of different groups *e.g.* Boots, Adrian Dunne Pharmacy, Meagher's Pharmacy *etc.* The remaining two questions related to the average number of staff members working in the pharmacy simultaneously on a daily basis and the average number of prescription items dispensed in the pharmacy daily.

The questions in this subsection were chosen following a review of the relevant literature, particularly a number of key papers[134-136], and careful evaluation of the relevant data required to investigate different hypotheses on receipt of responses; *e.g.* data on the *average number of items dispensed daily* was required to investigate if a there was a significant difference between the responses provided by a pharmacist in a busy pharmacy versus a quieter pharmacy.

All of the questions in this section were closed factual questions.

2.2.3.2. Opinions on current asthma treatment/management

There were 10 items in this subsection; one of the questions related to asthma care nationwide and the remaining 9 items referred specifically to the asthma patients that frequented the respondent's community pharmacy. Four of the questions in this subsection asked the respondent to estimate the percentage of his/her asthma patients who (1) *use their inhalers properly*, (2) *have peak flow meters they use regularly*, (3) *have well controlled asthma*, (4) *have personal asthma management plans*. Five of the remaining questions had 3-5 Likert response options. These items related to the asthma patients' level of understanding of asthma as a disease and of the indications for their asthma medications, medication compliance, incidence of asthma exacerbations and the quality of asthma care in pharmacies nationwide. The final question in this subsection asked the respondent if his/her patients typically had low expectations of asthma management and it had three response options: *yes, no, don't know*. The questions in this subsection were all closed questions.

The questions in this section were selected primarily on the basis that they would provide an insight into asthma patients' existing level of disease management and understanding, from the view of the community pharmacist, who generally meets these patients most frequently compared with other health-care professionals in primary care, and has access to detailed prescription data. It was assumed, for example, that the pharmacist could make a fairly accurate estimate of compliance and the percentage of patients with well controlled asthma, from the Patient Medication Records (PMRs) held in the pharmacy. However, these estimations, particularly those involving numerical estimates, were treated with caution, as they were speculative responses.

2.2.3.3. Interventions with asthma patients

This section consisted of one question divided into 17 parts. For the first 16 parts of the question the pharmacist was asked to rate how frequently he/she carries out a series of identified interventions relating to asthma with his/her asthma patients on a scale of 1-4 (*1 = always, 2 = often, 3 = sometimes, 4 = never*). The final part of the question asked the pharmacist to identify and rate the five interventions that he/she considers the most important from the list of 16 interventions identified.

René-Henri *et al.*[134] surveyed community pharmacists in Quebec, who were registered with the Ordre des Pharmaciens du Quebec in 2006, on the interventions they carried out with their asthma patients. This survey acted as the primary reference material for the formulation of questions in this section alongside a number of secondary references[135,137].

In addition, the researcher's personal experience of asthma patients as a community pharmacist, assisted in the question design process.

The items in this section encompassed a wide range of interventions. They included questions on device demonstration, medication compliance issues, the provision of advice, both pharmacological and non-pharmacological, asthma management issues, medication problems and so forth. The underlying aim in designing these questions was to include the interventions of most importance, necessary to keep the asthma patient well, and in doing so to remind pharmacists of their importance.

The final part of this question was included to gain an insight into the importance that pharmacists placed on certain interventions over others and to investigate if pharmacists performed these 'most important' interventions more frequently than others mentioned.

As is evident, these questions were all closed questions.

2.2.3.4. Factors influencing pharmacists' interventions with asthma patients

There were three questions in this section; but the first question had two parts and the third question was divided into 12 parts. The first two questions related to the pharmacist-patient relationship: the need for such a relationship in the promotion of good asthma management among patients, and the existence of any barriers to the development of such a relationship. Both questions were open questions.

The third question asked the respondent to indicate his/her level of agreement on a scale of 1-5 (*1 = strongly agree, 5 = strongly disagree*) with a set of individual statements. Each item identified a factor/situation that could theoretically influence the pharmacist's ability and/or desire to counsel his/her asthma patients. These factors/situations included time, the pharmacist's competency, the number of professional staff members, patient receptiveness, monetary reimbursement, and the pharmacist's role. In addition, the final part of this question asked the pharmacist to identify any additional factors, both positive and negative, that influenced his/her ability to counsel asthma patients. The first 11 parts of the third question were closed questions and the final part was an open question. The third question contained both positively and negatively worded items arranged in random order.

The questions in this section were chosen as a result of the researcher's personal experiences and the experiences of her colleagues, of factors that can influence a pharmacist's ability to counsel asthma patients in the primary care setting. Under the

'Financial Measures in the Public Interest Act 2009'[138] the Health Service Executive reduced payments to community pharmacists under the General Medical Services scheme and the community drugs schemes. These reduced payments greatly reduced the profit margins for medicines. One question was included to ascertain if these recent payment reductions had an influence on the service being provided by pharmacists, for example, '*I do not counsel my asthma patients because I feel I am underpaid to do so*'. A review of the relevant literature, particularly a number of key papers[134,139], also contributed to question formulation.

2.2.3.5. Communication with other health-care professionals

This subsection consisted of 11 items. The first 5 items related to communication between the pharmacist and GPs; the following 5 were identical in content to the first 5 items except that they referred to communication with practice nurses. All of these items related specifically to the communication between the pharmacist and GPs/practice nurses about asthma patients. They included questions on the frequency of communication, the communication form (*i.e.* telephone/fax *etc.*), the nature of the communication (*i.e.* medication side-effects, compliance, suggested medications changes *etc.*), the outcome of the communication, and the pharmacist's level of satisfaction with both the frequency and method of communication. The final item in this section questioned the need for increased inter-professional communication in order to optimise asthma care in the primary care setting.

This section consisted of both open and closed questions. The closed questions provided factual information and the open questions were included to gain an insight into the opinions of the pharmacist about certain communication issues. The response options were primarily dichotomous where relevant.

The items in this section were selected following an evaluation of the relevant literature, especially a number of key papers[134,135,139,140], conferring with colleagues in community pharmacy, and from a research need to investigate the level of inter-professional communication and co-operation currently prevalent in the primary care setting.

2.2.3.6. Proposed national asthma project

There were four questions in this section of the questionnaire and the first question was subdivided into three parts. All of the items in this section related to a proposed national asthma project based on the Demonstration Project. The cover letter, included with this questionnaire, explained in detail the aims and procedures involved in this project. It also

informed the respondent that the underlying aim was to facilitate the implementation of this project nationwide.
The questions in this section sought the opinions of the pharmacist about the proposed implementation of this project nationwide. The questions related to the feasibility of the project in terms of time constraints, patient co-operation and inter-professional co-operation. Other items related to the presence of potential barriers to the project's success and whether there were any factors about the project that were considered either desirable or undesirable to the respondent. All of the questions in this section were open questions that required the respondent to proffer an opinion.

The underlying aim in the design of the items in this section was to gain an insight into the acceptability of the proposed nationwide project from the point of view of the pharmacist, and to determine what, if any, were the major obstacles to its implementation. It was also hoped that the responses would provide an indication of pharmacists' attitudes to expanding their professional role in the community in the current climate.

2.2.4. Questionnaire content: QAM-GP and QAM-PN

Both questionnaires contained the following four subsections: (A) Baseline characteristics, (B) Opinions on current asthma treatment/management, (C) Communication with community pharmacists, and (D) Interventions with asthma patients. The Baseline characteristics subsection consisted of seven items in the QAM-GP and six items in the QAM-PN. Both questionnaires contained three items on the demographic characteristics of the respondent: respondent's gender, age range and the year that he/she began practising as a GP/practice nurse. The QAM-GP also contained an item on the respondent's professional status. The remaining three items were related to the characteristics of the general practice: county and regional location of the practice and the average number of patients seen by the respondent on a daily basis. All of the questions in this section were closed factual questions.

Subsection (B), Opinions on current asthma treatment/management was identical in content to the corresponding subsection in the QAM-CP. Subsection (C), Communication with community pharmacists, referred specifically to the communication between GPs/practice nurses and community pharmacists about asthma patients and it was modelled directly on the corresponding section in the QAM-CP.

The final subsection, (D), Interventions with asthma patients, consisted of three items but the first item was divided into fifteen parts. It consisted of fifteen of the sixteen

interventions included in the corresponding subsection of the QAM-CP. The intervention *Refer the patient to his/her GP in the case of drug-related problems* was omitted. In addition, one additional response option, *Job of practice nurse,* was included in the QAM-GP. The final two questions asked the respondent to estimate the average time spent in consultation with an asthma patient and whether this was sufficient to counsel the patient adequately. These items were included as the results of the QAM-CP revealed that insufficient time was considered a major barrier to patient counselling and thus it was considered necessary to investigate this issue among GPs and practice nurses.

The QAM-GP and QAM-PN were not piloted on a sample of GPs or practice nurses prior to their nationwide distribution as they were only minimally different to the QAM-CP and thus, it was considered that any potential ambiguities had been addressed when the QAM-CP was informally piloted.

2.2.5. Questionnaire administration: QAM-CP

The names and addresses of all of the community pharmacies registered with the Pharmaceutical Society of Ireland (PSI) in Ireland in February 2009 were obtained directly from the PSI in label format. One questionnaire was posted to each registered community pharmacy in Ireland with a postage paid envelope and a cover letter briefly outlining my research in asthma management, the Demonstration Project being implemented by the ASI and the ICGP at that time, and the proposed nationwide asthma management programme.

The same questionnaire, with a reminder letter and a postage paid envelope was posted to all of the registered community pharmacies approximately five weeks later to increase the response rate. The cover letter and the reminder letter are available in Appendix 1 and Appendix 2 respectively.

2.2.6. Questionnaire administration: QAM-GP and QAM-PN

A mailing list of GPs was obtained from the online version of the Irish classified telephone directory. The search term 'doctor general practitioner' was used to identify all of the GPs nationwide who were listed in the directory. In addition, when the name of the general practice was listed in place of individual GPs, an internet search was conducted to identify each of the GPs currently working in that general practice. It was hoped that addressing the questionnaire to an individual rather than a general practice would increase the response rate. The names and addresses were extracted from the results, inputted into a

Microsoft Office Word 2007 document and the mailmerge function was used to reformat the results into labels. These results were then analysed to exclude irrelevant results or duplicates.

A copy of the questionnaire was posted to each GP identified, with a cover letter briefly outlining the researchers' asthma management research and a postage paid envelope. As it was not possible to attain a comprehensive list of the practice nurses currently working in general practice in Ireland, a copy of the QAM-PN was included with the QAM-GP. To increase the response rate, a reminder letter with a second copy of both questionnaires and another postage paid envelope was mailed five weeks later. A copy of the cover letter and the reminder letter are available in Appendix 4 and Appendix 5 respectively. .

2.2.7. Questionnaire analysis

The results of each questionnaire were inputted into three separate datasets in SPSS version 16.0 and analysed individually. In some instances, two response categories were combined, where appropriate, to facilitate further analysis.

A comparative study of the results obtained from all three questionnaires was also conducted. This was achieved by merging the responses to the two subsections common to all three questionnaires: (1) Opinions on current asthma treatment/management and (2) Interventions with asthma patients, with one amendment. The intervention on the asthma action plan was excluded from comparative analysis because in the QAM-GP and QAM-PN this intervention referred to *providing* patients with an asthma action plan whereas in the QAM-CP it referred to *advising* patients to ask their GP for an action plan.

In all analyses, comparisons between groups were conducted using the Chi-square test for discrete variables, and one-way ANOVA was used to evaluate differences between groups of continuous variables. Probabilities of ≤ 0.05 were considered statistically significant. Standardised residuals were used to identify which categories were contributing to the significant result. The results of each questionnaire will be presented separately.

2.3. Results: QAM-CP

2.3.1. Baseline characteristics

1624 community pharmacies were registered with the PSI in Ireland in February 2009. 699 questionnaires were returned completed or partially completed. The overall response rate was 43%. 51.6% of the respondents were female *(N = 698)*. The maximum number of years practising as a community pharmacist recorded was 54 years and the average number of years was 12.8. Approximately 70% of respondents had been in practice for 2-15 years (*N = 658)*. 43.1% of respondents were pharmacy owners, the remainder were employee pharmacists *(N = 694)*. 50% of respondents worked in independently owned pharmacies, 21.5% worked in small chain pharmacies with 2-3 pharmacies in the chain, 10% worked in medium chain pharmacies (4-10 pharmacies in the chain) and 18.5% worked in large chain pharmacies (>10 pharmacies in the chain) *(N = 698)*. 43% of respondents worked in pharmacies located in towns, 25.5% worked in suburban pharmacies, 16.5% worked in rural pharmacies and the remaining 15% worked in city-based pharmacies (*N = 695)*. The average number of items dispensed daily was 190. The minimum number was 10 and the maximum number was 750. The age range of the respondents is displayed in Figure 2.1 below.

2.3.1.1. Age range of respondents

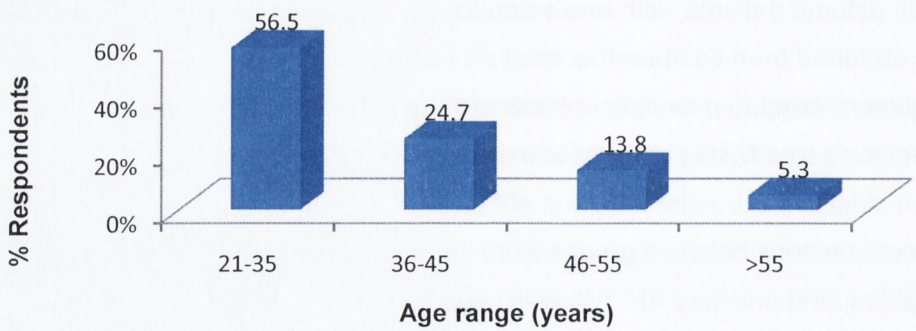


Figure 2.1: Age range of the respondents (N = 696).

2.3.2. Opinions on current asthma treatment/management

2.3.2.1. Satisfaction with asthma care in community pharmacy setting nationwide

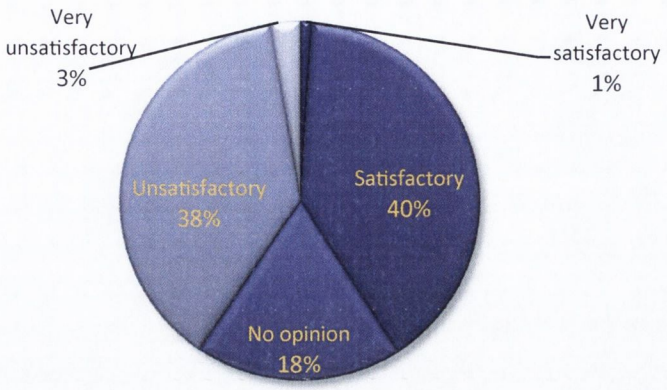


Figure 2.2: Level of satisfaction with current asthma care in the community pharmacy setting nationwide (N = 678).

2.3.2.2. Patients' understanding of asthma as a disease

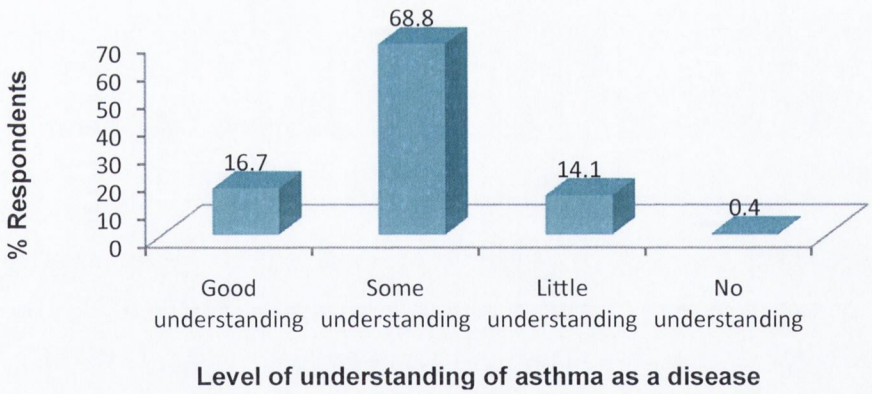


Figure 2.3: Patients' understanding of asthma as a disease as estimated by their pharmacists (N = 695).

2.3.2.3. Patients' understanding of the indications for their asthma medications

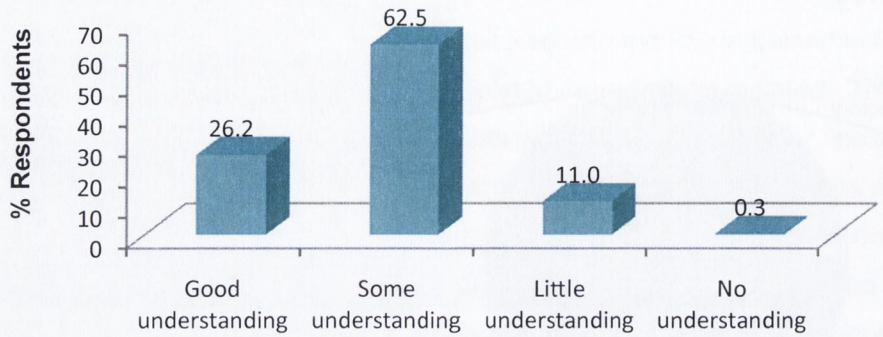


Figure 2.4: Patients' level of understanding of the indications for their asthma medications, as estimated by their pharmacists (N = 698).

2.3.2.4. Asthma patients estimated to use their inhalers properly

The mean percentage of asthma patients estimated by their community pharmacist to use their inhalers properly was 56.4% *(N = 687)*. The minimum percentage recorded was 5% and the maximum was 95%.

2.3.2.5. Asthma patients estimated to possess and use a peak flow meter regularly

According to the respondents, the mean percentage of their asthma patients estimated to be in possession of a peak flow meter that they use regularly was 10.9% *(N = 672)*. The minimum percentage recorded was 0% and the maximum was 90%. In fact, 11.6% of respondents estimated that 0% of their asthma patients use a peak flow meter regularly. Only 3.1% estimated that ≥ 50% of their patients routinely use a peak flow meter.

2.3.2.6. Asthma patients estimated to have well controlled asthma

The mean percentage of asthma patients with well controlled asthma, as estimated by the respondents, was 38.8% *(N = 669)*. The minimum recorded percentage was 0% and the maximum was 95%. 16.3% of respondents estimated that only 10% or less of their asthma patients have well controlled asthma.

2.3.2.7. Asthma patients' estimated level of medication compliance

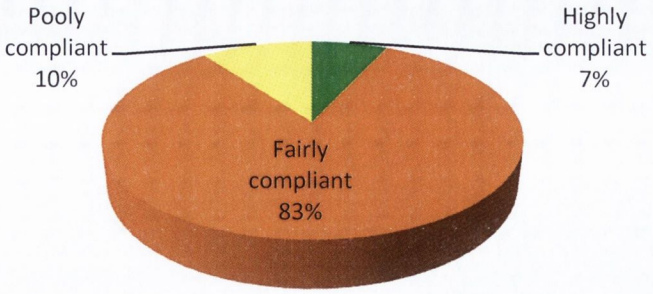


Figure 2.5: Level of medication compliance of asthma patients according to their pharmacists (N = 694).

2.3.2.8. Estimated frequency of asthma exacerbations (with hospitalisation)

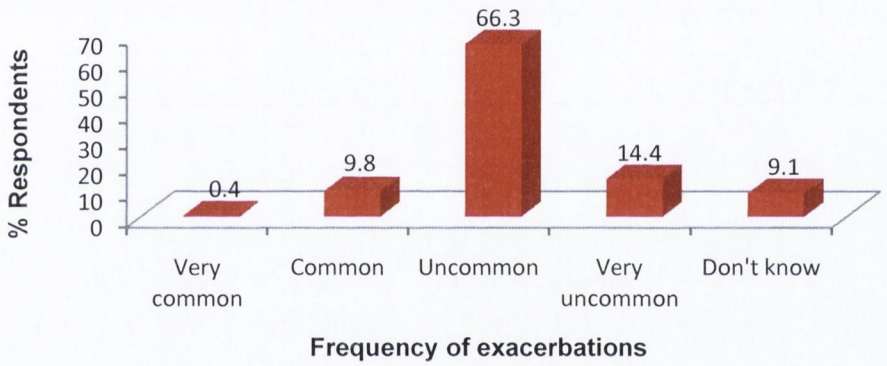


Figure 2.6: The frequency of asthma exacerbations among asthma patients according to their pharmacists (N = 695).

2.3.2.9. Asthma patients estimated to possess an asthma management plan

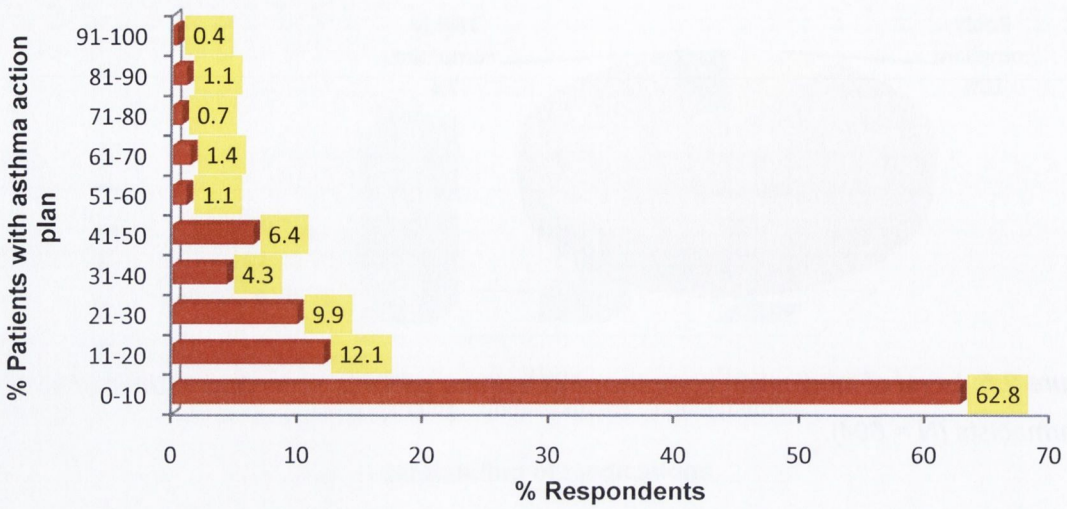


Figure 2.7: Percentage of asthma patients estimated by their pharmacists to have a personalised asthma management plan (N=282).

684 respondents completed this question, but 58.8% of them indicated that they had *no idea* how many of their asthma patients were in possession of a personal asthma management plan.

The mean percentage of patients estimated by their pharmacist to have an asthma management plan was 16.7%.

2.3.2.10. Patients' estimated expectations of asthma management

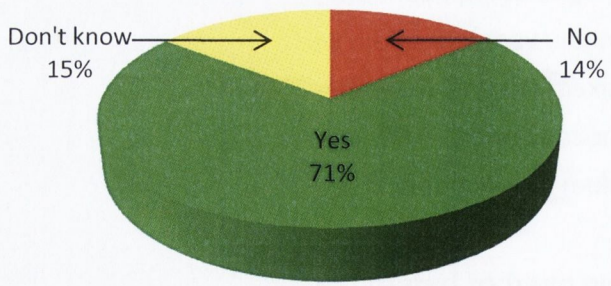


Figure 2.8: Respondents' views on whether or not their patients have low expectations of disease management (N = 678).

2.3.2.11. Influence of respondents' baseline characteristics on their opinions on current asthma treatment/management

Respondents' baseline characteristics influenced four items in this subsection on *opinions on current asthma treatment/management.* The item *patients' understanding of asthma*

as a disease was influenced by respondents' experience in community pharmacy practice and by their professional status. Respondents with the most experience in pharmacy practice (> 20 years) believe that a significantly greater proportion of their patients have a good understanding of asthma as a disease than respondents with less experience in practice *(N = 654, p = 0.049,* χ^2 test). In addition, a significantly greater number of pharmacy owners than employee pharmacists believe that their patients have a good understanding of asthma as a disease *(N = 690, p = 0.026,* χ^2 test).

The regional location of the community pharmacy in which the respondents worked influenced three items in this subsection: (1) *asthma patients estimated to use their inhalers properly,* (2) *asthma patients estimated to possess and use a peak flow meter regularly,* and (3) *patients' estimated expectations of asthma management.* The percentages of asthma patients estimated to use their inhalers properly and to use peak flow meters regularly were significantly lower among pharmacists working in city or town pharmacies compared to those based in suburban or rural locations *(inhalers: N = 683, p = 0.028, ANOVA; peak flow meter: N = 668, p = 0.033, ANOVA).* Similarly, a significantly higher percentage of respondents from city pharmacies believed that their patients had low expectations of disease management than respondents working in pharmacies in suburban and rural areas *(N = 674, p = 0.049,* χ^2 test*).*

2.3.3. *Interventions with asthma patients*

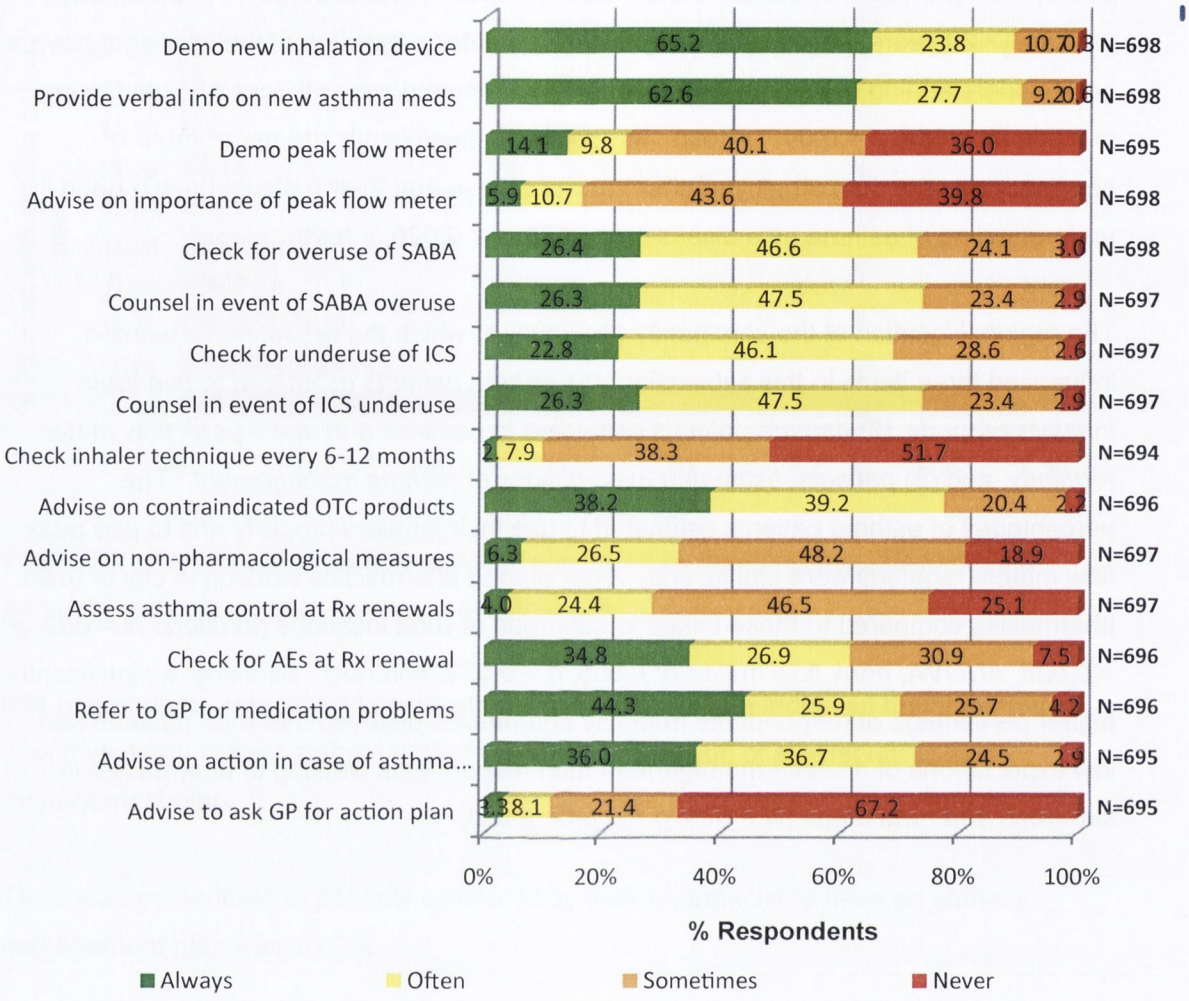


Figure 2.9: The frequency with which each respondent carries out the specified interventions with his/her asthma patients.

SABA = short-acting β-agonist; CS = corticosteroid, OTC = over-the-counter; Rx = prescription; AE = adverse effect

It was observed that the intervention most frequently carried out by the respondents is *demonstration of a newly prescribed inhalation device*, followed closely by *provision of verbal information about newly prescribed asthma medication*. The intervention least frequently preformed is *advising patients to ask their GP for a personalised asthma action plan*, this was followed by *check a patient's inhalation technique every 6-12 months.*

The mean response to each intervention varied quite considerably depending on the intervention in question, these are outlined in the table below.

Table 2.1: Mean frequency with which respondent pharmacists carry out each intervention with their patients

	Interventions with asthma patients	N	Mean	
1.	Demonstrate the use of a newly prescribed inhaler	698	1.46	Always
2.	Provide verbal information on newly prescribed asthma medications	698	1.48	Always
3.	Demonstrate the use of a peak flow meter	695	2.98:	Sometimes
4.	Advise patients on importance of peak flow meter in monitoring asthma control	698	3.17	Sometimes
5.	Check for overuse of SABA inhalers at prescription renewals	698	2.04	Often
6.	Counsel on in the event of overuse of SABA inhalers	697	2.04	Often
7.	Check for underuse of ICS inhalers at prescription renewals	697	2.11:	Often
8.	Counsel in the event of underuse of ICS inhalers	697	2.03	Often
9.	Check inhalation technique every 6-12 months	694	3.40	Sometimes
10.	Advise on contraindicated OTC products	696	1.86	Often
11.	Advise on non-pharmacological measures to improve QOL	697	2.80	Sometimes
12.	Ask patient questions to assess level of asthma control on prescription renewals	697	2.93	Sometimes
13.	Check for drug related adverse effects at prescription renewals	696	2.11	Often
14.	Refer to GP for medication problems	696	1.90	Often
15.	Advise patient on correct action to take in signs of worsening asthma	695	1.94	Often
16.	Advise patients to ask their GP for personalised asthma action plan to allow increased self-management	695	3.53	Never

SABA = short-acting β-agonist; ICS = inhaled corticosteroid, OTC = over-the-counter; QOL = quality of life

Each of the interventions with asthma patients was analysed to determine whether the baseline characteristics of the respondents had any influence on the results obtained. The results are outlined in the following subsections.

2.3.3.1. Influence of respondents' experience in pharmacy practice on their interventions with asthma patients

Respondents' experience in pharmacy practice influenced a number of interventions with asthma patients. As the number of years of pharmacy practice experience increases, the frequency with which each of the following asthma intervention is performed increases significantly:

- Provide advice on non-pharmacological measures to improve quality of life (*N = 656, p = 0.009, χ^2 test).*
- Check for drug related adverse-effects at prescription renewals *(N = 655, p = 0.011 χ^2 test).*
- Advise patients on correct action in event of worsening asthma *(N = 692, p = 0.038, χ^2 test).*

However, respondents with moderate experience (11-20 years) in pharmacy practice perform the following asthma interventions significantly more frequently than those with least experience (0-10 years) and those with most experience (> 20 years):

- Demonstrate the use of a peak flow meter *(N = 654, p = 0.012, χ^2 test).*
- Advise on the importance of the peak flow meter in monitoring asthma control *(N = 657, p = 0.001, χ^2 test).*
- Counsel the patient in the event of reliever overuse (N = 656, p = 0.002, χ^2 test).
- Check inhalation technique every 6-12 months *(N = 691, p = 0.015, χ^2 test).*
- Advise patients on contraindicated over-the-counter (OTC) products (*N = 655, p = 0.013, χ^2 test).*
- Advise patients to ask GP for a personalised asthma action plan *(N = 654, p = 0.027, χ^2 test).*

2.3.3.2. Influence of respondents' professional status on their interventions with asthma patients

Pharmacy owners conduct each of the following interventions significantly more frequently than employee pharmacists do:

- Provide verbal information on newly prescribed asthma medications *(N = 693, p = 0.019, χ^2 test).*
- Demonstrate the use of a peak flow meter *(N = 690, p =0 .002, χ^2 test).*
- Advise on the importance of the peak flow meter in monitoring asthma control *(N = 689, p = 0.002, χ^2 test).*

- Check inhalation technique every 6-12 months *(N = 698, p = 0.002, χ^2 test)*.
- Provide advice on non-pharmacological measures to improve quality of life *(N = 692, p = 0.006, χ^2 test)*.
- Assess level of asthma control at prescription renewals *(N = 692, p < 0.001, χ^2 test)*.
- Check for drug related adverse-effects at prescription renewals *(N = 692, p < 0.001, χ^2 test)*.
- Advise patients on correct action in event of worsening asthma *(N = 690, p < 0.001, χ^2 test)*.
- Advise patients to ask GP for a personalised asthma action plan *(N = 690, p = 0.011, χ^2 test)*.

2.3.3.3. Influence of regional location of the pharmacy on respondents' interventions with asthma patients

Respondents working in rural pharmacies conducted the following asthma interventions significantly more frequently than those working in town, city or suburban pharmacies:

- Demonstrate the use of a peak flow meter *(N = 691, p = 0.03, χ^2 test)*.
- Advise on the importance of the peak flow meter in monitoring asthma control *(N =694, p = 0.013, χ^2 test)*.
- Check for underuse of ICS at prescription renewals *(N = 693, p = 0.006, χ^2 test)*.
- Counsel the patient in the event of reliever *overuse (N= 693, p = 0.036, χ^2 test)*.

2.3.3.4. Interventions identified as most important

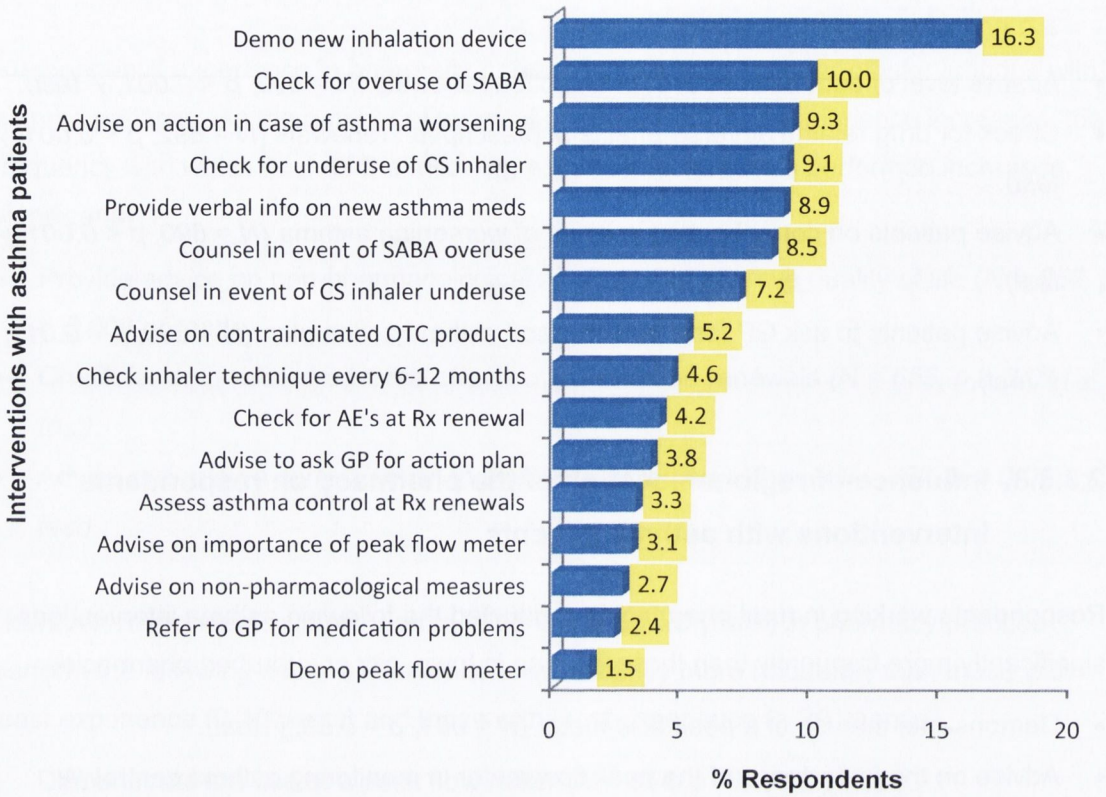


Figure 2.10: The frequency with which the respondents consider a particular intervention to be one of the top five most important interventions (N = 640).

SABA = short-acting β-agonist; CS = corticosteroid, OTC = over-the-counter; Rx = prescription; AE = adverse effect.

It is evident that respondents consider the *demonstration of a newly prescribed inhalation device* to be the most important intervention. However, *demonstration of a peak flow meter* is considered to be one of the top five most important interventions by only 1.5% of respondents.

2.3.4. Factors influencing pharmacists' interventions with asthma patients

2.3.4.1. The importance of the pharmacist-patient relationship in asthma management

97.8% of respondents believe that establishing such a relationship is necessary in the promotion of good asthma management *(N = 688).*

Respondents were asked to elaborate on their answer and the most frequent reason mentioned for the importance of the pharmacist-patient relationship was that establishing such a relationship *promotes trust* and thus *increases the likelihood that the patient will accept and value the advice provided on counselling.* Additional reasons mentioned by ≥ 10% of respondents included the fact that patients are *more receptive to advice* if a good relationship is established, that the *pharmacist is very accessible to patients and sees patients more frequently than other health-care professionals in the primary care setting* and that the *pharmacist can promote appropriate medication and device usage.*

Table 2.2: Responses to the need to establish a pharmacist-patient relationship to promote good asthma management (N = 409).

	Response	% Respondents
1.	Promotes trust ensuring patient values advice from pharmacist	37.7
2.	The pharmacist is the most accessible health-care professional	14.0
3.	A good relationship ensures more receptive patients	13.0
4.	The pharmacist can encourage appropriate medication and inhaler usage	11.7
5.	The pharmacist sees the patient very frequently	10.0
6.	Pharmacist can monitor compliance from Patient Medication Record	4.6
7.	Pharmacist can provide appropriate asthma advice	4.4
8.	The pharmacy is a relaxed environment	2.4
9.	GP often too busy to talk to patients in-depth	2.0
10.	Patients need education to improve their asthma	1.7
11.	Need approachable pharmacist to develop the pharmacist-patient relationship	1.7
12.	Patients need to see pharmacist as source of advice	1.5
13.	Patient participation needed to develop the pharmacist-patient relationship	1.0
14.	Free advice available from the pharmacist	1.0
15.	Good pharmacist-patient relationship allows patient to query therapy with confidence	0.7
16.	Need to establish mutual respect between patient and pharmacist	0.5
17.	More time in pharmacy to talk to patients	0.5
18.	Pharmacist knows drug therapy so can advise patients appropriately	0.5
19.	Also need liaison with nurse/GP	0.2
20.	Pharmacist better able to identify problems with inhalers, side effects *etc.*	0.2
21.	Patient responsible for own health	0.2

2.3.4.2. Barriers to developing the pharmacist-patient relationship

72.8% of respondents who completed this question stated that *time* was a major barrier. The next most frequent barriers mentioned were *patient interest*, *insufficient staffing levels* and the *prohibitive cost of medications*. Interestingly, only 3.5% of respondents stated that there were no barriers to developing the pharmacist-patient relationship.

Table 2.3: Major barriers to developing the pharmacist-patient relationship (N = 605).

	Barrier	% Respondents
1.	Time	72.8
2.	Patient interest	12.0
3.	Staffing levels	9.3
4.	Cost of medication	8.3
5.	Health Service Executive cutbacks	5.3
6.	Lack of privacy/consultation area	5.1
7.	Lack of understanding of pharmacist's role by patients	5.0
8.	Busy patients	4.5
9.	Lack of continuity of pharmacist	3.3
10.	Ability to get medication in any pharmacy	3.1
11.	GP-patient relationship	2.8
12.	Pharmacist's poor communication skills	2.3
13.	Patient not collecting own prescription	2.0
14.	Patients consider themselves experts on asthma	2.0
15.	Patient ignorance	1.7
16.	No access to medical notes	1.3
17.	Pharmacist-GP relationship	1.3
18.	Poor pharmacist training in asthma	1.2
19.	Lack of established protocol for counselling	1.0
20.	Patient embarrassment	0.7
21.	Refusal to listen to pharmacist if advice different to that of GP	0.5
22.	Lack of trust	0.5
23.	Peak flow meter not available on government health schemes	0.5
24.	Lack of placebo inhalers to demonstrate inhaler technique	0.5
25.	Language barrier	0.5
26.	Patient's belief that he/she has perfect inhaler technique	0.3
27.	Low expectations of disease management among patients	0.3
28.	Young men difficult to counsel	0.2
29.	Elderly sometimes disinterested in advice	0.2
30.	No ability to change medications on prescriptions	0.2
31.	Lack of up-to-date prescriptions from GPs	0.2
32.	Patient mobility	0.2
33.	Lack of review by GPs, blanket repeat prescribing	0.2
34.	Patient's fear of being chastised by pharmacist	0.2
35.	Lack of motivation of pharmacists due to Health Service Executive cutbacks	0.2

2.3.4.3. Factors influencing the counselling of asthma patients

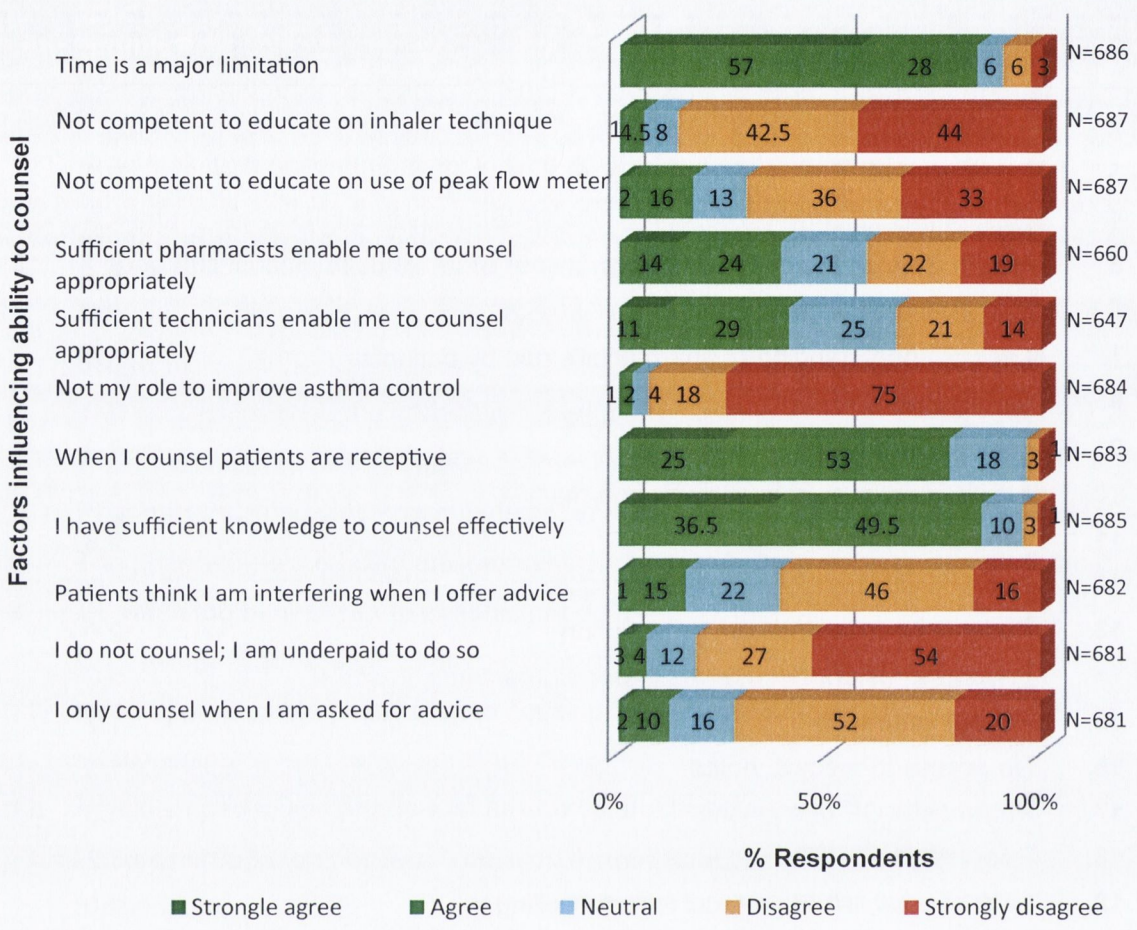


Figure 2.11: The frequency with which respondents agree with the influence that various factors have on their ability to counsel their asthma patients.

Respondents' mean responses to each of the identified factors are outlined in the table below.

Table 2.4: Mean response scores to factors affecting pharmacists' ability to counsel asthma patients

	Factors affecting pharmacists' ability to counsel	N	Mean response score	
1.	Time is major factor influencing my ability to counsel	686	1.70	Agree
2.	I do not feel competent to assess & educate on inhalation technique	687	4.23	Disagree
3.	I do not feel competent to assess & educate on use of peak flow meter	687	3.84	Disagree
4.	A sufficient number of pharmacists allows me to counsel my patients appropriately	660	3.08	Neutral
5.	A sufficient number of technicians allows me to counsel appropriately	647	2.97	Neutral
6.	It is not my role to counsel to improve asthma control	684	4.63	Strongly disagree
7.	When I counsel, patients are receptive	683	2.00	Agree
8.	I have sufficient knowledge to counsel effectively	685	1.83	Agree
9.	Patients think I am interfering when I offer advice	682	3.60	Disagree
10.	I do not counsel; I am underpaid to do so	681	4.26	Disagree
11.	I only counsel when I am asked for advice	681	2.75	Neutral

Each of the identified factors was analysed to determine whether they were influenced by one or more related items in the questionnaire and/or respondents' baseline characteristics. The results are outlined below.

2.3.4.4. Time as an influencing factor

Time as an influencing factor was influenced by the average number of items dispensed daily by the respondents.

a) Number of items dispensed daily and time as an influencing factor

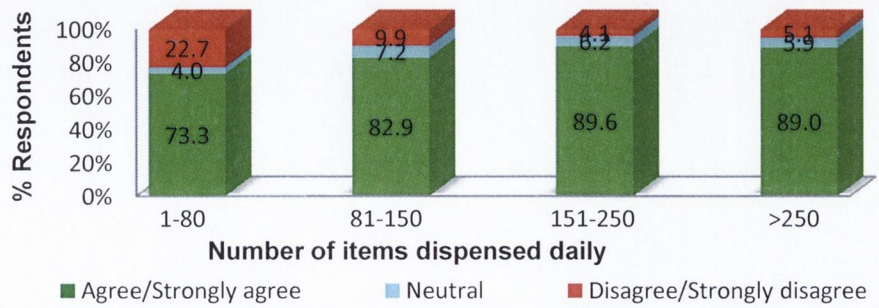


Figure 2.12: Level of agreement with the statement that time is a major influencing factor on counselling classified by number of items dispensed daily (N = 567, $p < 0.001$, χ^2 test).

As expected, respondents that dispense fewer items daily were significantly less in agreement with the statement than those respondents who dispense a greater number of items on a daily basis.

2.3.4.5. Competency in counselling on correct inhalation technique

A significant relationship was observed between this item and the frequency with which respondents demonstrate the use of a new inhaler.

a) *Demonstrating a new inhaler and competency in counselling on correct inhalation technique*

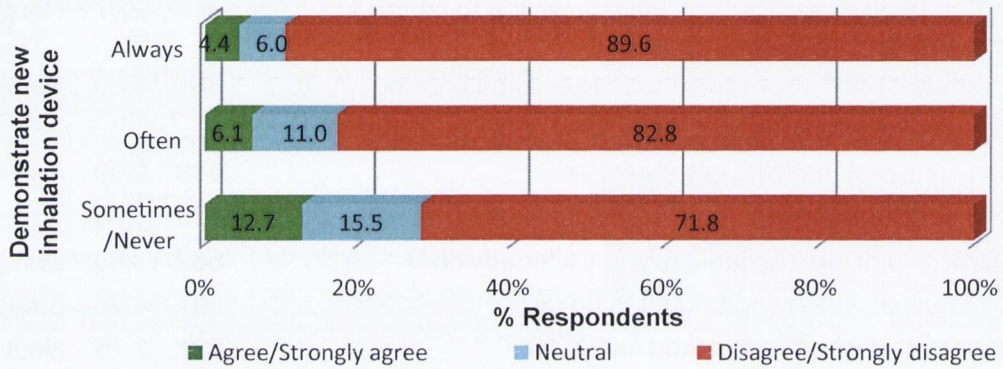


Figure 2.13: Level of agreement with the statement on competency in counselling on correct inhalation technique classified by the frequency with which respondents demonstrate a new inhalation device to their patients (N = 686, p = 0.001, χ^2 test)

Respondents who *agreed/strongly agreed* that they do not feel competent to counsel on correct inhalation technique demonstrate the use of a new inhalation device significantly less frequently than respondents who *disagreed/strongly disagreed* with the statement.

2.3.4.6. Competency in counselling on correct use of a peak flow meter

A significant relationship was observed between this item and (a) the frequency with which respondents demonstrate the use of a peak flow meter to their patients and (b) the frequency with which respondents advise their patients on the importance of the peak flow meter in monitoring asthma control.

a) *Demonstrating peak flow meter and ability to counsel on using peak flow meter*

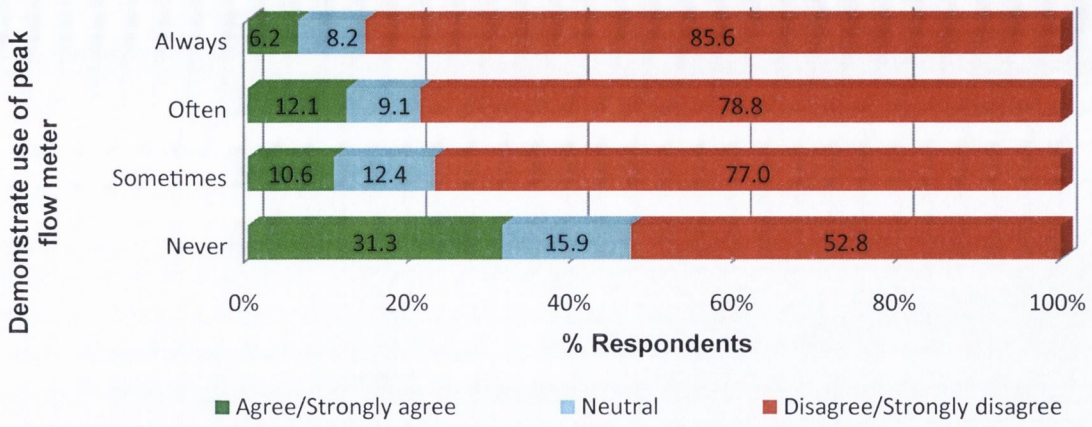


Figure 2.14: Level of agreement with the statement on competency in counselling on correct use of a peak flow meter classified by the frequency with which respondents demonstrate the use of a peak flow meter (N = 683, p < 0.001 χ^2 test).

As the level of agreement with the statement increases the frequency with which this intervention is carried out decreases. The differences between the groups are significant.

b) *Advising on importance of peak flow meter and ability to counsel on using peak flow meter*

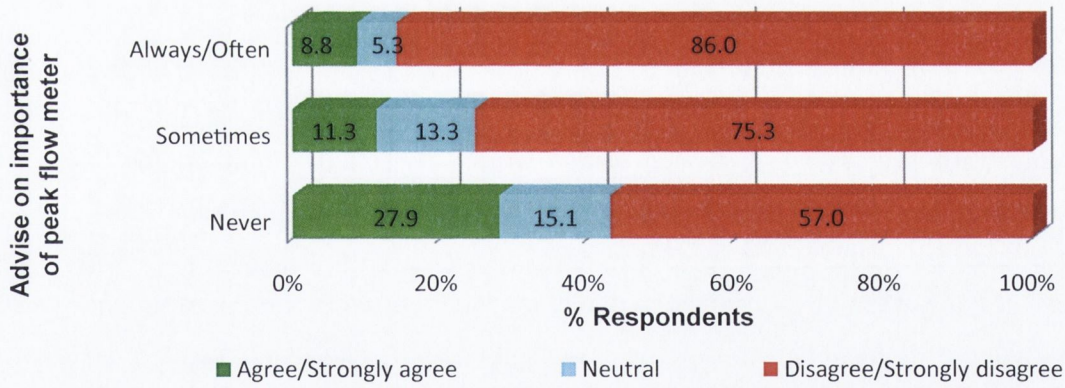


Figure 2.15: Level of agreement with the statement on competency in counselling on correct use of a peak flow meter classified by the frequency with which respondents advise on the importance of a peak flow meter in asthma control (N = 685, p < 0.001, χ^2 test)

As the level of agreement with the statement increases, the frequency with which respondents advise on the importance of a peak flow meter decreases. The differences between the groups are significant.

2.3.4.7. Asthma knowledge as an influencing factor

Analysis of the mean frequency with which respondents carry out interventions with their asthma patients and the level of agreement with the statement that they have sufficient knowledge about asthma to counsel patients effectively revealed that those respondents who *agreed/strongly agreed* with this statement carry out interventions with their asthma patients significantly more frequently than those who *disagreed/strongly disagreed* with the statement *($N = 642$, $p < 0.001$, ANOVA).*

2.3.4.8. Counselling only when asked for advice

Analysis of the mean frequency with which respondents carry out interventions with their asthma patients and the level of agreement with this statement revealed that those respondents who *disagreed/strongly disagreed* that they only counsel their asthma patients when they ask for their advice, carry out interventions with their asthma patients significantly more frequently than those who *agreed/strongly agreed* with the statement *($N = 638$, $p < 0.001$, ANOVA).*

2.3.4.9. Influence of respondents' demographic characteristics on the factors influencing patient counselling

Respondents' experience in pharmacy practice influenced two of the identified factors. A significantly greater proportion of respondents with moderate experience (6-20 years) in pharmacy practice *disagreed/strongly disagreed* with the statement *I do not feel competent to assess and educate on use of peak flow meter* than those with least experience (0-5 years) or most experience (> 20 years) *($N = 648$, $p = 0.005$, χ^2 test).* However, a significantly greater proportion of respondents with the most experience (> 20 years) *agreed/strongly agreed* with the statement *I do not counsel; I am underpaid to do so* than those with less experience *($N = 644$, $p = 0.011$, χ^2 test).* However, overall the percentage of respondents who agree that they do not counsel their patients because they feel they are underpaid is low.

Respondents' professional status also influenced three identified factors. A significantly greater proportion of pharmacy owners than employee pharmacists *agreed/strongly agreed* with the statements (a) *A sufficient number of pharmacists allows me to counsel my patients appropriately ($N = 656$, $p = 0.042$, χ^2 test,* and (b) *I do not counsel; I am underpaid to do so ($N = 677$, $p < 0.001$, χ^2 test).* Conversely, a significantly greater number of employee pharmacists than pharmacy owners *agreed/strongly agreed* with the

statement *I do not feel competent to assess & educate on use of peak flow meter (N = 683, $p < 0.001$, χ^2 test).*

2.3.4.10. Additional factors that influence pharmacists' ability to counsel

Respondents were asked to write freely about any additional factors (positive/negative) that influenced their ability to counsel their asthma patients. Despite the fact that *time* was mentioned in the previous statements, 23.8% of respondents who completed this question indicated that time was a factor that influenced their ability to counsel patients. Following *time, receptiveness to counselling* was the most frequently mentioned influencing factor.

Table 2.5: Positive and negative factors that influence community pharmacists' ability to counsel their asthma patients (N = 699)

	Factors influencing ability to counsel asthma patients	% Respondents
1.	Time	23.8
2.	Patients' receptiveness to counselling	22.6
3.	Health Service Executive cutbacks	12.0
4.	Lack of education on new inhalation devices	7.1
5.	Patient not collecting own prescriptions	6.5
6.	Staff levels	5.8
7.	Lack of privacy for consultations	5.8
8.	Lack of placebo inhalers	5.8
9.	Pharmacist's personal experience of asthma	3.9
10.	Cost of preventer inhalers	3.9
11.	Patient's lack of knowledge of pharmacist's role	3.9
12.	GPs not adhering to recommended asthma guidelines	3.2
13.	Patient often preferring to talk to his/her GP rather than pharmacist	1.9
14.	No access to medical notes/diagnosis	1.9
15.	No ability to change prescription	1.3
16.	No idea what advice patient has been given by GP/hospital	1.3
17.	Patients' level of education/literacy	1.3
18.	Lack of training in clinical pharmacy	1.3
19.	Busy patients	1.3
20.	Language barrier	1.3
21.	Patients that are not regular customers	0.6
22.	Lack of structured appointments with pharmacist	0.6
23.	Lack of patient knowledge on indications for different inhalers	0.6
24.	Age of patient	0.6
25.	Peak flow meters never prescribed	0.6

2.3.5. Communication with other health-care professionals: GPs

2.3.5.1. Communication frequency with GPs about asthma patients

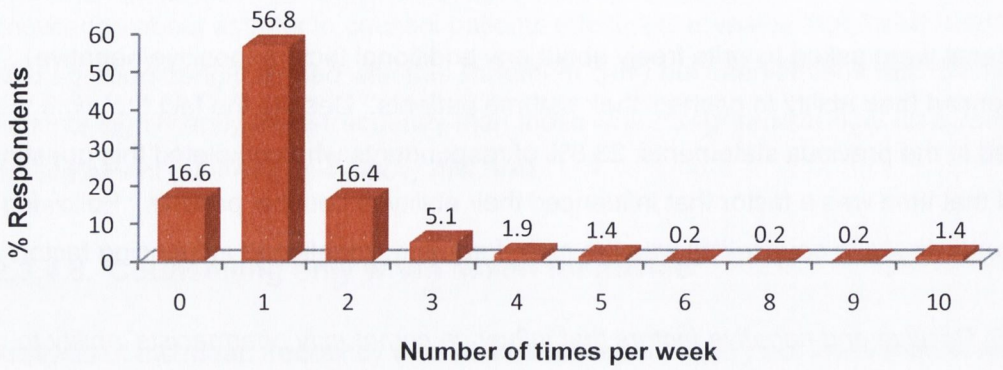


Figure 2.16: Frequency with which respondents communicate with a GP about an asthma patient in a typical week (N = 699).

The mean frequency of communication between the pharmacist and a GP about an asthma patient was 1.4 times/week.

2.3.5.2. Form of communication with GPs

For 96.4% of respondents the communication is usually by telephone. The remaining respondents usually communicate by fax (0.9%), by letter (0.2%), by a message carried by a patient (2.2%) or by other means (0.3%).

2.3.5.3. Nature of communication with GPs

Table 2.6: Mean prevalence with which each asthma medication problem is discussed with a GP

	Nature of communication	N	Mean
1.	Non-compliance (overuse of medication)	414	3.04
2.	Drug interactions	421	3.14
3.	Non-compliance (underuse of medication)	405	3.26
4.	Suggested dosage change	398	3.32
5.	Suggested inhaler device change	399	3.86
6.	Side-effects	393	3.99
7.	Other	376	6.52

Analysis of the mean prevalence with which each problem is discussed (excluding *other*) revealed that there is no significant difference in the prevalence of each issue (1 = most prevalent, 7 = least prevalent)

2.3.5.4. Issue resolution and satisfaction with communication

92.5% of respondents stated that the issued is usually resolved following communication with the GP *(N = 587).*

a) Satisfaction with frequency of communication

61% of respondents stated that the frequency of communication is satisfactory.

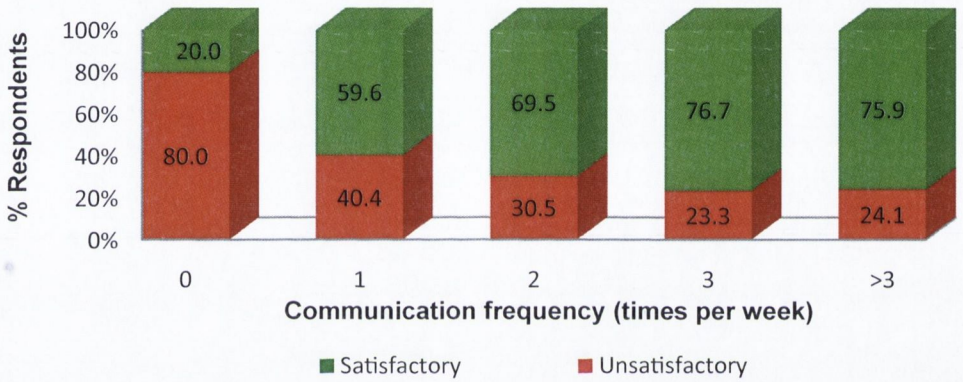


Figure 2.17: Satisfaction of respondents with the current state of communication classified according to the frequency of communication with a GP in a typical week (N = 511, p < 0.001)

As expected, as the frequency of communication with a GP increases the proportion of satisfied respondents increases. The differences between the groups are significant.

b) Satisfaction with method of communication

78.9% of respondents stated that the method of communication is satisfactory *(N = 498).*

2.3.5.5. Changes needed to improve unsatisfactory communication with GPs

Respondents were asked to write freely about what changes were needed to improve communication with GPs, but many respondents did not propose changes, they merely provided comments on the current state of communication.

Table 2.7: Comments provided by respondents on pharmacist-GP communication (N =157)

	Comments on current pharmacist-GP communication	% Respondents
1.	Need more structured form of communication with GPs	48.4
2.	GPs typically unreceptive of interventions by pharmacists	26.1
3.	Need more frequent communication with GPs	14.0
4.	GPs do not accept the role of the pharmacist	10.2
5.	Need easier accessibility of GP	6.4
6.	Pharmacist needs access to medical notes	5.7
7.	Both GP and pharmacist don't have enough time	5.1
8.	Pharmacist needs to be more proactive	3.8
9.	Pharmacists need more time to review patients	3.2
10.	Surgery hours are restrictive	3.2
11.	Pharmacist should be part of the primary health care team with regular meetings	3.2
12.	Better pharmacist-patient interface would lead to more GP communication	1.3
13.	Better record keeping by GPs needed	1.3
14.	Useful if queries could be referred to an asthma nurse	0.6
15.	Need structured method to keep records of patient counselling	0.6
16.	Need more pharmacist involvement in primary care	0.6
17.	Need quicker response from GP on patient queries	0.6
18.	Up-to-date education of GPs on asthma needed	0.6
19.	Need a structured asthma plan for all patients	0.6
20.	Patients should keep record of counselling	0.6

The percentages do not add to 100% as many respondents provided >1 response

The most prevalent issues raised by respondents related to the form and frequency of communication and the responsiveness of the GP to communication with the pharmacist.

2.3.6. *Communication with other health-care professionals: Nurses*

2.3.6.1. Communication frequency with practice nurses about asthma patients

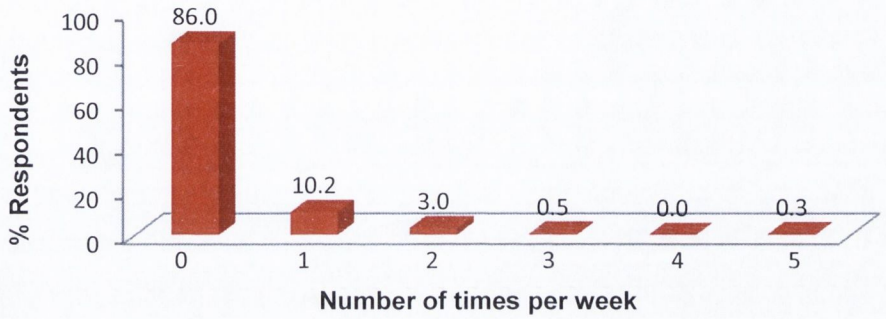


Figure 2.18: Frequency with which respondents communicate with a practice nurse about an asthma patient in a typical week (N = 630).

The majority of respondents typically have no communication with a practice nurse about asthma patients.

2.3.6.2. Form of communication with practice nurses

92.1% of respondents stated that the communication was usually by telephone. The remainder indicated that communication was usually by letter (0.1%), by fax (0.1%), a message carried by patient (4.0%), or by other means of communication (0.2%) *(N = 101).*

2.3.6.3. Nature of communication with practice nurses

Table 2.8: Mean prevalence with which each asthma medication problem is discussed with a practice nurse.

	Nature of communication	N	Mean
1.	Non-compliance (underuse of medication)	77	2.60
2.	Non-compliance (overuse of medication)	77	2.84
3.	Suggested inhaler device change	72	3.13
4.	Suggested dosage change	73	3.22
5.	Drug interactions	75	4.32
6.	Side-effects	71	4.32
7.	Other	66	6.92

The most prevalent issue discussed with a practice nurse is non-compliance: both underuse and overuse of medication (1 = most prevalent, 7 = least prevalent).

2.3.6.4. Issue resolution and satisfaction with communication

92.9% of respondents indicated that the issue is usually resolved following communication with the practice nurse. *(N =98)*

a) Satisfaction with frequency of communication

55.4% of respondents stated that the frequency of communication is satisfactory. However, only 139 respondents completed the question. 630 respondents completed the question asking them about the frequency with which they communicated with the practice nurse and 542 of them had no communication with the nurse in a typical week. Due to the vast discrepancy in the number of respondents completing both questions, it cannot be assumed that the result of this question is representative of the respondents as a whole.

b) Satisfaction with method of communication

71.3% of respondents stated that the method of communication is satisfactory but as discussed above, the number of respondents who completed this question was only 115.

2.3.6.5. Changes needed to improve unsatisfactory communication with nurses

As discussed in 2.3.5.5 above, respondents were asked to write freely about the changes needed to improve pharmacist-nurse communication but the majority of those who responded only commented on the current state of communication.

Table 2.9: Comments provided by respondents on pharmacist-nurse communication (N = 27)

	Comments on current pharmacist-nurse communication	% Respondents
1.	Do not know who the practice nurses are	59.3
2.	Do not know how to contact the practice nurses	51.9
3.	Need regular communication with practice nurses	29.6
4.	Would like contact with practice nurses	29.6
5.	Nurses need to be made aware of pharmacist's role	14.8
6.	Need protocol for communication with practice nurses	11.1
7.	Need clarity on whether the practice nurse/GP is consulting with patient to know who to contact with queries	3.7
8.	Many surgeries don't employ practice nurses	3.7
9.	Nurses often feel threatened by pharmacists	3.7
10.	Don't know role of nurse in asthma care	3.7

The percentages do not add to 100% as many respondents provided >1 response

The majority of responses to this question referred to a lack of knowledge about the practice nurses in terms of their identity, a means of contacting them *etc.*

2.3.6.6. Need for increased inter-professional communication to optimise asthma care

92.7% of respondents indicated that there is a need for increased communication between pharmacists and GPs to optimise asthma care *(N = 590).*

94% respondents indicated that there is a need for increased communication between pharmacists and practice nurses *(N = 553).*

When asked to elaborate on the issue, the most prevalent response was that better communication is needed to improve the overall health of asthma patients, but only 177 respondents elaborated on the need for increased communication with either GPs or practice nurses.

Table 2.10: Issues raised by respondents in relation to the need for increased inter-professional communication between pharmacists and GPs/practice nurses (N = 177).

	Responses to need for increased inter-professional communication	% Respondents
1.	Better communication needed to improve asthma patients' overall health	28.0
2.	Therapeutic alliance needed between GPs, pharmacists and practice nurses	11.2
3.	Structured protocols needed to improve communication	9.0
4.	Lack of acceptance by GPs about the role of the pharmacist	7.5
5.	GP often not aware of level of patient compliance with asthma medications	7.3
6.	Need more communication with health-care professionals	5.6
7.	Need access to medical notes	5.1
8.	Little communication with nurses at present	4.5
9.	Need to know who the nurses are and how to contact them	4.5
10.	Pharmacists' opinions not respected by GPs	2.8
11.	No time to increase communication	2.8
12.	Better training of health-care professionals needed	2.3
13.	Pharmacists see patients more frequently than either GPs or practice nurses	1.7
14.	Unsure of nurse's role in asthma care	1.7
15.	Nurses are valuable source of information not supplied by GPs	1.7
16.	Need to increase patient receptiveness to advice from health-care professionals	1.7
17.	Need improved rate of resolution of patient queries/issues by GP/practice nurse	1.1
18.	Lack of patient assessment by GPs in relation to repeat prescriptions for asthma medication	1.1
19.	Communication with nurses is pointless as GP approval needed in most cases	0.6
20.	Nurse should be point of contact in surgery in relation to asthma patients	0.6
21.	Contact always made by pharmacist, not by GP/practice nurse	0.6
22.	Pharmacist needs to be more proactive	0.6
23.	Increased communication would reduce errors	0.6

The percentages do not add to 100% as occasionally respondents provided >1 response

2.3.7. Proposed national asthma project

2.3.7.1. Feasibility of the proposed asthma project nationwide

a) Time constraints

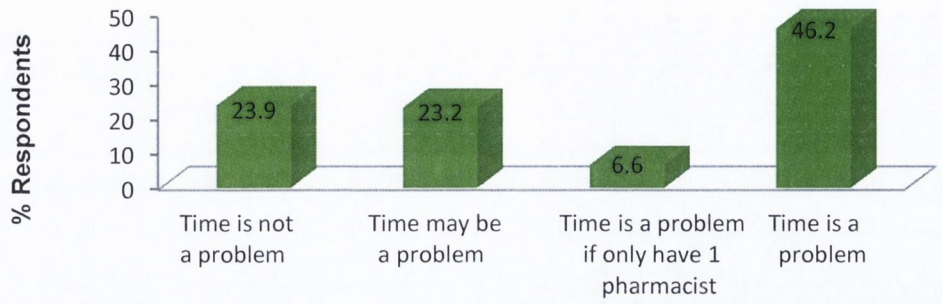


Figure 2.19: Proportion of respondents who consider time a barrier for pharmacists in terms of the feasibility of a nationwide asthma management programme (N = 452).

Only 1.3% of respondents consider that time constraints would be a problem for patients.

b) Patient co-operation

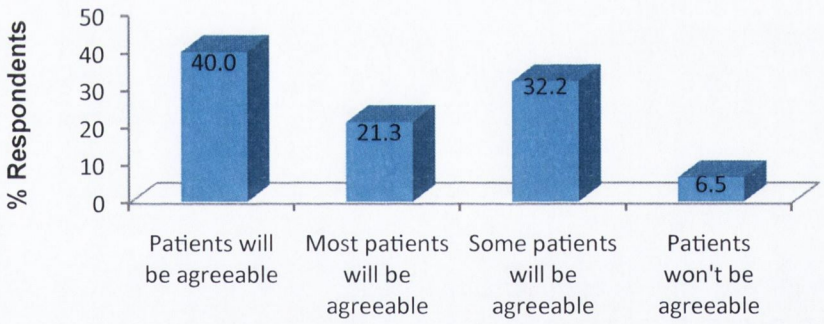


Figure 2.20: Proportion of respondents who consider patient co-operation to be an issue in terms of the feasibility of a nationwide asthma management programme (N = 432).

The majority of respondents believe that patient co-operation would not be a barrier to the implementation of a nationwide asthma management programme.

A number of additional issues were mentioned by respondents in relation to the feasibility of the project in terms of patient co-operation and these are illustrated in Table 2.11 below.

Table 2.11: Issues raised by respondents in relation to patient co-operation and the feasibility of the proposed national asthma project (N = 90)

	Issues relating to patient co-operation	% Respondents
1.	Patients need to be told this is designed to improve their health	22.2
2.	Patient will need encouragement and follow-up to ensure co-operation	16.7
3.	Patients often don't think they have a problem with asthma control	15.6
4.	Need publicity to encourage patient cooperation	14.4
5.	Cost of medication is a prohibitive factor	10.0
6.	Co-operation will depend on pharmacist-patient relationship	5.6
7.	Lack of understanding of pharmacist's knowledge by patient is a barrier	5.6
8.	Cost of GP visits is a prohibitive factor	3.3
9.	Patients don't always collect their own prescriptions	2.2
10.	Patients often reluctant to accept responsibility and make lifestyle changes	2.2
11.	It would improve pharmacist-patient relationship	1.1
12	Patients would get involved if there was more privacy in the pharmacy	1.1

c) Interprofessional communication

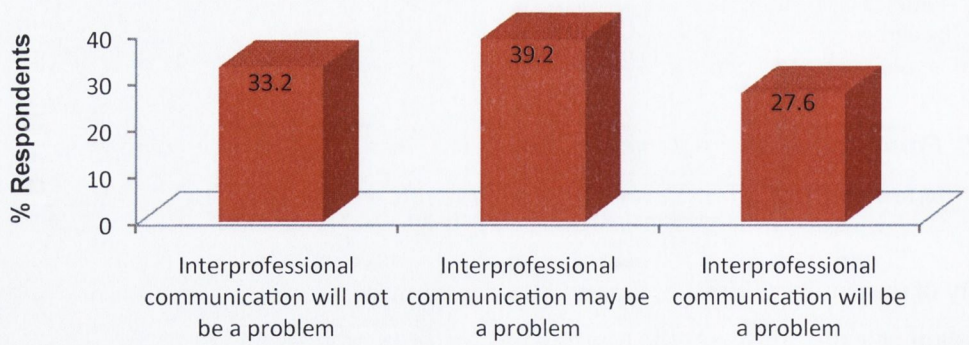


Figure 2.21: Proportion of respondents who consider interprofessional communication to be an issue in terms of the feasibility of a nationwide asthma management programme (N = 398).

The majority of respondents consider interprofessional communication a problem in relation to the feasibility of the project.

A number of additional issues were mentioned with reference to interprofessional communication and these are illustrated in Table 2.12 below.

Table 2.12: Issues raised by respondents in relation to interprofessional communication (N = 188).

	Issues relating to interprofessional communication	% Respondents
1.	Time is a problem	30.8
2.	Not all health-care professionals are open to suggestions	24.5
3.	Good opportunity to improve communication	10.1
4.	Need more structured communication to facilitate this	8.0
5.	Need all health-care professionals on board	6.9
6.	Need better communication with all health-care professionals	5.9
7.	Little communication occurs at present	4.8
8.	The project will help break through some barriers	2.7
9.	Need to establish relationship with nurses	2.1
10.	Need initial contact to establish a protocol for successful communication	2.1
11.	Need clearly defined roles for all health-care professionals	1.6
12.	Need multidisciplinary training to facilitate this.	0.5

2.3.7.2. Major barriers to the success of the proposed project

97.9% of respondents think that major barriers exist that may impede the project. The mean number of barriers identified by individual respondents was 1.6 *(N = 476).* The barriers identified by the respondents are outlined in the table below.

Table 2.13: Barriers to the success of the project (N = 466).

	Barriers to success of the project	% Respondents
1.	Insufficient time	57.1
2.	Lack of reimbursement	24.7
3.	Patient recruitment	19.1
4.	GP acceptance of pharmacist's role	16.5
5.	Establishing and maintaining regular communication with other HCPs	12.8
6.	Lack of motivation/interest among pharmacists following HSE cutbacks	8.8
7.	Obtaining commitment and cooperation from the other HCPs	6.9
8.	Appropriate training of all HCPs needed	3.6
9.	Lack of established role for pharmacists	2.4
10.	Project needs structure/protocols	2.1
11.	Cost for patient	2.1
12.	Health Service Executive commitment	1.5
13.	The role of each group of HCPs should be clearly defined	0.9
14.	Increased workload for pharmacists	0.6
15.	Continuity between GP/practice nurse and pharmacist	0.6
16.	Project needs strong leadership	0.4
17.	Lack of interest by patients and HCPs	0.4
18.	Lack of knowledge of pharmacist's ability by patients and HCPs	0.2
19.	Availability of emergency reliever medication	0.2

HCPs = Health-care professionals

The percentages do not add to 100% as many respondents provided >1 response

2.3.7.3. Desirable factors about the proposed project

The desirable factors about the proposed project are outlined in the table below

Table 2.14: Factors respondents found desirable about the proposed project (N = 408).

	Desirable factors	% Respondents
1.	Improved patient care	49.0
2.	Improved therapeutic outcomes	48.5
3.	Education of patients about asthma	20.1
4.	Increased pharmacist role/responsibility	17.6
5.	Development of interprofessional relationships	14.0
6.	Improved patient compliance	12.5
7.	Increase patient contact/improved patient relationships	10.5
8.	Savings in the healthcare system	8.8
9.	Improved education of pharmacists in asthma care	5.4
10.	Use of pharmacists' knowledge and expertise	5.4
11.	Increased awareness of pharmacist's role	5.2
12.	Patients will become actively involved in asthma management	3.4
13.	Reduction of medication misuse	3.0
14.	Reduction of medication wastage	1.7
15.	Improved counselling of patients	1.7
16.	Variation in workload/job satisfaction for pharmacists	1.2
17.	Development of an inter-professional scheme with other health-care professionals	1.0
18.	Establishment of a protocol for asthma management	1.0
19.	Increased respect for pharmacists in the community	0.7
20.	Increased pharmacy services	0.7
21.	Patients would really appreciate such a project	0.5
22.	Development of a structured approach to counselling	0.5

The percentages do not add to 100% as many respondents provided >1 response

Of the respondents that indicated that there were aspects about the proposed project that they found desirable, the number of desirable factors for each respondent was computed. The mean number of desirable factors identified by individual respondents was 2.1 *(N = 408)*.

2.3.7.4. Undesirable factors about the proposed project

48.7% of the respondents who completed this item stated that they found nothing undesirable about the proposed project *(N = 279)*. The most frequently mentioned undesirable factors about the project were the time it would require and the lack of remuneration for providing such a service.

Table 2.15: Factors respondents found undesirable about the proposed project (N = 279)

	Undesirable factors	% Respondents
1.	Nothing undesirable about the project	48.7
2.	Time required	25.4
3.	Lack of remuneration	20.8
4.	Increased workload for pharmacists	5.0
5.	Other health-care professionals may not participate	3.2
6.	Lack of appreciation of pharmacists input	2.9
7.	Working with the Health Service Executive	1.8
8.	Some patients are not receptive to advice; therefore it could be a waste of time	1.8
9.	GPs may not be receptive to many suggestions from pharmacists	1.4
10.	Patients may feel they are being lectured by the pharmacist	1.4
11.	It may detract from other patients/conditions	1.1
12.	Cost to patients	0.7
13.	Lack of practicality	0.7
14.	Cost of peak flow meters	0.4
15.	Need structured communication between all health-care professionals	0.4
16.	Project should be led by a specialist in asthma management	0.4

The percentages do not add to 100% as a number of respondents provided >1 response

2.4. Results: QAM-GP

2.4.1. Baseline characteristics

The questionnaire was mailed to 2,150 GPs. 619 questionnaires were returned completed or partially completed. The overall response rate was 28.9%.

63.3% of the respondents were male and 36.7% were female *(N = 618)*. The mean number of years in practice recorded was 21.5 years and the maximum time recorded was 50 years. Approximately 60% of respondents have been in general practice for >20 years. 86.9% of respondents indicated that they own or have a stake in the general practice. The mean number of patients seen daily was 29 (SD = 10) and he maximum number was 60 patients. 33.4% of the respondents worked in towns, 25.2% worked in suburban based practices, 21.8% worked in rural locations and the remaining 19.5% worked in city based practices *(N = 607)*. The age range of the respondents is displayed below.

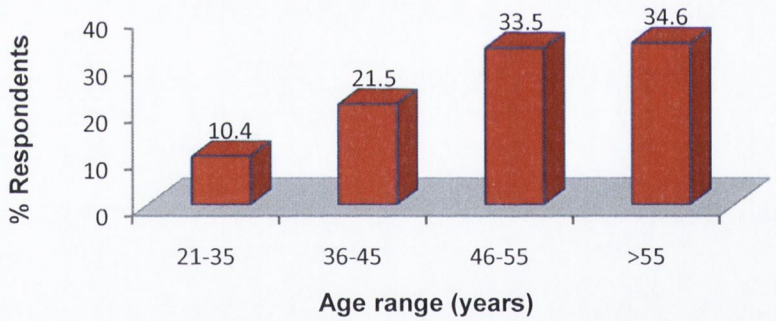


Figure 2.22: Age range of respondents (N = 618).

2.4.2. Opinions on current asthma treatment/management

2.4.2.1. Satisfaction with asthma care in the primary care setting nationwide

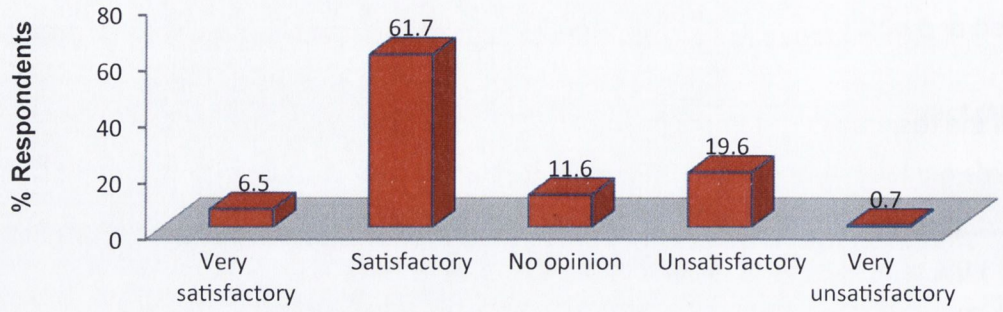


Figure 2.23: Level of satisfaction with nationwide asthma care in the primary care setting (N = 603).

2.4.2.2. Patients' understanding of asthma as a disease

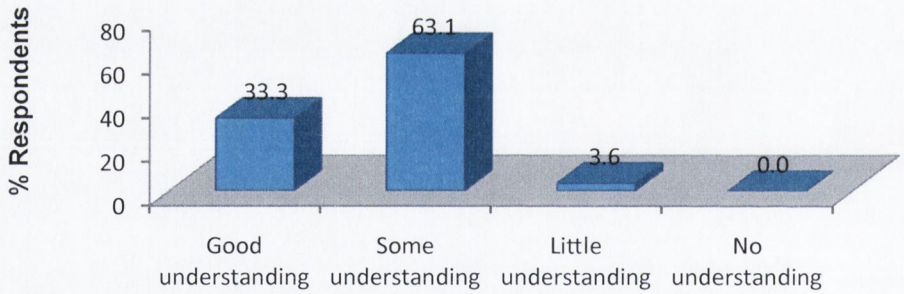


Figure 2.24: Patients' understanding of asthma as a disease, as estimated by their GPs (N = 616).

2.4.2.3. Patients' understanding of the indications for their asthma medications.

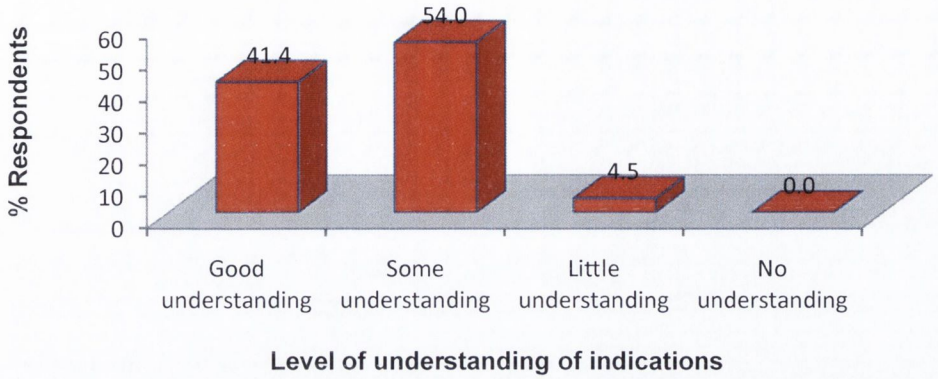


Figure 2.25: Patients' understanding of the indications for their asthma medications, as estimated by their GPs (N = 618).

2.4.2.4. Asthma patients estimated to use their inhalers properly

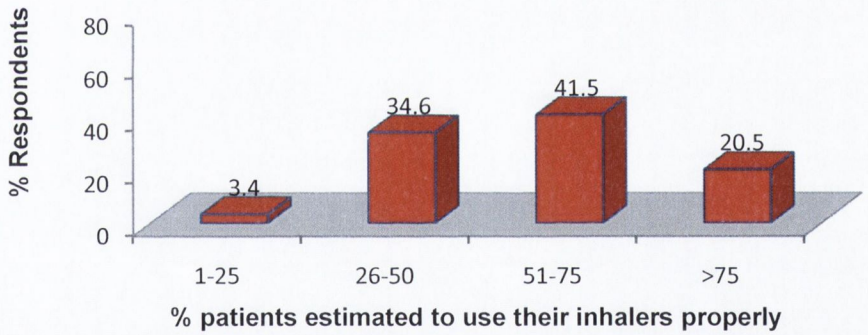


Figure 2.26 The percentage of patients estimated by their GP to use their inhalers correctly (N = 610).

The mean percentage of patients estimated to use their inhalers properly was 61% (SD =17). The minimum and maximum estimated percentages were 3% and 100% respectively.

2.4.2.5. Asthma patients estimated to possess and use a peak flow meter regularly

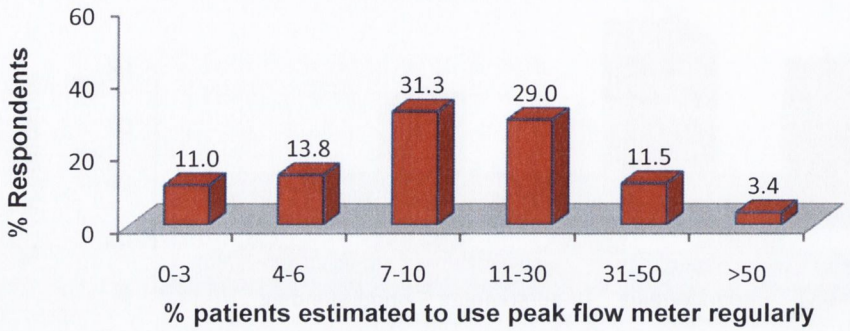


Figure 2.27: The percentage of patients estimated by their GP to have a peak flow meter that they use regularly (N = 610).

The mean estimated percentage was 18% (SD=17) and the minimum and maximum estimates were 0% and 100% respectively.

2.4.2.6. Asthma patients estimated to have well controlled asthma.

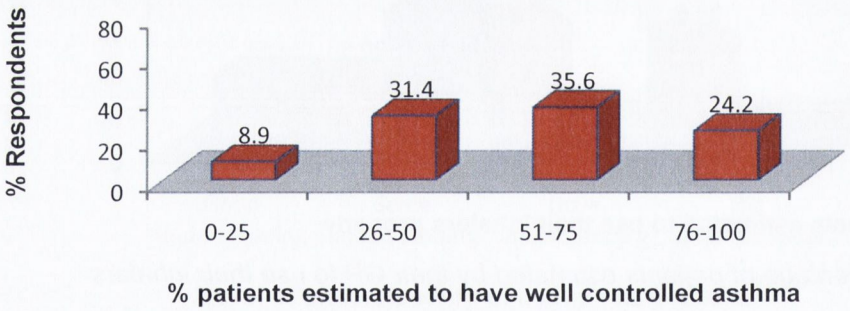


Figure 2.28: The percentage of patients estimated by their GPs to have well controlled asthma (N = 596).

The mean estimated percentage of patients with well controlled asthma was 60%. The maximum and minimum estimated values were 100% and 0% respectively.

2.4.2.7. Asthma patients' estimated level of medication compliance

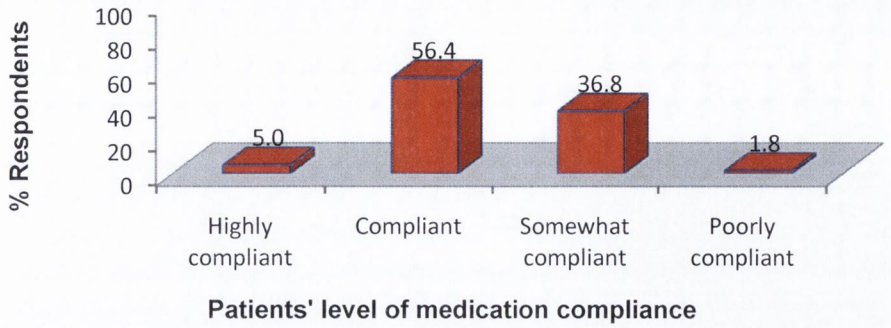


Figure 2.29: Patients' level of medication compliance as estimated by their GPs (N = 617).

2.4.2.8. Estimated frequency of asthma exacerbations (with hospitalisation).

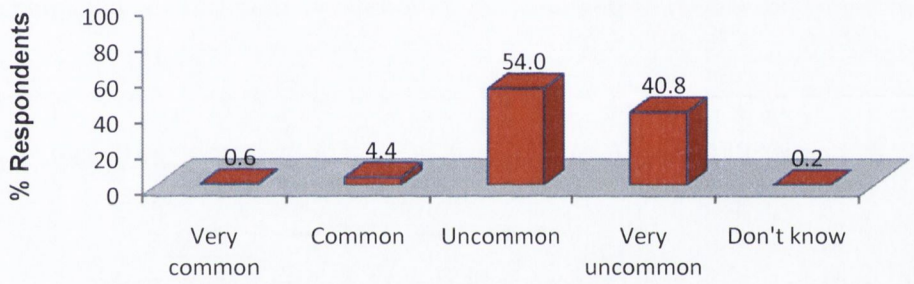


Figure 2.30: Frequency of asthma exacerbations (with hospitalisation) among patients as estimated by their GPs (N = 617).

2.4.2.9. Asthma patients estimated to possess an asthma management plan.

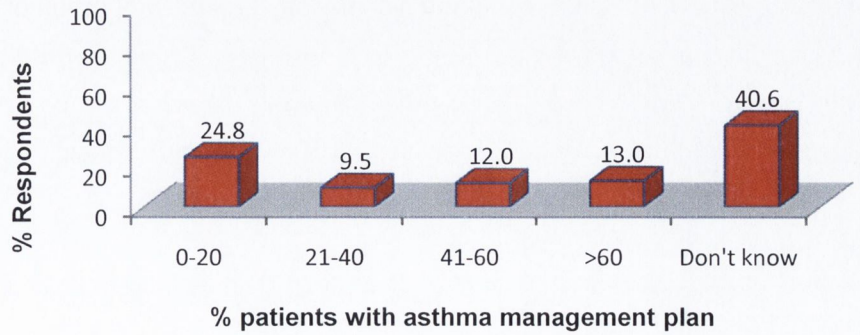


Figure 2.31: The percentage of patients with a personal asthma management plan and who are actively involved in their treatment, as estimated by their GPs (N = 608).

The mean percentage of patients estimated to possess an asthma management plan was 38% (SD = 29). The minimum and maximum percentage estimates were 0% and 100% respectively. *(N = 361).*

2.4.2.10. Patients' estimated expectations of asthma management.

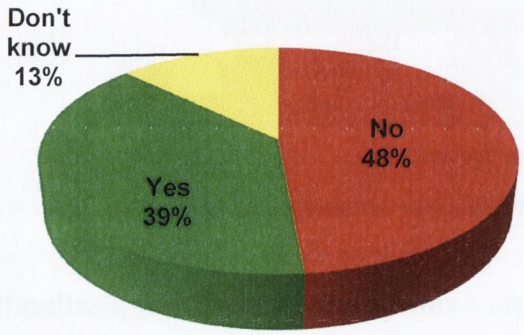


Figure 2.32: Respondents' views on whether or not their patients have low expectations of disease management (N = 610).

2.4.2.11. Influence of respondents' baseline characteristics on their opinions on current asthma treatment/management

Respondents' experience in general practice influenced a number of items in this subsection on *opinions on current asthma treatment/management.* A significantly greater proportion of respondents with > 20 years experience estimate that their asthma patients (1) have a *good understanding of asthma as a disease (N = 580, p < 0.001, χ^2test), (2)* have a *good understanding of the indications for their asthma medications (N = 616, p <0.001, χ^2 test),* and (3) are *highly compliant/compliant with their asthma medications (N = 580, p = 0.006, χ^2 test)* than those with less experience in general practice. Similarly, respondents with > 20 years experience estimate that a significantly greater proportion of their patients (1) *use their inhalers correctly (N = 574, p = 0.01, ANOVA),* (2) *have a peak flow meter that they use regularly (N = 574, p < 0.001, ANOVA)* and (3) *have a personalised asthma management plan (N = 345, p < 0.001, ANOVA)* than their less experienced colleagues.

Respondents" professional status also influenced a number of items in this subsection. A significantly greater proportion of practice owners/stakeholders believe that their patients (1) *have a good understanding of asthma as a disease (N = 607, p < 0.001, χ^2test),* and (2) *have a good understanding of the indications for their asthma medications (N = 608, p <0.001, χ^2 test)* than employee GPs. Similarly, practice owners/stakeholders estimate that

a higher proportion of their patients (1) *use a peak flow meter regularly (N = 602, p = 0.02, ANOVA)*, and (2) *possess a personalised asthma management plan (N = 598, p = 0.008, ANOVA)* than employee GPs. Finally, employee GPs believe that a significantly greater proportion of their patients *have low expectations of disease management* than practice owners/stakeholders *(N = 600, p < 0.05, χ^2 test)*.

2.4.3. Interventions with asthma patients

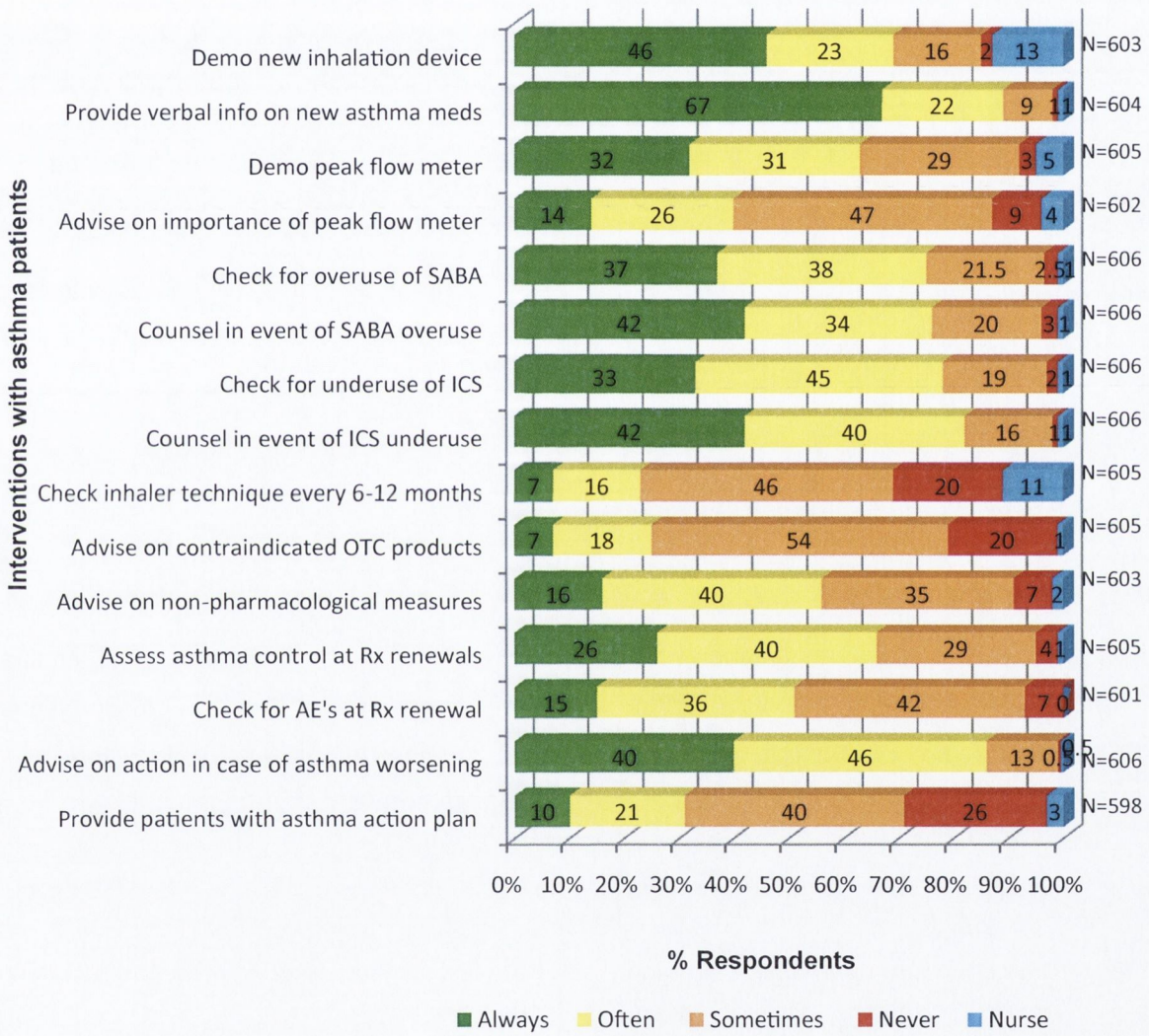


Figure 2.33: The frequency with which each respondent GP carries out the specified interventions with his/her asthma patients.

SABA =short acting β-agonist, ICS =inhaled corticosteroid, OTC =over-the-counter, Rx =prescription, AE = adverse effect.

The graph illustrates that the intervention most frequently carried out by GPs with their asthma patients is *providing verbal information on new asthma medications*, followed closely by *advising on action to take in case of worsening asthma.* The intervention conducted least commonly is *checking patients' inhalation technique every 6-12 months*, and this is followed by *advising on contraindicated OTC products.*

Table 2.16: Mean frequency with which respondent GPs perform specified interventions with their asthma patients.

	Interventions with asthma patients	N	Mean	
1.	Demonstrate the use of a newly prescribed inhaler	603	2.13	Often
2.	Provide verbal information on newly prescribed asthma medications	604	1.46	Always
3.	Demonstrate the use of a peak flow meter	605	2.20	Often
4.	Advise patients on importance of the peak flow meter in monitoring asthma control	602	2.62	Sometimes
5.	Check for overuse of SABA inhalers at prescription renewals	606	1.92	Often
6.	Counsel in the event of overuse of SABA inhalers	606	1.87	Often
7.	Check for underuse of ICS inhalers at prescription renewals	606	1.92	Often
8.	Counsel in the event of underuse of ICS inhalers	606	1.78	Often
9..	Check inhalation technique every 6-12 months	605	3.12	Sometimes
10.	Advise on contraindicated OTC products	605	2.89	Sometimes
11.	Advise on non-pharmacological measures to improve QOL	603	2.38	Often
12.	Ask patient questions to assess level of asthma control on prescription renewals	605	2.14	Often
13.	Check for drug related adverse effects at prescription renewals	601	2.43	Often
14.	Advise patient on correct action to take in signs of worsening asthma	606	1.75	Often
15.	Provide patients with personalised asthma action plan to allow increased self-management	598	2.91	Sometimes

SABA = short acting β-agonist, ICS = inhaled corticosteroid, OTC = over-the-counter, QOL = quality of life.

Each of the interventions with asthma patients was analysed to determine whether the baseline characteristics of the respondents had any influence on the results obtained. The results are outlined in the following sections.

2.4.3.1. Influence of respondents' experience in general practice on their interventions with asthma patients

Respondents' experience in general practice influenced a number of interventions with asthma patients. As the number of years of general practice experience increases the frequency with which each of the following asthma intervention is performed increases significantly:

- Advise patients on importance of peak flow meter in monitoring asthma control *($N = 545$, $p < 0.001$, χ^2 test).*
- Advise on contraindicated OTC products *($N = 564$, $p = 0.039$, χ^2 test).*
- Advise patients on correct action to take in event of worsening asthma *($N = 568$, $p = 0.007$, χ^2 test).*
- Provide patients with a personalised asthma action plan *($N = 545$, $p = 0.004$, χ^2 test).*

However, as general practice experience increases the proportion of respondents who *always/often demonstrate the use of a newly prescribed inhaler* increases, up to 21-25 years experience when it starts to decrease again. The differences between the groups are statistically significant *($N = 601$, $p = 0.005$, χ^2 test).* Indeed, a significantly greater proportion of practice nurses are identified as responsible for this intervention by the most experienced respondents than by less experienced GPs.

2.4.3.2. Influence of respondents' professional status on their interventions with asthma patients

Practice owner/stakeholder GPs conduct both of the following interventions significantly more frequently than employee GPs:

- Demonstrate the use of a newly prescribed inhaler *($N = 595$, $p = 0.003$, χ^2 test).*
- Check patients' inhalation technique every 6-12 months *($N = 596$, $p = 0.011$, χ^2 test).*

2.4.3.3. Consultation time per asthma patient

a) Average time spent in consultation with an asthma patient

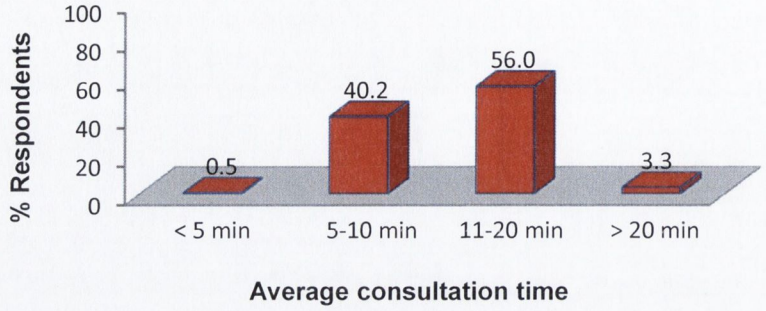


Figure 2.34: Average time spent in consultation with an asthma patient

b) Adequacy of time available to counsel asthma patients

31.5% of respondents do not believe that they have sufficient time to adequately counsel an asthma patient.

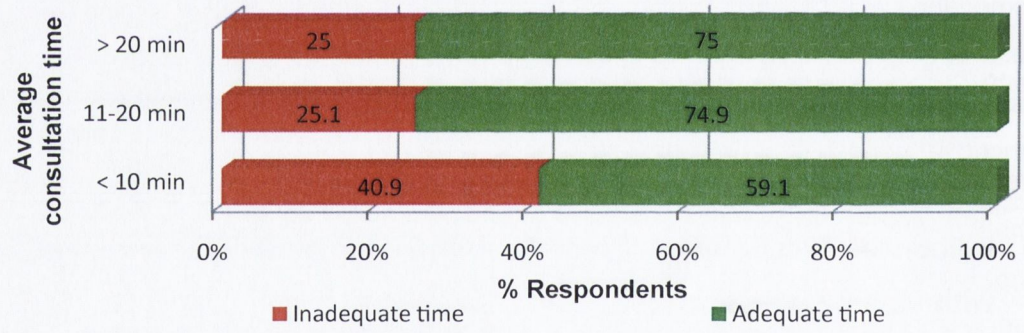


Figure 2.35: Adequacy of time spent counselling an asthma patient classified according to the average time spent in consultation per patient (N = 593, $p < 0.001$, χ^2 test).

As expected, a significantly greater proportion of respondents who spend an average of <10 minutes in consultation with an asthma patient believe that they have inadequate time to adequately counsel their asthma patients compared with respondents who spend >10 minutes per consultation.

2.4.4. Communication with community pharmacists

2.4.4.1. Communication frequency with community pharmacists about asthma patients.

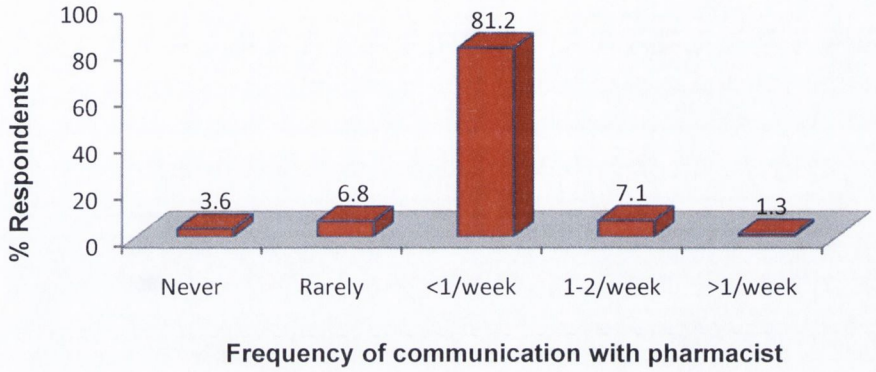


Figure 2.36: Frequency with which GPs communicate with a community pharmacist about an asthma patient (N = 617).

Significant relationships were observed between this item and respondents' age and the regional location of their general practice.

a) Age and frequency of communication

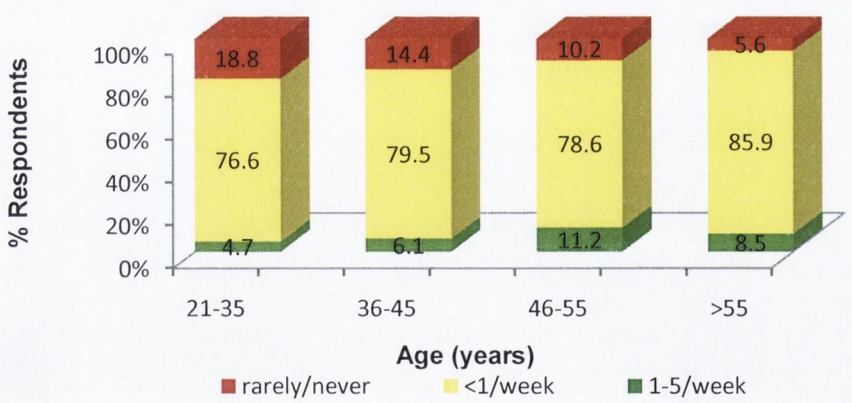


Figure 2.37: Frequency of communication between GPs and community pharmacists classified according to age (N = 615, p = 0.02, χ^2 test).

Younger respondents communicate significantly less frequently with community pharmacists about asthma patients than their older counterparts.

b) Regional location and frequency of communication

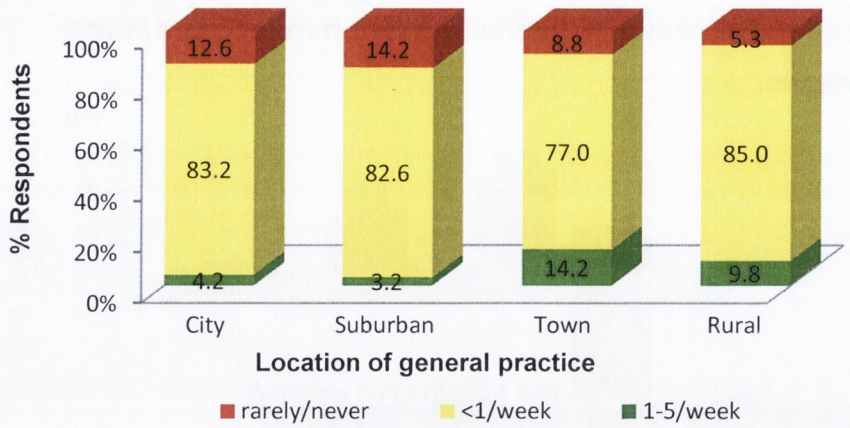


Figure 2.38: Frequency of communication between GPs and community pharmacists classified according to location of the practice (N = 611, p = 0.001, χ^2 test).

Communication with community pharmacists, about asthma patients, occurs significantly less frequently in city and suburban practices than practices located rurally or in towns.

2.4.4.2. Form of communication with community pharmacists

96% of respondents indicated that they usually communicate with the pharmacist, about an asthma patient, by telephone. 2.5% usually communicate using messages carried by patients, 0.2% by fax, 0.4% by letter and 0.5% use an alternative communication method *(N = 563).*

2.4.4.3. Nature of communication with community pharmacists

Table 2.17: Mean prevalence with which each asthma medication problem is discussed with a community pharmacist.

	Nature of communication	N	Mean
1.	Inhaler device change	309	2.15
2.	Dosage change	292	2.10
3.	Non-compliance (overuse of medication)	237	3.73
4.	Non-compliance (underuse of medication)	239	3.75
5.	Side-effects	223	4.11
6.	Drug interactions	251	4.18
7.	Other	162	5.47

The two issues most frequently discussed between GPs and community pharmacists about asthma medications are changes in the inhaler device and dosage changes. Drug interactions are least frequently discussed (1 = most prevalent, 7 = least prevalent).

Respondents were asked to identify other communication issues that they discuss with the community pharmacist and these are outlined in the table below.

Table 2.18: Identification and prevalence of other issues relating to asthma discussed with the community pharmacist (N = 56).

	Other communication issues	% Respondents
1.	Prescription needed by pharmacist	30.4
2.	Pharmacist asked to demonstrate inhaler technique	12.5
3.	Discussion about spacer devices	8.9
4.	Discussion about price of inhalation devices	7.1
5.	Pharmacist repeating medications without prescription	5.4
6.	Item missing from prescription	5.4
7.	Addition of medication for acute exacerbation to prescription	5.4
8.	General queries/clarifications	5.4
9..	Change medication brand/change to generic	5.4
10.	Medication/device unavailable	5.4
11.	Ineffective medications	3.6
12.	Frequency of collecting new inhalers	1.8
13.	Change to long acting medications	1.8
14.	Advice on inhalation devices	1.8

2.4.4.4. Issue resolution following communication

95% of respondents stated that the issue was resolved following communication with the community pharmacist *(N = 520)*. Only 6 of the respondents, who indicated that communication does not always resolve the issue, specified the reasons for lack of resolution (see Table 2.19).

Table 2.19: Reasons for lack of resolution following communication with pharmacist ***(N = 6).***

	Reasons for lack of resolution	Respondents N (%)
1.	Medications have already been dispensed by pharmacist	2 (33.3)
2.	Often there is no follow-up on query	2 (33.3)
3.	Pharmacists do not understand the issues	1 (16.7)
4.	Patients are not willing to comply with advice	1 (16.7)

2.4.4.5. Satisfaction with method and frequency of communication

a) Satisfaction with current frequency of communication

88.5% of respondents indicated that the frequency of communication was satisfactory *(N = 522)*.

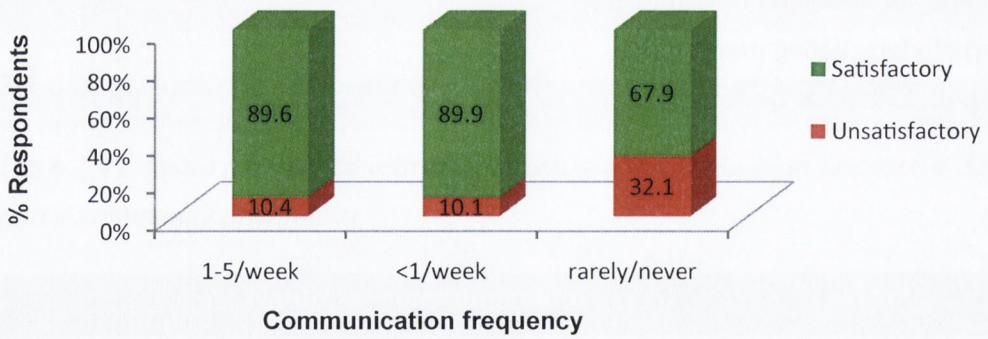


Figure 2.39: Satisfaction with level of communication classified according to frequency of the communication (N = 521, p = 0.002, χ^2 test).

As expected, a significantly greater proportion of respondents who *rarely/ never* communicate with a community pharmacist are dissatisfied with the current level of communication than those who communicate more frequently.

b) Satisfaction with current method of communication

90.7% of respondents were satisfied with the current method of communication with the pharmacist *(N = 355).*

c) Changes needed to improve unsatisfactory communication with pharmacists

If respondents were dissatisfied with the current state of communication with community pharmacists, they were asked to write freely about what changes could be made to improve communication, but the majority of respondents simply commented on the current situation.

Table 2.20: Comments proposed by respondents on current communication with community pharmacists (N = 58).

	Changes needed to improve GP-pharmacist communication	% Respondents
1.	Communication with community pharmacists is rare	19.0
2.	Need better method of communication, local protocols	17.2
3.	Increased communication with community pharmacists is needed	13.8
4.	Need more regulation of pharmacists re dispensing without prescriptions	12.0
5.	Need frequent updates on patients' repeat medications/compliance	8.6
6.	No need to talk to pharmacists	8.6
7.	GP-pharmacist communication is only a secondary issue, patients are main problem	5.2
8.	Too many phone calls from pharmacists, it is disruptive during surgery hours	5.2
9.	Better education of patients is needed	3.4
10.	Less demand for prescribing rights by pharmacists is needed	1.7
11.	Coordination between GPs and pharmacists re patient health and education is needed	1.7
12.	Patient education on pharmacists' skills is needed	1.7
13.	Unclear on what advice, if any, pharmacists are providing to asthma patients	1.7

Two distinct themes are evident from the table. On one hand, a proportion of respondents believe that, at present, communication with community pharmacists is very infrequent, needs to be increased, and a better system of communication is required. However, there is another proportion of respondents who do not appear to be well disposed towards pharmacists and do not seem to welcome communication with pharmacists nor deem it necessary.

2.5. Results: QAM-PN

2.5.1. Baseline characteristics

1519 practice nurses were registered with the professional development coordinators, responsible for continuing education of practice nurses in primary care in Ireland in 2010[141]. 264 questionnaires were returned completed or partially completed. The overall response rate was 17.4%.

99.2% of the respondents were female *(N = 264)*. The mean number of years practising as a nurse was 17.8 years (SD = 10.3). The maximum time recorded was 45 years. Approximately 65% of respondents had been practising as a nurse for ≤ 20 years. 18.9% of respondents were in the 21-35 years age bracket, 33% were aged 36-45 years, 40.5% were aged 46-55 years and the remaining 7.6% were >55 years *(N = 262)*. The mean number of patients seen daily was 22 (SD = 8). The maximum and minimum number of patients were 2 and 60 respectively *(N=253)*. 35.5% of the respondents worked in town based practices, 24% worked in rural locations, 16.8% worked in suburban practices, 19.1% worked in city locations, and the remaining 4.6% worked in both town and rural practices *(N = 262)*.

2.5.2. Opinions on current asthma treatment/management

2.5.2.1. Satisfaction with current asthma care in the primary care setting nationwide

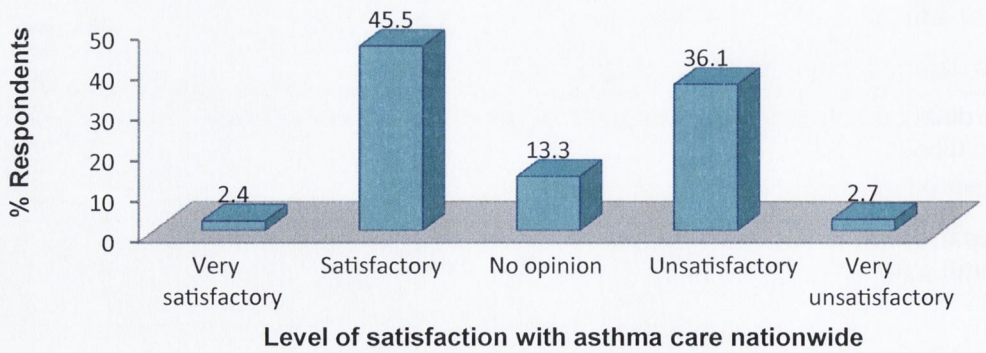


Figure 2.40: Respondents' level of satisfaction with the current level of asthma care in the primary care setting nationwide (N = 255).

2.5.2.2. Patients' understanding of asthma as a disease

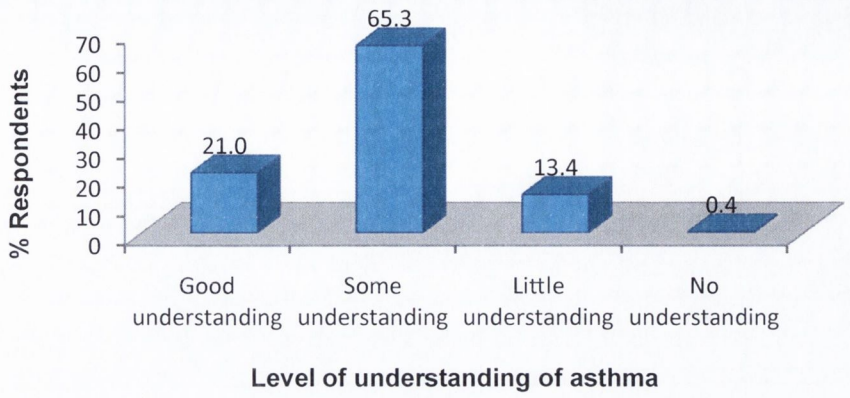


Figure 2.41: Patients' understanding of asthma as a disease as estimated by their practice nurses (N = 262).

2.5.2.3. Patients' understanding of the indications for their medications

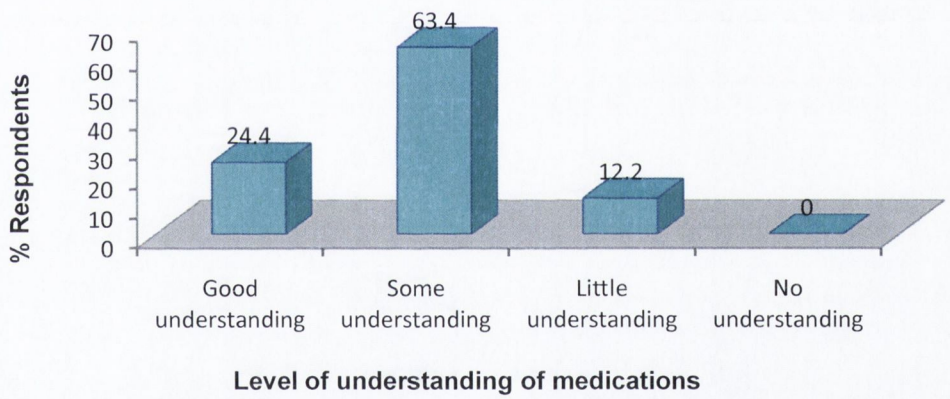


Figure 2.42: Patients' understanding of the indications for their asthma medications as estimated by their practice nurses (N = 262).

2.5.2.4. Asthma patients estimated to use their inhalers properly

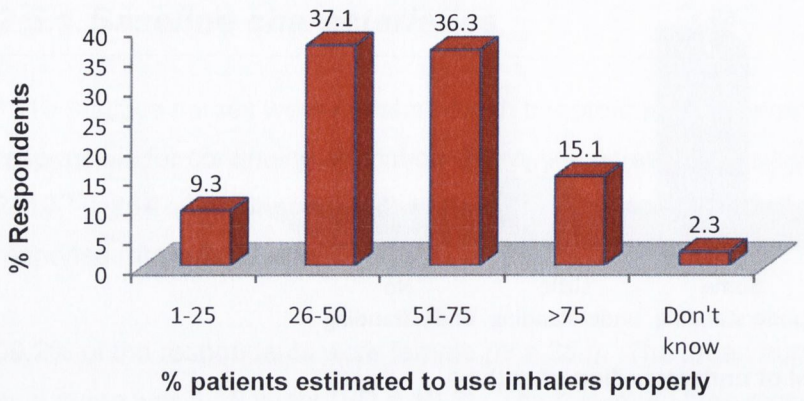


Figure 2.43: Percentage of patients estimated by their practice nurses to use their inhalers properly (N=259).

The mean percentage of patients estimated to use their inhalers correctly was ~56% (SD = 19). The minimum and maximum estimated percentages were 4% and 91% respectively. *(N = 254).*

2.5.2.5. Asthma patients estimated to use a peak flow meter regularly

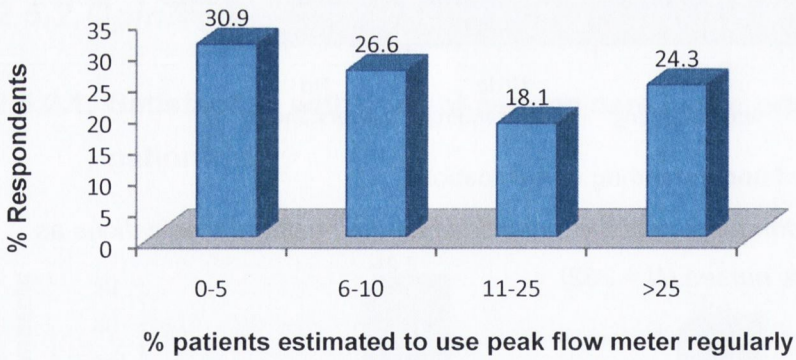


Figure 2.44: Percentage of patients estimated by their practice nurses to use a peak flow meter regularly (N = 259).

The mean percentage of patients estimated to use a peak flow meter regularly was 17% (SD = 17). The maximum and minimum estimated values were 0% and 100% respectively *(N = 251).*

2.5.2.6. Asthma patients estimated to have well controlled asthma

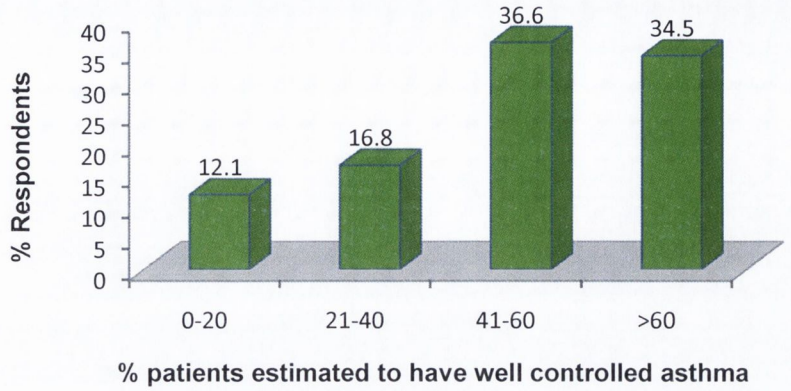


Figure 2.45: Percentage of patients estimated by their practice nurses to have well controlled asthma (N = 232).

The mean percentage of patients estimated to have well controlled asthma was 53% (SD = 21.5). The maximum and minimum estimates were 5% and 95% respectively *(N = 232).*

2.5.2.7. Asthma patients' estimated level of medication compliance

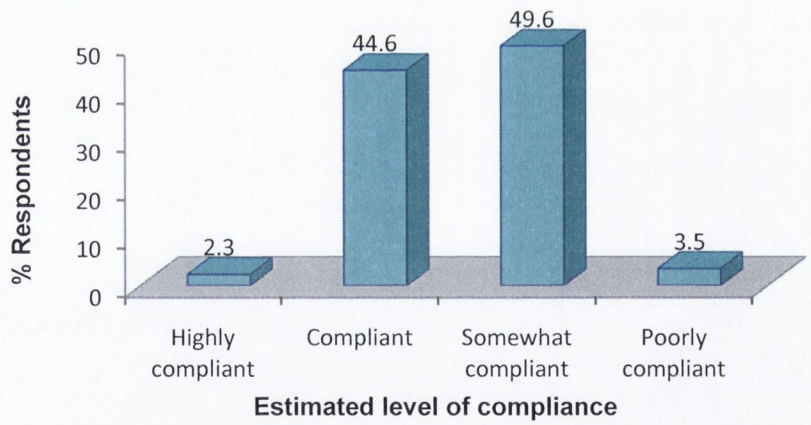


Figure 2.46: Patients' level of medication compliance as estimated by their practice nurses (N = 258).

2.5.2.8. Estimated frequency of asthma exacerbations (with hospitalisation)

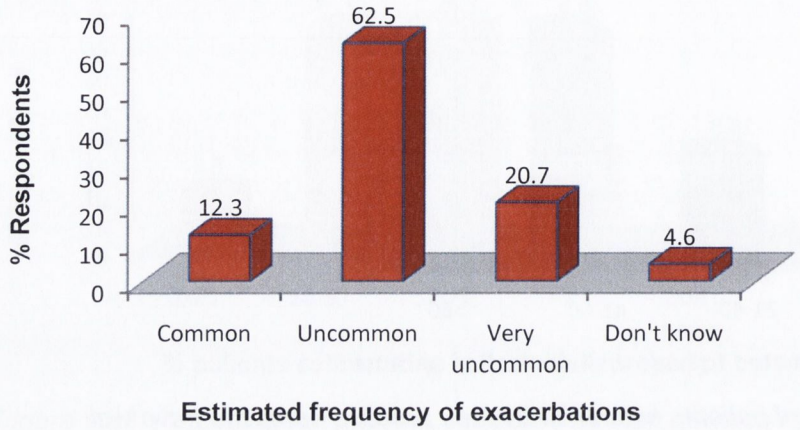


Figure 2.47: Frequency of asthma exacerbations (with hospitalisations) among patients as estimated by their practice nurses (N = 261).

2.5.2.9. Patients estimated to possess an asthma management plan

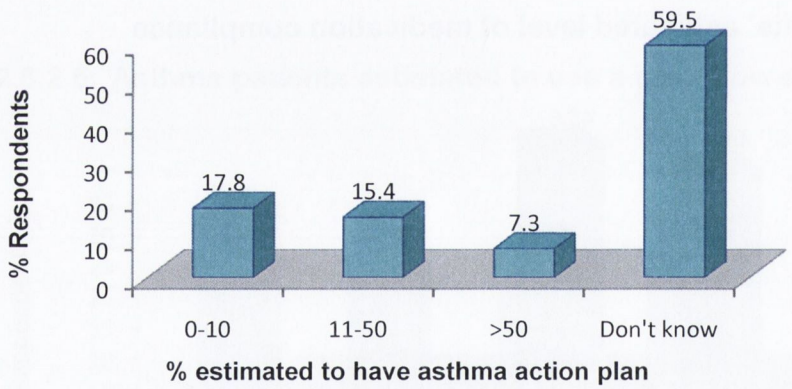


Figure 2.48: Percentage of patients estimated by their practice nurses to have a personal asthma management plan (N = 259).

The mean percentage of patients estimated to possess an asthma management plan was 29% (SD = 26). The minimum and maximum percentage estimates were 0% and 100%. However, only 40.5% of respondents provided a percentage estimate in response to this question, 59.5% were unable to provide an estimate and 6 respondents did not complete the question.

2.5.2.10. Patients' estimated expectations of disease management

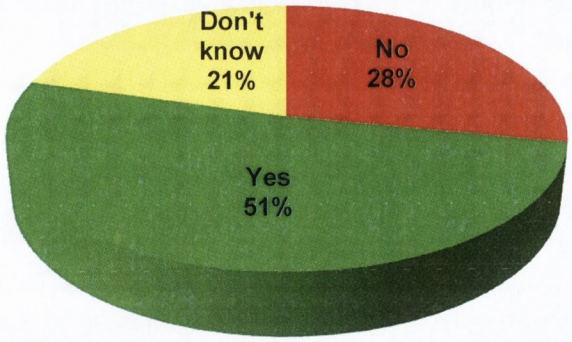


Figure 2.49: Respondents' views on whether or not their asthma patients have low expectations of disease management (N = 253).

2.5.2.11. Influence of respondents' baseline characteristics on their opinions on current asthma treatment/management

Respondents' demographic characteristics only influenced one item, *patients' understanding of asthma as a disease,* in this subsection on *opinions on current asthma treatment/management.* A significantly greater proportion of respondents with the least nursing experience (0-10 years) believe that their patients have *little/no understanding of asthma as a disease* than respondents with a greater amount of nursing experience. In addition, a significantly lesser proportion of nurses with a moderate amount of experience (11-30 years) believe that their patients have *little/no understanding* than those with the least or the most experience *(N=255, p = 0.037, χ^2 test).*

2.5.3. Interventions with asthma patients

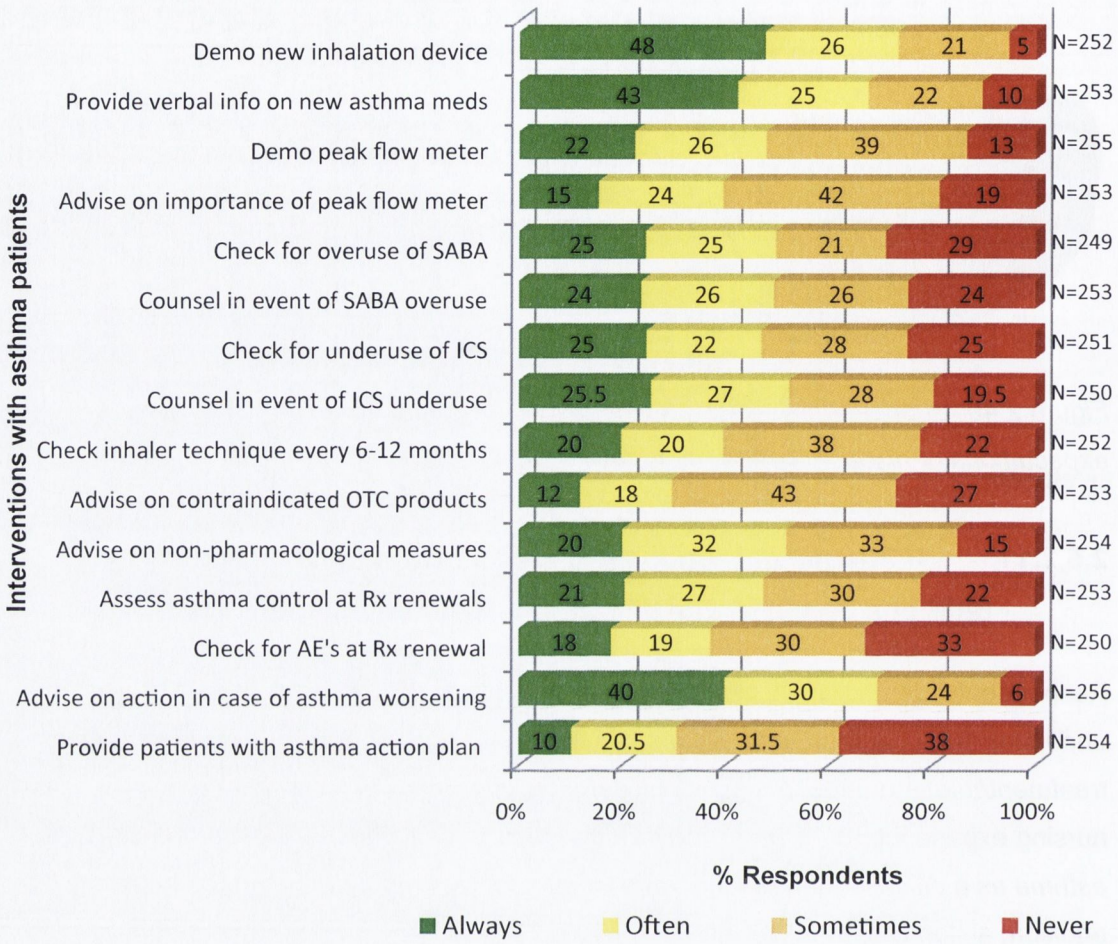


Figure 2.50: The frequency with which each respondent nurse carries out the specified interventions with her asthma patients.

SABA = short acting β-agonist, ICS = inhaled corticosteroid, OTC = over-the-counter, Rx = prescription, AE = adverse effect.

The graph illustrates that the intervention carried out most frequently is *demonstrate the use of a newly prescribed inhalation device,* followed closely by *advise on correct action to take in the event of asthma worsening.* The intervention conducted least frequently is *provide patients with a personalised asthma action plan to allow self-management of asthma,* followed by *advise patients on contraindicated OTC products.*

Table 2.21: Mean frequency with which respondent nurses perform specified interventions with their asthma patients.

	Interventions with asthma patients	N	Mean	
1.	Demonstrate the use of a newly prescribed inhaler	252	1.84	Often
2.	Provide verbal information on newly prescribed asthma medications	253	2.00	Often
3.	Demonstrate the use of a peak flow meter	255	2.43	Often
4.	Advise patients on importance of peak flow meter in monitoring asthma control	253	2.64	Sometimes
5.	Check for overuse of SABA inhalers at prescription renewals	249	2.55	Sometimes
6.	Counsel on in the event of overuse of SABA inhalers	253	2.51	Sometimes
7.	Check for underuse of ICS inhalers at prescription renewals	251	2.53	Sometimes
8.	Counsel in the event of underuse of ICS inhalers	250	2.42	Often
9..	Check inhalation technique every 6-12 months	252	2.63	Sometimes
10.	Advise on contraindicated OTC products	253	2.85	Sometimes
11.	Advise on non-pharmacological measures to improve QOL	254	2.43	Often
12.	Ask patient questions to assess level of asthma control on prescription renewals	253	2.54	Sometimes
13.	Check for drug related adverse effects at prescription renewals	250	2.78	Sometimes
14.	Advise patient on correct action to take in signs of worsening asthma	256	1.97	Often
15.	Provide patients with personalised asthma action plan to allow increased self-management	254	2.97	Sometimes

SABA = short acting β-agonist, ICS = inhaled corticosteroid, OTC = over-the-counter, QOL = quality of life.

Each of the interventions with asthma patients was analysed to determine whether the baseline characteristics of the respondents had any influence on the results obtained. Respondents' experience in general practice was the only characteristic that influenced any of the interventions. The results are outlined in the following section.

2.5.3.1. Influence of respondents' experience in general practice on their interventions with asthma patients

Respondents' experience in general practice influenced a number of interventions with their asthma patients. Respondents with the least amount of experience in general practice conduct the interventions outlined below significantly less frequently than those with greater experience. In addition, respondents with the most experience (> 30 years) conduct these interventions significantly more frequently than those with fewer years experience. The aforementioned interventions are:

- Demonstrate the use of a peak flow meter *(N = 248, p = 0.04, χ^2 test).*
- Advise patients on importance of peak flow meter in monitoring asthma control *(N = 246, p = 0.03, χ^2 test).*
- Counsel in the event of overuse of reliever inhalers *(N = 246, p = 0.003, χ^2 test).*
- Check for underuse of preventer inhalers at prescription renewals *(N = 244, p = 0.011, χ^2 test).*
- Advise on contraindicated OTC products *(N = 246, p = 0.019, χ^2 test).*

2.5.3.2. Consultation time per asthma patient

a) Average time spent in consultation with an asthma patient

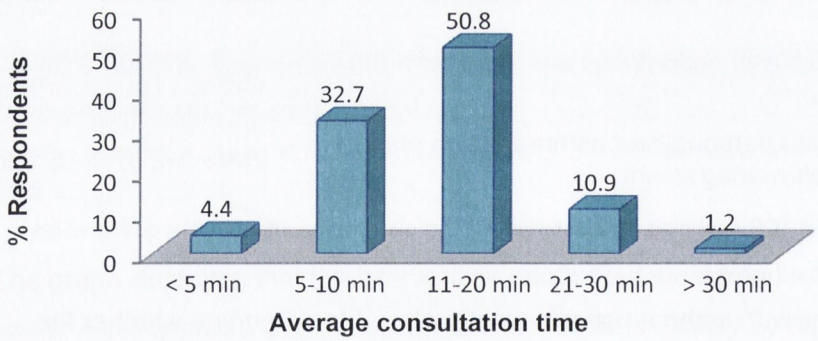


Figure 2.51: Average time spent in consultation with an asthma patient (N = 248).

A significant relationship was observed between the amount of time spent in consultation with an asthma patient and the mean frequency with which a respondent conducted the specified asthma interventions with a patient.

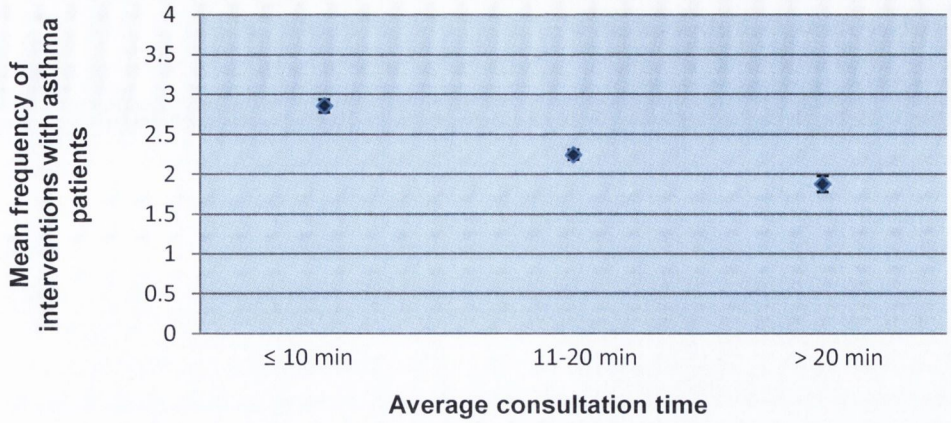


Figure 2.52: Average consultation time per asthma patient classified according to the mean frequency (± SE) with which respondents conducted the specified interventions with their patients (N = 247, p < 0.001, ANOVA) (Mean frequency: 1-4, 1=always, 4 = never).

Respondents who spend an average of ≤10 minutes per consultation with an asthma patient conduct the specified interventions significantly less frequently than those who have a greater amount of time per consultation.

b) Adequacy of time available to consul asthma patients

50.6% of respondents do not believe that they have sufficient time per consultation to adequately counsel their asthma patients.

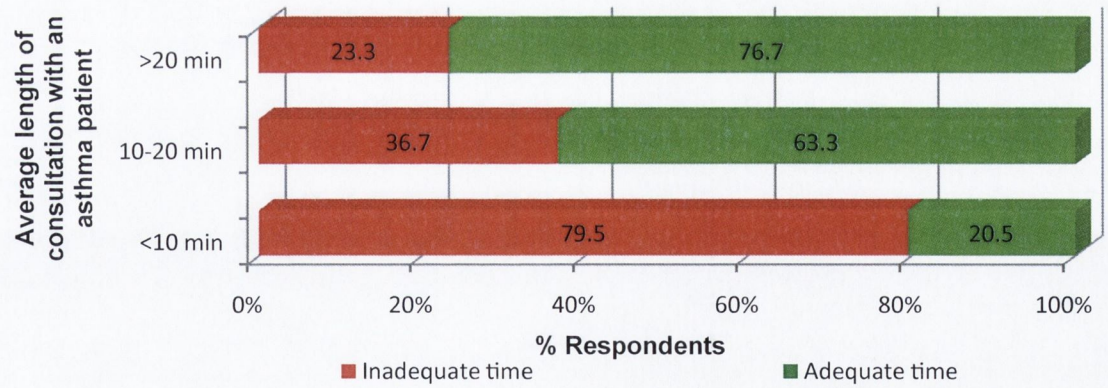


Figure 2.53: Adequacy of time spent in consultation with an asthma patient classified according to average time spent in consultation per patient (N = 238, p <0.001, χ^2 test).

As expected, as the average time spent in consultation with an asthma patient increases the proportion of respondents who believe this length of time is inadequate decreases and the differences between the groups are significant.

2.5.4. Communication with community pharmacists

2.5.4.1. Frequency of communication with pharmacists about asthma patients

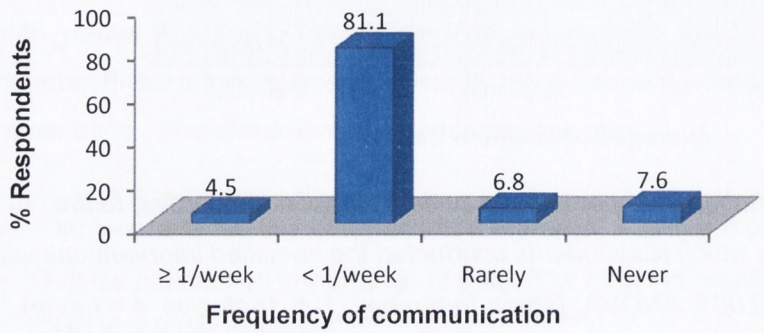


Figure 2.54: Frequency of communication between nurses and pharmacists about asthma patients (N = 264).

2.5.4.2. Form of communication with community pharmacists

The majority of the communication between nurses and pharmacists about asthma patients usually occurs by telephone (87.6%). 9.4% of respondents indicated that they usually communicate using a message carried by the patient. The remainder communicated by letter or by an alternative (unspecified) form. *(N = 234).*

2.5.4.3. Nature of communication with community pharmacists

Table 2.22: Mean prevalence with which each asthma medication problem is discussed with a community pharmacist.

	Nature of communication	N	Mean
1.	Inhaler device change	142	1.94
2.	Dosage change	118	2.03
3.	Non-compliance (overuse of medication)	89	3.10
4.	Non-compliance (underuse of medication)	99	3.56
5.	Side-effects	90	4.17
6.	Drug interactions	105	4.42

The two issues discussed most frequently by practice nurses and community pharmacists are *inhaler device changes* and *dosage changes*. *Drug interactions* are discussed least frequently.

2.5.4.4. Issue resolution following communication

96% of respondents indicated that communication usually led to a resolution of the issue *(N = 216).* Respondents were asked to elaborate on the possible reasons why communication did not usually lead to a resolution of the issue, if this was their opinion on the matter. However, only five respondents (1.9%) provided a reason. Four respondents stated that the issue is not resolved due to *patient issues e.g. lack of education*, and one respondent stated that the reason for lack of resolution is an *absence of follow-up.*

2.5.4.5. Satisfaction with method and frequency of communication

82% of respondents are satisfied with the current frequency of communication with community pharmacists *(N=227).* 85% are satisfied with the current method of communication *(N = 264).*

If they were dissatisfied with the current state of communication, respondents were asked to write freely about what changes could be made to improve communication with pharmacists. Only 9.1% responded to this item and the majority of them commented on the current state of communication without proposing any improvements.

Table 2.23: Comments proposed by respondents on communication with community pharmacists (N = 24).

	Changes needed to improve nurse-pharmacist communication	% Respondents
1.	Need more understanding by pharmacists about level of knowledge of nurses about asthma	33.4
2.	Need to establish structured communication links with pharmacists	16.7
3.	Need more patient education	12.5
4.	Need follow-up information from pharmacists especially regarding compliance	12.5
5.	Pharmacist should not be dispensing emergency supplies of reliever inhalers	8.3
6.	GP related issues	8.3
7.	Need more asthma clinics	4.2
8.	Need more communication between pharmacist and nurse	4.2

The key issue illustrated by the results is that nurses believe that pharmacists are unaware of level of knowledge that nurses have in the area of asthma management. There does seem to be a desire overall to increase communication with pharmacists and to do so in a more structured manner.

2.6. Results: Comparative study

2.6.1. Opinions on current asthma treatment/management

2.6.1.1. Satisfaction with asthma care in primary care setting nationwide

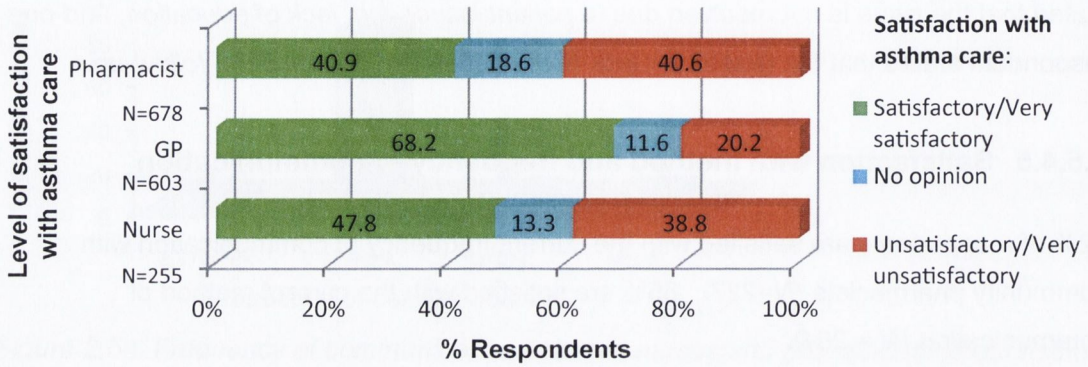


Figure 2.55: Level of satisfaction with current level of asthma care in the primary care setting nationwide classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of pharmacists than GPs or nurses believe that asthma care nationwide is *unsatisfactory/very unsatisfactory* and a significantly greater proportion of GPs than pharmacists or nurses believe that it is *satisfactory/very satisfactory*.

2.6.1.2. Patients' understanding of asthma as a disease

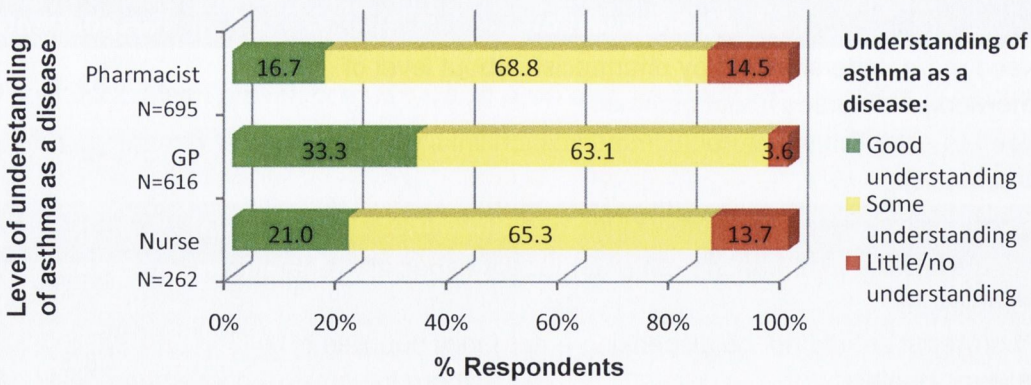


Figure 2.56: Patients' understanding of asthma as a disease as estimated by their pharmacists/GPs/nurses classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of pharmacists than GPs or nurses believe that their patients have *little/no understanding* of asthma as a disease and a significantly greater proportion of GPs than pharmacists or nurses believe that their patients have a *good understanding* of asthma as a disease.

2.6.1.3. Patients' understanding of indications for their asthma medications

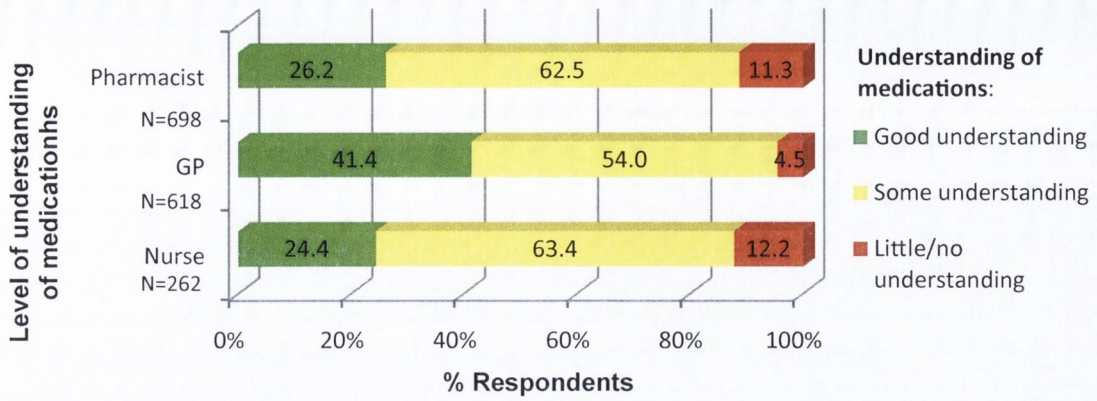


Figure 2.57: Patients' understanding of the indications for their medications as estimated by their pharmacists/GPs/nurses classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of GPs than pharmacists or nurses believe that their patients have a *good understanding* of the indications for their asthma medications. A significantly greater proportion of pharmacists than GPs or nurses believe that their patients have *little/no understanding* of their medications.

2.6.1.4. Asthma patients estimated to use their inhalers properly

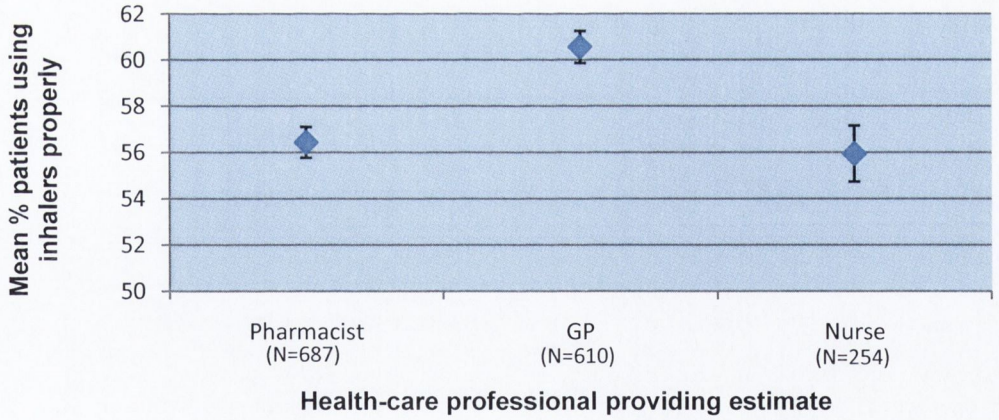


Figure 2.58: Mean percentage of patients (±SE) estimated by their pharmacists/GPs/nurses to use their inhalers properly, classified according to profession ($p < 0.001$, ANOVA).

The mean percentage of patients estimated by their GPs to use their inhalers properly is significantly higher than the mean percentages estimated by pharmacists or nurses.

2.6.1.5. Asthma patients estimated to use a peak flow meter regularly

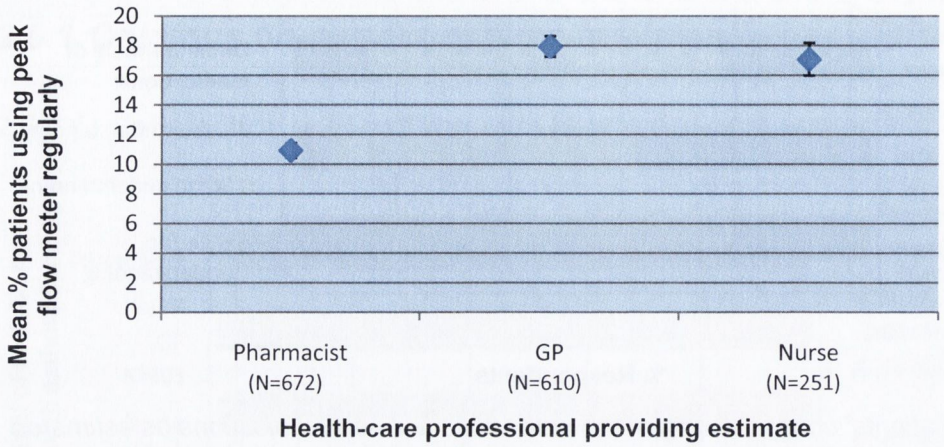


Figure 2.59: Mean percentage of patients (±SE) estimated by their pharmacists/GPs/nurses to use a peak flow meter regularly, classified according to profession ($p < 0.001$, ANOVA).

The mean percentage of patients estimated by their pharmacists to use a peak flow meter regularly is significantly lower than the mean percentages estimated by GPs and nurses.

2.6.1.6. Asthma patients estimated to have well controlled asthma

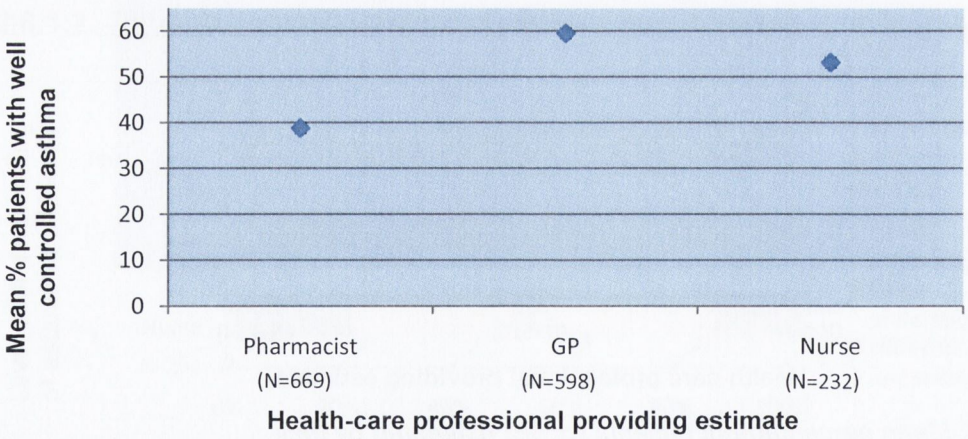


Figure 2.60: Mean percentage of patients (±SE) *estimated by their pharmacists/GPs/nurses to have well controlled asthma, classified according to profession ($p < 0.001$, ANOVA).*

A significant difference exists between the mean percentage of patients estimated to have well controlled asthma provided by their GPs, pharmacists and nurses. The GPs provided the largest estimate, followed by the nurses and the smallest estimate was provided by the pharmacists.

2.6.1.7. Asthma patients' estimated level of medication compliance

The QAM-CP was the first of the three questionnaires to be designed and it only had 3 Likert responses to the question that asked respondents to estimate their patients' level of medication compliance. These responses were *highly compliant, fairly compliant* and *poorly compliant.* On analysis of the results of this survey, it was considered that an additional response option was required therefore, the QAM-GP and QAM-PN had four response options: *highly compliant, compliant, somewhat compliant* and *poorly compliant.* To facilitate a comparison study the response *fairly compliant* was considered equivalent to the combined *compliant/somewhat compliant* response option.

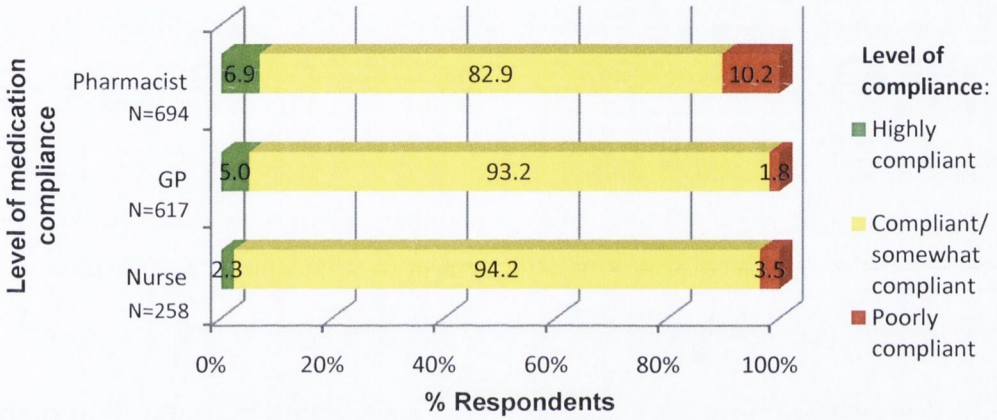


Figure 2.61: Patients' level of medication compliance as estimated by their pharmacists/GPs/nurses classified according to profession ($p < 0.001$, χ^2 test).

A significantly smaller proportion of nurses than either GPs or pharmacists believe that their patients are *highly compliant.* A significantly greater proportion of pharmacists than either GPs or nurses believe that their patients are poorly compliant. A significantly smaller proportion of GPs than pharmacists or nurses believe that their patients are poorly compliant.

2.6.1.8. Estimated frequency of asthma exacerbations (with hospitalisation)

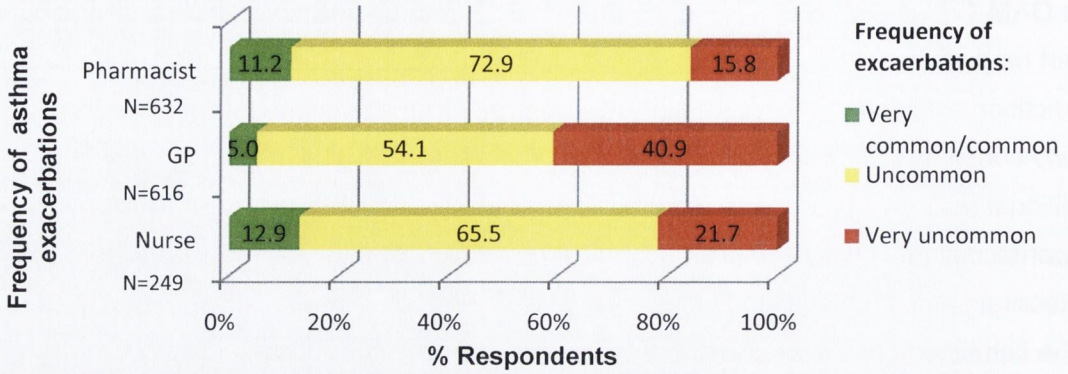


Figure 2.62: Frequency of asthma exacerbations (with hospitalisation) among patients as estimated by their pharmacists/GPs/nurses, classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of nurses than GPs or pharmacists believe that asthma exacerbations (with hospitalisation) are very common/common among their patients. A significantly greater proportion of GPs than pharmacists or nurses believe that exacerbations are very uncommon among their patients.

2.6.1.9. Asthma patients estimated to possess an asthma management plan

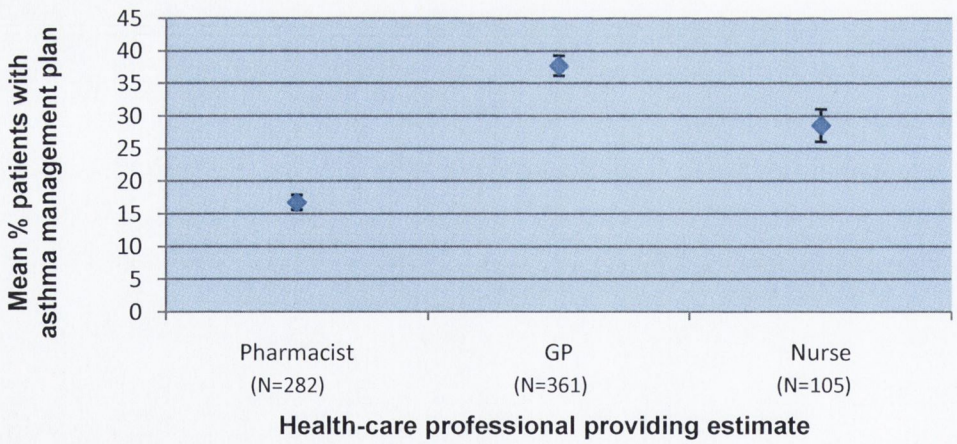


Figure 2.63: Mean percentage of patients (±SE) estimated by their pharmacists/GPs/nurses to possess an asthma management plan, classified according to profession ($p < 0.001$, ANOVA).

There are significant differences in the mean percentage of patients estimated by their pharmacists, GPs or nurses to possess an asthma management plan. The greatest mean estimate was provided by GPs, followed by nurses and the smallest mean estimate was provided by pharmacists.

2.6.1.10. Patients' estimated expectations of asthma management

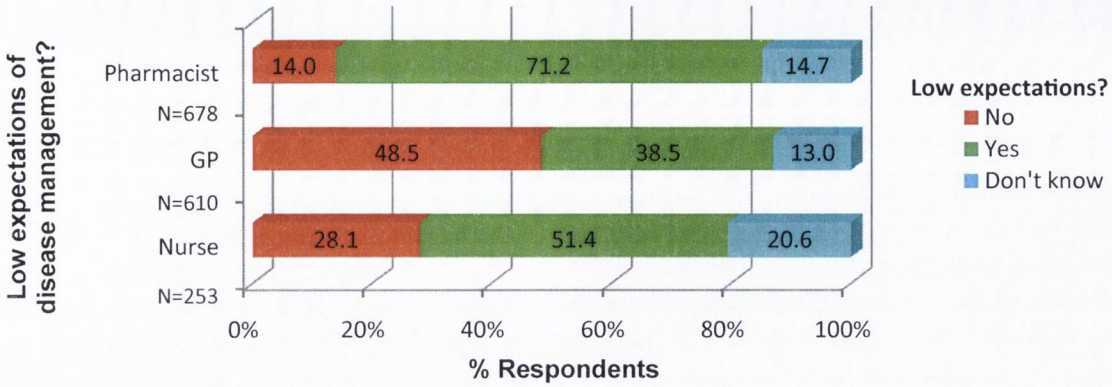


Figure 2.64: Patients' expectations of disease management as estimated by their pharmacists/GPs/nurses, classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of GPs than pharmacists or nurses believe that their patients do not have low expectations of asthma management. A significantly greater proportion of pharmacists than GPs or nurses believe that their patients do have low expectations and a significantly greater proportion of nurses than pharmacists or GPs are unaware of their patients' disease management expectations.

2.6.2. *Interventions with asthma patients*

2.6.2.1. Demonstrate the use of a newly prescribed inhaler

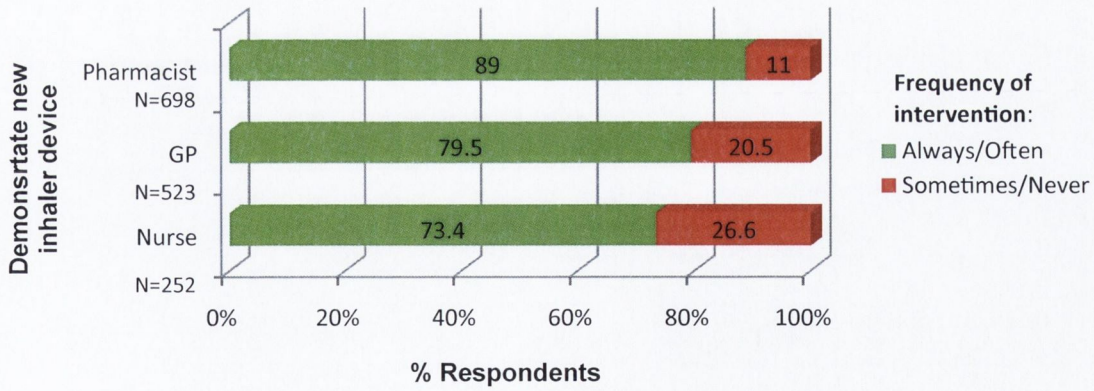


Figure 2.65: Frequency with which respondents demonstrate the use of a newly prescribed inhaler, classified according to profession ($p < 0.001$, χ^2 test).

A significantly smaller proportion of pharmacists than GPs or nurses *sometimes/never demonstrate the use of a newly prescribed inhaler.* A significantly greater proportion of nurses than GPs or pharmacists *sometimes/never* conduct this intervention.

2.6.2.2. Provide verbal information about newly prescribed asthma medications

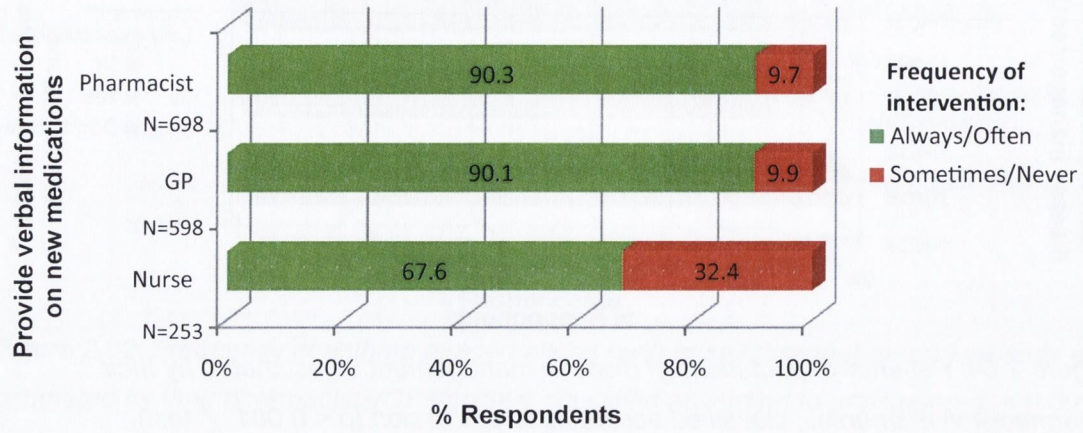


Figure 2.66: Frequency with which respondents provide verbal information on newly prescribed asthma medications, classified according to profession (N = 1549, p < 0.001, χ^2 test).

A significantly smaller proportion of nurses than GPs or pharmacists *always/often provide verbal information on new medications.* A significantly smaller proportion of GPs and pharmacists than nurses *sometimes/never* conduct this intervention.

2.6.2.3. Demonstrate the use of a peak flow meter

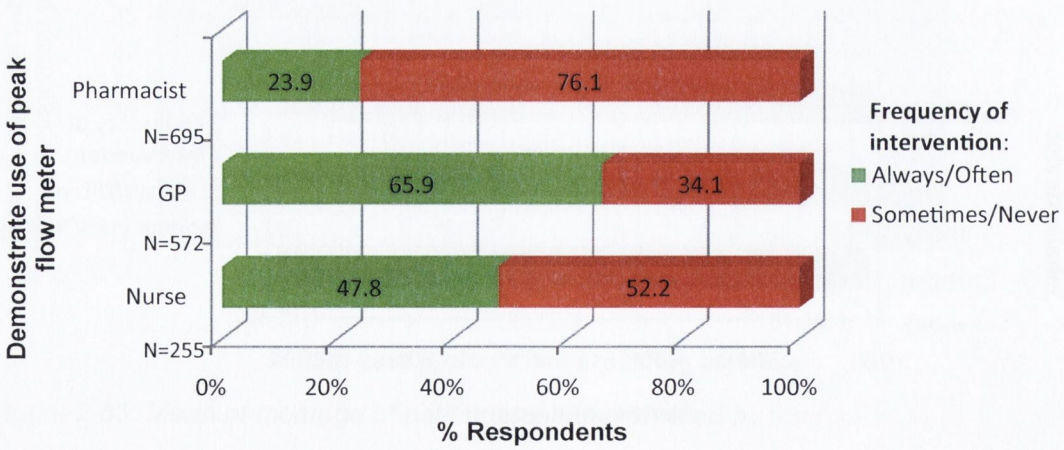


Figure 2.67: Frequency with which respondents demonstrate the use of a peak flow meter, classified according to profession (p < 0.001, χ^2 test).

A significantly larger proportion of GPs than pharmacists or nurses *always/often demonstrate the use of a peak flow meter.* A significantly larger proportion of pharmacists than GPs or nurses *sometimes/never* conduct this intervention with their asthma patients.

2.6.2.4. Advise on importance of a peak flow meter in monitoring asthma control

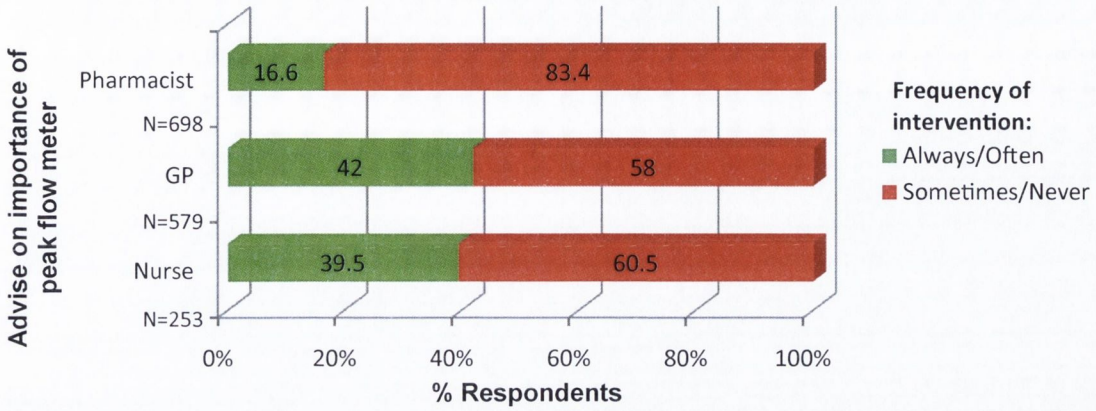


Figure 2.68: Frequency with which respondents advise their patients on the importance of the peak flow meter, classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of GPs and nurses than pharmacists *always/often advise their patients on the importance of the peak flow meter in monitoring asthma control.* GPs conduct this intervention significantly more frequently than nurses do. A significantly greater proportion of pharmacists than GPs or nurses *sometimes/never* conduct thus intervention.

2.6.2.5. Check for overuse of reliever inhalers at prescription renewals

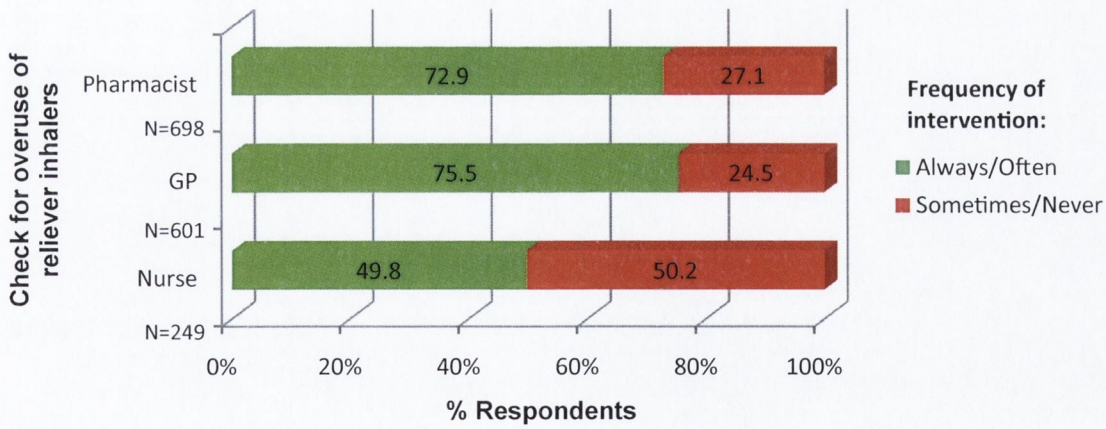


Figure 2.69: Frequency with which respondents check for overuse of reliever inhalers at prescription renewals, classified according to profession ($p < 0.001$, χ^2 test).

A significantly smaller proportion of nurses than GPs or pharmacists *always/often check for overuse of reliever inhalers.* A significantly smaller proportion of GPs than pharmacists/nurses *sometimes/never* conduct this intervention.

2.6.2.6. Counsel the patient in the event of reliever overuse

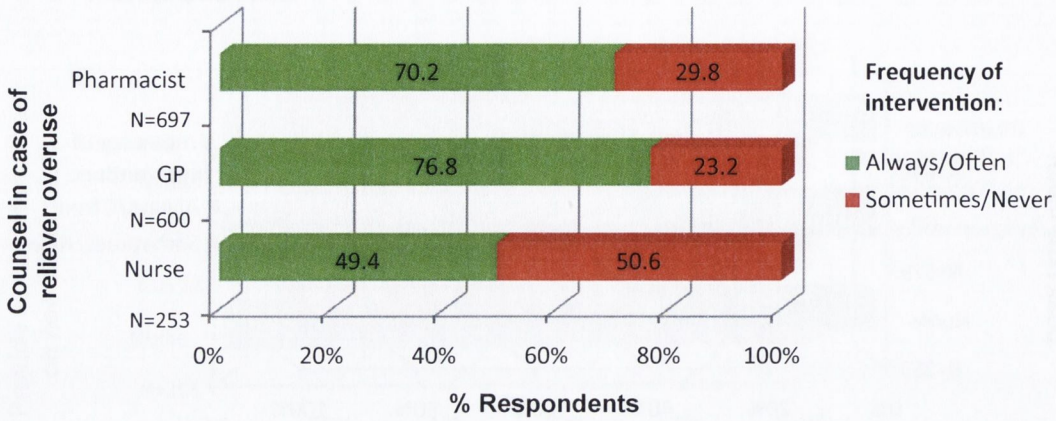


Figure 2.70: Frequency with which respondents counsel in the event of overuse of reliever inhalers at prescription renewals, classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of GPs than pharmacists or nurses *always/often counsel their patients in the event of reliever overuse*. A significantly greater proportion of nurses than pharmacists or GPs *sometimes/never* conduct this intervention.

2.6.2.7. Check for underuse of ICS at prescription renewals

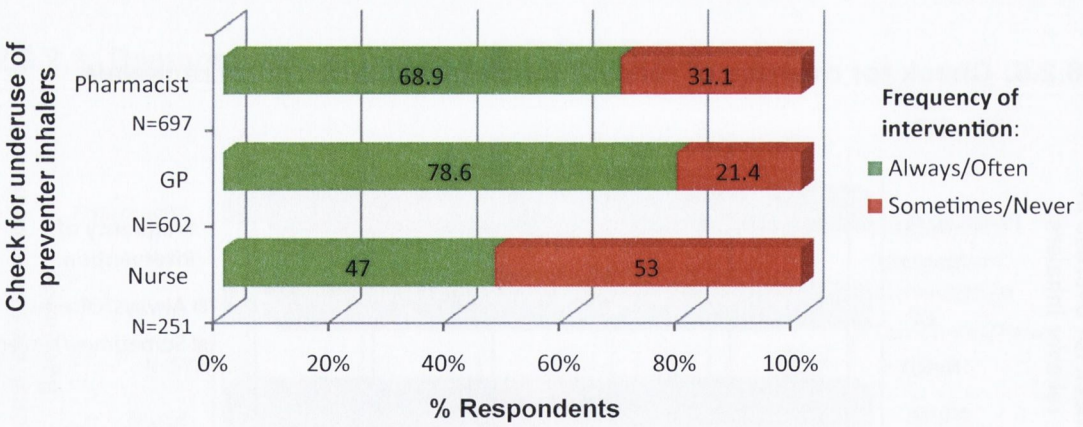


Figure 2.71: Frequency with which respondents check for underuse of preventer inhalers at prescription renewals, classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of GPs than nurses or pharmacists *always/often check for underuse of preventer inhalers at prescription renewals.* A significantly greater proportion of nurses than GPs or pharmacists *sometimes/never* conduct this intervention.

2.6.2.8. Counsel in event of ICS underuse

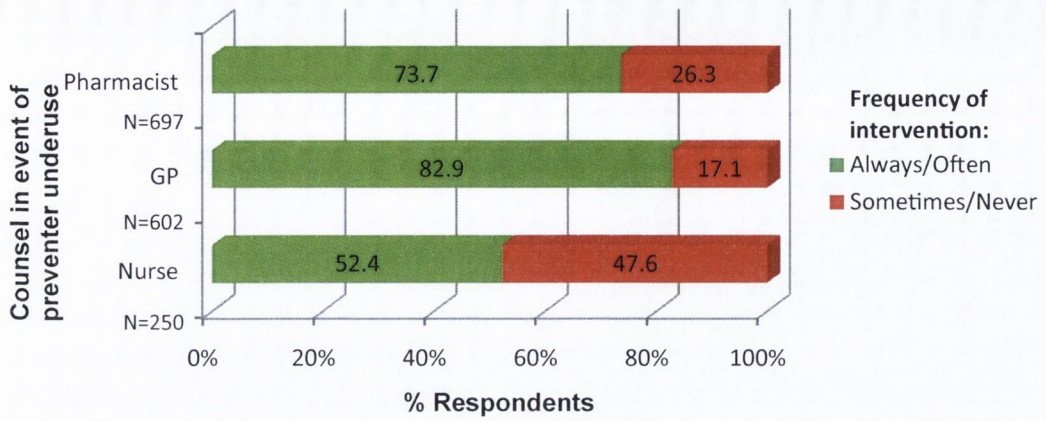


Figure 2.72: Frequency with which respondents counsel in the event of underuse of preventer inhalers at prescription renewals, classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of GPs than nurses or pharmacists *always/often counsel their patients in the event of underuse of preventer inhalers at prescription renewals.* A significantly greater proportion of nurses than GPs or pharmacists *sometimes/never* conduct this intervention.

2.6.2.9. Check inhalation technique every 6-12 months

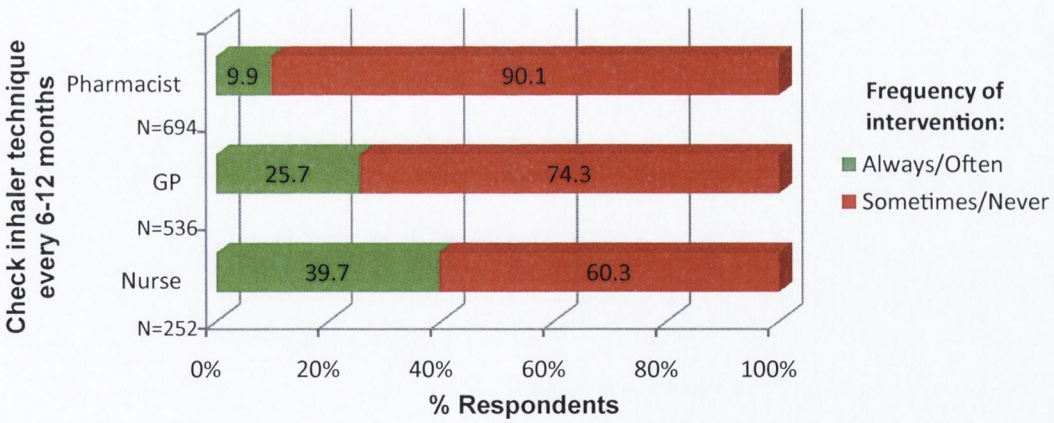


Figure 2.73: Frequency with which respondents check inhalation technique every 6-12 months, classified according to profession ($p < 0.001$, χ^2 test).

A significantly smaller proportion of pharmacists than nurses and GPs *sometimes/never check inhalation technique every 6-12 months.* A significantly greater proportion of nurses than GPs *always/often* conduct this intervention.

2.6.2.10. Advise patients on contraindicated OTC products

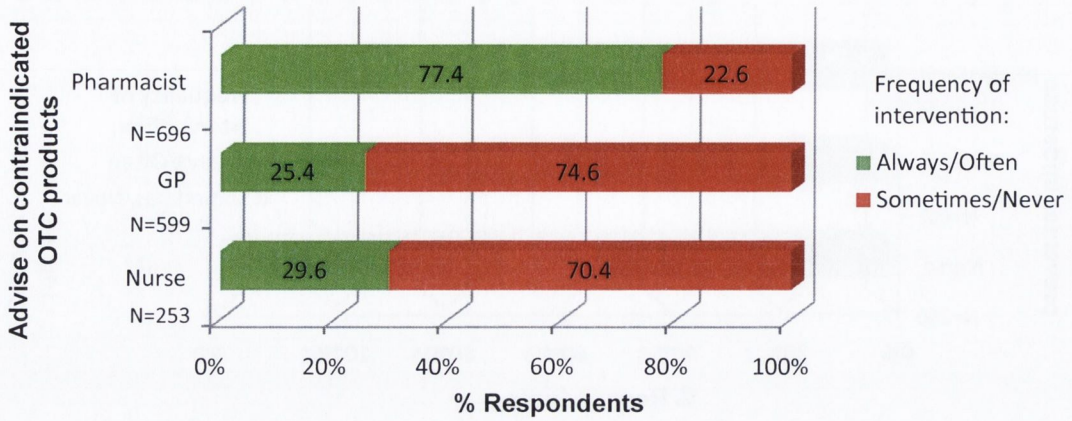


Figure 2.74: Frequency with which respondents advise their patients on contraindicated OTC products, classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of pharmacists than GPs or nurses *always/often advise their patients on contraindicated OTC products.* A significantly greater proportion of GPs than nurses or pharmacists *sometimes/never* conduct this intervention.

2.6.2.11. Provide advice on non-pharmacological measures to improve quality of life

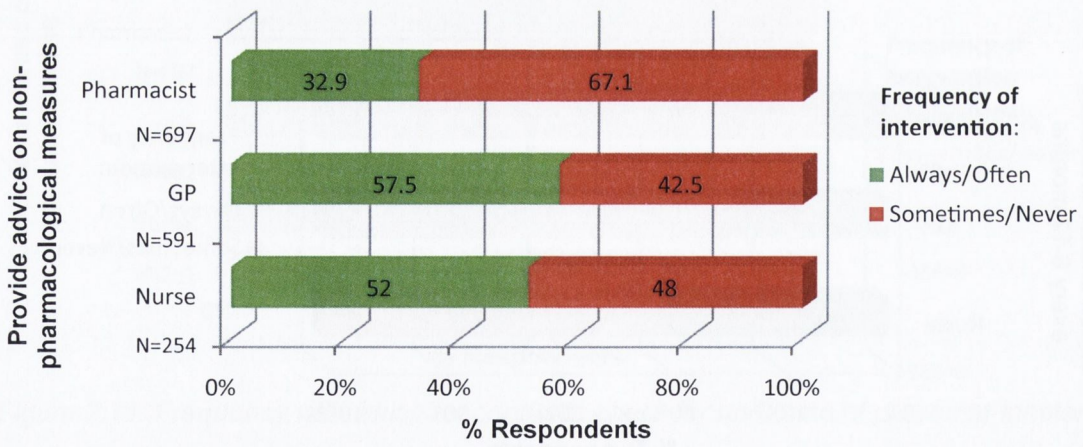


Figure 2.75: Frequency with which respondents provide advice to their patients on non-pharmacological measures to improve their quality of life, classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of GPs than pharmacists or nurses *always/often provide advice on non-pharmacological measures.* A significantly greater proportion of pharmacists than GPs or nurses *sometimes/never* conduct this intervention.

2.6.2.12. Assess level of asthma control at prescription renewals

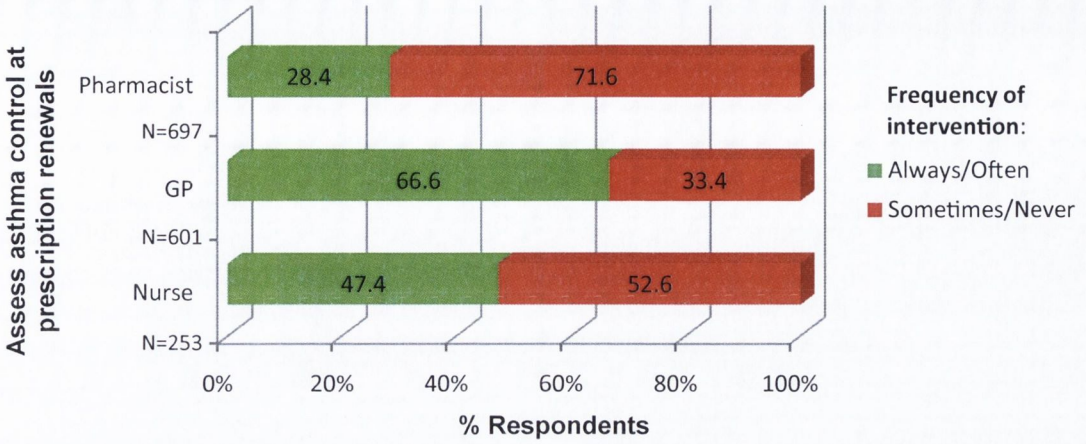


Figure 2.76: Frequency with which respondents assess patients' level of asthma control at prescription renewals, classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of GPs than nurses or pharmacists *always/often assess asthma control at prescription renewals*. A significantly greater proportion of pharmacists than GPs or nurses *sometimes/never* conduct this intervention.

2.6.2.13. Check for drug-related adverse effects at prescription renewals

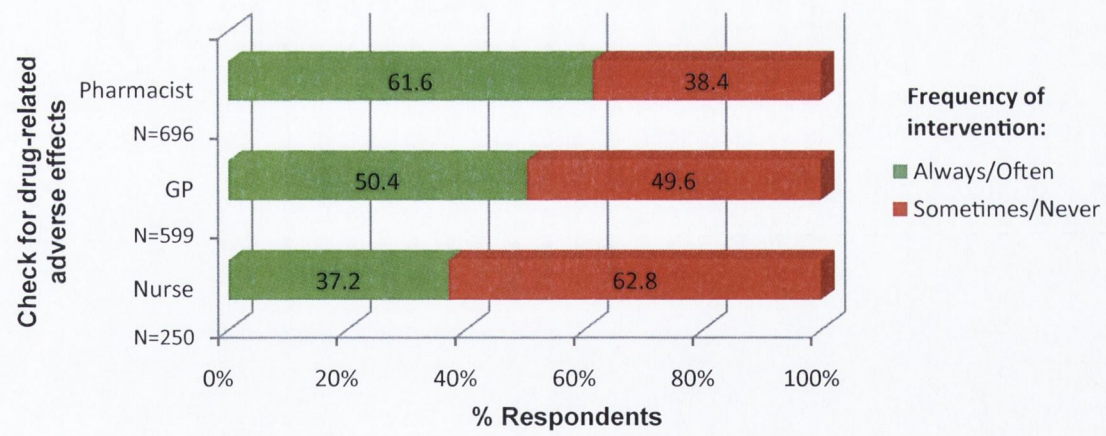


Figure 2.77: Frequency with which respondents check for drug-related adverse effects at prescription renewals, classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of pharmacists than GPs or nurses *always/often check for drug-related adverse effects at prescription renewals*. A significantly greater proportion of nurses than GPs or pharmacists *sometimes/never* conduct this intervention.

2.6.2.14. Advise patients on correct action in the event of worsening asthma

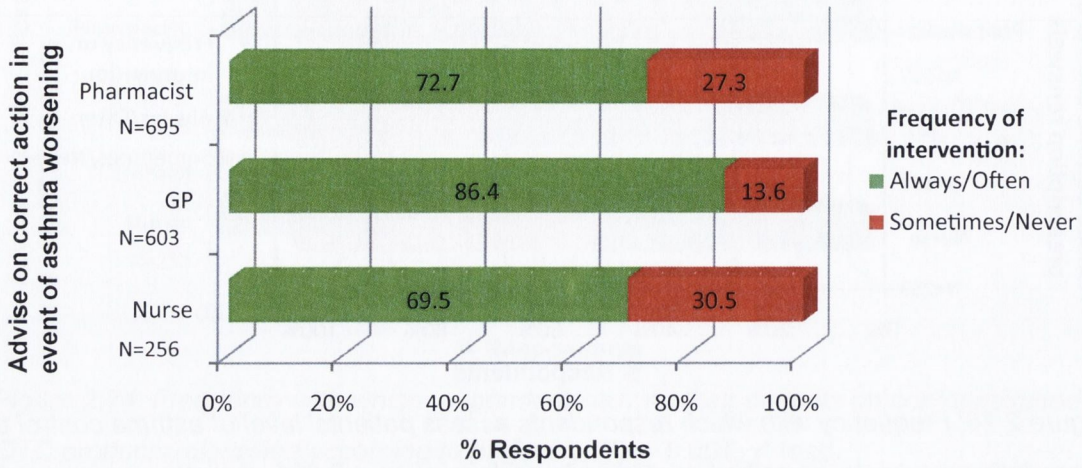


Figure 2.78: Frequency with which respondents advise patients on the correct action to take in the event of worsening asthma, classified according to profession ($p < 0.001$, χ^2 test).

A significantly greater proportion of GPs than nurses or pharmacists *always/often advise their patients on the correct action to take in the event of worsening asthma.*

2.7. Discussion: QAM-CP

2.7.1. Baseline characteristics

An in-depth analysis of the baseline characteristics of the respondents produced some interesting results: Firstly, there are significantly more respondents with less pharmacy experience working in pharmacies in city and suburban locations and significantly more pharmacists with more pharmacy experience working in towns and rural pharmacies. Unsurprisingly, the proportion of pharmacy owners increased significantly with increasing experience. It is reasonable therefore, that there are also significantly more pharmacy owners in pharmacies in towns and rural locations. Finally, a significantly larger proportion of more experienced pharmacists are working in independently owned pharmacies than their less experienced colleagues. Understandably, there are also a greater proportion of pharmacy owners than employee pharmacists working in independently owned pharmacies.

2.7.2. Opinions on current asthma treatment/management

2.7.2.1. Asthma care in the primary care setting nationwide

Interestingly, respondents appear to be divided in their opinions on the current level of asthma care in the community nationwide with approximately 40% indicating that care is *unsatisfactory* and another 40% specifying that care is *satisfactory*. Furthermore, this result is not influenced by any of the demographic characteristics of the respondents or the results from any of the items on frequency of interventions *etc.*

2.7.2.2. Patients' understanding of asthma as a disease

Only approximately 17% of respondents believed that their asthma patients had a *good understanding* of asthma as a disease. Knowledge about asthma in conjunction with good medication adherence has been shown to be associated with better asthma control[142] and better asthma self-management[143]. Thus, educating patients about the chronic inflammatory nature of asthma is an important step in the long-term improvement of asthma care[144]. Saini and collegues[144] conducted a community pharmacist-led intensive educational intervention tailored to asthma patients' individual needs over a six-month period. This intervention resulted in a significant increase in patients' asthma knowledge that was sustained for 12 months after the conclusion of the intervention study. In addition, patients' qualitative feedback revealed that they appreciated the service they

received from community pharmacists. Thus, by individualising the delivery of patient education, community pharmacists can improve patients' asthma knowledge.

When this result is analysed more closely it is evident that respondents with greater experience in pharmacy practice believed that significantly more of their patients had a *good understanding* of asthma than less experienced respondents. A possible explanation for this may be that more experienced respondents may have built up good relationships with their patients over the course of their careers; consequently patients may be receptive to their advice, making counselling more effective than that from a less experienced respondent. Indeed, Hermansen and Wiederholt[145] investigated the pharmacist-patient relationship using five interpersonal constructs, 'felt indebtedness', 'collaborative willingness', 'interpersonal relationship quality', 'critical interpersonal incidents' and 'medication use beliefs'. They found that the construct 'interpersonal quality' significantly predicted patients' 'felt indebtedness' toward and 'collaborative willingness' with their pharmacists. Thus, they concluded that the demonstration by pharmacists of their trustworthiness, care and respect for patients might be instrumental in building patient-pharmacist relationships and fostering patient willingness towards collaboration. However, trust develops gradually over time through the consistent provision of high quality patient care. Therefore, more experienced pharmacists may have demonstrated their trustworthiness and commitment to patient care to their patients over time, thus building and strengthening the pharmacist-patient relationship whereby their patients are more receptive to counselling than patients of less experienced pharmacists. The establishment of trust between the pharmacist and the patient leads to more open communication between them. Onda and colleagues[137] investigated the relationship between pharmacist-patient communication and asthma care. They discovered that good pharmacist-patient communication was associated with patient understanding of pharmacotherapy and an ability to use inhalation devices.

Conversely, the reason for this difference in opinion may be that younger respondents who have recently graduated have higher expectations of what constitutes 'understanding asthma' and do not consider that their patients meet these criteria.

It was also observed that pharmacy owners considered that a greater proportion of their patients have a *good understanding* of asthma than employee pharmacists. There are two possible explanations for this result: Firstly, pharmacy owners may not work in the pharmacy as frequently as their employees and so may have less of an insight into the level of understanding of their patients. Equally, a significantly greater proportion of pharmacy owners than employees are older, more experienced respondents,

consequently, as discussed above, they may have built up strong relationships with their patients over the years and thus they may have a greater insight into their patients' level of understanding of the disease and their patients may be more receptive to counselling than patients of their less experienced colleagues.

2.7.2.3. Patients' understanding of the indications for their asthma medications

Approximately 26% of respondents considered that their asthma patients had a *good understanding* of the indications for their asthma medications. Barber and colleagues[146] investigated medication adherence and they found that ~50% of patients prescribed a new medication for a chronic condition expressed a need for increased information about the medication 10 days and 4 weeks after initial dispensing. Clifford and colleagues[147] conducted a randomised controlled trial investigating the effect of a pharmacist-led intervention on adherence in patients receiving a new medication for a chronic illness. Trained pharmacists telephoned patients in the intervention group two weeks after recruitment and enquired about adherence, medication problems and provided them with additional information about their medications as needed. Four weeks after recruitment patients in the intervention group were found to be significantly more adherent, have less medication-related problems and have more positive beliefs about their medicines than the control group. Thus, pharmacists can be instrumental in promoting medication adherence by ensuring patients are adequately informed about their medicines.

Surprisingly, unlike the previous question, this item was not influenced by any of the demographic characteristics of the respondents.

2.7.2.4. Patients' ability to use their inhalers properly

The mean percentage of patients who were estimated to use their inhalers properly by their community pharmacist was 56%. This result corresponds with the findings of the Aerosol Drug Management Improvement Team who reviewed the literature on inhaler technique in six European countries up to and including 2005 and concluded that up to 50% of asthma patients across six European countries have inadequate inhaler technique[148].

The amount of drug delivered to the lungs can be considerably affected by inhaler technique[149]. Newman and colleagues[2] reported a ~33% difference in the lung deposition of patients with poor coordination of pMDI actuation and inhalation compared to those with good coordination. In addition, poor inhaler technique in the delivery of ICS has been

shown to be strongly associated with asthma instability[10]. There may be two possible explanations for the increase in asthma instability in these patients. Firstly, poor inhaler technique may result in a reduction in lung deposition of ICS leading to a decrease in clinical efficacy and impaired asthma control. Alternatively, it may be that the decrease in efficacy due to inadequate technique may result in a reduction in compliance[10]. Incorrect inhaler technique can also lead to increased side effects due to increased deposition of medication in the oropharynx. Increased side-effects and a sub-optimal response due to inappropriate technique can reinforce poor compliance[150].

It is noteworthy that a significant difference was observed in the mean percentage estimated by respondents depending on the regional location of the pharmacy. The most significant difference was recorded between respondents in cities and towns, and those in rural and suburban locations. A possible explanation for this result may be that in cities and towns there are often fewer regular patients than in suburban and rural pharmacies due to 'passing trade'. As discussed above, the pharmacist-patient relationship develops over time through the consistent demonstration of trustworthiness, patient care and respect[145]. Thus, patients who are not regular customers of the pharmacy may be less receptive to counselling due to the lack of an established patient-pharmacist relationship and because of a lack of background information on the patient's asthma. Consequently, respondents in pharmacies in cities and towns may believe that a significantly smaller proportion of their asthma patients overall use their inhalers appropriately, due to a difficulty in counselling them effectively, than those in rural and suburban locations.

2.7.2.5. Patients using a peak flow meter regularly

The mean percentage of asthma patients estimated to be in possession of a peak flow meter, which they use regularly, is only approximately 11%. This result is in accordance with the findings of the Asthma Insights and Reality in Ireland (AIRI) survey, which found that only 13% of respondents use a peak flow meter regularly[151]. The GINA guidelines[1] indicate that peak flow measurements can be an important support in the monitoring of asthma. Peak flow measurements can provide an early indication of deteriorating asthma before the patient experiences any physical symptoms. Consequently, a peak flow meter should be considered an essential tool in monitoring one's level of asthma control.

A potential reason for such a low estimation may be the price of the peak flow meter: ~€25 for an adult device. In addition, the peak flow meter is not included in any of the government funded Primary Care Reimbursement Services (PCRS) schemes, which may act as a further deterrent to its purchase.

A more intensive analysis of the results revealed that respondents in cities and towns believed that the mean proportion of their asthma patients using a peak flow meter regularly was significantly lower than that estimated by respondents in rural and suburban locations. As discussed in 2.7.2.4 above, this may be related to the higher proportion of 'passing trade' in pharmacies in towns and cities than that in suburban and rural locations.

2.7.2.6. Patients with well-controlled asthma

Consistent with the other results in this section, the mean percentage of asthma patients estimated to have well controlled asthma was also low; approximately 40%. Reports of inadequately controlled asthma among patients is widespread in the literature and ranges from ~60-95% of patients studied depending on the method used to quantify asthma control[152-156]. Armour and colleagues[154] demonstrated the role that community pharmacists could play in identifying patients with inadequate asthma control. Using a risk assessment and severity tool based on the revised Jones morbidity index and reported reliever use pharmacists identified 77% of patients with suboptimal asthma control who were at risk for poor asthma outcomes. The identification of patients with sub-optimal asthma control provides an opportunity for pharmacists to intervene and possibly improve asthma management through appropriate education and counselling and/or through GP referral for an adjustment in patients' therapeutic management[154]. Indeed Barbanel and colleagues[157] demonstrated that an educational intervention provided by trained pharmacists on inhaler technique, self-management, avoidance of triggers *etc.* resulted in an improvement in asthma symptom scores in the intervention group compared with the control group.

2.7.2.7. Patients' level of medication compliance

The level of medication compliance was estimated to be *fair* by 83% of respondents. This result was not influenced by respondents' demographic characteristics. Pharmacists are in a unique position to have a positive impact on medication adherence due to their frequent contact with patients, due to prescription refills, and as they are usually the last health-care professionals in contact with the patients before they take the medication. The PMR is also a useful tool in monitoring adherence through prescription refill rates but one must be mindful that choosing to have a medication dispensed does not necessarily translate into medication adherence, a patient may chose not take the medication at all or he/she may chose to take it in a manner other than that prescribed[158]. In addition, the PMR does not contain any information on a patient's diagnosis and this may hinder the pharmacist's ability to provide counselling on adherence. The pharmacist may directly encounter nonadherence at the point of dispensing if a patient indicates that he/she does

not want a particular prescribed drug, *e.g.* an ICS, to be dispensed. Thus, the pharmacist can identify and attempt to improve medication adherence in a number of ways. Firstly, the establishment of a good pharmacist-patient relationship that promotes trust, openness and frank discussion can improve patient adherence[159,160]. Facilitating open discussions with patients may allow them to express freely any fears or concerns they may have about their medications, which can then be addressed by the pharmacist[158]. In addition, as adherence to asthma medications has been reported to range from 30-70%[149,161-163] it can be difficult to predict where in the spectrum a patient may lie, thus, the Stages of Change behavioural model has been proposed as a valid measure to determine adherence and to decide on the intervention that would be most suitable to improving adherence, if applicable[164]. This behavioural model is a five stage model through which individuals progress as they alter their behaviour. The five stages are (1) precontemplation, (2) contemplation, (3) preparation, (4) action and (5) maintenance[165] For example, Stages of Change theory suggests that individuals in pre-contemplation and contemplation stages would benefit from interventions highlighting the benefits of treatment whereas monitoring techniques and reminders would be more beneficial for those in later stages[166].
Pharmacists can also provide practical assistance to promote adherence such as verbally reinforcing the dosage instructions at the time of dispensing, collaborating with the patient to incorporate the medication regimen into the daily activities and using medication reminders such as calendars or schedules specifying the time to take each medication[167].

2.7.2.8. Patients in possession of an asthma management plan

The mean percentage of asthma patients estimated to have a personal asthma management plan was approximately 17%. Even more concerning is fact that almost 20% of respondents estimated that none of their patients had an asthma management plan and approximately 60% of respondents did not know whether or not their patients had such a plan. A personal asthma management plan facilitates the early recognition of deteriorating asthma control as indicted by respiratory symptoms or peak expiratory flow readings and allows patient to adjust their therapy according to written pre-determined guidelines[1,168]. According to research[169,170], the use of a written action plan in conjunction with patient education, self-monitoring and regular review resulted in a reduction in hospitalisations, absenteeism, nocturnal wakening, unscheduled visits to the GP for asthma and ED visits by 33%-66% on average. However, less intensive interventions, particularly those without a written self-management plan were found to be less effective[170]. This evidence highlights the importance of the asthma action plan in monitoring asthma control.
While the provision of an asthma self-management plan is considered the role of the GP[1] pharmacists can also encourage self-management behaviours among their patients.

Armour and colleagues[171] conducted the Pharmacy Asthma Care Program (PACP), a randomised controlled trial implemented by community pharmacists over a six-month period. The PACP was based on a continuous cycle of assessment, goal setting, monitoring, review and GP referral if necessary. Goal setting was an integral part of the program to encourage asthma self-management. Patients in the intervention group, in collaboration with their pharmacists, set a mean of three goals for themselves over the course of the study and at study conclusion 30% had achieved their goals and ~60% were continuing to work towards them. In addition, pharmacists can encourage their patients to obtain self-management plans from their GPs. In the aforementioned study[171], 80% of intervention patients were referred to their GP over the course of the study and the most common reason for referral was to obtain a self-management plan. Indeed, by the end of the study the percentage of patients with an asthma management plan had increased from 23% to 64%.

2.7.2.9. Patients' expectations of disease management

Greater than 70% of respondents believed that their asthma patients have low expectations of disease management. Given that 40% of respondents indicated that they believed the level of asthma care nationwide to be satisfactory, this result is contradictory. It is possible that as the respondents completed the more specific questions about their own asthma patients they realised that the level of asthma care nationwide is not as satisfactory as they initially indicated.

Low expectations of asthma management among patients is a global problem. The AIR survey conducted in 29 countries in the US, Western Europe, Asia-Pacific, Japan and Central and Eastern Europe revealed that 39%-70% of asthma patients experiencing moderate symptoms and 23%-49% of patients experiencing severe symptoms believed their asthma to be currently 'well controlled' or 'completely controlled'[172]. Bellamy and Harris[173] conducted a survey of >800 asthma patients and >800 GPs from Italy, France, Germany, UK, Spain, Canada and Australia on asthma control. 94% of patients surveyed indicated that they would like to live without asthma symptoms but 90% said the asthma symptoms they experienced were part of having asthma and 85% said that the currently available asthma therapies could not eradicate asthma symptoms but simply reduce them. Thus, it is evident that a large proportion of asthma patients worldwide are not aware of the level of asthma control that is achievable with the appropriate pharmacotherapy and asthma management strategies.

Once again, a significant difference was discovered between respondents in pharmacies in cities and towns and those in rural and suburban locations. The same possible reasons discussed in 2.7.2.4 above are valid here.

2.7.3. Interventions with asthma patients

2.7.3.1. Counselling on inhaler technique

Approximately 90% of respondents indicated that they *always/often demonstrate the use of a newly prescribed inhaler* to their patients. René-Henri and colleagues[134] investigated the interventions conducted by Canadian pharmacists in Quebec with their asthma patients and the factors influencing these interventions, in an anonymised postal survey (the primary reference source for this subsection). 97% of respondents indicated that they always/often demonstrate a new inhalation device to their patients. Similarly, Erickson and colleagues found that >85% of American pharmacists surveyed educated patients on inhaler technique when a new device is prescribed. Conversely, in a survey of ~100 pharmacists in Maryland on paediatric asthma counselling only 21% of respondents reported demonstrating a new inhaler device to a child and 31% stated that they provided a demonstration to the child's carer in the last month[174].

A number of pharmacist-led interventions have been successful in improving patients' inhaler technique. Giraud and colleagues[6] conducted a study investigating the feasibility and acceptability of inhaler technique training by pharmacists in France. Community pharmacists recruited >700 patients and the percentage of patients with correct inhaler technique rose from 24% before training to 79% afterwards. Basheti and colleagues[175] investigated the optimum strategy that should be employed by pharmacists when educating patients on TH technique and they concluded that verbal counselling in conjunction with a physical demonstration was significantly more effective than verbal counselling alone.

Approximately 90% of respondents indicated that they *sometimes/never check a patient's inhalation technique every 6-12 months.* A similar result was obtained by Rene-Henri and colleagues; 91.5% of respondents indicated that they sometimes/never reassess patients' inhaler technique[134]. In the aforementioned study on paediatric asthma counselling in Maryland 5% of respondents stated that they demonstrated inhaler technique to the child and 8% demonstrated technique to the carer for a refill prescription in the last month[174]. Research has shown that in order to maintain correct inhalation technique, education on technique must be regularly repeated[41]. The fact that the vast majority of respondents rarely reinforce inhaler technique may be due to a lack of knowledge among pharmacists about the need for repeated reassessment and education. A sample of community pharmacists completed a survey of attitudes, knowledge and beliefs about educating patients to use pMDIs before and six months after a four hour educational intervention on

asthma that included case studies and workshops on pMDIs. A significant increase in the percentage of patients who 'strongly agreed' that frequent assessment and education on MDI technique was observed six months after the education programme[136]. There is evidence in the published literature that a substantial proportion of pharmacists, and indeed other health-care professionals, are not competent in correct inhaler technique[29,58,176,177], and this may influence their ability to counsel their patients effectively. In addition, patients may not be aware that their inhalation technique is incorrect and thus they may not be receptive to counselling and assessment on a device, which they have being using for some time. In an inhaler technique intervention conducted by Basheti and colleagues 74% of patients, who had being using their inhalers for an average of 2-3 years, believed that their inhaler technique was correct but on assessment only 10% had correct technique[41].

Less experienced respondents (0-10 years experience) routinely check patients' inhalation technique least frequently. Those with 11-20 years experience perform these interventions most frequently and those with the most experience carry it out with intermediate frequency. As discussed in 2.7.2.2, older, more experienced pharmacists may have developed a stronger relationship with their patients over the course of their careers and thus their patients may be more receptive to their advice and counselling[145]. This may be particularly relevant in this instance as patients often are not aware that their inhaler technique is incorrect[41] and so may not be receptive to counselling on this issue if they have not developed trust in their pharmacist. Respondents with >20 years experience may not be familiar with all of the different inhalation devices currently available and this may explain why they conduct this intervention with intermediate frequency. Pharmacy owners conduct this intervention significantly more frequently than employee pharmacists do. As pharmacy owners are usually older than employee pharmacists are the aforementioned reasons for this finding are relevant here.

2.7.3.2. Provision of information on newly prescribed medication

Approximately 90% of respondents *always/often provide verbal information (other than dosage instructions) on a newly prescribed medication* to their patients. Similarly, a survey of Dutch pharmacists on the care provided in community pharmacies revealed that ~80% of respondents 'often/regularly' provide their patients with information on the use and side-effects of a newly prescribed medication. In the aforementioned survey by Rene-Henri and colleagues on Canadian pharmacists[134] ~97% of respondents always/often provided their patients with verbal information on new asthma medications. The nature of the information usually provided by pharmacists was outside the scope of this instrument, but a recent review of the counselling practices of community pharmacists

revealed that information on the name of the medicine, the indications, directions for use and dosage were more frequently provided than information on side effects, precautions, interactions and contraindications to use[178].

2.7.3.3. Counselling on the peak flow meter

On average, respondents indicated that they *sometimes demonstrated the use of a peak flow meter* and *sometimes advised patients on the importance of a peak flow meter in monitoring asthma control.* As the mean percentage of patients estimated by respondents to use a peak flow meter regularly was only 11%, this result is unsurprising. However, it is possible that the low frequency with which respondents conduct these interventions has an influence on the low percentage of patients estimated to use a peak flow meter regularly. In a study conducted by Bheekie and colleagues[179] on the initiation of peak flow rate or symptom self-monitoring from community pharmacies they discovered that patients using symptom self-monitoring had a significantly higher frequency of inappropriate medication use and had a significantly greater tendency to underestimate asthma severity than patients in the peak flow self-monitoring group. This study highlights the importance of peak flow monitoring in providing patients with an objective measure of their asthma control. This is particularly important given the high proportion of patients who perceive their asthma to be controlled when in fact the converse is true[172].

In-depth analysis of these results revealed that less experienced respondents (0-10 years experience) carry out these interventions least frequently. Those with 11-20 years experience perform these interventions most frequently and those with the most experience carry them out with intermediate frequency. The same possible explanation discussed in 2.7.2.2 is applicable here. However, with regards to respondents with >20 years experience it is possible that their knowledge on the peak flow meter technique and/or the importance of the peak flow meter in monitoring asthma control is not up-to-date and so they may not consider such interventions to be of great importance to asthma patients.

Respondents working in rural pharmacies perform these interventions significantly more frequently than those working in other regional locations. The smallest proportion of young inexperienced respondents are based in rural pharmacies. Consequently, this result provides further support for the findings above. Pharmacy owners carry out these interventions significantly more frequently than employee pharmacists do. As discussed earlier, this may be because pharmacy owners have developed a good relationship with their patients over the years and are consequently more comfortable counselling them on the use of peak flow meters especially as peak flow meters are expensive devices. From

a commercial perspective, the sale of peak flow meters would generate revenue for pharmacy owners and it is possible that this also influences their actions.

2.7.3.4. Counselling on medication adherence: reliever medication

Greater than 70% of respondents *always/often check for overuse of reliever inhalers at prescription renewals* and *counsel their patents in the event of overuse of reliever inhalers.* However, in the survey conducted by Rene-Henri and colleagues[134] ~91% of respondents checked for SABA overuse at prescription renewals and ~85% intervened when a patient was deemed to be overusing his/her reliever medication. From this comparison, it appears that a significantly greater proportion of respondents in Ireland are not actively promoting appropriate medication usage among their asthma patients. The possible reasons for this become more apparent in 2.7.4.

Bereznicki and colleagues[180,181] demonstrated how community pharmacists could use the PMRs to identify patients who appeared to use excessive quantities of reliever medication, indicating sub-optimal asthma control, and subsequently conduct an intervention to improve asthma management. The researchers devised a 'data mining' software application that identified patients who had received three or more reliever inhalers in the past six months. The intervention patients received a letter advising them to visit their GP for an asthma management review, educational material about asthma and a series of questionnaires on asthma control, quality of life *etc.* The preventer to reliever ratio (P:R) was calculated as an outcome measure and the P:R for the intervention group was significantly higher than the control group at the end of the study. In addition, a significant improvement in asthma control and asthma-specific quality of life was observed for the intervention group but not for the control group between the pre- and post-intervention stages. This study provides evidence that pharmacists are ideally placed to identify patients who may have uncontrolled asthma, provide them with education on asthma and refer them to their GP for an asthma management review, which should result in an improvement in their asthma control and appropriate medication usage.

Interestingly, the demographic characteristics of the respondents did not influence the result for the intervention on checking for overuse of preventer inhalers at prescription renewals, but experience in community pharmacy practice did influence the intervention on counselling in the event of such overuse. As before, it was observed that the less experienced respondents perform this intervention least frequently, those with 11-20 years experience carry it out most frequently and the oldest, most experienced respondents conduct the intervention with intermediate frequency. In this instance, it is unlikely that

lack of knowledge is influential in the frequency of counselling; it is more likely that, as discussed in 2.7.2.2, those with more experience have established relationships with their regular asthma patients and so are more comfortable counselling them. The fact that the oldest, most experienced respondents perform this intervention slightly less frequently than their counterparts with 11-20 years experience may simply be a case of advancing age reducing motivation or energy.

The regional location of the pharmacy influenced this result also. As observed previously, respondents in rural locations carry out this intervention significantly more frequently than those in pharmacies in cities, towns or suburban locations. The same possible reason discussed in 2.7.3.3 above may apply in this instance.

Surprisingly, there was no relationship between the level of frequency with which respondents conduct both of these interventions and their estimated level of medication compliance for their asthma patients. This observation is worrying as it may mean that pharmacists believe that patients are unreceptive to advice on the overuse of their reliever inhalers and that the provision of such advice does not increase compliance in their patients. Indeed, Cvetovski and colleagues[182] interviewed pharmacists on their perceptions and attitude towards asthma management and the most significant barrier to optimal asthma management identified by pharmacists was the patients themselves, in particular their lack of understanding about the role of the pharmacist in asthma care and their poor understanding of asthma as a disease.

2.7.3.5. Counselling on medication adherence: preventer medication

Greater than 30% of respondents *sometimes/never check for underuse of ICS at prescription renewals* and ~26% *sometimes/never counsel their patients in the event of ICS underuse.* Once again, when compared to the results of the survey conducted by Rene-Henri and colleagues[134] Irish pharmacists appear to be less active in checking for medication adherence among their patients; only ~14% of Canadian respondents sometimes/never check for underuse of ICS at prescription renewals.

2.7.3.6. Counselling on contraindicated OTC products

Almost 80% of respondents indicated that they *always/often advise patients on contraindicated over-the-counter products.* According to the European Self-medication Industry the non-prescription pharmaceutical market represented ~12% of the total pharmaceutical market in Ireland in 2010[183]. Simoens and colleagues[184] surveyed a random sample of patients purchasing OTC medicines in Flemish pharmacies. They

found that for >60% of patients the pharmacist was the first point of contact for OTC medicines indicating the important role of the pharmacist in the provision of safe and comprehensive advice to patients. The vast majority of patients surveyed felt that pharmacists provided sufficient information on the minor ailment and OTC medication use in general, but pharmacists appeared to provide information on drug interactions and contraindications less frequently than information on dosage, treatment duration, usage and choice of OTC medicines. The opinions and knowledge of Italian pharmacy customers on non-prescription medicines was investigated by Cuzzolin and Benoni[185]. They discovered that ~55% of those interviewed agreed that non-prescription medicines are safe to use. A similar opinion was observed among ~50% of Hungarian pharmacy customers who either agreed/strongly agreed that non-prescription medicines are 'totally safe to use'[186]. This belief that non-prescription medicines are 'totally safe' may prevent patients from consulting their pharmacist about these medications prior to use and this could have potentially serious consequences for patients with chronic illnesses such as asthma where medications such as aspirin or non-steroidal anti-inflammatory medications (NSAIDs) can precipitate asthma exacerbation/bronchospasm and attacks of rhinitis 30 minutes to 3 hours after ingestion in a condition known as aspirin-induced asthma[187]. Indeed only 44% of those surveyed in the aforementioned Hungarian study reported asking their pharmacist about the non-prescription medication that they had purchased.

The Italian study[185] also revealed that >55% of those interviewed reported taking at least one prescription medicine in association with non-prescription medicine purchased. 60% of these customers were referred to the pharmacist who provided them with information on interactions in almost 100% of cases. However, it is unclear whether the remaining 40% of customers, who did not consult with the pharmacist, were provided with any information on potential drug interactions or contraindications with their prescription medications. The lack of involvement of the pharmacist in the majority of OTC medication interactions has been reported in the UK[188] and a similar situation is likely in Ireland. This is concerning as poor compliance with good practice guidelines on the safe provision of non-prescription medication among pharmacy staff has been reported in the literature[188,189] indicating that patients may not be adequately counselled when purchasing non-prescription medicines from community pharmacies.

Experience in community pharmacy practice influenced this result. Once again, respondents with a moderate level of experience in community pharmacy practice (11-20 years) perform this intervention most frequently, followed by those with the most experience (>20 years). Respondents with the least experience (0-10 years) carry out the

intervention with the lowest frequency. The same possible reasons discussed in 2.7.3.1 above apply in this instance.

2.7.3.7. Counselling on non-pharmacological measures

Only ~33% of respondents *always/often provide advice on non-pharmacological measures to improve their patients' quality of life.* Similarly ~33% of respondents always/often provided information to their patients on non-pharmacological measures in the survey conducted by Rene-Henri and colleagues[134].

Asthma exacerbations may be caused by a variety of risk factors, known as triggers, including tobacco smoke[1]. McLeish and Zvolensky[190] conducted a review of asthma and cigarette smoking and they concluded that current smoking was associated with a reduction in asthma control to the order of 50-174% depending on the study methodology. In addition, smokers with asthma have an increased risk of mortality, suffer more frequent asthma symptoms and exacerbations and have a greater decline in lung function. Furthermore, concurrent smoking reduces the efficacy of ICS and systemic glucocorticosteroids among asthma patients[191,192], thus smoking cessation should be actively encouraged among asthma patients especially[1]. As community pharmacy is the primary retail outlet for nicotine replacement therapies (NRT) and pharmacists are in frequent contact with asthmatic patients due to prescription refills, they are optimally positioned to promote and encourage smoking cessation. Maguire and colleagues[193] conducted a randomised controlled trial of a smoking cessation intervention led by community pharmacists based on the Pharmacists' Action on Smoking model. Control patients received usual pharmaceutical care (including NRT as appropriate) and test patients had an initial consultation with the pharmacist, they were provided with NRT as appropriate, and were asked to return at weekly intervals for four weeks for follow-up advice and then at monthly intervals for three months thereafter. 14.3% of the test group compared with 2.7% of the control group had abstained from smoking for 12 months, a significant difference. Thus, community pharmacists can be effective in promoting and sustaining smoking cessation among their patients.

As the level of experience of the respondents increased, the level of frequency with which they perform this intervention also increased. This differs from the previous observations on age range and experience where those with moderate experience conducted the interventions with the greatest frequency. Under the 'Financial Measures in the Public Interest Act 2009'[138] the Health Service Executive has made considerable reductions to the payments to community pharmacists for medicines. These cutbacks have been severe and extremely controversial. It is evident from the extent of the cutbacks that in

order for community pharmacy to survive pharmacists must expand their role and no longer focus primarily on dispensing medication but instead use their knowledge and experience to provide additional clinical services to patients, such as counselling on smoking cessation. Consequently, community pharmacists with the most experience may have recognised this need to diversify and are counselling their patients more holistically than the younger less experienced respondents.

Pharmacy owners also carry out these interventions significantly more frequently than employee pharmacists do and the above reasoning also applies to them, as it is possible that they recognise the need to expand the role of the pharmacist so that their businesses can survive the cutbacks.

2.7.3.8. Counselling on asthma control at prescription renewals

Approximately 72% of respondents *sometimes/never assess their patients' level of asthma control at prescription renewals.* As discussed in 2.7.2.6, the ability of community pharmacists to identify patients with sub-optimal asthma control and intervene appropriately was demonstrated in a recent study by Armour and colleagues[154]. Furthermore, Thornley and colleagues[194] investigated the extent to which pharmacists and their support staff delivered a brief intervention to assess patients' asthma symptom control and provided the appropriate lifestyle advice over a four month period, using mystery shoppers. The pharmacists received documentation on three basic questions on asthma symptoms that were to be used in conjunction with communications on up-to-date lifestyle advice relevant to patients with asthma. Pharmacists and pharmacy support staff were assessed and ~80% of pharmacists and ~70% of the support staff assessed delivered the brief intervention. Thus, providing pharmacists with effective tools to deliver a brief intervention on asthma control can be implemented effectively and with minimal disruption.

As observed in 2.7.3.7, as respondents increase in experience the frequency with which they deliver this intervention also increased. In addition, pharmacy owners conduct this intervention significantly more frequently than employee pharmacists do. The possible reasons discussed in 2.7.3.7 are also relevant in this instance.

2.7.3.9. Counselling on adverse effects at prescription renewals

Greater than 60% of respondents indicated that they *always/often check for drug-related adverse effects at prescription renewals.* This was significantly greater than the result obtained by Rene-Henri and colleagues[134] whereby only ~23% of respondents

always/often checked for adverse effects due to asthma medication. Vainio and colleagues[139] investigated the role of the pharmacist in asthma management, as perceived by the pharmacists themselves. 77% of pharmacists considered that enquiring about problems in drug use at prescription renewals was 'important/very important'.

Laforest and colleagues[195] investigated adverse effects reported by patients that they attributed to their asthma medication. Approximately 60% of patients surveyed reported at least one adverse effect that they considered to be due to their asthma medication. A significantly greater number of patients with poorly controlled asthma reported at least two adverse effects that they attributed to their asthma medication compared to patients with better asthma control. Tiredness, insomnia and headaches were commonly reported symptoms that may, in fact, be a consequence of inadequate asthma control not an adverse effect of asthma therapy. In addition, palpitations and tremor were also attributed to asthma therapy, but these symptoms may be due to overuse of reliever medications, and this also suggests sub-optimal asthma control. However, if patients believe these symptoms, likely to be due to poor asthma control, are attributable to their asthma therapy they may become non-adherent to their asthma medication and this may further worsen their asthma control[195]. In addition, the most common adverse effect attributed to asthma therapy was tiredness (~22% of patients), an unlikely side-effect of asthma medication. Thus, the study highlights a need for increased patient education on the potential side effects of asthma medications to help prevent nonadherence due to symptoms that are not attributable to asthma therapy as patients with concerns about adverse effects have been associated with significantly lower rates of adherence than patients without such concerns[196].

Once again, pharmacy owners and the most experienced respondents perform this intervention more frequently than younger employee pharmacists and the reasons discussed in 2.7.3.7 above remain relevant in this instance.

2.7.3.10. GP referral in case of medication problems

Approximately 70% of respondents *always/often refer their patients to their GPs in the case of medication problems*. Similarly, ~77% of Canadian respondents always/often refer their patients to a doctor when a medication-related problem arises[134]. No significant relationships were observed between this item and respondents' demographic characteristics.

2.7.3.11. Counselling on worsening asthma

Approximately 73% of respondents *always/often advise their patients on the correct action to take in the event of worsening asthma.* This result is encouraging given the widespread reports of inadequate asthma control among asthma patients worldwide[172]. Once again, pharmacy owners and the most experienced respondents perform this intervention more frequently than younger employee pharmacists and the reasons discussed in 2.7.3.7 above remain relevant in this instance.

2.7.3.12. Advising patients to obtain an asthma action plan from their GPs

Approximately 90% of respondents *sometimes/never advise their patients to obtain an asthma action plan from their GPs.* It is possible that the low frequency with which this intervention is conducted may be due to low frequency with which GPs provide their patients with such self-management plans. The results of the QAM-GP (2.4.3) revealed that only 31% of GP respondents *always/often provide their patients with a personalised asthma self-management plan.* The infrequent provision of asthma management plans is not a phenomenon unique to Ireland, worldwide the percentage of physicians regularly providing their patients with self-management plans ranges from 9-26%[197-200]. It is also possible that a proportion of respondents are not aware of the importance of the asthma self-management plan in asthma care.

This result was influenced by a number of demographic characteristics: Firstly, the intervention is carried out most frequently by respondents with moderate experience. The youngest, least experienced respondents perform the intervention least frequently and the oldest most experienced respondents carry it out with intermediate frequency. In addition, pharmacy owners carry out this intervention more frequently than employee pharmacists do. The same possible reasons discussed in 2.7.3.1 are applicable here.

2.7.3.13. Interventions identified as most important

Respondents recorded the five interventions that they considered to be of most importance. Demonstrating a newly prescribed inhaler to patients appears to be the intervention considered the most important as 16.3% of respondents included it in their top five most important interventions but only 4.6% included reassessing patients' inhaler technique every 6-12 months. Only 1.5% of respondents indicated that they considered *demonstrating the use of a peak flow meter* to be one of the top 5 most important interventions and only 3.8% included the intervention *advise patients to ask their GP for*

an asthma action plan in their top five interventions. These results are broadly in accordance with the frequency with which respondents reported conducting these interventions with their patients. However, almost 40% of respondents who *sometimes/never advise patients to ask for as asthma action plan* indicated that they considered this intervention to be one of the five most important interventions. This result supports the theory that one of the possible reasons why some respondents infrequently advise their patients to obtain an asthma self-management plan may be due to the low incidence with which GPs appear to provide these plans to their patients.

2.7.4. Factors influencing pharmacists' interventions with asthma patients.

2.7.4.1. The pharmacist-patient relationship and barriers to its development

According to the GINA guidelines[1] the development of a relationship between the health-care professional(s) and the asthma patient is an essential aspect in the effective management of the condition. In these guidelines, this relationship refers to that between the GP and the patient, but is not exclusive to this group of health-care professionals. An overwhelming majority of respondents (~98%) agreed that the establishment of the pharmacist-patient relationship is necessary for the promotion of good asthma management. Kansanaho and colleagues[201] investigated the opinions of a random sample of Finnish community pharmacists on concordance. They found that 96% of respondents strongly agreed/agreed that the establishment of a 'therapeutic alliance' was the highest priority in the pharmacist-patient consultation.

The most frequent elaboration on the need for the establishment of the pharmacist-patient relationship was that the establishment of such a relationship *promotes trust* and ensures that the *patient is more receptive and trusting of the counselling provided by the pharmacist*. This result is very encouraging as it is in accordance with the aforementioned international guidelines produced by GINA on promoting effective asthma management[1]. It also supports the theory proposed above to explain why more experienced respondents reported conducting many of the specified asthma interventions significantly more frequently than their less experienced colleagues, *i.e.* more experienced pharmacists may have established a stronger relationship with their patients, based on trust, which might facilitate an increased receptiveness among their patients to counselling. This theory is supported by the literature[145], as discussed above.

Respondents also made reference to the fact that pharmacists are the most accessible health-care professionals and that they are in a unique position in that they see patients

more frequently than any other group of health-care professionals in the primary care setting. Unfortunately, given the poor frequency with which respondents indicated that they perform some of the interventions considered essential in asthma management, *e.g. checking inhalation technique every 6-12 months*, it appears that a proportion of respondents may not be taking full advantage of their unique position.

The most frequently cited barrier to the development of the pharmacist-patient relationship was *time,* but a litany of barriers was mentioned. In fact, only 3.5% of respondents stated that no barriers existed to developing such a relationship. This finding is of great concern because the establishment of the pharmacist-patient relationship is thought to encourage patient willingness towards collaboration and lead to more open, bidirectional communication[145]. As discussed in 2.7.2.2, an association between good pharmacist-patient communication and patient understanding of pharmacotherapy and competency in the use of inhalers was demonstrated by Onda and colleagues[137].

2.7.4.2. Factors influencing the counselling of asthma patients

a) Time influences patient counselling

Approximately 85% of respondents *strongly agreed/agreed* with the statement *time is a major factor influencing my ability to counsel my asthma patients.* Schommer and colleagues[202] used data from the 2004 National Pharmacist Workforce Survey to investigate the desired amount of time and the actual amount of time spent by pharmacists in four activities: dispensing, patient consultation, business management and medication use management. They found that pharmacists in all practice settings would like to spend more time on patient consultations and medication use management and less time on dispensing. Indeed, community pharmacists were more likely to report a difference between desired and actual time spent in dispensing compared to their colleagues in other practice settings, indicating that time spent dispensing medication reduces the amount of time they have available to conduct other activities like counsel patients.

McCann and colleagues[203] investigated and quantified the amount of time community pharmacists in the Greater Belfast area spent on different workplace activities using a self-reported work-sampling methodology. They discovered that pharmacists spent the greatest amount of time (~23%) on medication assembly and labelling compared to only 5% of time spent personally handing out prescriptions and patient counselling. This result supports the finding that the majority of respondents agreed that time influences their

ability to counsel their patients and it is unsurprising as pharmacists are currently paid on a 'fee per item' basis that provides little incentive to encourage patient counselling.

As expected, as the number of items dispensed daily increased the proportion of respondents who *agreed/strongly agreed* that *time* influences their ability to counsel also increased. This result was supported by the findings of Svarstad and colleagues who investigated the influence of busyness, pharmacist age and state regulations on the provision of patient counselling in community pharmacies[204]. They discovered that patients who attended a 'busy' pharmacy (defined by the patient awaiting a prescription and confirmed by counting the number of other patients waiting in the prescription area) were less likely to have any verbal interaction with the pharmacist, receive any oral information about their prescription or have their understanding of the prescription assessed than patients who attended a pharmacy that was not considered busy.

b) Competency in counselling on correct inhalation technique

Greater than 86% of respondents *disagreed/strongly disagreed* that they *do not feel competent to assess and educate on correct inhalation technique.* However, a number of studies have a revealed a lack of competency among pharmacists when their ability to use different inhalation devices was independently assessed. The mean percentage technique demonstration scores for Diskus and Turbohaler devices ranged from 43%-62%[57,176]. In addition, only 6% of participating pharmacists correctly demonstrated all of the pMDI technique steps in an American study of ~40 community pharmacists[136]. Thus, this subjective result should be viewed with caution.

A significant relationship was observed between this item and the frequency with which respondents *demonstrate a newly prescribed inhalation device*. A significantly greater proportion of respondents who *sometimes/never* conduct this intervention *agreed/strongly agreed* that they do not feel competent to counsel their patients on correct inhaler technique. However, the percentage of respondents who agreed with this statement on lack of competency was very low overall.

c) Competency in counselling on using a peak flow meter

Approximately one-fifth of respondents *agreed/strongly agreed* that they *do not feel competent to assess and educate on the correct use of the peak flow meter.* When this result was analysed in conjunction with the two interventions, *demonstrating the use of the peak flow meter* and *advising on the importance of the peak flow meter,* significant relationships were observed. In both instances, a significantly greater proportion of respondents who *never* conducted these aforementioned interventions *agreed/strongly*

agreed with the statement on competency compared to respondents who conducted these interventions more frequently. Thus, a lack of competency explains why a proportion of respondents infrequently conduct these interventions with their asthma patients. Similarly, Vainio and colleagues[139] found that 38% of respondent pharmacists perceived their lack of knowledge and skills to be a problem influencing their ability to counsel their asthma patients. However, following a training intervention that consisted of an average of six in-house training sessions this percentage reduced to 9% and the percentage of new and existing patients that were counselling by the participating pharmacists increased significantly.

A significant relationship was observed between the two aforementioned interventions and respondents' experience in pharmacy practice. This revealed that a significantly larger proportion of respondents with the least experience (0-5 years) and the most experience (> 20 years) *agreed/strongly agreed* with this statement on lack of competency than their counterparts with a moderate level of experience (6-20 years). Respondents with 0-5 years experience are predominantly new graduates so it is possible that there is a deficiency in the practical education of students on the use of peak flow meters. In relation to those respondents with most experience, it may be that the importance of peak flow meters in asthma management was not recognised when they were educated and they have not kept abreast of current best practice in asthma management.

d) Sufficient pharmacists/technicians influences patient counselling

Approximately 40% of respondents *agreed/strongly agreed* that a *sufficient number of pharmacists/pharmaceutical technicians allows them to counsel their patients appropriately.* As the average number of pharmacists and pharmaceutical technicians working together daily was 1.2 and 0.8 respectively, this result was unsurprising. In a recent study, Hughes and colleagues[205] investigated the provision of pharmaceutical care and factors that could influence its provision across thirteen European countries, including Ireland. They found that in Ireland and the UK as the number of pharmacists per pharmacy increased the provision of pharmaceutical care also increased significantly. Furthermore, in the aforementioned study by McCann and colleagues[203] on the time pharmacists spent on different workplace activities, they found that pharmacists with three or more staff members spent significantly less time on coding and endorsing prescriptions than those with less staff. In addition, those who employed a pre-registration pharmacy student spent significantly less time assembling and labelling medication than those who did not. It is evident that lack of time, a significant influencing factor on counselling for the majority of respondents, could be overcome by employing more pharmacists. However, as that is not a practical solution in many instances in the current economic climate,

employing non-pharmacists to help in the preparation of prescriptions could provide the pharmacist with more time for patient counselling.

e) Role of the pharmacist in counselling on asthma control

Greater than 90% of respondents *disagreed/strongly disagreed* with the statement, *it is not my role to counsel an asthma patient to improve his/her level of asthma control.* Conversely, only ~30% of respondents indicated that they *always/often assessed their patients' level of asthma control at prescription renewals* and only ~10% *always/often check their patients' inhaler technique every 6-12 months.* Pradel and colleagues[174] explored the factors influencing paediatric counselling by pharmacists. They discovered that while the median response on the importance of counselling paediatric asthma patients on a scale of 1-7 was 6, 'important', respondents only counselled paediatric asthma patients and their carers 'a few times' and 'fairly often' respectively, in the past month. Thus, this result supports the findings in this survey that considering a particular set of counselling behaviours to be important or within one's role specification does not necessarily mean that the counselling will be implemented. This may be as a consequence of other influencing factors such as lack of time, lack of competency or lack of understanding about what is involved in counselling patients to improve asthma control. For example, a proportion of respondents may consider that checking and counselling patients on adherence in their use of preventer and reliever inhalers is sufficient to improve a patient's asthma control. However, achieving asthma control is not reliant solely on adherence with the prescribed medication regimen; a multi-faceted approach is needed involving education and reinforcement of appropriate inhalation technique, self-monitoring of symptoms or peak flow readings, and patient-directed self-management using a written personal asthma action plan[1].

f) Asthma patients as a factor influencing counselling

While ~ 78% of respondents agreed/strongly agreed that when they counsel their patients are receptive, approximately 16% *agreed/strongly agreed* that *patients think they are interfering when they offer advice.* Thus, for a proportion of pharmacists the patients themselves act as a barrier to counselling. There may be a number of reasons for this. Firstly, as discussed above, patients appear to consistently perceive their level of asthma control to be better than it is in reality[151,172]. Similarly, many patients believe that their inhaler technique is correct until an independent assessment proves otherwise[41]. Thus, if patients believe they are managing their asthma and their medications adequately they may not be receptive to advice or counselling that implies the contrary. In addition, patients may not be aware of the potential role that the pharmacist can play in asthma management and this may influence their receptiveness to counselling. Naik Panvelkar

and colleagues[206] investigated patient preferences for community pharmacy based asthma services among patients who had ('experienced patients') and had not ('naive patients') previously experienced a specialised asthma service. 'Naive patients' had lower expectations than their 'experienced' counterparts about the potential role of the pharmacist in asthma management, only identifying the dispensing of medicines and the provision of information on medicines as potential roles. In addition, they had low expectations about the level of asthma monitoring that the pharmacist could provide and they did not consider that inhaler technique training should be conducted by the pharmacist. This contrasted greatly with the expectations of 'experienced patients' who identified a number of potential roles for the pharmacist in asthma management including asthma monitoring, inhaler technique training, lung function testing and the provision of comprehensive information on asthma and asthmatic medications. Thus, demonstrating the ability of pharmacists to expand their role in asthma management appears to increase patient expectations of their pharmacists and thus increases their receptiveness to counselling.

g) Asthma knowledge as an influencing factor

Only approximately 4% of respondents *disagreed/strongly disagreed* with the statement that they *have sufficient knowledge to counsel effectively.* Similarly, in the survey conducted by Rene-Henri and colleagues only ~5% of respondents disagreed that their knowledge about asthma and asthma therapies enables them to intervene effectively with their patients[134].

However, this survey does not clarify the meaning of *sufficient knowledge about asthma.* Respondents may have interpreted this statement in terms of the pathophysiology of asthma and this knowledge does not necessarily translate into knowledge about the need for repeated reinforcement on inhaler technique, the value of the peak flow meter, or the importance of an asthma management plan, all interventions that were infrequently conducted by the majority of respondents.

h) Payment as an influencing factor

While >70% of respondents *disagreed/strongly disagreed* with the statement *I do not counsel my asthma patients because I feel I am underpaid to do so* the result was influenced by a number of demographic characteristics. Firstly, as the level of experience of the respondents increased the level of agreement with the statement increased significantly. In fact ~13% of respondents with >20 years experience agreed with the statement in contrast to just 1.3% of those with 0-5 years experience. A possible explanation for this may be related to the aforementioned HSE cutbacks, which have led

to salary reductions for many pharmacists. Older, more experienced pharmacists may have become accustomed to a generous salary over the course of their careers and the subsequent salary reduction due to the cutbacks may have contributed to this response. In addition, a significantly greater proportion of pharmacy owners than employee pharmacists agreed with this statement. The HSE cutbacks may have greatly reduced the profit margins for medicines and it is pharmacy owners who felt the brunt of these cutbacks directly. This may explain their responses to this statement.

i) Counselling only when asked for advice

The mean response to the statement *I only counsel my asthma patients when they ask for my advice* was *neutral.* This result is quite concerning as it has been repeatedly reported in the literature that asthma patients frequently over-estimate their level of asthma control[172] and are often unaware that their inhalation technique is incorrect[41]. Consequently, patients may infrequently seek advice and so it is vital that pharmacists proactively approach their patients, irrespective of whether their advice is actively sought out or not, in an attempt to improve asthma control.

j) Additional factors influencing counselling

Despite the fact that *time* was the focus of one of the statements, it was reiterated by ~24% of respondents as influencing their ability to counsel their asthma patients. Time appears to be very instrumental in the pharmacist's ability to counsel effectively. It was also mentioned by >70% of respondents as a major barrier to developing the pharmacist-patient relationship. Surprisingly, ~23% of respondents stated that patient's receptiveness to counselling influenced their ability to counsel, even though the majority of them felt that patients were generally receptive to counselling and do not think that they are interfering when they offer advice. Similar findings were observed by Dunlop and Shaw[207] who conducted a study on pharmaceutical care implementation in New Zealand that included investigating any barriers to pharmaceutical care provision. Insufficient time was identified by a barrier by 87% of respondents and >64% agreed that lack of patient demand was a barrier to providing pharmaceutical care.

2.7.5. Communication with other health-care professionals: GPs

Approximately 17% of respondents indicated that in an average week they had no communication with a GP about an asthma patient. Limited communication and professional engagement between community pharmacists and GPs have been reported by pharmacists themselves in the literature[182,208]. Professional interaction has been identified as one of the variables associated with the establishment of successful

collaborative working relationships (CWRs) between pharmacists and GPs[209,210]. However, the direction of communication is an important factor. Unidirectional communication, from pharmacist to GP, has been associated with lower levels of collaboration compared to bidirectional/reciprocal communication[211]. Bidirectional communication is needed to facilitate the routine sharing of patient information, which can assist therapeutic monitoring and decision making when preformed in a timely manner[212]. In the early stages of the establishment of a successful CWR, communication may be one-directional, initiated by the pharmacist, but as the relationship develops, the GP may also initiate communication as interdependency increases[209] between the professionals.

From the results obtained, a proportion of respondents may have limited professional relationships with their local GPs, evidenced by the limited or lack of reported communication about asthma patients. Snyder and colleagues[213] investigated CWRs between pharmacists and physicians and they found that pharmacists were the relationship initiators in successful CWRs, a role acknowledged by both pharmacists and physicians. Thus, in order to foster the development of CWRs with local GPs, pharmacists may benefit from organising face-to-face meetings with the GPs as a means of initiating personal relationships and to explain their goals for patient care[213].

Approximately 60% of respondents were satisfied with the current frequency of communication but on analysis, it was observed that as the frequency of communication decreased the proportion of respondents who were satisfied with the communication decreased significantly. If dissatisfied with the current state of communication, respondents were asked to write freely about what changes could be made to improve communication, but the majority of respondents commented on the current communication rather than providing suggestions for its improvement. Approximately 30% stated that communication with GPs needed to be in a more structured format. Indeed, identifying the most efficient and convenient method of communication has been associated with the effective development of a viable communication system and this, in turn, facilitated the development of CWRs between GPs and pharmacists[212]. Establishing a structured form of communication should also help address the barrier of GP accessibility that was identified by ~6% of respondents and was also identified in the literature as a barrier to interprofessional cooperation[214].

Two other issues that featured quite prominently in relation to the current state of communication were the lack of receptiveness among GPs of pharmacists' interventions (~26%) and their lack of acceptability of the pharmacist's role in patient care (~10%). Similar barriers to the development of CWRs were identified by pharmacists in the

literature. Hughes and McCann investigated the perceived barriers to CWRs among pharmacists and GPs[214]. Among the barriers identified by pharmacists was the belief that GPs viewed them as commercial 'shopkeepers' who were not members of the primary healthcare team and that they did not understand the role of the pharmacist in primary care. A study of CWRs between physicians and pharmacists, conducted by Dey and colleagues, revealed that pharmacists believed that the poor attitude of GPs towards pharmacists was a significant barrier to teamwork[208].

2.7.6. Communication with other healthcare professionals: Nurses

Approximately 86% of respondents indicated that they had no communication with a practice nurse about an asthma patient in a typical week. A more in depth analysis of this result revealed that the main reasons for this lack of communication were a lack of knowledge about both the identity of the practice nurses and a means of contacting them. However, almost 30% of respondents indicated that they would like contact with practice nurses and stated that regular communication with nurses is needed, indicating a positive attitude to CWRs between nurses and pharmacists. Similarly, While and colleagues[215] investigated the opinions of community pharmacists towards collaboration with nurse prescribers and found a willingness among pharmacist respondents towards collaboration with nurse prescribers. Numerous examples are available in the literature that illustrate the benefits of pharmacist-nurse collaboration and these are described in 2.9.3.3.

2.7.7. Proposed national asthma project

2.7.7.1. Project feasibility nationwide

Only less than one-quarter of respondents did not believe that *time* would/could represent a feasibility issue. This result is unsurprising given the vast majority of patients who agreed that *time* influences their ability to counsel their asthma patients. Dobson and colleagues[216] investigated the attitudes of pharmacists towards participating in interprofessional healthcare teams and they discovered that ~65% of respondents 'agreed/strongly agreed' that they had insufficient time to participate in 'team-based activities' and an additional 22% 'somewhat agreed' with this statement.

The majority of respondents did not believe that patient cooperation would be problematic in implementing this project. This result is quite surprising as both GPs and pharmacists identified patients as the most significant barrier to optimal asthma management in a recent Australian study[182]. In addition, asthma patients who never experienced a specialised asthma service in community pharmacies may be unaware of the role the

pharmacist can play in asthma management and thus may be reluctant to participate in the project[206]. Furthermore, patients' poor perception of their degree of asthma control[172] and/or their inadequate inhaler technique[41] has been widely reported in the literature and may cause some patients to be unreceptive to an asthma intervention due to a belief that it is unnecessary. However, patients who have participated in asthma interventions conducted by community pharmacists have generally expressed positive views about their experiences[41,217,218].

The majority of respondents believed that interprofessional communication would/could be a problem in the successful implementation of the proposed project. Once again, this result is unsurprising due to the infrequent communication currently reported to occur between pharmacists and both GPs and practice nurses. As discussed above, bidirectional communication is one of the key factors associated with successful CWR[209,210]. Insufficient time was identified yet again by >15% of respondents, in this instance as a barrier to interprofessional communication. The other issue most frequently raised in relation to interprofessional communication was that not all healthcare professionals were open to suggestions be community pharmacists, this issue was also raised in 2.7.5 above indicating that it may be a significant issue for a proportion of respondents.

2.7.7.2. Major barriers to the success of the project

Greater than 97% of patients indicated that major barriers exist that may impede the success of the proposed project. Once again, *time* featured as a major barrier; in fact, ~57% of respondents stated that time was a major impediment. The second most frequently quoted barrier was *money*. Almost 25% of respondents stated that they should be compensated for the time they would have to spend on this project. This desire for remuneration may have arisen as a reaction to the aforementioned HSE cutbacks. Pharmacists may now be investigating new methods to generate revenue and payment for the provision of professional services is one that is frequently cited. Indeed, the report on Primary Medical Care in the Community published in February 2010 by the Joint Committee for Health and Children[219] recommended expanding the role of the pharmacist in the community to include additional healthcare services to patients.

As discussed in 2.7.4.2(j) Dunlop and Shaw[207] explored the barriers to the implementation of pharmaceutical care as perceived by a random sample of ~500 community pharmacists in New Zealand. System-related barriers were investigated as part of the survey and >80% of respondents agreed that a lack of reimbursement system was a barrier to the provision of pharmaceutical care. In addition, only ~30% did not believe that doctor/nurse

resistance would be a problem, the remainder were unsure (~30%) or believed it would be a problem (~40%). Lack of GP acceptance was identified as a major barrier by >12% of respondents in this survey.

2.7.7.3. Desirable factors about the project

There were numerous desirable factors cited by respondents and those that were most frequently alluded to were related to the improvement of patient care, therapeutic outcomes and patient education, improved relationships with patients was also frequently mentioned. In addition, the project was seen as a means of expanding the role of the pharmacist in asthma management and increasing his/her responsibility. This is a very positive outcome as it indicates the desire of pharmacists to expand their role in primary care to include, not only the dispensing of medication, but also the provision of clinical services to improve patient care in the community setting. Furthermore, approximately 14% of respondents saw the project as a way of developing inter-professional relationships with other health-care professionals in primary care. Many respondents indicated a sense of dissatisfaction with the current level of communication with GPs and practice nurses so this result is very encouraging as it indicates a sense of initiative among pharmacists to improve communication links. Lalonde and colleagues[220] investigated the views of pharmacists, physicians and patients following the implementation of a physician-pharmacist collaborative care intervention for the treatment of patients with dyslipidaemia. The participating pharmacists highlighted many benefits of the collaborative intervention that were also proposed by the respondents of this survey. They had positive views about the intervention believing that it improved clinical outcomes, improved both pharmacist-patient and pharmacist-GP relationships, and expanded the role of the pharmacist[220]. Bereznicki and colleagues investigated the perceptions of a sample of participants (pharmacists, GPs and patients) about a community pharmacist-led asthma intervention, discussed in 2.7.3.4 above[221]. The pharmacists interviewed had positive perceptions of the intervention and believed that it expanded their role in asthma care.

2.7.7.4. Undesirable factors about the project

Greater than 50% of respondents stated that they found nothing undesirable about the project, which may indicate a desire to form CWRs with other healthcare professionals in primary care. The most frequently cited undesirable factors were very similar to the most frequently cited major barriers: *time* (41%) and a *lack of remuneration* for the provision of such a service (~34%).

2.7.8. Limitations of the study

There are a number of limitations to this study. Firstly, the validity and reliability of the questionnaire was not assessed. In addition, it was not possible to analyse the characteristics of the non-respondents. It is likely that those who completed the questionnaire are more motivated to provide pharmaceutical care to their asthma patients than those who did not respond. As a result, it is possible that a proportion of community pharmacists in Ireland intervene in the care of their asthma patients considerably less frequently than the results of this questionnaire suggest. The use of an anonymous postal questionnaire was hoped to reduce the bias of social desirability, thus encouraging respondents to answer the questions as truthfully as possible.

2.8. Discussion: QAM-GP

2.8.1. Baseline characteristics

Respondents' demographic data were analysed in detail and a number of interesting findings emerged. A significantly greater proportion of respondents with the least experience worked in city practices, a greater proportion of those with moderate experience worked in towns or suburban areas and a greater proportion of those with the most experience worked in rural areas. In addition, a significantly greater proportion of the more experienced respondents were practice owners/stakeholders than their less experienced colleagues. Finally, respondents in practices in towns or rural areas saw significantly more patients daily than respondents in city or suburban practices.

2.8.2. Opinions on current asthma treatment/management

2.8.2.1. Asthma care in the primary care setting nationwide

The majority of respondents appeared to be satisfied with asthma care in the primary care setting nationwide and this result was not influenced by respondents' demographic data.

2.8.2.2. Patients' understanding of asthma as a disease

Only one-third of respondents believed that their patients had *a good understanding* of asthma as a disease. This corresponds with the literature whereby only 50% of primary care asthma patients surveyed answered at least half of the knowledge questions in the Knowledge Attitudes and Self-Efficacy Asthma Questionnaire correctly[222]. Furthermore, in a survey of adult asthmatic outpatients only ~40% of respondents understood the inflammatory nature of the disease[223]. In addition, ~40% of Italian GPs surveyed thought that their patients lacked awareness about the chronic nature of asthma[198].

A more in-depth analysis revealed that a greater proportion of the less experienced respondents believed that their patients have *some/little understanding* of asthma whereas a greater proportion of their more experienced colleagues estimated that their patients had a *good understanding* of the disease. There are two possible explanations for this. More experienced GPs may have built up a good relationship with their patients over the course of their careers and consequently their patients may be more receptive to their advice/counselling. Adams and colleagues[224] investigated the factors associated with patient involvement in treatment decision making by physicians and they found that the duration of the doctor-patient relationship was significantly correlated with

'participatory decision-making'. The GINA guidelines[1] recommend the development of a partnership between the patient and his/her physician to facilitate optimal asthma management. A recent study[225] investigating the impact of the patient-physician relationship on asthma outcomes concluded that the patient-physician alliance is a contributory factor in the improvement of asthma management, as patients with a good relationship with their physicians were shown to have better asthma control and better quality of life than those who did not experience a good patient-physician partnership.

However, it is also possible that less experienced GPs, especially those who have only recently completed their training, may have higher expectations about what 'a good understanding of asthma' should mean to their patients. As a result, they may believe that the majority of their patients have not achieved this level of understanding of the disease.

A greater proportion of practice owner/stakeholder GPs believed that their patients have a good understanding of asthma. As a greater proportion of practice owners/stakeholders are older, more experienced GPs; this result is logical and corresponds with the above result.

2.8.2.3. Patients' understanding of the indications for their asthma medications

40% of respondents believed that their patients had *a good understanding* of the indications for their asthma medications. This result appears higher than reports in the literature. The Asthma General Awareness and Perceptions II (GAP II) Survey investigated the behaviours and beliefs of asthma patients and physicians[226]. Approximately 70% of asthma patients believed that reliever medication could be taken daily. In addition, while the majority of patients recognised the risks associated with discontinuing preventative medication, >40% agreed that it is appropriate to reduce the frequency of preventer medication when they experience a reduction in asthma symptoms. Furthermore, only ~25% of patients surveyed agreed that it was appropriate to take preventative medication when they were asymptomatic[226].

As observed above, a greater proportion of the more experienced GPs believed that their patients have a *good understanding* of the indications for their asthma medications than their less experienced colleagues. In addition, a greater proportion of practice owner/stakeholder GPs than employee GPs believe that their patients have a good understanding of the indications for their asthma medications. The same possible reasons discussed in 2.8.2.2 above are relevant in this instance.

2.8.2.4. Patients' ability to use their inhalers properly

The mean percentage of patients estimated to use their inhalers properly was ~60%. This result seems quite optimistic given the widespread reporting of poor inhaler technique among patients in the literature[6,11,13,43,69]. The consequences of incorrect inhaler technique have been discussed in 2.7.2.4.

Once again, this result was influenced by respondents' experience in general practice. Respondents with >20 years experience estimated that the mean percentage of their patients estimated to use their inhalers correctly is significantly higher than that estimated than their less experienced colleagues. The same possible reasons described in 2.8.2.2 above are relevant here.

2.8.2.5. Patients using a peak flow meter regularly

The mean percentage of patients estimated to possess a peak flow meter that they use regularly was only 18%. Indeed, only ~15% of respondents estimated that >30% of their patients used a peak flow meter regularly. This result is in accordance with the literature[151].

Patient preference may contribute to the poor uptake of peak flow monitoring. Harver and colleagues[227] reported a robust preference for symptom monitoring over peak flow monitoring to detect deteriorating asthma control, for both adults and children irrespective of disease severity. The preference for symptom monitoring may be effort-related. Symptom monitoring simply requires the patient to direct his/her attention to breathing; it requires minimal time and effort. By comparison, peak flow monitoring can be unwieldy and impractical in some situations. However, the accuracy of symptom monitoring has been questioned. Some patients perceive symptoms more accurately than others despite a similar degree of airway obstruction[228], while perceptual error is more pronounced in certain groups of asthmatics than others, such as those with forced expiratory volume at 25-75% of capacity[229], and those with prolonged airway obstruction[230]. Consequently, symptom self-monitoring can underestimate the degree of asthma severity leading to inappropriate medication usage, thus it has been proven to be a less accurate tool than peak flow rate measurement to monitor asthma control[179].

In addition, the low estimation of patients who use a peak flow meter regularly may be a consequence of its infrequent recommendation by the GPs. In a survey of primary care paediatricians on self-reported adherence to the 1997 National Heart, Lung and Blood

Institute (NHLBI) asthma guidelines, only 38% of respondents indicated that they instructed patients on daily peak flow meter use[231].

As observed above, more experienced respondents and practice owners/stakeholders believed that a significantly higher proportion of their patients use a peak flow meter regularly than their less experienced colleagues and employee GPs. The aforementioned reasons (see 2.8.2.2) are also valid in this case.

2.8.2.6. Patients with well controlled asthma

The mean estimated percentage of patients with well controlled asthma was 60%. This result is surprisingly high given the results of multinational studies investigating the level of asthma control among patients. The International Asthma Patient Insight Research (INSPIRE) study[155] discovered that only 28% of those surveyed had well controlled asthma as measured by the Asthma Control Questionnaire[232]. Furthermore, the Asthma Insights and Reality in Europe (AIRE) study[156] concluded that only ~5% of respondents had well controlled asthma and the AIRI found that only 8% of those surveyed achieved complete asthma control as defined by GINA guidelines[1]. However, a number of studies had shown that a significant discrepancy exists between patients' level of asthma control as estimated by their physicians and the reality of their asthma control status, with physicians consistently overestimating the proportion of their patients with well controlled asthma[233,234]. This discrepancy may be due to a lack of communication between physicians and their patients. In the Asthma Control and Expectations survey of 1000 patients in the UK 89% of patients stated that they did not discuss the impact that asthma symptoms had on their lifestyle with their physicians[235]. Physicians' overestimation of their patients' level of asthma control could have a significant impact on their clinical treatment, resulting in the possible under-treatment of patients due to a perception that their asthma is controlled[233].

2.8.2.7. Patients' level of medication compliance

Greater than 60% of respondents estimated that their patients were *highly compliant/compliant*. Once again this result appears unrealistically high given the results of a World Health Organisation (WHO) report which states that 50% of patients with a chronic illness do not use their medications as prescribed[236]. Low adherence rates to the therapeutic regimen for asthma have been widely reported and range from 30-70%[149,161-163]. There are two related types of non-adherent behaviour: unintentional and intentional non-adherence. Unintentional non-adherence occurs when external factors prevent the patient from taking the medication as prescribed[237]. These factors include

forgetfulness[161,163], poor comprehension especially in the case of complex therapeutic regimens[237] and incorrect inhaler technique[238]. Indeed, Takemura and colleagues[238] discovered that adherence to therapy was strongly associated with receiving repeated instruction on inhaler technique. Intentional non-adherence occurs when a patient takes the medication in an alternative manner to that prescribed or simply refuses to take the medication[239,240]. A number of reasons for intentional non-adherence have been identified. Firstly, adherence rates have been associated with self-perceived degree of asthma severity; patients who perceived their asthma to be severe were more adherent than those who perceived their disease to be mild[162]. Patients who doubted their need for preventative therapy were less adherent than those who did not[196]. The relationship between perceived need and adherence is concerning, as the lack of correlation between patients' perceived degree of asthma control and the objective measures of control has been widely documented worldwide, with patients consistently believing that their asthma is better controlled than it is in reality[172]. A possible reason for this lack of correlation is that patients may have low expectations of asthma management and thus they are unaware of the best practice guideline goals for well controlled asthma[241].

Intentional non-adherence is also related to anxiety about the effects of long-term ICS usage and the potential side-effects. In fact, in a survey investigating self-reported behaviours towards ICS ~25% of respondents agreed that the 'constant use of respiratory drugs is unhealthy' and this belief was strongly correlated with non-adherence[163]. In addition, Horne and Weinman[196] reported that approximately one third of patients surveyed had concerns about the adverse effects of ICS and there was a significant correlation between reported adherence rates and concerns about side effects.

As before, a greater proportion of more experienced GPs believed that their patients were *highly compliant/compliant* than their less experienced colleagues. The previously described reasons (see 2.8.2.2) also apply here.

2.8.2.8. Frequency of severe asthma exacerbations among patients

Greater than 90% of respondents believed that asthma exacerbations (with hospitalisation) are *uncommon* or *very uncommon* among their patients. According to the Activity in Acute Public Hospitals Annual Report 2009, asthma was the principal diagnosis for 4,726 in-patients (adults and children) in 2009[242]. As approximately 7% of the adult population suffer from asthma, according to the Health Status and Health Service Utilisation National Household Survey quarterly report 2010[116], estimating that exacerbations necessitating hospitalisation are uncommon/very uncommon is in accordance with the national average.

2.8.2.9. Patients in possession of an asthma management plan

The mean percentage of patients estimated to possess an asthma management plan and be actively involved in their asthma treatment was 38%. However, 41% of respondents were unable to provide an estimate and only 25% of respondents estimated that >40% of their patients had an asthma management plan. This infrequent provision of asthma self-management plans is in accordance with the literature where only 9-26%[197-200] of physicians regularly provide written asthma action plans to their patients. In addition, in a survey of ~500 asthma patients in the UK 80% stated that they had never received an asthma self-management plan[241].

Numerous reasons for the infrequent provision of asthma action plans by physicians have been identified in the literature. Lack of self-efficacy and doubt about the efficacy of asthma action plans have been identified as barriers to their provision in primary care[200,243,244]. In addition, the perception that asthma management plans are only suitable for certain motivated or adherent patients has been associated with their infrequent use[200,243,245,246]. Organisational factors such as insufficient time were also mentioned as barrier issues[200,243,246].

As observed previously, more experienced respondents, and practice owners/stakeholders estimate that a greater proportion of their patients possess an asthma management plan than less experienced respondents and employee GPs. The previously mentioned reasons (see 2.8.2.2) are applicable here.

2.8.2.10. Patients' expectations of disease management

Respondents appear to be divided on whether or not they believe their patients have low expectations of asthma management. In the Living and Breathing study[241] of ~500 adult patients with asthma, 66% of those surveyed experienced symptoms at least two to three times weekly, but 58% stated that they were satisfied with their asthma treatment. However, when patients were shown the asthma symptom management goals outlined in the GINA guidelines[1] this dropped to 33%. It is evident from the results of this study that patients had low expectations of disease management and were unaware that their asthma could be better managed. The differences in opinion about patients' expectations of asthma management may be related to the degree of patient-physician communication. As discussed in 2.8.2.6 above, 89% of respondents in the Asthma Control and Expectations survey indicated they did not discuss the effect that their asthma symptoms had on their daily life[235]. A lack of open discussion about the impact of asthma on quality

of life may lead physicians to assume that their patients have a better degree of asthma management than they do in reality and this in turn may influence their opinions about their patients' disease management expectations.

2.8.3. Interventions with asthma patients

2.8.3.1. Counselling on inhaler technique

The mean frequency with which respondents demonstrate a new inhalation device to their patients is 2.13 (*Often*). This result corresponds with the results of a nationwide Swiss survey of general physicians where 77% of respondents indicated that they demonstrated inhaler technique to their patients[199]. As respondents increased in experience, the proportion of them who conducted this intervention also increased up to 25 years experience, after which the proportion of respondents decreased again. As discussed previously, more experienced practitioners may have established a relationship over time with their patients and consequently their patients may be more receptive to any advice or counselling provided. The most experienced physicians may no longer be up-to-date with the various inhalation devices currently available and thus may not be competent in their ability to demonstrate the correct technique. This theory is supported by the fact that a greater proportion of respondents with >25 years experience believe that demonstrating correct inhaler technique is the job of the practice nurse who they may feel is more informed about the variety of different inhaler devices currently available commercially.

Only 23% of respondents *always/often* check their patients' inhalation technique every 6-12 months. This result is consistent with the literature where the percentage of asthma patients who stated that they had never received repeated instruction on inhaler technique was high, ranging from 69-96%[43,48,238]. It has been consistently illustrated that correct inhaler technique declines over time therefore repeated reinforcement is imperative[43,75,104]. Furthermore, Melani and colleagues[9] found that patients who had at their inhaler technique reassessed at least once had a significantly lower risk of performing a critical inhalation error than those who had never received such reinforcement. It is possible that physicians are not aware of the need for repeated education to maintain correct inhaler technique over time. This theory is supported by the absence of a relationship between this intervention and the percentage of patients estimated to use their inhalers properly.

The fact that the majority of respondents do not appear to check their patients' inhaler technique routinely may explain the high mean percentage of patients estimated by respondents to use their inhalers properly. If respondents do not check patients' inhaler technique regularly, it cannot be assumed that the percentage estimate of patients with

the correct technique is accurate or based on real experience. In fact, it is more likely to be higher than the reality due to the extensively reported decline in correct technique that occurs over time[43,75,104].

In addition, it has been reported that patients believe that their inhaler technique is optimal when in fact this is frequently not the case. In a recent study[247] assessing patients' inhaler technique, 1005 of patients stated that they knew how to use their prescribed inhalers but on assessment >80% of patients made at least one error in technique. If patients believe they are using their inhalers correctly, they may not be receptive to counselling on inhaler technique due to a belief that it is unnecessary.

2.8.3.2. Provision of information on new asthma medications

The intervention *providing verbal information to patients on newly prescribed medications* is the intervention conducted most frequently on average; the mean score was 1.46 (*Always*).

Unfortunately investigating the nature of the information provided was outside the scope of this survey. Tarn and colleagues[248] investigated the quality of physician communication when prescribing new medications. The vast majority of physicians stated the name and purpose of the newly prescribed medication, but only approximately one third of those surveyed provided information to the patient on possible side effects or duration of treatment. Lack of information on treatment duration might result in a patient not refilling a prescription for a chronic medication. Furthermore, patients may have concerns about possible side effects, these concerns could be addressed by the physician and promote greater medication adherence[248].

2.8.3.3. Counselling on the peak flow meter

The mean frequency with which respondents *demonstrate the use of a peak flow meter* was 2.20 (Often) but the mean frequency with which they *advise their patients on the importance of the peak flow meter in monitoring asthma control* was 2.62 (*Sometimes*). As the mean percentage of patients estimated to possess a peak flow meter that they use regularly was only 18% it is possible that respondents demonstrate the use of a peak flow meter more frequently than advising on its use because they measure patients' peak expiratory flow rate at patient consultations and thus, the patient must use the peak flow meter correctly to ensure an accurate reading. However, they appear to counsel their patients on the importance of the peak flow meter as a tool for monitoring asthma control at home less frequently. Similarly, in the literature only 38% of primary care paediatricians

indicated that they recommended the regular use of a peak flow meter to their patients[231]. Infrequent recommendations on the importance of the peak flow meter may be related to beliefs about poor patient compliance in using the devices regularly and effectively. In this instance, health-care professionals may believe that recommending their patients to use a peak flow meter to monitor their asthma will have little or no impact and so they rarely make such recommendations. Cabana and colleagues investigated barriers to adherence to asthma guidelines among paediatricians using focus groups[249] and a cross sectional survey[231]. One of the guidelines investigated was the instruction of patients on regular use of the peak flow meter. One of the main reasons for nonadherence recorded from both investigations was a belief that recommending the device would be ineffective due to poor patient compliance.

Interestingly, a significant relationship was observed between *advising patients on the importance of the peak flow meter* and respondents' experience in general practice but not with the intervention *demonstrating the use of the peak flow meter*. This result supports the aforementioned theory for the discrepancy between the mean frequency rates for these interventions. As discussed previously in 2.8.2.2, more experienced respondents may have established a relationship with their patients over time and consequently their patients may be more receptive to their advice on the importance of the peak flow meter. As a peak flow meter is quite expensive and is not reimbursable under the PCRS schemes, and adherence is considered an issue[231,249], a good relationship between patient and physician may be important in promoting the use of this asthma control tool.

2.8.3.4. Counselling on medication adherence: reliever inhalers

Approximately 75% of respondents *always/often* check for overuse of SABAs at prescription renewals and counsel their patients in the event of SABA overuse. This result is very encouraging given the widespread excessive reliever inhaler usage. GINA best-practice guidelines[1] state that one of the characteristics of controlled asthma is the need for reliever treatment ≤ twice/week. However, in the previously mentioned INSPIRE study (see 2.8.2.6), 74% of respondents indicated that they had used their reliever inhaler daily in the last seven days[155]. It is possible that patients are not aware that the need for regular reliever usage is an indication of poorly controlled asthma. Indeed, results of the GAP II survey revealed that >40% of respondents thought that their asthma was well controlled when they 'only needed' to use their reliever inhaler three times per week[226]. Overuse of SABAs may also be a consequence of a lack of awareness that reliever inhalers should not be used regularly but on an 'as needed' basis. 32% of respondents in

the INSPIRE study took their reliever medication daily regardless of whether they needed it or not[155].

2.8.3.5. Counselling on medication adherence: preventer inhalers

Greater than three-quarters of respondents *always/often* check for underuse of ICS at prescription renewals and counsel their patients in the event of ICS underuse. As discussed above, low adherence to ICS widespread among asthma patients[149,161-163], therefore repeated adherence monitoring and counselling is essential. Regular use of low dose ICS has been associated with a reduced risk of death from asthma[250]. An association has also been demonstrated between regular ICS use and a 31% reduction in hospitalisation and a 34% reduction in hospital readmission compared to irregular ICS use or no ICS therapy[251].

2.8.3.6. Counselling on contraindicated OTC products

Only 25% of respondents *always/often* advise patients on contraindicated OTC products. Aspirin-induced asthma (AIA) is a distinct clinical syndrome characterised by the precipitation of an asthma exacerbation/bronchospasm and attacks of rhinitis 30 minutes to 3 hours after the ingestion of aspirin or other NSAIDs[187]. The reported prevalence of AIA is variable with rates as high as 21% in adults and 5% in children reported following oral provocation[252]. Asthma exacerbations can be severe and even life-threatening in some cases[253-255]. Ibuprofen and aspirin products are widely available in community pharmacies nationwide and there is an increasing trend for consumers to self-medicate in the case of minor ailments, thus there is a need for patient education on the risks of AIA. It is possible that respondents infrequently conduct this intervention as they assume that community pharmacists will counsel patients appropriately when these medications are being purchased. However, in a recent study[188] on the supply of OTC medicines in Scotland ~87% of the medicines purchased were obtained solely from pharmacy support staff and in >60% of cases the patient was not asked about concurrent medication despite almost universal awareness of the WWHAM mnemonic designed to aid support staff OTC consultations[256]. Similarly >80% of observed consultations for OTC products in community pharmacies in the UK were deemed deficient in information collection and advice provision[257].

As frequently observed above, more experienced respondents conduct this intervention significantly more frequently than their less experienced colleagues and the aforementioned possible reasons for this are also valid in this instance.

2.8.3.7. Counselling on non-pharmacological measures

56% of respondents *always/often* advise their patients on non-pharmacological measures to improve quality of life. In a study of asthma management in primary care in Australia only ~26% of physicians routinely educated their patients about trigger factors[197]. Temporary worsening of asthma may occur as a result of exposure to risk factors or 'triggers' such as air pollution or allergens. By reducing a patient's exposure to certain risk factors asthma control may be improved and less medication may be required[1]. However, assessment of risk factors and discussion of practical avoidance measures between the patient and physician is obviously needed if a patient is to limit or reduce his/her exposure to these triggers.

2.8.3.8. Counselling on asthma control at prescription renewals

33% of respondents indicated that they *sometimes/never* assess their patients' level of asthma control at prescription renewals. As discussed in 2.8.2.6 above, the results of multinational studies such as INSPIRE[155] and AIRE[156] have revealed that asthma control worldwide appears to be sub-optimal. In addition, a number of studies have found a lack of agreement between physician and patient estimations of disease control with physicians consistently overestimating their patients' level of asthma control[233,234,258]. Consequently, it is imperative that GPs consistently assess their patients' degree of asthma control at prescription renewals. In the literature, primary care paediatricians in the U.S. were surveyed on maintenance asthma care, the majority of respondents reported questioning their patients on the frequency of asthma symptoms and the use of reliever medications but fewer asked about absenteeism from school or assessed the degree of activity limitations[259].

2.8.3.9. Counselling on adverse effects at prescription renewals

Just over half of the respondents (51%) indicated that they *always/often* check for drug-related adverse effects at prescription renewals. The Global Asthma Physician and Patient (GAPP) survey[260] was conducted in 16 countries worldwide in an effort to identify barriers to optimal asthma management. The results revealed that >70% of patients indicated that they *never/rarely* discussed medication side effects with their physician. In contrast, in the same study >60% of physicians stated that they *always/sometimes* discussed side effects with patients. In addition, when patients were asked about the reasons for discontinuation or switching ICS therapy the occurrence of side effects was the reason provided by 21% of respondents and another 18% stated that the primary reason was their concerns about the potential incidence of side effects. These findings

are in line with the necessity/concerns hypothesis demonstrated by Horne and Weinman[196] to predict adherence to ICS medication where patients with concerns about potential side effects reported lower adherence rates than those without such concerns. These findings indicate the importance of checking for side effects of therapy in an effort to promote adherence to preventative therapy.

2.8.3.10. Counselling on deteriorating asthma control

86% of respondents *always/often* advise their patients on the correct action to take in the event of signs of asthma worsening. According to the Vital Statistics Fourth Quarter and Yearly Summary[261] published by the Central Statistics Office there were 34 deaths from asthma in 2010, a decrease of ~40% on previous years. Despite the decrease in annual asthma deaths, 34 deaths with asthma as the principal cause is an unacceptable number for a disease that can be well controlled with the appropriate treatment. Due to the aforementioned prevalence of poorly controlled asthma worldwide[155,156] it is imperative that patients are educated on how to respond to deteriorating asthma control.

The nature of the advice provided in response to worsening asthma is unclear given the results of the final specified intervention. Only 31% of respondents *always/often* provide their patients with a personalised asthma action plan to allow self-management of asthma. The purpose of the asthma action plan is to allow patients to adjust their medication in response to changes in their level of asthma control, according to written pre-determined guidelines, to prevent asthma exacerbations[1]. Thus, if the majority of respondents infrequently provide their patients with an action plan to manage deteriorating asthma control what advice is being provided on the 'correct action to take in the event of signs of asthma worsening'? Are patients being advised to adjust their medication without the aid of an action plan or are they simply being advised to contact their GP or a hospital ED in the event of asthma worsening? Interestingly, in two separate patient surveys in Denmark[262] and the UK[243], ~60% of those surveyed reported that while they had not received a written asthma action plan their physicians had advised them verbally on the correct action to take in the event of asthma deterioration. However, the provision of this vital information in a verbal manner does not appear to be effective because, in the same Danish study[262], only 23% of patients reported increasing both their reliever and controller medication in response to deterioration whereas ~60% reported increasing their reliever medication only.

The majority of asthma patients are able to recognise deteriorating asthma control[155,262]. However, in the absence of a written asthma action plan providing clear instructions on the correct action to take to prevent an exacerbation patients appear to intervene and

adjust their medication in a sub-optimal manner, *i.e.* increasing their reliever medication[155,262]. This represents a missed opportunity that could be contributing to the widespread sub-optimal asthma control[155].

As observed previously, the more experienced respondents conduct both of these interventions (*advise on action in case of asthma worsening* and *provide patients with asthma action plan*) significantly more frequently than their less experienced colleagues and the same possible reasons are applicable in this instance.

2.8.3.11. Consultation time per asthma patient

The majority of respondents spend an average of either 5-10 minutes or 10-20 minutes in consultation with an asthma patient and ~one-third do not believe that this is sufficient time to counsel their patients adequately. As expected a significantly greater proportion of physicians who spend ≤ 10 minutes per consultation believe that this is an inadequate amount of time compared to those who spend more time per consultation. One of the reasons that respondents do not appear to be following all the recommended guidelines for appropriate asthma care may be due to insufficient time. Ostbye and colleagues[263] estimated the minimum amount of family physician time needed to deliver guideline-concordant care for 10 chronic diseases. They concluded that, in an average general practice with 2,500 patients, 3.5 hours per day was required to provide care for the 10 most prevalent chronic diseases, provided these diseases are stable. However, when this estimate was recalculated based on increased time requirements for uncontrolled disease, the time requirement increased by a factor of 3, to 10.6 hours per day. Yarnall and colleagues[264] calculated the total amount of physician time required each day for acute care, preventative care and chronic disease management of 2,500 patients and they concluded that 21.7 hours was required daily to sufficiently address the needs of an average cohort of patients. Thus, insufficient time is a key contributor to the inadequate provision of guideline-concordant care.

One viable solution to the time constraints encountered by GPs may be the establishment of team-based care where the role of the practice nurses is extended and there is increased collaboration with community pharmacists[264]. This should increase the amount of time available for patient care and allow GPs to focus on patients with the most severe or complex medical problems.

2.8.4. Communication with community pharmacists

2.8.4.1. Frequency of communication with community pharmacists

Communication between GPs and community pharmacists about asthma patients occurs very infrequently. The vast majority of respondents indicated that communication occurs less than once per week. There is limited research investigating communication frequency between physicians and community pharmacists specifically in relation to asthma. However, studies which included an investigation into the frequency of general communication between the two groups of health-care professionals revealed that communication is generally infrequent. Owens and colleagues[265] found that the median frequency of communication between physicians and pharmacists on a scale of +2 (very frequent) to -2 (very infrequent) was -0.5 (no definition of the communication frequency was defined in the research publication). Alkhateeb and colleagues[266] discovered that ~52% of physician respondents reported that they never/rarely had personal communication with a pharmacist about a patient's medication.

A more in-depth analysis revealed that older GPs communicate significantly more frequently with pharmacists than their younger colleagues. In addition, communication between the two groups of health-care professionals is significantly more frequent in towns or rural areas. McDonough and Doucette developed a conceptual framework for physician/pharmacist collaborative CWR[267]. There are three categories of variables that drive the development of a CWR, participant, context and exchange characteristics (relationship initiation, role specification and trustworthiness)[267]. All three domains in the exchange relationship driver have been repeatedly shown to be associated with the development of a successful CWR between pharmacists and physicians[209,210,213]. Trustworthiness, an exchange characteristic, develops over time. Pharmacists who have worked with GPs over a period of time have had opportunities to demonstrate clinical competency[210]. When pharmacists make consistently valuable contributions over time physicians develop confidence in their abilities, become more familiar with them and this leads to the development of trust and more open communication between the two groups[209,210]. Thus, older GPs may have developed a relationship with community pharmacists over the course of their careers, aided by consistently useful recommendations/advice made by both parties; this in turn may have led to more frequent and open communication between both groups.

Relationship initiation, another exchange variable, was also found to be a driver of a successful pharmacist-physician CWR[213]. Snyder and colleagues[213] conducted interviews with pharmacists and physicians involved in successful CWRs and they found that the

pharmacist usually initiated the relationship by approaching each of the physicians in the local area and conducting face-to face meetings often scheduled in advance. The importance of face-to-face meetings was emphasized by both physicians and pharmacists as an important factor in the development of a relationship. It is possible that pharmacists and GPs in rural areas and towns may be more familiar with each other and more likely to have had face-to-face contact than those in larger cities or suburban areas due to the population size. Consequently, they may have developed a better CWR than those in larger, more populated areas where there may be more physicians and pharmacists making familiarity and the development of a CWR more difficult.

2.8.4.2. Nature of communication with community pharmacists

The two issues most frequently discussed between GPs and pharmacists were related to changes in the inhaler device and dosage changes. Communicating about changes in the patient's medication, while encouraging, implies that the purpose of the communication is frequently to simply impart information, a factual exchange which may not encourage discussion or foster the development of CWRs between pharmacists and physicians. Communication on patients' medication adherence, both underuse and overuse, occurred significantly less frequently. As discussed above, low adherence rates to asthma medication have repeatedly been reported worldwide[149,161-163]. Laubscher and colleagues[268] conducted a survey that included investigating physicians' opinions about the role of the pharmacist in enhancing adherence to chronic medications. While an overwhelming majority of physician respondents (~ 97%) believed that pharmacists had a role in promoting medication adherence, only ~25% regularly communicated with pharmacists about adherence issues. The majority of respondents agreed that some degree of collaboration between the two groups of health-care professionals could be accomplished to improve adherence but the activities that received the most support among physicians were those in which the pharmacist would identify nonadherent patients and notify their physicians. These activities do not lend themselves to the development of CWRs, instead they imply that the pharmacist's only role in adherence is to notify the physician, not to discuss nonadherence with the patient involved or work with the physician to address adherence in a meaningful way other than as a conduit for information.

A number of other issues that were discussed with the community pharmacist were specifically identified. However, communication on these issues occurred less frequently than communication on the other aforementioned issues. ~30% of respondents, who identified another communication issue (*N=56)*, stated that the communication referred to the pharmacist's need for a prescription. Indeed, communication on prescription refill

requests was the most common reason for communication between GPs and pharmacists in a postal survey of 500 physicians in West Virginia. ~13% of respondents, who named an additional communication topic, said it involved asking the pharmacist to demonstrate inhaler technique to a patient and ~9% stated that they discussed spacer devices. While these percentages represent a minority of respondents *(N=56)* it is encouraging to observe that, at least in some instances, GPs recognise the contribution that pharmacists can make in the area of asthma management.

2.8.4.3. Satisfaction with communication with community pharmacists

Despite the infrequent level of communication (<1/week), ~89% of respondents indicated satisfaction with this communication frequency. However, a significantly greater proportion of respondents who *rarely/never* communicate with a community pharmacist expressed dissatisfaction with the level of communication than those who communicate more frequently. A number of respondents wrote freely about changes that were needed to improve communication and two distinct themes emerged. A proportion of respondents would like increased communication with pharmacists and believe such communication is a necessity. However, another share of respondents do not appear to be well disposed to pharmacists and do not feel that there is any need to communicate with them at all.

A conceptual model for CWRs between physicians and pharmacists has been developed, which proposes that the professional relationship between both groups of health-care professionals passes through stages of increasing collaboration[267]. The model is composed of five stages outlined in Figure 2.79 below.

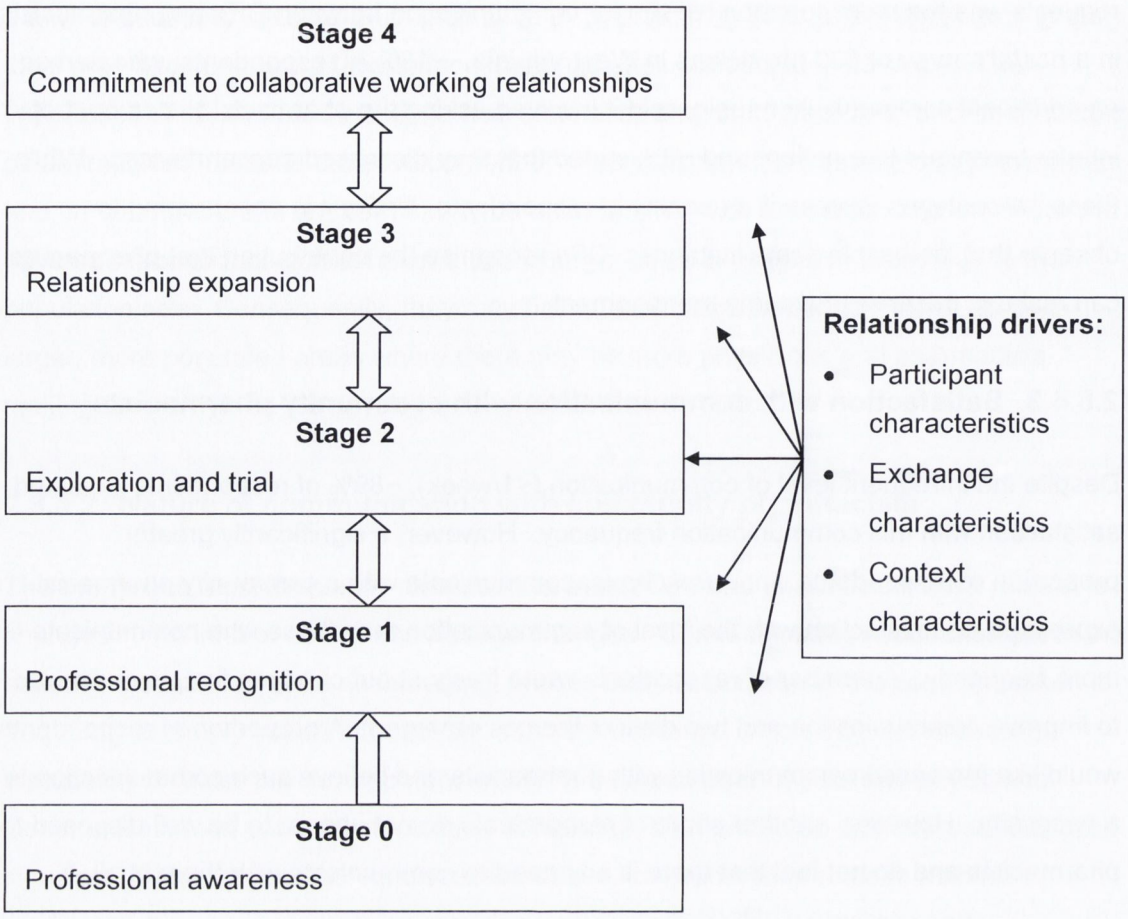


Figure 2.79: Theoretical model of pharmacist/physician collaborative working relationships[267].

At Stage 0, a professional awareness is established between pharmacists and physicians and exchange is minimal. At Stage 1, the pharmacist begins to proactively promote exchanges with the physician in an attempt to establish trust. The development of professional recognition is contingent on the ability of the pharmacist to highlight his/her usefulness to the physician. At Stage 2, both health-care professionals evaluate their compatibility, trustworthiness and expectations for this potential collaborative relationship. The pharmacist continues to be the initiator. At Stage 3, an increase in benefits for both groups can help expand the relationship at this stage and lead to increased interdependence. At this stage, an increase in bidirectional communication is also observed. At Stage 4, collaboration occurs when the benefits to the general practice arising from exchanges with the pharmacist outweigh the risks[212], it is characterised by mutual trust[210]. As the inter-professional relationship develops, communication becomes bidirectional with both parties active. From the results of this survey, it would appear that the majority of respondents are at Stage 0; professional awareness exists between GPs

and pharmacists but communication is infrequent and most GP respondents are satisfied with this lack of collaboration.

Numerous barriers to the development of CWRs between physicians and pharmacists have been identified. This discussion will focus on physician-related barriers. The 'shopkeeper' image of community pharmacy was identified as a major barrier to CWRs in a series of focus groups of physicians and pharmacists conducted in Northern Ireland[214]. Many of the GP participants viewed community pharmacists as business-people with a commercial interest and believed that this represented a conflict of interest with the appropriate provision of health-care that prevented their integration into primary health-care teams. The 'professional culture' has also been identified as a potential barrier[269]. Physicians are trained to assume the leadership role and to take responsibility for decisions, thus one of their challenges in the development of CWRs, will be to share leadership and facilitate the establishment of a status-equal environment between both groups of health-care professionals[269]. The barrier of professional culture is related to the barrier of hierarchy with regard to GPs' professional standing and role in healthcare[214,269]. In the aforementioned focus group study GPs expressed concern about pharmacists encroaching on roles they considered to be solely in their realm[214]. Indeed, the existence of high levels of collaboration between GPs and pharmacists was found to be associated with GPs adoption of a non-territorial approach to roles and responsibilities[211].

A barrier that was frequently mentioned in the literature was the lack of understanding by GPs of the potential contributions pharmacists could make to patient care or their limited understanding of the knowledge and skills that pharmacists possess[208,211]. In addition, a lack of awareness by GPs of the education and training of pharmacists was also mentioned as a barrier[214]. Finally, a lack of motivation on the part of GPs was mentioned as a potential barrier. In a series of semi-structured interviews on collaboration between GPs and pharmacists, GPs were asked about the benefits they would receive as a result of collaboration and they stated that they had less to gain than the pharmacists from developing an inter-professional relationship[208].

While, numerous barriers to collaboration have been described above, in practice, many of these barriers are not realised and the benefits of collaboration far outweigh the potential risks. In Ontario, Canada the Integrating Family Practices and Pharmacy to Advance Primary Care Therapeutics (IMPACT) program was initiated as part of a large scale Ontario Primary Health Care Transition Fund demonstration project[270]. This program involved the integration of seven non-dispensing pharmacists into family practices from June 2004 to July 2006. The pharmacists worked 2.5 days per week in the

practices and conducted patient medication assessments, provided patient education, academic detailing and office-system enhancements to optimise drug therapy. Two separate studies were conducted on the IMPACT participants: One investigated physicians' perceptions of collaborative practice 12 months after project initiation[271] and the second investigated physicians' perceptions of their contributions and that of pharmacists to the medication process as the project progressed[272]. The first study on physicians' perceptions of collaborative practice revealed a number of salient points[271]. Firstly, the initial concerns of physicians about collaboration were not realised in practice. In addition, while operational challenges existed initially in integrating pharmacists into physicians' daily routines, as time progressed, the inclusion of the pharmacist helped save time for the physician. There were a number of clinical and practice level benefits mentioned as a result of collaboration. With regard to clinical benefits, pharmacists were able to provide drug information and additional security to the physician when prescribing. At a practice level, physicians concluded that the inclusion of the pharmacist contributed to better overall care of patients, provided a link to community pharmacists and provided education to the practice.

The second study revealed changes in physicians' perceptions of pharmacists' contributions to the medication use processes as the integration progressed[272]. Initially, physicians rated pharmacists' contributions significantly lower than their own in the areas of 'diagnosis and prescribing', 'monitoring' and 'administrative/documentation', reflecting physicians' views of the traditional role of the pharmacist. However, as integration progressed the physicians perceived a greater role for the pharmacist in areas traditionally seen as within the remit of the physician alone, *e.g.* 'diagnosis and prescribing' and 'monitoring'. These results suggest that through integration physicians came to recognise the professional capabilities and expertise of pharmacists facilitating improved working relationships.

2.8.5. Limitations of the study

The limitations outlined in 2.7.8 are also applicable to this study. In addition, it was not possible to obtain a comprehensive list of GPs registered in Ireland at the time of the study, so a mailing list was obtained from the online Irish classified telephone directory. As a result, it is possible that not every GP received a copy of the questionnaire and the response rate may not be accurate.

2.9. Discussion: QAM-PN

2.9.1. Opinions on current asthma treatment/management

2.9.1.1. Asthma care in the primary care setting nationwide

Respondents appeared to be divided in their opinions on the current level of asthma care in the primary care setting nationwide: ~48% believe that it is *satisfactory/very satisfactory* but ~38% feel that it is *unsatisfactory/very unsatisfactory* and the remainder have no opinion. The possible reasons for this divided opinion become more apparent on analysis of the interventions conducted by respondents with their asthma patients.

2.9.1.2. Patients' understanding of asthma and asthma medications

The majority of respondents (>60%) estimated that their patients had *some understanding* of asthma as a disease and *some understanding* of the indications for their asthma medications. There is evidence in the literature of the limited understanding among asthma patients about their medications. In a survey of children with asthma and their parents only 22% of children stated that their preventative medication was the most helpful for their asthma whereas 65% of children and 59% of their parents felt that the reliever inhaler was the most helpful treatment indicating a lack of understanding of the indications for their asthma medications[273].

As patient education is considered by many nurses to be an important part of their job[274] this result is quite surprising. Indeed, Katon and colleagues[275] reviewed the common approaches that have been found to improve the care of patients with chronic illness and they concluded that one of the optimal roles for nurses is the provision of patient education. However, in order to provide effective patient education it is vital that nurses themselves are sufficiently knowledgeable. In a U.S. survey of a nationally representative sample of primary care nurses <10% of those surveyed identified airway inflammation as the underlying cause of asthma symptoms and ~44% believed that only the symptoms could be treated[274].

A study[276] investigating the impact of asthma education provided by health-care professionals on parental illness representation in childhood asthma found that asthma education had a positive impact on parents' attitudes to anti-inflammatory medications and facts about asthma. Indeed, the greater the amount of education received the closer their representations of asthma were to the professional model. An association between non-adherence to ICS and both doubts about its necessity and concerns over its use has been

demonstrated in the literature[196]. Patients were more likely to adhere to their therapeutic regimen for asthma if they perceived asthma to be a chronic condition with negative consequences. Thus, educating patients about the chronic nature of asthma and addressing their fears about the possible side effects of ICS should have a positive impact on medication adherence. A nurse-led educational intervention on asthma for children resulted in an improvement in asthma knowledge, a reduction in the distress caused by asthma and a reduction in the feeling of asthma severity[277].

A significant relationship was observed between respondents' nursing experience and patients' estimated understanding of asthma as a disease. A significantly greater proportion of respondents with the least amount of nursing experience believed that their patients had *little/no understanding* of asthma as a disease. The GINA guidelines on asthma management[1] highlight the importance of developing a partnership between the asthma patient and his/her health-care professional(s) in effective asthma management. It is possible that less experienced nurses may not yet have developed a strong relationship with their patients that promotes the provision of effective education on asthma. Trust is considered an essential component of nursing practice[278] and it is a critical element in the establishment of the nurse-patient relationship[279]. However, the nurse must earn the patient's trust over time by demonstrating clinical competence and fostering goodwill towards the patient[279] and this in turn will lead to the development of a strong therapeutic relationship between both parties.

2.9.1.3. Patients' ability to use their inhalers properly

The mean percentage of patients estimated to use their inhalers properly was 56%. This result is in accordance with the literature[148,280]. The consequences of incorrect inhaler technique have been discussed in depth in 2.7.2.4.

2.9.1.4. Patients using a peak flow meter regularly

The mean percentage of patients estimated to use a peak flow meter regularly was 17%. Indeed ~60% of respondents estimated that 0-10% of their patients had a peak flow meter that they used regularly. This result is similar to the results obtained from the QAM-CP and QAM-GP where the mean percentage estimates were 11% and 18% respectively.

2.9.1.5. Patients with well controlled asthma

The mean percentage of patients estimated to have well controlled asthma was 53%. This result appears quite optimistic on consideration of the results of several

multinational[155,156,172] and Irish[151] studies investigating asthma control. It is possible that this unrealistic result may be as a consequence of the overestimation of patients' level of asthma control. Price and colleagues[273] investigated the perceptions of children with asthma, their parents and both GPs and practice nurses on a range of issues including asthma symptoms and perceived control. They concluded that both GPs and nurses greatly underestimate the prevalence of asthma symptoms among their patients. 60% of patients indicated that they experienced difficulty breathing, 52% stated that they experienced nocturnal wakening and 47% said that their ability to talk was affected at least once a month. However, practice nurses estimated that only 24% of their patients experienced breathing difficulties, 26% experienced nocturnal wakening and ability to talk affected only 8% at least once a month.

This possible overestimation of their patients' asthma control may be related to a communication gap between health-care providers and patients or their care-givers, especially in the case of paediatric asthma. Yoos and colleagues[281] investigated the symptoms used by children and their care-givers to describe an asthma exacerbation. 22% of those interviewed did not use any of the standard asthma symptoms when describing an asthma exacerbation. Thus, health-care professionals may use different language to their patients/care-givers to describe uncontrolled asthma and this may contribute to an overestimation of asthma control among respondents.

2.9.1.6. Patients' level of medication compliance

Respondents estimated that ~47% of their patients are highly compliant/compliant. This result is in accordance with a report by the WHO that states that 50% of patients with chronic illness do not adhere to their therapeutic regimens[236]. The nurse-patient relationship is vital in the promotion of adherence[282]. Practice nurses are ideally placed to have a positive impact on medication adherence by providing time to address the patients' concerns about their medication, understand their health beliefs and experiences about asthma and provide education on the chronic nature of the disease[282]. Nurses can also provide advice on practical ways in which patients can incorporate their medication into their daily routines[282]. Indeed, Kyngas and Rissanen[283] discovered that support provided by nurses was the most important predictor of compliance among adolescents with chronic disease. This support included encouraging patient self-management and adopting a practical approach when considering treatment options.

2.9.1.7. Frequency of severe asthma exacerbations among patients

The majority of respondents indicated that exacerbations requiring hospitalisation were uncommon/very uncommon. However, ~12% of respondents stated that severe exacerbations were common among their patients. It is possible that this result may reflect the demographic characteristics of their patient population because hospitalisation with asthma as the primary diagnosis occurs more frequently among children <15 years than older children or adults. According to the Activity in Acute Public Hospitals Annual Report 2009[284], almost 40% of those hospitalised for asthma were children < 15 years.

2.9.1.8. Patients in possession of an asthma management plan

The mean percentage of patients estimated to possess an asthma management plan was 29%. However, ~60% of respondents were unable to provide an estimate. It is possible that those who were unable to provide an estimate do not discuss the use of the asthma management plan with their patients because they do not have sufficient training in the area. Robertson and colleagues[285] investigated nurses' perception of their role in asthma reviews and they discovered that nurses without advanced training in asthma were less likely than those with such training to provide or review an asthma self-management plan. Similarly, Hoskins and colleagues[286] found that a significantly greater proportion of nurses with a diploma in asthma provided their patients with an asthma management plan compared to those who did not have additional asthma education.

The estimated mean percentage of patients in possession of an asthma management plan was very low and in accordance with the literature[241,243]. Interestingly, in two individual UK studies practice nurses were more likely than GPs to provide their patients with an asthma management plan[243,245].

A number of barriers to the provision of self-management plans were identified by nurses in the literature. Self-management plans were considered unsuitable for asthma patients who did not have well controlled asthma or had poor medication compliance[245,287]. In addition, it was suggested that providing patients with an asthma management plan would prevent them from returning for a regular review of their asthma and could thus mitigate against optimal asthma management[287]. Insufficient time was also routinely mentioned by nurses as a barrier to the provision of asthma management plans[243,245,246].

2.9.1.9. Patients' expectations of disease management

Just over half of the respondents believed that their patients had low expectations of asthma management. This result is in accordance with the literature where numerous studies have found that patients or their care-givers perceive their asthma to be well controlled despite the presence of asthma symptoms and the excessive use of reliever treatments[156,273,288,289]. It is possible that patients are not aware of the meaning of 'well controlled asthma'. In the Asthma GAP II survey of greater than 1,000 adults in the U.S., there was a lack of consensus among respondents about the meaning of 'well-controlled' asthma[226]. For example, 44% agreed that their asthma was well controlled if they only needed their reliever inhaler three times per week, while 55% agreed that well-controlled asthma meant that it bothered them less than half the time when they exercised.

The fact that greater than one-fifth of respondents were unaware of their patients' expectations of asthma management is concerning. However, the reason for this may be that the practice nurses in some general practices are not actively involved in asthma management and thus they are unaware of their patients' opinions and expectations. Rosemann and colleagues[290] conducted semi-structured interviews with a stratified sample of GPs, practice nurses and patients on the current involvement of nurses in patient care and the possibility of extending that role in the future. They discovered that there was only a minimal involvement of nurses in patient care beyond simple routine examinations. The respondent GPs identified a lack of medical knowledge by nurses and a lack of acceptance by the patients as barriers to the increased involvement of nurses in patient care. These barriers were echoed by the patients. The nurses also identified a lack of medical knowledge as a significant barrier that prevented them from discussing diseases and their treatments with patients.

Conversely, a recent study in the UK investigating the views of GPs on nurse-led asthma services for children and adolescents found that 90% of those surveyed did provide these nurse-led services and 89% believed that they benefited patients[291]. Indeed, a pilot study of a sample of primary care nurses in the UK found that those interviewed estimated that they provided 68% of the management of chronic respiratory diseases in their practices[292].

The differences in the organisation of primary care services between countries may be a reflection of national government policy. As far back as 1999, the Department of Health in the UK published *Making a difference: strengthening the nursing, midwifery and health visiting contribution to health and healthcare*[293], a document that advocated the provision of nurse-led primary care services to 'improve accessibility and responsiveness'. The 2004 GP contract in the UK provided practice nurses with the opportunity to extend and

expand their roles[294]. One of the most prominent elements of the contract was the Quality and Outcomes Framework that consisted of a number of evidence-based performance indicators for quality of care, mainly in the context of chronic diseases. Compliance with each indicator accumulates points, which in turn are converted into practice income[295]. However, complying with the specific performance indicators requires considerable organisational effort within the practice as a whole and is not simply dependent on the individual GPs[295], thus facilitating an expansion of the role of practice nurses, particularly within the area of chronic disease management. McDonald and colleagues[296] investigated the impact of this new GP contract on 20 nurses working in the primary care setting. They found that the vast majority of the respondents had assumed a greater responsibility for chronic disease management and experienced greater autonomy in their work. To facilitate adopting greater responsibility most nurses acquired new knowledge and training. By creating incentives for GPs to facilitate nurses to expand their role within the practice the new contract was seen as enabling nurses to acquire new qualifications[296].

In Ireland, in 2001, the Department of Health and Children published *Quality and Fairness: a health system for you* that set the agenda for the new Health Strategy[297]. This was accompanied by the document *Primary Care: A New Direction*[298]. The Health Strategy envisaged strengthening primary care as one of the key frameworks for change[297]. One of the main features of the new primary care model was the development of an interdisciplinary primary care team facilitating a greater distribution of the workload among the team members[298]. However, from the results of the survey, particularly Section D *Interventions with asthma patients,* it would appear that a proportion of nurses might not have experienced an expansion in their roles, particularly in the area of chronic disease management.

2.9.2. Interventions with asthma patients

Analysis of the results of this subsection revealed that the majority of the specified asthma interventions are only frequently conducted by approximately half of the respondents. Most of the interventions specified are in accordance with international best-practice guidelines for asthma[1]. There may be two possible key reasons for this. Firstly, it is probable from the results that best practice guidelines for asthma are not being implemented in a large proportion of general practices. This may be the case in the general practice as a whole or it may only be occurring at the level of the practice nurse. A survey of health-care professionals on their knowledge and adherence to Spanish guidelines to asthma management (GEMA) revealed that while 55% of primary care

physicians and 65% of nurses were familiar with these guidelines 45% of physicians and 59% of nurses indicated that they 'never/seldom' followed them[299].

Wiener-Ogilvie and colleagues[300] investigated the implementation of the British Thoracic Society/Scottish Intercollegiate Guidelines Network (BTS/SIGN) asthma guidelines in a sample of primary care practices in the UK. The found that the organisation of the general practice, centred around delegation of work to nurses, was a key factor mediating the practice's level of compliance with the guidelines. Successful delegation necessitates a distribution of responsibilities among the practice members who possess the requisite knowledge and training, open bidirectional communication and trust in one another's abilities. Insufficient time has been identified by GPs in the literature as a barrier to implementation of best practice guidelines[243,300,301], but successful delegation to appropriately trained nurses could provide a viable solution to the problem.

Alanen and colleagues[302] conducted a series of focus groups with primary care nurses on guideline implementation. A number of themes were identified as important elements affecting guideline implementation, these included organisational factors, nurse-related factors and patient-related factors[302]. Organisational factors that facilitated the implementation of guidelines were the adaptation of the guideline within the practice with clearly defined responsibilities for each professional group and the availability of resources needed for implementation. The physician appeared to have a key role in guideline implementation; physician support and adherence to the guidelines acted as major facilitators for nurses in their successful implementation. Nurse-related factors that facilitated the implementation of guidelines were an awareness of the guidelines and a positive attitude towards them. However, these factors alone were not sufficient to facilitate implementation, nurses also had to have a personal commitment to implementing the guidelines and needed to engage actively with them by attending training sessions *etc*. With regard to patient-related factors, successful implementation was related to good patient awareness of the guidelines.

The second possible reason that a large proportion of respondents infrequently conduct the specified asthma interventions may be due to the level of involvement of the practice nurse in asthma management in her individual practice. If a proportion of respondents are only minimally involved in asthma management in their practices it follows that the frequency with which they conduct specified interventions with their asthma patients will be low. This is discussed in detail in 2.9.1.9 above.

2.9.2.1. Counselling on inhaler technique

The intervention *demonstrate the use of a newly prescribed inhalation device* is the intervention carried out most frequently by the respondents. The mean frequency with which it is conducted is 1.8, *often*. However, in contrast, 60% of respondents *sometimes/never check a patients' inhalation technique every 6-12 months.* There appears to be a minimal amount of research specifically focused on the demonstration of a newly prescribed inhaler by nurses and the literature on routine assessment of inhaler technique differs greatly depending on the origin of the study. In a recent American study of thirty-four nurses (majority working in primary care) participating in a Nurse Asthma Care Education seminar, participants were asked to rate the frequency with which they had a patient/care-giver demonstrate their inhaler technique to them in the last 12 months on a scale of 1 (never) to 10 (always) and the mean frequency was 3.77[303]. In contrast, a study of a national, randomly selected, representative sample of 80 nurses working in the US, primarily in primary care, revealed that ~76% ask their patients to demonstrate inhaler technique, but the frequency with which this occurs was not investigated in the study[274]. In a Scottish study of ~170 primary care nurses 90% of respondents always reviewed a patient's inhaler technique at an asthma review[285].

There may be a number of possible reasons for the infrequent reinforcement of inhaler technique among the majority of nurses. There may be a lack of awareness about the need for repeated education on inhaler technique due to the decline in correct technique over time. Indeed, following a National Asthma Education Program for nurses in the US a significant increase was observed in the importance that nurses placed on having their patients demonstrate the correct inhaler technique[303].

In order to educate patients on the correct inhaler technique it is vital that nurses themselves are knowledgeable about the correct technique. A number of studies of both primary care and hospital nurses have revealed that the majority of those surveyed made at least one error when demonstrating inhaler technique[29,57,304]. Consequently, it is important that nurses are educated on the correct technique prior to educating their patients.

2.9.2.2. Provision of information on new asthma medications

The majority of respondents indicated that they *always/often provide verbal information to their patients on newly prescribed asthma medications* but the content of this information was outside the scope of this questionnaire.

2.9.2.3. Counselling on the peak flow meter

The mean frequency with which respondents *demonstrate the use of the peak flow meter* to their patients is 2.4, *often*, but the mean frequency with which they *advise their patients on the importance of the peak flow meter in monitoring asthma control* is 2.6, *sometimes*. As the mean percentage of patients estimated to use a peak flow meter regularly was 17% it is possible that respondents demonstrate the use of a peak flow meter more frequently than they advise on its importance in asthma control as they may measure the patients' peak expiratory flow rate during consultations and thus they need to ensure the patient can perform the manoeuvre correctly to ensure an accurate reading.

The fact that the majority of respondents appear to infrequently advise their patients on the importance of the peak flow meter may be due to patient and/or nurse-related factors. In a survey of nurses and GPs in Northern Ireland on the barriers to evidence-based practice in primary care, poor patient compliance was identified by nurses as one of the most significant barriers[305]. In addition, it is possible that nurses themselves are not aware of the importance of the peak flow meter in asthma control. A survey of paediatric nurses based in a medical centre in Taiwan on the care of paediatric asthma patients revealed that the majority of those surveyed had a limited knowledge of assessment guidelines and monitoring optimum peak flow[306].

A significant relationship was observed between both interventions and respondents' nursing experience. In both cases, respondents with the least experience conduct this intervention significantly less frequently than their more experienced colleagues. Similarly, in the afore-mentioned study of nurses participating in a Nurse Asthma Care Education seminar, nurses with < 10 years experience preformed all of the guideline concordant activities (including demonstrating the use of a peak flow meter) less frequently than their colleagues with ≥ 10 years experience[303]. The differences in the frequency with which these interventions are conducted may be due to a lack of awareness among less experienced nurses about the benefits of using the peak flow meter to monitor asthma control or perhaps a lack of confidence in using the peak flow meter correctly whereas more experienced nurses may have acquired this knowledge through working experience[290]. In addition, as discussed in 2.9.1.2 above, nurses with greater experience may have developed stronger therapeutic relationships with their patients over time than their less experienced colleagues and thus their patients may place greater trust in their advice and recommendations.

2.9.2.4. Counselling on medication adherence

Overall, only approximately half of the respondents *always/often* check their patients' adherence to their asthma therapy or counsel them in the event of non-adherence. This result is very concerning given the results from the literature indicating that patient adherence to ICS ranges from 30-70%[149,162,163,236] and that the overuse of reliever inhalers is widespread among asthma patients[155,156,273].

Gould and Mitty[307] proposed a new model for promoting medication adherence, ACE-ME: assessment, collaboration, education-monitoring and evaluation, a progression of the model proposed by Bergman-Evans and colleagues[308]. This model was originally designed for older adults but the core concepts appear relevant to promotion of medication adherence as a whole. These five activities of ACE-ME are within the nurse's practice remit and thus are considered activities in which nurses can provide leadership in promoting medication adherence among their patients[307]. Patient-centred care is considered an essential component necessary to promote adherence[309] thus, this model adopts a patient-centred approach. Patient-nurse communication should be patient-centred[309]. A communication style that uses open-ended questions, addresses a patient's fears and worries and allows a patient to feel heard is considered patient-centred[310].

Assessment, collaboration and education (ACE) constitute the first part of achieving medication adherence[307]. Patient assessment is a fundamental component of nursing. In medication adherence *assessment* the nurse must assess the patient's ability to adhere to the therapeutic regimen *e.g.* suitability of inhaler device, and determine what, if any, intentional or non-intentional reasons for non-adherence may be applicable to the individual patient. *Collaboration* involves the development and maintenance of a set of adherence behaviours that are relevant to the individual patient and that are created in partnership with the patient. Shared-decision making incorporates the patient's opinions and experiences in the development of solutions to address barriers to adherence[311]. The third component of ACE is *education.* In this component the patient is educated about their medications, but the education must be patient-specific and compatible with the patient's level of health-care literacy[312].

The second part of this model involves *monitoring* and *evaluation. Monitoring* involves observing how well the adherence plan is being implemented and identifying any non-adherent behaviours. *Evaluation* entails recognising when an adherence plan is faltering, exploring the reasons for this and initiating a new cycle of the ACE-ME beginning again with assessment, collaboration and education[307].

Support provided by nurses has already been discussed as an important predictor in medication adherence[283]. A respiratory nurse-led intervention underpinned by the Compliance Therapy Model resulted in the successful improvement of medication adherence among patients with difficult to treat asthma[313].

A possible reason for the infrequent monitoring and counselling on adherence to ICS may be due to a lack of awareness or agreement with best-practice guidelines on ICS use. A survey of ~100 primary care nurses in the UK revealed that 70% of respondents sometimes advised their patients at BTS Step 2 that they could take their ICS intermittently and 85% sometimes advised their patients (at BTS Step 2) to temporarily stop taking their ICS if their asthma is well-controlled[314]. This advice contradicts best-practice guidelines for asthma management[1] that state that ICS therapy does not 'cure' asthma and consequently its discontinuation results in a deterioration in asthma control within weeks or months in a proportion of patients[315,316].

Significant relationships were observed between the interventions *counselling in the event of overuse* and *checking for underuse of preventer inhalers,* and nursing experience. The same possible reasons discussed in detail in 2.9.1.2 above are also applicable in this instance.

2.9.2.5. Counselling on contraindicated OTC products

The intervention *advise on contraindicated OTC products* is *sometimes/never* conducted by 70% of respondents. A possible reason for this may be a lack of knowledge about contraindicated medications for asthma patients or perhaps a belief that this intervention is the remit of the community pharmacist. In the survey of physicians and mid-level provider (physician assistants and nurse practitioners) about communication with community pharmacists, conducted by Owens and colleagues and referenced in 2.8.4.1,mid-level providers felt that communication with the community pharmacist on potential adverse effects and drug interactions was helpful and they considered this type of communication to be significantly more helpful than respondent physicians did[265]. This may be because nurses have not received sufficient education in pharmacology. However, as discussed in 2.8.3.6, OTC medication is frequently supplied by pharmacy support staff[188] and the consultations for OTC products are frequently insufficient at obtaining and providing all the necessary information[257].

Older, more experienced nurses conduct this intervention significantly more frequently than their younger, less experienced colleagues do. The possible reasons discussed in 2.9.1.2 above are also relevant here.

2.9.2.6. Counselling on non-pharmacological measures

Approximately half of respondents *always/often advise their patients on non-pharmacological measures to improve quality of life.* A key component of asthma management in best-practice guidelines is the identification and reduction of exposure to risk factors such as tobacco smoke, pollutants and allergens thus improving asthma control and reducing medication needs[1]. A possible reason that this intervention is infrequently carried out by a large proportion of respondents may be a lack of awareness among nurses about how to identify and reducing exposure to triggers as evidenced in a recent study of a group of paediatric nurses in Taiwan[306].

2.9.2.7. Counselling on asthma control at prescription renewals

Less than half of the respondents indicated that they *always/often assess patients' level of asthma control at prescription renewals*. This result is concerning due to the reported lack of consensus between asthma patients' level of control as perceived by their health-care professionals and their actual degree of control[233,234].

2.9.2.8. Counselling on adverse effects at prescription renewals

Greater than 60% of respondents *sometimes/never check for drug-related adverse effects at prescription renewals*. Under the necessity/concerns hypothesis demonstrated to predict adherence to ICS, patients with concerns about the side-effects of ICS, both real and perceived, had lower adherence rates than patients without such concerns[196]. Thus, it is vital that existence of adverse effects is investigated as many can be easily addressed, for example, rinsing the mouth with water after ICS use can help prevent oral candidiasis.

2.9.2.9. Counselling on deteriorating asthma control

Approximately 70% of respondents *always/often advise their patients on the correct action to take in the event of asthma worsening* but only approximately 30% frequently *provide patients with an asthma action plan.* The primary purpose of an asthma management plan is to provide patients with written instructions on how to adjust their therapy in response to deteriorating asthma control in order to prevent an asthma exacerbation[1]. Thus, respondents may be simply advising their patients to contact a health-care professional when their asthma deteriorates or they may be providing their patients with verbal instructions on how to adjust their medication without formalising them in a written

asthma action plan. Indeed, a survey investigating the level of compliance among primary care practices in the UK with best-practice asthma guidelines found that while only 23% of patients stated that they had received a written asthma action plan, 62% had received such information verbally[243]. The barriers perceived by nurses to the provision of personalised asthma management plans have been discussed in 2.9.1.8 above.

2.9.2.10. Consultation time per asthma patient

Approximately half of the respondents spend an average of 11-20 minutes in consultation with an asthma patient and ~50% do not believe that have sufficient time per consultation to counsel their asthma patients adequately. As expected, a significantly greater proportion of respondents who spend less time, on average, in consultation with their asthma patients believe that this is inadequate than those who have longer consultation times.

Insufficient time may also explain why many of the specified interventions are conducted infrequently by a proportion of the respondents. Respondents who spend an average of ≤ 10 minutes in consultation with an asthma patient conduct the specified interventions significantly less frequently, on average, than their colleagues with a greater amount of time per consultation

2.9.3. Communication with community pharmacists

2.9.3.1. Frequency of communication with community pharmacists

Communication between practice nurses and community pharmacists about asthma patients appears to occur very infrequently. Only ~5% of respondents indicated that they communicated with a pharmacist ≥1/week. There is a limited amount of research investigating communication between community pharmacists and practice nurses. In the study by Owens and colleagues[265], discussed in 2.9.2.5, the median frequency of communication between pharmacists and both mid-level providers on a scale of +2 (very frequent) to -2 (very infrequent) was -0.23. A UK study investigated the views of community pharmacists on nurse prescribing found that despite the fact that >70% of the pharmacists surveyed dispensed 1-19 nurse prescriptions each month >45% of pharmacists had never communicated with a nurse prescriber and only 14% communicated once a week[215]. Holden and collegues[317] investigated collaboration and communication in primary care and they found that only 76% of nurses rated pharmacists 'high/very high' on collaboration and communication. This contrasted with physicians whom 85% of nurses rated highly. Possible reasons mentioned for the differences in

collaboration ratings included the physical separation of the pharmacy and the medical clinic and the fact the nature of the interaction with the pharmacist is often perceived as adversarial, communicating mainly when there is a potential problem with a prescription[317].

2.9.3.2. Nature of communication with community pharmacists

The two issues discussed most frequently between nurses and pharmacists were changes in inhaler devices and dosage changes. Communication on these issues implies that the majority of the communication, when it does occur, is primarily to exchange factual information and does not appear to promote collaboration between the health-care professionals. Similarly, in the survey conducted by Owens and colleagues[265], communication between mid-level providers and pharmacists occurred infrequently in relation to medication adherence but when such communication occurred, it was perceived as helpful.

2.9.3.3. Satisfaction with communication with community pharmacists

The majority of respondents are satisfied with the current frequency and method of communication with community pharmacists despite the fact that the communication is very infrequent in the majority of cases. This seems to imply a lack of interest in establishing CWRs with pharmacists in primary care. However, this may be due to a lack of awareness of the benefits of collaboration. Numerous studies have been conducted on the effects of nurse-pharmacist collaboration in a variety of settings and across different disease states. In the nursing home setting a wound care team of community pharmacists and nurses resulted in a significant improvement in chronic wound healing and cost savings compared to usual nursing home care[318]. At the interface of hospital and home health care pharmacist-nurse collaboration designed to identify and resolve medication-related discrepancies in patients being transferred from hospital to home care resulted in a significant improvement in resolving medication discrepancy compared to usual care[319]. In the primary care setting the collaboration between nurses and pharmacists in partnership with physicians produced significant improvements in anticoagulation control and blood pressure reduction compared to non-collaborative care[320,321]. Practice nurses have skills that complement those of the community pharmacists and due to their training in communication skills and patient assessment, they are ideal candidates for collaboration with pharmacists in the area of chronic disease management[321].

Respondents were asked to write freely about what changes could be made to improve communication with pharmacists if they were currently dissatisfied with the current state of communication. One-third of those who completed this section indicated that there was a need to educate pharmacists about the level of knowledge of nurses about asthma. Goldman and colleagues[322] investigated the views and experiences of family health care teams on inter-professional collaboration in Canada. Interestingly, both pharmacists and nurse practitioners identified the challenge of educating their colleagues about their knowledge and expertise and their contributions to patient care. However, in a study of physicians, community pharmacists and nurses providing team-based care to high-risk patients a significant improvement was observed in understanding the roles of other team members specifically pharmacists and nurses as the study progressed. Thus, it is evident that active collaboration can address some of the perceived barriers to the provision of team-based care. Inter-professional education of nurses and pharmacists can also promote an increased mutual understanding of their roles. At Brigham and Women's Hospital in Boston a joint education program for nurses and pharmacists on the medication use process including a job-shadowing component was developed[323]. Feedback from program participants indicated that the program facilitated an increased awareness of the various roles of both nurses and pharmacists and increased communication and awareness between the two professions. However, in order to develop collaborative working relationships it is vital that the frequency of bidirectional communication is increased[322].

2.9.4. Limitations of the study

The limitations outlined in 2.7.8 are also relevant to this study. In addition, it was not possible to obtain a comprehensive list of nurses working in general practice at the time of the study so one copy of the questionnaire was sent with the QAM-GP to the list of GPs obtained from the Irish classified telephone directory. As the letter was addressed to the GP, it is possible that a number of practice nurses never received the questionnaire. It is also possible that there was more than one nurse in some practices but only one QAM-PN was mailed and no completed photocopied questionnaires were received. Consequently, the response rate might not be accurate.

2.10.Discussion: Comparative study

This comparative study is unique as it appears to be the first such study to compare the opinions and asthma interventions of the three groups of healthcare professionals in involved in asthma care in the primary care setting.

2.10.1. Opinions on current asthma treatment/management

The most significant and consistent findings arising from a comparative analysis of the results provided by pharmacists, GPs and nurses in this subsection was that, on average, respondent GPs have a significantly higher opinion of their patients' asthma management skills and level of understanding than respondent pharmacists. Indeed, the GPs' estimations of the percentage of their patients who use their inhalers correctly and have well controlled asthma were significantly and consistently higher than the estimates provided by pharmacists. While there does not appear to be any evidence in the literature that pharmacists or nurses are better able to predict their patients' ability to manage their asthma than GPs, when the results are compared with the findings in the literature (see 2.7.2 and 2.8.2) it appears more likely that, overall, the responses provided by the pharmacists reflect the current situation more accurately than those provided by the GPs, which appear more optimistic than realistic.

Differing beliefs/views between both physicians and asthma patients, and physicians and objective measures are widely reported in the literature across a range of issues including asthma control, provision of education, symptom frequency and existence of side effects. A number of studies have highlighted the discrepancy between patients' level of asthma control as estimated by their physicians and their actual level of asthma control, with physicians generally overestimating the degree of control. Boulet and colleagues[324] investigated the evaluation of asthma control of ~850 asthma patients by their physicians in Canada. Greater than 40% of physicians rated their patients' asthma control as 'adequate' or 'good' but, according to asthma guidelines, all of the patients included in the study had uncontrolled asthma. Prieto and colleagues[233] investigated the degree of asthma control among ~800 Spanish patients and the degree of concordance between their physicians' perceptions of their asthma control and the reality. They discovered that physicians only classified ~12% of their patients as 'not well controlled' but in reality, ~67% were classified as 'not well controlled'. Similarly, in a study assessing the level of asthma control among ~10,400 patients, physicians overestimated their patients' asthma control, regarding only 42% as 'uncontrolled' when in reality 59% had 'uncontrolled' asthma[234].

Differences were also observed between physicians' estimations and patients' experiences of asthma symptoms. Price and colleagues[273] investigated the degree of asthma morbidity experienced by ~1300 asthmatic children and estimated by a nationally representative sample of GPs and practice nurses. They discovered that GPs and nurses significantly underestimated the prevalence with which patients experienced a variety of asthma symptoms. For example, GPs and nurses estimated that 24% of patients experienced difficulty breathing at least once in the past month, whereas in reality 60% had breathing difficulties. Similar 52% of patients experienced nocturnal waking at least once in the last month, but GPs thought 17% of patients experienced this symptom.

Discrepancies were observed between patients' actual awareness about the potential side-effects of their asthma medications and their awareness as estimated by GPs. In an Australian study[325] of ~1700 asthma patients and ~1700 physicians who treated asthmatics 92% of physicians believed that their patients are aware of the long-term side-effects of ICS whereas only ~50% of patients reported such awareness. Similarly only ~70% of patients were aware of the short-term side-effects of ICS whereas physicians believed that 98% had such awareness.

The GAPP survey, conducted by Canonica and colleagues[260], revealed a number of discrepancies in the level of education reportedly provided by GPs and received by asthma patients. 69% of patients compared to 95% of GPs reported regular discussions of inhaler technique. Similarly, >70% of patients said that they 'never' or 'rarely' had discussions on medication side-effects with their physician whereas >60% of physicians stated that they 'sometimes' or 'always' discussed side-effects with their patients.

There may be a number of reasons why the results provided by GPs in this study appear less realistic and less concordant with the published literature than those provided by pharmacists. Firstly, it may be due to the frequency of contact between GPs and their asthma patients. In a study of patients with multiple morbidities, conducted by Townsend and colleagues[326], consulting a GP was considered by patients as the 'last resort' that only occurred when symptoms were very severe or ongoing. As studies have shown that asthma patients and their caregivers frequently have poor perceptions of uncontrolled asthma[172,327,328] this may result in infrequent GP consultations due to a perceived lack of necessity. Frequency of patient consultations may also be affected by repeat prescribing where prescriptions are re-issued, usually at the request of the patient, without a GP consultation. Connolly and McGavock[329] investigated repeat prescribing in a stratified quota sample of 22 general practices in Northern Ireland over a 2 week period. The mean percentage of all items prescribed that were issued as repeat prescriptions was ~61%.

In addition, asthma was the diagnosis most frequently associated with repeat prescriptions. Indeed a prescription for an asthma medication was issued 2.7 times more frequently as a repeat prescription than as a result of a GP consultation, and salbutamol was the third most frequently prescribed repeat prescription item. Partridge and colleagues[330] conducted a survey of >1,000 asthma patients from five European countries and he discovered that the mean frequency of GP visits due to asthma was 10.4 months. In the Living and Breathing study conducted by Haughney and colleagues[241] 43% said that they did not have regular consultations with a GP/nurse and attended the general practice only when they needed to collect a repeat prescription. In a study of ~100 children with asthma, conducted by Halterman and colleagues[331], patients who had attended a physician consultation in the past 6 months were significantly more likely to have their degree of asthma severity correctly classified by their physician compared to those who had not had a recent consultation. Thus, it is possible that one of the reasons that the results provided by GPs appear unrealistic may be due to their infrequent patient contact, which may be a consequence of the increasing rate of repeat prescribing which is estimated to range from 29% to 75% of all items prescribed[332].

The methods used by GPs to assess asthma control may be inadequate and may not be in accordance with the definitions for control outlined in best practice guidelines[1] thus leading to an overestimation of asthma control among patients. In a study by Chapman and colleagues[327] on asthma control, ~260 Canadian physicians were surveyed and while 82% indicated that they used the Canadian Asthma Consensus guidelines always or most of the time, when asked how they assessed their patients' level of asthma control, on average, most respondents only used one or two of the guideline criteria in this assessment. Similarly, in a survey of >800 Italian GPs, ~60% of respondents stated that they were familiar with the Asthma Control Test but only ~20% actually used it as a means of assessing their patients' level of asthma control[333]. In addition, the language used by patients to describe asthma symptoms may differ from that used by GPs and this may present difficulties for GPs when trying to determine accurately their patients' level of asthma control. This was demonstrated by Yoos and colleagues[281] who investigated the language used by children and their carers to describe their asthma symptoms. While 78% of parents used at least one 'standard' asthma symptom when describing an exacerbation nearly 50% also reported 'non-standard' symptoms, the most common being fatigue and malaise.

Limited communication and incomplete disclosure on the part of the patient may also lead to an overestimation of his/her asthma management, knowledge and skills by the GP. In a study conducted by Bellamy and Harris[173] on ~800 asthma patients from five European

countries, Canada and Australia, 37% of respondents indicated that they generally did not report their asthma symptoms to their GP. Similarly, in a qualitative study by Moffat and colleagues[245] on patients with severe and difficult asthma, poor communication during GP consultations was a common issue. While only three of the fourteen participants were adherent with their medication, the remainder never volunteered information on non-adherence unless specifically questioned by the GP. Fitzgerald and colleagues[334] investigated beliefs about asthma medications and associated oropharyngeal symptoms in ~1,000 Canadian patients. They found that while 24% of patients had experienced oropharyngeal symptoms one-third of these had never reported the symptoms to their GPs.

There may be a number of reasons for the lack of patient disclosure. Firstly, failure to disclose asthma symptoms or a reduction/lack of asthma control may be due to an ability to perceive accurately inadequately controlled asthma or a lack of understanding of the meaning of 'controlled' asthma. Indeed, Braido and colleagues[198] surveyed >2,000 GPs and ~8,000 asthma patients and they discovered that the most importance aspect of asthma management about which patients felt under-informed was the meaning of asthma control. The lack of agreement between patients' or their caregivers' perceptions of asthma control and the reality has been widely reported in the literature[172,241,273,327,328]. In addition, patients may have low expectations of disease management and thus may be unaware that experiencing asthma symptoms routinely or the frequent need for a reliever inhaler is not an inevitable consequence of having asthma. In the aforementioned study by Bellamy and Harris[173] 90% of patients said that they expected to experience asthma symptoms because they had asthma and 87% said that the currently available asthma medications could reduce their asthma symptoms but could not eradicate them. In the aforementioned Living and Breathing[241] study ~60% of patients indicated that they were satisfied with their current level of asthma care but this fell to 33% when they were shown the GINA asthma control guidelines[1]. Other reasons, such as a belief that non-pharmacological issues are outside the domain of the doctor have also been highlighted by asthma patients to explain why they do not volunteer information to their GPs about lifestyle problems, asthma trigger factors *etc*[245,335].

Inadequate information exchange and limited communication during patient-GP consultations may also be due to physician-related factors. In the aforementioned study conducted by Braido and colleagues[198], the communication behaviours of physicians were also investigated. It was discovered that approximately one-fifth of physicians surveyed were not prone to investigating what 'being sick' meant to the patients themselves and ~30% did not usually encourage their patients to 'express doubts, expectations and fears'.

In addition, >60% tended to frighten their patients by depicting the risks related to asthma. Fiscella and colleagues[336] demonstrated that patients' trust in their physicians was associated with physicians who investigated patients' experiences of their disease or illness during the consultation. Thus, a failure among GPs to explore adequately their patients' personal knowledge and experience of asthma may negatively affect the patient-physician relationship and information sharing and this may lead to an inaccurate perception of the patient's asthma management skills and expectations by his/her GP. Street and colleagues conducted two separate studies on patient participation in GP consultations[337] and physicians' communication styles and perceptions[338]. They found that while active patient participation in the consultation (defined as asking questions, providing opinions and expressing concerns/fears) was seven times more likely to be patient-initiated than GP-initiated, patients participated more actively in the consultation when physicians engaged in 'partnership building' and 'supportive talk'[337]. In addition, physicians exhibited more patient-centred communication with patients who were active participants in the consultation and who were not contentious[338], but from the results of the study it is not possible to determine whether the patient-centred communication was the cause or the result of active patient participation. Irrespective, these results demonstrate the reciprocity of the communication, indicating that both the patient and the physician are responsible for promoting active and open communication within the consultation, which should lead to better understanding and insight by both parties.

The lack of concordance between the results provided by GPs in this study and the published literature may also be due to an inaccurate perception by GPs about their patients' health beliefs, which in turn predict their health behaviours such as medication adherence[339]. Poor or limited awareness of a patient's health beliefs could prevent physicians from identifying gaps between their own and their patients' understanding of their illness[340] and lead to inaccurate estimations or assumptions on the part of the physician. Street and Haidet[339] investigating physicians' awareness of their patients' health beliefs among a convenience sample of 29 primary care physicians in Texas. They discovered that a significant difference existed between physicians' perceptions of their patients' health beliefs and patients' actual health beliefs. Furthermore, in four of the six domains investigated in the study, the physicians assumed a shared understanding, believing that their patients' beliefs were similar to their own, when in fact this was not the case. However, physicians had a better understanding of their patients' health beliefs when their patients actively participated in the consultation by asking questions, expressing concerns *etc.* Thus, this study also highlights the importance of communication reciprocity.

2.10.2. *Interventions with asthma patients*

A comparative study of the frequency with which pharmacists, GPs and nurses conduct the specified interventions with their asthma patients revealed that, overall, the three groups of health-care professionals are still practising predominantly within the confines of their traditionally defined roles. The majority of asthma care within the primary care setting appears to be conducted by GPs, with limited input from nurses, and the pharmacist's role appears to be confined to issues directly related to the medication dispensed. For example, one of the three interventions conducted significantly more frequently by pharmacists than either GPs or nurses was *checking for drug-related adverse effects at prescription renewals*. Eight of the remaining ten interventions were conducted significantly more frequently by GPs than nurses. The only intervention conducted more frequently by nurses than GPs or pharmacists was *checking a patient's inhalation technique every 6-12 months* and this intervention was infrequently conducted by all three groups. In addition, the results from all three individual surveys revealed that communication between community pharmacists and both GPs and nurses is infrequent, implying that collaborative asthma care is limited or even non-existent in many cases.

In order to improve asthma care nationwide it is evident that the current system of care, where health-care professionals are isolated within personal silos and certain areas, considered important in asthma management, are predominantly neglected, needs to be radically overhauled. All health-care professionals should be delivering asthma care that is in accordance with best practice GINA guidelines[1]. In the primary care setting GPs, pharmacists and practice nurses should have distinct, specific roles in asthma care to ensure that all areas of asthma care are addressed and there is limited unnecessary duplication, as the individual surveys have illustrated that time constraints are an issue for the majority of the healthcare professionals nationwide. The 10 year National Asthma Programme in Finland[115] and the Australian National Asthma Strategy[107], are examples of how the standard of asthma care can be improved on a national scale using a collaborative model of care in which each group of health-care professionals has a set of clearly defined roles and responsibilities. In the Finnish model, GPs are responsible for the initial diagnosis of asthma with specialist consultations as needed, they initiate anti-inflammatory treatment immediately and prescribe medications according to evidence-based guidelines; they also conduct annual patient follow-up visits[115]. Practice nurses are responsible for patient-centred asthma education with written action plans, they conduct spirometry measurements and provide training on peak flow measurements and inhaler technique. Nurses are also involved in patients' annual follow-up visits[115].

Community pharmacists are responsible for educating patients about the indications and side effects of their asthma medications, monitoring patient adherence and promoting adherence to anti-inflammatory medications, assessing and educating patients on inhaler technique and correct use of the peak flow meter and referring patients to their physician when inadequate asthma control is suspected[341,342].

In both the Finnish and the Australian models, there is an emphasis on collaboration and communication, indeed this was considered fundamental to the successful implementation of the Finnish programme[115]. In Finland, each healthcare centre has at least one physician and one nurse with responsibility for the local coordination of activities. In addition, an asthma contact person had been nominated in 603 Finnish pharmacies by March 2000[342] and they were responsible for meeting with the contact people in the healthcare centres to ensure a coordinated system of care[341]. In the Australian National Implementation Strategy 1999[107] one of the strategies designed to 'achieve planned and shared responsibility for asthma' was to 'establish better communications between health-care professional groups, taking advantage of technological developments in communications'. Furthermore, in the Australian National Asthma Strategy 2006-2008[108] one of the key strategic directions highlighted was the to improve the integration of care. One of the desired outcomes included under this strategy was to achieve effective inter-professional communication by identifying communication barriers and including training on communication in the continuing professional development modules for asthma management.

In order to achieve sustainable changes in asthma care, best practice guidelines must be implemented and circulated at local and national levels[1]; thus, it is imperative that asthma be recognised as a public health issue at government level. In Finland, the Ministry for Social and Public Affairs was responsible for establishing the national asthma programme in 1993[115]. In Australia, the Federal Government made asthma the sixth National Health Priority Area in 1999 and pledged $8 million dollars for asthma from 1999-2001 inclusive[107]. In Ireland, in 2009, asthma was one of a number of chronic disease programmes established under the HSE Quality and Clinical Care Directorate and it was included in the HSE National Service Plan 2010[106] with a view to the development and implementation of a national asthma programme designed to improve patient outcomes. In accordance with the recommendations in the GINA guidelines[1] and the strategy employed in Finland[115]and in Australia[107], a National Asthma Programme working group was established in Ireland 2010. This steering committee is being led by a consultant respiratory physician and consists of health-care professionals from both primary and secondary care. The National Asthma Programme in Ireland is outlined in Chapter 6.

2.11.Conclusion

2.11.1. QAM-CP

This questionnaire has revealed a number of significant points: Firstly, respondent community pharmacists believe that, overall, their asthma patients have some level of understanding of asthma and the relevant medications. However, they estimated that just over 50% of their patients use their inhalers properly, and only a minority of them are believed to use a peak flow meter regularly, possess an asthma action plan or are deemed to have well controlled asthma. In addition, the majority of patients are estimated by their pharmacists to have low expectations of disease management. Thus, the respondent pharmacists believe that, on the whole, their patients' level of asthma management is sub-optimal. Unfortunately, their estimations and beliefs about their patients' level of asthma control, ability to use their inhalers, peak flow meter usage, level of medication adherence and disease management expectations are in accordance with the literature, providing evidence that poor asthma management is a worldwide problem[148,149,151-155,161-163,172,173].

Analysis of the frequency with which interventions are carried out by community pharmacists with their asthma patients revealed that overall community pharmacists appear to have a narrow perception of their role in the promotion of asthma management among their patients. This is evidenced by the fact that while they frequently counsel patients on medication-related issues such as adherence or the demonstration of new inhalation devices they seldom advise patients on non-medication related issues such as providing advice on non-pharmacological measures to improve quality of life, providing advice on using a peak flow meter, or advising patients to obtain an asthma management plan from the GP. A lack of awareness about the importance of the peak flow meter and the asthma action plan in effective asthma management[1] may be a causative factor in some cases, therefore, the introduction of mandatory continuing professional development for pharmacists, arising from the Pharmacy Act 2007[343], is a welcome and vital development that should ensure the universal competency of pharmacists.

There is an abundance of evidence in the literature on the positive impact that community pharmacists can have on asthma management. For example, McLean and colleagues[218] demonstrated that community pharmacist-initiated pharmaceutical care of asthma patients resulted in significant improvements in clinical, humanistic and economic outcomes compared to patients receiving 'usual care'. Using a pre/post study design Mangiapane and colleagues[344] found that pharmaceutical care interventions resulted in a significant

improvement in asthma severity, self-reported symptoms, peak expiratory flow rates (PEFR), medication adherence, and quality of life over a 12-month period. Bunting and Cranor[345] conducted a community pharmacy-based medication therapy management program for asthma patients over a five year period and they found a significant reduction in all subjective and objective measures of asthma control, absenteeism reduced from10.8 days/year to 2.6 days/year and ED visits reduced from 9.9% to 1.3%.

It was observed that many of the specified asthma interventions were conducted significantly more frequently by more experienced pharmacists (11-20 years experience) than their younger less experienced colleagues. This was attributed to the stronger pharmacist-patient relationship that may be established by more experienced pharmacists[145] and highlights the importance of such a relationship in the promotion of effective counselling and asthma management. Indeed, the importance of the development of a therapeutic alliance between the pharmacist and the patient was acknowledged by the vast majority of respondents.

Evaluation of the factors influencing pharmacists' ability to counsel revealed that overall pharmacists believe themselves to be competent and sufficiently knowledgeable to counsel patients effectively and they generally find patients receptive to counselling. However, insufficient time is the most important factor that influences their ability to counsel patients and this may explain the low frequency with which some of the non-medication related interventions are conducted.

The current state of communication between a proportion of pharmacists and GPs is concerning. It is evident that a structured method of regular communication is needed. In addition, the role of the pharmacist in the primary care setting needs to be clearly defined to improve inter-professional relationships. In addition, the majority of respondents have no contact with practice nurses but most would like to establish contact in an attempt to improve patient care.

Finally, with regard to the proposed nationwide roll-out of an asthma management programme, a significant number of benefits, including improved patient care and the expansion of the role of the pharmacist, were identified. However, insufficient time, a lack of reimbursement and difficulties in inter-professional communication appear to be the major barriers to implementation. Nonetheless, it is evident from the results of this survey that asthma patients nationwide are believed to have sub-optimal asthma management, thus, current asthma management in the primary care setting appears to be inadequate necessitating a significant overhaul of the current system.

In conclusion, community pharmacists believe that overall, their asthma patients are managing their asthma quite badly. Pharmacists themselves need to expand their role in asthma management beyond counselling primarily on the medications dispensed. However, insufficient time appears to be a universal problem, therefore greater collaboration with GPs and practice nurses may help to ensure that the interventions conducted within the time constraints are not a duplication of those already conducted by GPs/nurses and are of most benefit to the patient in question.

2.11.2. QAM-GP

In comparison with the published literature, the GPs surveyed appear to have an optimistic and possibly unrealistic opinion, of their patients' level of asthma management, in particular in relation to the proportion of their patients who they estimate have well controlled asthma, who use their inhalers properly and who are compliant with their therapeutic regimens. The lack of agreement between physicians' estimated level of asthma control among their patients and the reality has been identified in the literature[233,234]. This may explain the discrepancy between the percentages of patients with well controlled asthma identified in the literature worldwide and that estimated by the respondents of this survey. As the majority of respondents do not appear to be checking their patients' inhaler technique routinely after initially demonstrating the correct technique when the inhaler was initially prescribed, it is possible that the percentage of patients estimated to use their inhalers correctly may be an overestimation due to the decline in correct inhaler technique that occurs over time without repeated education and reinforcement[43,75,104].

Estimated patient compliance was also surprisingly high, especially given the WHO report[236] on adherence in chronic diseases. Approximately three-quarters of respondents indicated that they regularly check for overuse and underuse of SABA and ICS respectively. However, due to the infrequent communication between respondents and community pharmacists it is likely that checking for patient adherence relies on self-reporting by patients and not on dispensing records. The accuracy of self-reported adherence has been questioned due to the possible influences of memory ability, social desirability and assessment mode[346]. Bender and colleagues[346] investigated the accuracy of self-reported adherence among children with asthma and their parents and they found that both children and their parents greatly over-reported their adherence to ICS and approximately one-third of respondents reported 100% adherence when no medication had been taken in the study time-frame. Thus, the large proportion of respondents who

estimated that their patients were compliant/highly compliant may be due to an over-reporting of adherence by their patients.

Communication between respondents and community pharmacists was infrequent in the majority of cases. In addition, the communication, when it did occur, was primarily as a method of imparting information on a device/dosage change. Despite the infrequent communication, the majority of respondents were satisfied with the current state of affairs. It is evident that few GPs and community pharmacists have established a collaborative working relationship based on bidirectional communication. There is extensive evidence in the literature that suggest that collaboration between pharmacists and physicians can improve patient outcomes in a range of chronic diseases such as diabetes[347-349], hypertension[350-352], hyperlipidaemia[353,354], asthma[355] and depression[356]. Inter-professional education has been proposed as a possible method to improve the working relationships between both groups of health-care professionals[357]. However, Gallagher and Gallagher[357] highlighted the importance of distinguishing between shared 'learning' and shared 'teaching'. It is common practice in many third level institutes for undergraduate medical and pharmacy students to undertake the same courses together, but in the absence of active learning involving student interaction, simply sitting in the same lecture theatres is unlikely to lead to an appreciation of another profession or foster an improved inter-professional working relationship in the future[357]. However, inter-professional education on communication skills[358] and medication reviews[359] which involved collaborative learning models were well received and deemed beneficial by both physicians and pharmacists. Furthermore, an inter-professional learning module on health promotion in asthma involving medical, nursing and pharmacy students was very well received by all three groups and it resulted in a positive change in students' attitudes towards teamwork in health and towards teamwork and collaboration[360].

Analysis of the interventions conducted by respondents with their asthma patients revealed mixed results. The majority of respondents frequently conduct interventions on medication adherence, and provide verbal and practical advice on newly prescribed medications. However, most respondents do not appear to be adhering to many of the GINA guidelines[1] for optimal asthma management: The peak flow meter is infrequently recommended as a tool to monitor asthma control, inhaler technique is rarely checked, education is only occasionally provided on trigger factors and a written asthma action plan is infrequently provided by the majority of respondents. Numerous possible reasons for lack of guideline concordance have been discussed such as lack of self-efficacy, lack of outcome expectancy, patient factors and perhaps the most ubiquitous problem; insufficient time.

A significant number of the results were influenced by respondents' experience in general practice. Overall, more experienced respondents tended to conduct many of the interventions with their asthma patients significantly more frequently than their less experienced colleagues, in particular interventions on advice provision that were conducted infrequently by respondents as a whole. This may explain why these older respondents estimated that a greater proportion of their patients had good asthma management compared to younger respondents. As discussed, these older respondents may have established good relationships with their patients over the years[224] and this in turn has been linked to better patient outcomes and health-related quality of life[225]. Thus, these results highlight the importance of establishing a good patient-physician relationship, as recommended by GINA guidelines[1].

It is evident from the results of the survey that many GPs may not be aware of the level of asthma management among their patients and that the majority of patients are receiving sub-optimal asthma care. Time appears to be a limiting factor to the delivery of guideline concordant care given the burden of chronic disease, the presence of co-morbidities and an aging population. Collaboration between GPs and other health-care professionals, namely practice nurses, community pharmacists may be the solution to alleviating some of the time pressure currently experienced by GPs nationwide, and this in turn may lead to enhanced patient care.

2.11.3. QAM-PN

The majority of the respondent nurses believe that their asthma patients have sub-optimal asthma management. On average, only approximately 50% of patients are believed to use their inhalers correctly or adhere to their therapeutic regimens. Less than one-third of patients are believed to possess a written asthma management plan and less than one-fifth are estimated to use a peak flow meter regularly. Furthermore, there appears to be a lack of awareness among a proportion of respondents about certain aspects of their asthma patients' care, for example, their asthma management expectations or their possession of an asthma management plan. However, analysis of the frequency with which respondents conduct specified interventions with their asthma patients may provide a possible explanation for these results. Of the fifteen specified asthma interventions, the majority of which are in accordance with best-practice guidelines for asthma management, only three are reportedly conducted *always/often* by > 55% of respondents. This may account for the lack of awareness about some aspects of their patients' asthma care among a proportion of respondents. It may also explain why respondents believe that, on average, at least half of their patients have inadequate asthma management skills.

If the general belief among a large proportion of respondents is that their asthma patients have sub-optimal disease management and that asthma care nationwide is unsatisfactory, why are at least half of the respondents infrequently counselling their patients on the majority of issues, deemed important by best-practice guidelines? This may be due to two possible reasons: limited involvement of some nurses in asthma management in their individual practices or the lack of implementation of best-practice guidelines for asthma at either practice level and/or nurse level.

As discussed on analysis of the QAM-GP, GPs do not have sufficient time to manage each chronic disease in accordance with recommended guidelines as well as care for acute problems and provide preventative services[264]. Wagner developed the Chronic Care Model (CCM) for the effective treatment of patients with chronic diseases in the primary care setting[361]. One of the key elements of the CCM is the 'Delivery system design'. This entails a reorganisation of the general practice structure so that acute and chronic care are separated and practice teams are created where labour is divided and individual roles and responsibilities are clearly outlined. In this model, physicians treat acute patients and difficult to treat chronic cases. Non-physicians, *i.e.* nurses and allied health professionals, are trained to support patient self-management, conduct routine assessments and ensure regular patient follow-up.

Inadequate implementation of best-practice guidelines for asthma management has been widely reported in the literature[200,231,243,299]. In Spain, despite numerous formal presentations of GEMA and their extensive distribution in both electronic and paper formats, implementation of the guidelines among primary care physicians and nurses was poor[299]. Lomas[362] reviewed 19 guidelines and found that isolated publication and guideline promotion did not result in behavioural change among health-care professionals, thus awareness alone is not sufficient to promote implementation. A number of measures have been proposed to improve guideline implementation: Ensuring that the general practice is equipped with the resources needed to facilitate implementation *e.g.* peak flow guidelines[363], educating health-care professionals on the positive impact that the guidelines can have on patient care to cultivate a positive attitude towards the guidelines[364], incorporation of the guidelines into the patient chart as part of routine clinical documentation[246], and integration of checklists into routine clinical practice that require completion and confirmation[365,366].

In addition, to facilitate implementation of the guidelines at nurse level there is a need for increased training in asthma care as studies have shown that some nurses lack sufficient knowledge to provide appropriate education and training to their patients[57,274,306,314]. In

addition, nurses with specialised asthma training provided more advanced asthma care[285] and their patients had better clinical outcomes than those without such training[286].

Communication between practice nurses and community pharmacists was infrequent in most cases but the majority of respondents were satisfied with current state of communication. Collaboration between nurses and pharmacists has been shown to have a positive impact on patient care across a range of diseases and settings[318-321]. Thus, to facilitate collaboration, the frequency of bidirectional communication needs to be increased[209,210] and both professions need to be educated on each other's skills and knowledge[323].

Respondents with greater nursing experience conducted a number of the specified interventions more frequently than their colleagues with less experience did. As discussed, this may be due to the establishment of a therapeutic relationship based on trust between the patient and his/her nurse over time that leads to an increased receptiveness to counselling and advice[279]. It may also be due to a deficit in nursing education on some aspects of asthma care that is only acquired through work experience[290].

In conclusion, a significant proportion of nurses do not appear to be providing guideline concordant asthma care to their patients due to perhaps a lack of involvement in chronic disease management within their individual practices and/or a lack of implementation of best-practice guidelines at practice/nurse level. Guideline concordant asthma care provided by an interdisciplinary team is vital to ensure the improvement of asthma care nationwide.

2.11.4. Comparative study

It is evident from analysing the results of this comparative study that respondent GPs appear to have more optimistic and unrealistic beliefs about their patients' ability to manage their asthma compared to respondent pharmacists and the relevant literature. As discussed, there may be a number of factors, both patient- and physician-related, that have contributed to these overestimations, for example, infrequent consultations, inadequate assessment methods and poor communication. However, such optimistic and inaccurate beliefs, on the part of GPs, may have serious consequences for their asthma patients. For instance, an overestimation of a patient's ability to use his/her inhalers may lead to insufficient inhaler technique assessment and training. As correct inhaler technique declines over time[41], this may lead to inadequate treatment or even treatment

failure[10] due to a reduction in drug deposition in the lungs[2]. Furthermore, overestimation of a patient's level of asthma control may lead to an inadequate therapeutic regimen arising from the belief that the current medication is successfully controlling a patient's asthma symptoms. Consequently, it is imperative that GPs have an accurate perception of their patients' understanding and asthma management.

One key way that may lead to a more accurate insight into patients' knowledge and ability to manage their asthma is conducting regular reviews with patients. Indeed, the GINA guidelines recommend that review consultations should take place at regular intervals[1]. Pinnock and colleagues[367] recommended a number of key components that should be included in every asthma review and these encompass most, if not all, of the issues that appear to be inaccurately perceived by GPs in this study. They proposed that each review should include the following components[367]: Firstly, asthma control should be assessed using specific morbidity questions that investigate the presence of symptoms, activity limitations, sleep disturbances and reliever usage. These specific questions are essential to avoid the underestimation of morbidity[368]. If the patient's asthma is not considered to be controlled, prior to stepping-up therapy, inhaler technique should be assessed and adherence should be investigated. Enquiring about adherence should be based on a non-judgemental assumption of non-adherence to facilitate an open and honest discussion on the benefits of adherence and any fears or concerns that may contribute to non-adherence[367]. Finally, patient education should form an integral part of the review as misunderstanding of the chronic nature of asthma, a lack of understanding about the need for regular ICS, and fears about potential side effects of ICS, act as obstacles to achieving asthma control[367]. However, while the content of the review is important, it is equally important that communication within the review is patient-centred as the development of a partnership between the patient and his/her physician is essential for successful asthma management[1]. In patient-centred communication the patient is seen as a person, social and psychological factors are taking into account, and the emphasis is on bidirectional dialogue[369]. Central to patient-centred care is the physician's investigative communication skills[370], which should encourage the patient to discuss openly his/her concerns, fears, beliefs and symptoms and become a more active participant in the consultation[371,372].

The comparative study also revealed that, overall, both pharmacists and practice nurses appear to have a narrow perception of their roles in asthma management and the majority of asthma care appears to be considered the remit of the GPs. Furthermore, collaborative asthma care appears to be limited between pharmacists and both GPs and practice nurses. However, the inadequacies of the current system of asthma care have been

recognised by the Irish government leading to the establishment of the multidisciplinary National Asthma Programme working group responsible for the design and implementation of the National Asthma Programme in Ireland. The Finnish National Asthma Programme is being used a model for the Irish programme and it is hoped that it will achieve the same level of support and success as that obtained in Finland. This is discussed in more detail in Chapter 6.

3. Demonstration Project: Investigating the role of the community pharmacist

3.1. Introduction

According to the Health Status and Health Service Utilisation National Household Survey quarterly report 2010[116], published by the Central Statistics Office, 7% of the adult population of Ireland suffer from asthma. Indeed, asthma is the most prevalent condition (10%) among young adults (18-24 years). Phase III of the International Study of Asthma and Allergies in Childhood[373] revealed that the percentage of Irish children, aged 13-14 years, reported to have had asthma at some time in their lives increased from 15.2% in 1995 to 21.5% in 2003, an annual increase of 0.79% per year.

The AIRI survey[151] revealed that only 8% of respondents had controlled asthma, as defined by international guidelines[1]. Patients with controlled asthma should not experience limitations to their daily activities, nocturnal wakening, or daytime symptoms, nor should they need reliever medication more frequently than twice per week[1]. However, 29% of those surveyed missed days from work/school due to asthma, 19% experienced nocturnal wakening at least once a week, 46% experienced daytime asthma symptoms at least once a week and 57% reported using reliever medication over the last four weeks, 69% of whom indicated a usage of up to three times daily for symptom relief[151]. Thus, overall asthma control in Ireland appears to be suboptimal and there is an urgent need for an improvement in asthma management nationwide.

3.2. Methods: Demonstration Project

The ASI and the ICGP collaborated on a Demonstration Project designed to investigate the barriers and facilitators to the implementation of best practice asthma guidelines in primary care. The ASI and the Quality in Practice Committee of the ICGP jointly adapted the GINA 2006 guidelines and produced a document entitled 'Asthma Control in General Practice', a user-friendly adaptation of the GINA guidelines. These guidelines served as the primary reference source for health-care professionals participating in the Demonstration Project.

General practices were considered for inclusion in the project if they expressed an interest following the announcement of the project in the medical press, or they were an ICGP

Research Practice, or an established Primary Care Team. Participating practices were chosen based on practice size, regional location and the presence of a practice nurse. Community pharmacies were recruited if they expressed an interest in the project following the nationwide circulation of a memorandum by the Irish Pharmacy Union (IPU) and they were located within the catchment area of a participating GP.

27 general practices and 73 community pharmacies were recruited to the project. Prior to participation all general practitioners, practice nurses and community pharmacists completed a compulsory on-line education programme consisting of 10 modules. The topics of the modules included the pathophysiology of asthma, diagnosis and classification of asthma in adults and children, the pharmacological treatments available, the development of the doctor-patient relationship, assessing, treating and monitoring asthma, managing exacerbations and identifying and reducing exposure to risk factors. In addition, the participants had to attend a practical training day that addressed inhaler technique, spirometry *etc.*

Patients were recruited by their GPs either opportunistically or in response to a letter of invitation issued by their GPs. Each patient consultation was conducted in accordance with the 'Asthma Control in General Practice' guidelines. The initial/baseline consultation adhered to the guideline approach of 'assess, treat and monitor'. All subsequent visits, patient education *etc.* were scheduled according to clinical need in accordance with the guidelines. Patients were managed according to the guidelines for six months.

Data on asthma patients were gathered from October 2009 to June 2010, by means of self-administered questionnaires completed by the patients (available in Appendix 9). The questionnaires were administered prior to the initial/baseline consultation and repeated approximately six months later. The data, which were supplied in the form of a Microsoft Office Excel 2007 spreadsheet, was imported into SPSS version 16 and analysed with a view to exploring the role of pharmacists in asthma management. Comparisons between groups were conducted using the Chi-square test for discrete variables, and one-way ANOVA was used to evaluate differences between groups of continuous variables. Probabilities of ≤ 0.05 were considered statistically significant. The responses to four questions were examined in detail:

1. *Has your pharmacist ever given you advice or information on inhaler technique?*
2. *Has your pharmacist ever given you advice or information on the peak flow meter?*
3. *Has your pharmacist ever discussed your asthma medications with you?*
4. *Has your pharmacist ever queried your use of reliever (blue) inhaler with you?*

In particular, the possibility that these questions might be influenced by demographic or other factors was explored, and the role of pharmacists was considered in the context of asthma management by health-care professionals in general.

3.3. Methods: Evaluation Project

The Demonstration Project focused on implementation rather than evaluation. The researcher intended to interface with the Demonstration Project, gathering appropriate baseline data and monitoring these parameters longitudinally, in order to evaluate the impact of the project on asthma management in the community setting. This project is referred to hereafter as the Evaluation Project to differentiate it from the Demonstration Project.

3.3.1. Design of protocol for Evaluation Project

Ethical approval was obtained from the Faculty of Health Sciences Research Ethics Committee (available in Appendix 8). Extensive research was conducted on the published literature with a focus on papers deemed particularly relevant[134,152,171,217,374-377] in order to devise an appropriate protocol to evaluate the patient impact of the Demonstration Project in the community pharmacy setting. As part of the Demonstration Project, the participating practice nurse instructed the enrolled patients on correct inhaler technique. In addition, it has been extensively documented that incorrect inhaler technique results in poor asthma control and increased hospitalisation[10,378]. Thus, it was logical to include an assessment of patients' inhaler technique in the Evaluation Project, using inhaler technique protocols devised with reference to those prepared by Mrs. Cicely Roche, Senior Lecturer in the School of Pharmacy and Pharmaceutical Sciences and to the protocols promoted by the ASI. The participating practice nurse also demonstrated the appropriate use of the peak flow meter and each patient was provided with a peak flow meter courtesy of the ASI. The GINA guidelines[1] indicate that peak flow measurements can be an important support in the monitoring of asthma. Peak flow measurements can provide an early indication of deteriorating asthma before the patient experiences any physical symptoms[1]. Therefore, an asthma diary was included in the Evaluation Project and it was designed to record PEFR readings over a period of two weeks to provide an insight into the patient's level of asthma control and to encourage the use of the peak flow meter. The asthma diary also included questions on reliever inhaler use, absenteeism and unscheduled GP or hospital visits related to asthma, to provide additional information on the patient's level of asthma control. The Asthma Diary was designed with reference that used in a study conducted by Mehuys and colleagues[374]

The provision of patient education on asthma and appropriate self-management of the disease was a key aspect of the Demonstration Project. Thus, it was essential to assess the success of this part of the project in the Evaluation Project. Two separate questionnaires were designed. The first questionnaire, annotated the control, knowledge and adherence questionnaire (CKAQ) included items on patient demographics to help contextualise the results, items on asthma control, asthma knowledge and medication adherence. These items were designed with reference to the relevant literature[379-383]. An adult and a paediatric version of this questionnaire were designed. In order to explore the impact that patients' asthma symptoms had on their daily lives their quality of life was measured using the mini Asthma Quality of Life Questionnaire[384] for patients 12 years and over. For patients 7-11 years old the paediatric mini Asthma Quality of Life Questionnaire' was used. Both of these questionnaires have been validated for use in asthma patients and have demonstrated excellent psychometric properties[384,385]. The aforementioned data collection forms and questionnaires are very similar to those used in the Brief Intervention (Chapter 5) with some minor modifications/improvements. These forms and questionnaires are available in Appendices 28-32, 34 and 36.

3.3.2. Recruitment of health-care professionals and patients to Evaluation Project

Under the direction of Mr. Louis Coyne, the Research and Education officer with the ASI, a selection of eight GP practices, from those participating in the Demonstration Project, were chosen to participate in the Evaluation Project. These GP practices were chosen on the basis that a good relationship existed between the general practice and the local community pharmacist, the general practice and the community pharmacy were in close proximity, and the GP was thought to be very enthusiastic about the Demonstration Project.

In order to maximise the participation of the health-care professionals (GPs, practice nurses and community pharmacists) in the Evaluation Project face-to-face meetings were arranged with each of the selected GPs and their practice nurses, and with the local community pharmacists. The purpose of these meetings was to recruit the health-care professionals and to explain what was required of them as participants in the Evaluation Project.

Each GP and community pharmacist who agreed to participate in the Evaluation Project signed an informed consent form to that effect. The participating GPs committed to asking their asthmatic patients, at the time when they enrolled them in the Demonstration

Project, if they would agree to participate in the Evaluation Project. In order to provide baseline data patients who were already participating in the Demonstration Project could not be enrolled in the Evaluation Project, only newly recruited patients to the Demonstration Project could be enrolled in the Evaluation Project. The patients were provided with an information leaflet explaining the nature of the project and an informed consent form to sign if they agreed to participate. The GP also provided the participating patients with an identification card, with an anonymous patient number, to facilitate their identification in the local community pharmacy and to ensure continuity and conformity of data between the GP practice and the community pharmacy.

3.3.3. Implementation of protocol for Evaluation Project

Each community pharmacist who consented to participate in the Evaluation Project agreed to carry out the following tasks with the participating patients at the initial consultation and at the second consultation after a six month period: Firstly, on identification of a participating patient, the pharmacist would provide the patient with two separate (age appropriate) questionnaires; a CKAQ and a quality of life questionnaire. These questionnaires were designed for self-completion and could be completed while the patient was waiting for his prescription to be dispensed. In addition, the pharmacist asked the patient to demonstrate his inhaler technique using a placebo inhaler and provided education on the correct technique with the aid of a physical demonstration where appropriate. The patient's initial inhaler technique was scored and recorded. Finally, the pharmacist provided the patient with an Asthma Diary in which the patient recorded his peak flow readings over a two week period as well as recording reliever inhaler usage and any absenteeism from work/education due to asthma. The pharmacist was provided with postage paid envelopes to mail all completed documentation to the researcher. Likewise, the pharmacist provided the patient with a postage paid envelope to return his completed Asthma Diary to the researcher. Pharmacists were advised to telephone patients within one week of the consultation to encourage them to complete and return the Asthma Diary.

Each participating pharmacist received a comprehensive *Pharmacist Pack*. This consisted of an expandable file with twelve separate indexed sections. These sections contained the following items: The Evaluation Project protocol, an information leaflet for the pharmacist, quality of life questionnaires for patients ≥ 12 years, quality of life questionnaires for patients 7-11 years, CKAQs for patients ≥ 12 years, CKAQs for patients 7-11 years, asthma diaries, inhaler technique checklists for nine different types of inhalation device, and postage paid envelopes. Twenty copies of each document were

provided in the pack and they were all colour coded in bright colours to ensure ease of identification.

The recruitment phase ran from May 26th to June 29th 2010. Within two weeks of recruitment, each of the participating pharmacists was contacted to discuss any problems or queries they had on closer inspection of the project protocol. As the project progressed each of the participating pharmacists were contacted on two separate occasions to discuss progress and any problems that they were encountering.

3.3.4. Exit interview with all community pharmacists participating in Demonstration Project

3.3.4.1. Exit interview format

Due to poor patient recruitment to the Evaluation Project, a structured interview was designed for telephone administration with all community pharmacists who agreed to participate in the Demonstration Project *and* whose local GP was participating in the project. 73 community pharmacists volunteered to participate in the Demonstration Project but only 33 were located in close proximity to a participating GP practice. It was these pharmacists who were telephoned and asked to consent to an interview. As the pharmacists would be contacted in their workplace, during working hours, the interview was designed to be brief (~5-7 minutes) to encourage maximum participation.

Each interview was conducted in the same format and consisted of 25 questions on four distinct topics: (1) Time commitment and communication with asthma patients, (2) Interprofessional communication, (3) Success of the project and (4) Demographic characteristics. The interview questions are outlined in Appendix 10.

1) Time commitment and communication with asthma patients

There were nine questions on this topic and the ninth question was divided into three parts. The first question the respondent was asked was whether he had counselled any patients who were officially participating in the Demonstration Project. If the respondent had counselled any of these patients, he was asked to answer the next eight questions in relation to these patients. However, if he had not counselled any patients who were participating in the Demonstration project he was asked to answer the following eight questions in relation to his asthma patients in general.

The next three questions related to time: the average length of time needed to counsel an asthma patient, the level of acceptability of this time expenditure and the feasibility of incorporating this level of counselling into daily practice. Respondents were then asked to estimate the percentage of patients they sought to counsel since the launch of the Demonstration Project and they were also asked to rate the how receptive their patients were to counselling on asthma. Questions were included on patients' level of understanding of their medications and their ability to use their inhalers prior to counselling. The final question asked respondents to rate the level of importance of having demonstration devices of (1) placebo inhalers, (2) peak flow meters and (3) spacer devices when counselling their asthma patients.

The respondents were provided with 3-5 Likert response options when they were asked to rate their patients' receptiveness to counselling, level of understanding, ability to use their inhalers and when they were asked to rate the acceptability of the time spent counselling an asthma patient. The remaining questions were closed, factual questions.

The questions on this topic were selected for a number of reasons. Firstly, to provide an insight into pharmacists' participation in the project and the feasibility of the project in relation to time expenditure and patient receptiveness. Questions were also included to assess the success of the project in terms of patient education. Even if pharmacists had not encountered any patients who were officially participating in the project, as they had volunteered to participate in the Demonstration Project and completed the online education modules, it was considered that they may have been more proactive in counselling their asthma patients overall, and so the interview continued on that basis.

2) Interprofessional communication

There were six questions on this topic. The first three questions referred to communication between the pharmacist and the participating GP in relation to the Demonstration Project. The following three questions were identical in content to the first three questions except that they referred to communication with the participating practice nurse. Respondents were asked to rate the frequency of communication and their level of satisfaction with both the frequency and the method of communication. All of the questions on this topic had 3-5 Likert response options, which were provided to the respondent.

Questions were included on interprofessional communication to investigate the degree of collaboration between the pharmacist and the GP/practice nurse as the patients were

being recruited to the Demonstration Project by their GP in conjunction with the practice nurse.

3) Success of the project

There were two questions on this topic; the success of the Demonstration Project from the respondent's perspective and the feasibility of rolling out the project on a national scale. These questions had dichotomous response options.

4) Demographic characteristics

The respondents were asked eight questions on this topic, three of which related to the demographic characteristics of the respondent community pharmacist: the respondent's age, professional status and number of years in community pharmacy practice. Respondents were also asked about the regional location of the pharmacy within the county and the type of pharmacy *e.g.* independently owned/chain pharmacy. The remaining three questions related to the average number of pharmacists working in the pharmacy simultaneously on a daily basis, the average number of prescription items dispensed in the pharmacy daily and the average number of hours worked by the respondent on a weekly basis.

3.3.4.2. Exit interview administration

The names and addresses of each community pharmacist who agreed to participate in the Demonstration Project were obtained from Mr. Louis Coyne of the ASI. The interviews were conducted from October 11th-October 22nd 2010 as it was considered that this two-week period would be quieter than the beginning or the end of the month in terms of patient demand for refill prescriptions and the completion of reimbursement claims for the PCRS.

The interview commenced with a brief personal introduction outlining the asthma research and each pharmacist was asked if he/she would consent to a brief interview about the Demonstration Project. The interviewee was advised that the researcher was not affiliated with the ASI or the ICGP, to minimise positive bias, and that all responses would be confidential and recorded anonymously. If the pharmacist consented, the researcher proceeded with the interview but if consent was not provided, the pharmacist was thanked for their time and the telephone call was terminated.

3.3.4.3. Interview analysis

The responses from each interview were coded, inputted into SPSS version 16.0 and analysed.

3.4. Results: Demonstration Project

3.4.1. Basic demographics

There were approximately equal proportions of male and female respondents: 48.2% male, 51.8% female. On average the respondents had been diagnosed with asthma for 15.25 years (SD = 13.5). This time period ranged from 1 - 70 years. The mean age of the respondents was 34.6 years (SD = 21.5) and the age range was 1 - 86 years *(N = 911).*

3.4.2. Baseline data on asthma management in last 12 months

In the 12 months preceding the study 4.1% of patients had been hospitalised and 9.4% of patients had attended the ED due to asthma. Approximately 25% of patients were nebulised due to asthma, 43% of patients were prescribed oral steroids for their asthma and 28% of respondents were absent from work/school due to asthma in the last 12 months. The mean number of days absent was 2.4 and the minimum and maximum number of days were 0 and 50 respectively *(N=911).* The number of GP visits due to asthma in the preceding 12 months is outlined in Figure 3.1 below.

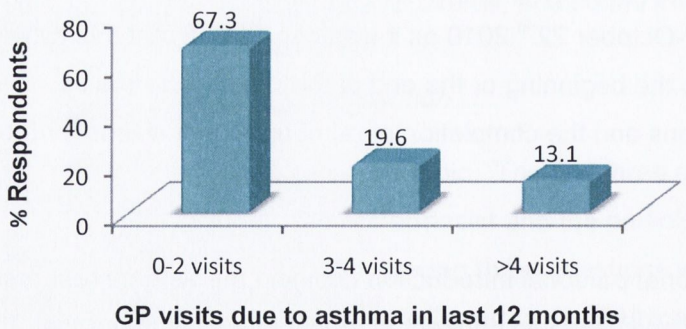


Figure 3.1: Number of GP visits due to asthma in the last 12 months (N = 911)

The mean number of GP visits was 2.2 (SD = 2.7) and the minimum and maximum number of visits were 0 and 25 respectively.

The mean Asthma Control Test (ACT) score was 17.7 (SD = 4.9) and the minimum and maximum scores were 5 and 25 respectively *(N=696).* An ACT score of <20 is an

indication that asthma is not well controlled and the patient may need an evaluation to determine methods to improve control[386].

3.4.3. Provision of advice by the pharmacist on inhaler technique

3.4.3.1. Baseline data

23% of patients reported that they had received advice from their pharmacist on inhaler technique *(N = 911)*.

A more in-depth analysis was performed between this item and patients' demographic data. No significant relationship was observed between the provision of advice on inhaler technique and the number of years with diagnosed asthma. However, a significant relationship was observed with the age range of respondents.

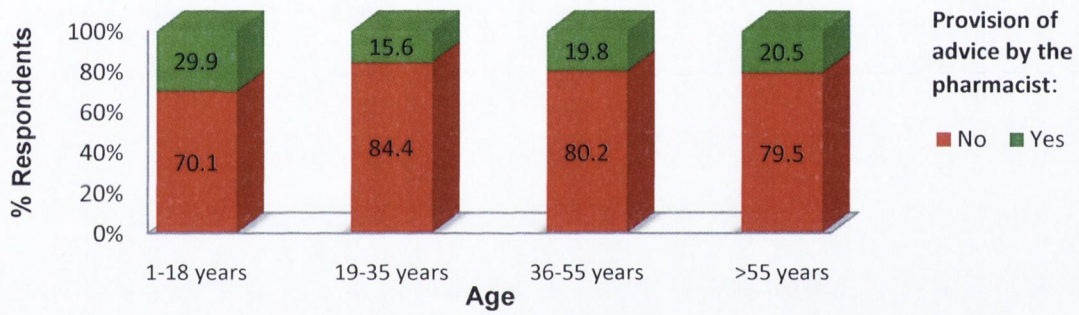


Figure 3.2: The provision of advice by the pharmacist on inhaler technique classified according to age range of respondents (N = 905, p = 0.001, χ^2 test).

A significantly greater proportion of the youngest patients (1-18 years) had received advice from their pharmacist on inhaler technique than older patients.

No relationship was observed between the provision of advice by the pharmacist on inhaler technique and the following items:

- Number of ED visits due to asthma in the last 12 months.
- Hospitalisation due to asthma in the last 12 months.
- Prescription for oral steroids for asthma in the last 12 months.
- Possession of a personal, written asthma action plan.
- Receipt of the influenza vaccine last year.
- Possession of an Asthma Attack card.
- Patient's ACT score.

However, a significant relationship was observed with the following items:

1) Number of general practitioner visits due to asthma in the last 12 months.



Figure 3.3: The provision of advice by the pharmacist on inhaler technique classified according to the patient's number of GP visits due to asthma in the last 12 months (N = 911, p = 0.002, χ^2 test).

A significantly greater proportion of patients who visited their GP more than four times in the last 12 months, due to asthma, received information from their pharmacist on inhaler technique, than those who made 0-4 visits to their GP.

2) Absenteeism from work/school due to asthma in the last 12 months.

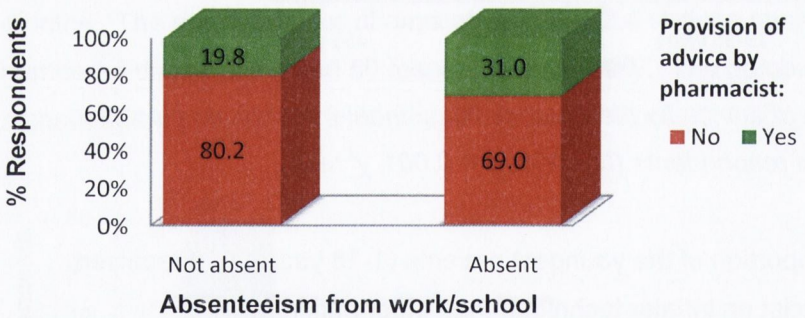


Figure 3.4: The provision of advice by the pharmacist on inhaler technique classified according to whether the patient was absent from work/school due to asthma in the last 12 months (N = 911, p < 0.001, χ^2 test).

A significantly greater proportion of patients who were absent from school/work due to asthma received advice from their pharmacist on inhaler technique than those who were not absent.

A more in-depth analysis was subsequently conducted to investigate if the length of the absence influenced this result. It was observed that as the period of absence increased the percentage of patients who were counselled by their pharmacist also increased and the differences between the groups were significant *(N = 911, p = 0.003, χ^2 test).*

Table 3.1: Percentage of patients who did receive counselling from their pharmacist on inhaler technique classified according to a series of interventions for asthma (N = 911).

Intervention for asthma	Yes	No	χ^2 test
Use of a nebuliser for asthma in last 12 months	**Used nebuliser: 29.2%**	**Did not use nebuliser: 20.9%**	**p=0.01**
Spirometry measurement	**Had spirometry: 27.8%**	**Did not have spirometry: 20.6%**	**p=0.016**
Received written information/education on asthma	**Received information: 29.7%**	**Did not receive information: 19.5%**	**p=0.001**

A significantly greater proportion of patients who used a nebuliser for asthma over the last 12 months, or who had spirometry testing, or who had received written information/education about asthma, received advice from their pharmacist on inhaler technique than those who did not have such interventions.

3.4.3.2. Second/subsequent appointment data

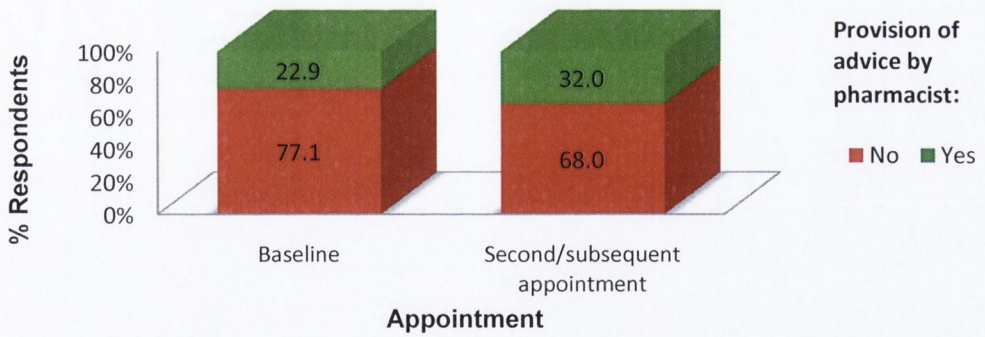


Figure 3.5: The provision of advice by the pharmacist on inhaler technique classified according to appointment number (N = 1159, p = 0.004, χ^2 test).

A significantly greater proportion of patients received advice from their pharmacist on inhaler technique once the Demonstration Project had commenced than prior to its initiation.

No significant relationship was observed between the provision of advice by the pharmacist on inhaler technique and patients' demographic data, or any other item in the questionnaire, for second/subsequent appointment data.

3.4.4. Provision of advice by the pharmacist on the peak flow meter

3.4.4.1. Baseline data

4% of patients indicated that they had received advice from their pharmacist on the peak flow meter *(N = 911)*.

A more detailed analysis was conducted on this item in conjunction with patients' demographic data. No significant relationship was observed between the provision of advice on the peak flow meter and patients' age range, or number of years with diagnosed asthma.

Furthermore, no significant relationship was observed between the provision of advice by the pharmacist on the peak flow meter and the following items:

- Number of GP visits due to asthma in the last 12 months.
- Use of a nebuliser for asthma in the last 12 months.
- Prescription of oral steroids for asthma in the last 12 months.
- Absenteeism from work/school due to asthma.
- Frequency of reliever use per week.
- Receipt of the influenza vaccine last year.
- Possession of an Asthma Attack card.
- Patient's ACT score.

A significant relationship was observed with three items tabulated below.

Table 3.2: Percentage of patients who did receive counselling from their pharmacist on the peak flow meter classified according to a series of interventions for asthma (N = 911).

Intervention for asthma	Yes	No	χ^2 test
Possession of a personal, written asthma action plan	**Possess plan: 11.6%**	**Do not possess plan: 3.6%**	**p=0.001**
Spirometry measurement	**Had spirometry: 6.7%**	**Did not have spirometry: 2.9%**	**p=0.008**
Received written information/education on asthma	**Received information: 7.2%**	**Did not receive information: 2.6%**	**p=0.001**

A significantly greater proportion of patients who possessed an action plan, had spirometry testing or received written information on asthma, received advice from their pharmacist on the peak flow meter than those who had not. However, it is important to note that only a very small proportion of patients overall received advice on the peak flow meter from their pharmacist.

3.4.4.2. Second/subsequent appointment data

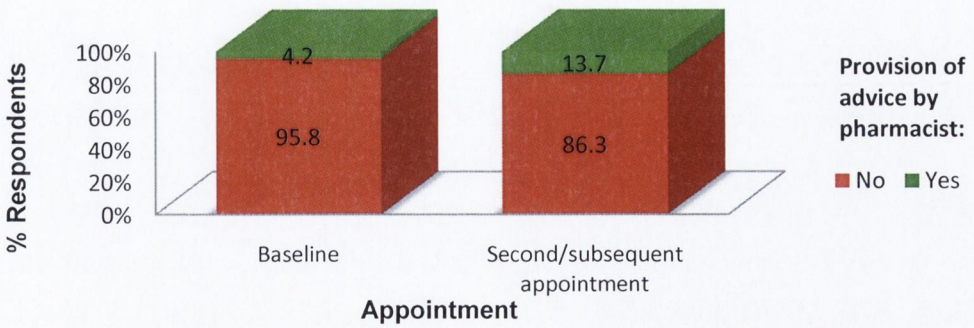


Figure 3.6: The provision of advice by the pharmacist on the peak flow meter classified according to appointment number (N = 1159, p <0.001, χ^2 test).

A significantly greater proportion of patients had received advice from their pharmacist on the peak flow meter by the time of the second/subsequent GP appointment (*i.e.* once the Demonstration Project had commenced) than at baseline.

No significant relationship was observed between the provision of advice by the pharmacist on the peak flow meter and the following items, for second/subsequent appointment data:

- Use of a nebuliser for asthma in the last 12 months.
- Absenteeism from work/school due to asthma in the last 12 months.
- Frequency of reliever use per week.
- Possession of a personal, written asthma action plan.
- Receipt of the influenza vaccine last year.
- Spirometry measurement.
- Possession of an Asthma Attack card.
- Receipt of written information/education about asthma.

A significant relationship was observed with the following two items:

1) *Prescription of oral steroids for asthma, in the last 12 months.*

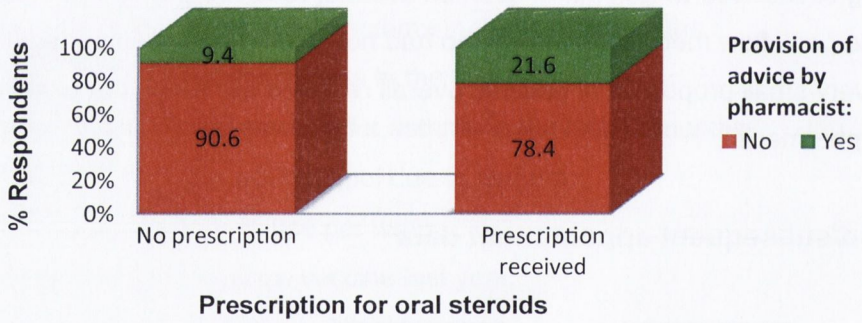


Figure 3.7: The provision of advice by the pharmacist on the peak flow meter classified according to whether or not the patient had been prescribed oral steroids for asthma in the last 12 months (N = 248, p = 0.007, χ^2 test).

A significantly greater proportion of patients who received a prescription for oral steroids for asthma in the last 12 months received advice from the pharmacist on the peak flow meter than those who did not need such a prescription.

2) *Patients' ACT scores.*

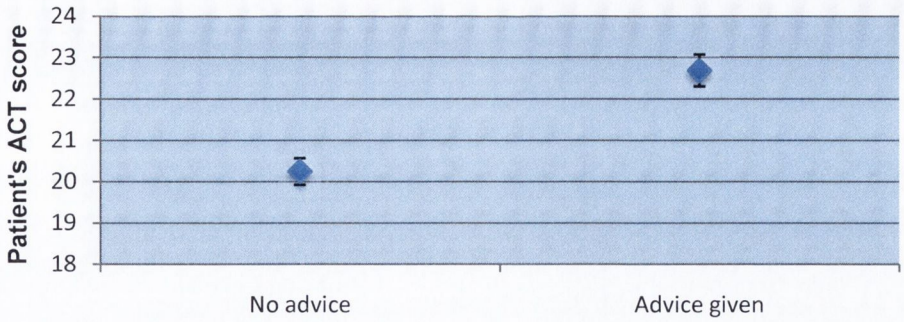


Figure 3.8: Provision of advice by pharmacist on the peak flow meter classified by patients' mean ACT scores (±S.E.) (N = 168, p = 0.005, ANOVA).

Patients who received advice from the pharmacist on the peak flow meter had significantly higher ACT scores than those who did not receive such advice.

3.4.5. Pharmacist-patient discussion on a patient's asthma medications

3.4.5.1. Baseline data

24% of patients discussed their asthma medications with their pharmacist *(N = 911).*

This item was analysed in conjunction with patient demographic data and no significant relationship was observed with patients' age range, or number of years with asthma.

No significant relationship was observed between this item and the following items:

- Number of GP visits due to asthma in the last 12 months.
- Number of ED visits due to asthma in the last 12 months.
- Hospitalisation due to asthma in the last 12 months.
- Use of a nebuliser for asthma in the last 12 months.
- Prescription of oral steroids for asthma in the last 12 months.
- Frequency of reliever use per week.
- Receipt of the influenza vaccine last year.
- Spirometry measurement.
- Possession of an Asthma Attack card.
- Patient's ACT score.

A significant relationship was observed with the three items tabulated below

Table 3.3: Percentage of patients who discussed their asthma medications with their pharmacist classified according to a series of actions for/due to asthma (N = 911).

Action for/due to asthma	Yes	No	χ^2 test
Possession of a personal, written asthma action plan	**Possess plan: 42%**	**Do not possess plan: 22.2%**	**p<0.001**
Absenteeism from work/school in last 12 months due to asthma	**Absent: 28.7%**	**Not absent: 21.7%**	**p=0.027**
Received written information/education on asthma	**Received information: 34.6%**	**Did not receive information: 18.2%**	**p<0.001**

The table illustrates that a significantly greater proportion of patients who missed work/school due to asthma, or who possess a written asthma action plan, or who received written information/education on asthma have discussed their asthma medications with their pharmacist than those who have not.

3.4.5.2. Second/subsequent appointment data

Following the initiation of the Demonstration Project 29% of patients indicated that they had discussed their asthma medications with their pharmacist *(N = 248)*. There was no significant difference between the proportions of patients who had discussed their asthma medication with the pharmacist at baseline and by the time of the second/subsequent GP appointment, once the Demonstration Project had commenced.

No significant relationship was observed between the pharmacist-patient discussion of asthma medications and patients' demographic data or the following items:

- Number of GP visits due to asthma in the last 12 months.
- Use of a nebuliser for asthma in the last 12 months.
- Prescription of oral steroids for asthma in the last 12 months.
- Absenteeism from work/school due to asthma in the last 12 months.
- Frequency of reliever use per week.
- Receipt of the influenza vaccine last year.
- Spirometry measurement.
- Possession of an Asthma Attack card.
- Patient's ACT score.

A significant relationship was observed between the pharmacist-patient discussion of asthma medications and two items tabulated below.

Table 3.4: Percentage of patients who discussed their asthma medications with their pharmacist classified according to a series of interventions for asthma (N = 248).

Intervention for asthma

Intervention for asthma	Yes	No	χ^2 test
Possession of a personal, written asthma action plan	**Possess plan: 57.7%**	**Do not possess plan: 41.8%**	**p=0.023**
Received written information/education on asthma	**Received information: 49.1%**	**Did not receive information: 28.8%**	**p=0.028**

The table illustrates that a significantly greater proportion of patients who received a personal written asthma action plan or who received written information/education about asthma have had a discussion with their pharmacist about their asthma medications than those that have not received such items.

3.4.6. Querying use of reliever inhaler by the pharmacist

3.4.6.1. Baseline data

4% of patients indicated that their pharmacist had ever queried their reliever inhaler usage *(N = 911).*

The data were analysed to investigate if patients reported excessive weekly reliever use, which necessitated detection and investigation by the pharmacist on dispensing.

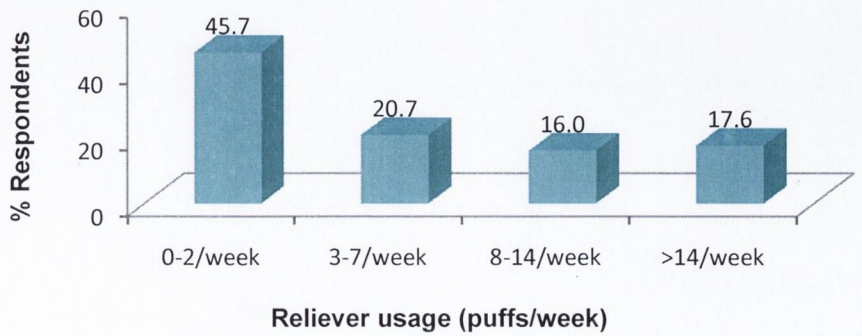


Figure 3.9: Patients' weekly reliever usage (N = 911).

The majority of the patients surveyed used their reliever inhalers more frequently than that recommended for well controlled asthma (≤ 2/week)[1].

Querying patients' reliever use by the pharmacist was analysed in conjunction with patient demographic data. A significant relationship was observed with patients' age range, but not with number of years with diagnosed asthma.

1) Patients' age range

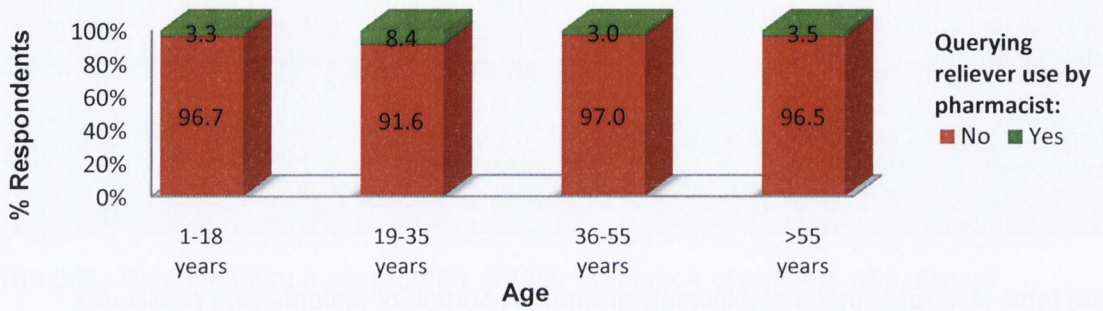


Figure 3.10: Querying patients' reliever use by the pharmacist classified according to patients' age range (N = 905, p =0.029, χ^2 test).

A significantly greater proportion of patients 19-35 years old had their reliever inhaler use queried than older or younger patients.

This result was analysed further by investigating whether or not patient's reliever use varied with age. It was observed that reliever inhaler usage was significantly more frequent among patients of an intermediate age (19-55 years) than among the youngest (0-18 years) or the oldest (> 55 years) patients *(N = 905, p < 0.001, χ^2 test).*

No significant relationship was observed between querying patients' reliever use by the pharmacist and the following items:

- Number of GP visits due to asthma in the last 12 months.
- Use of a nebuliser for asthma in the last 12 months.
- Prescription of oral steroids for asthma in the last 12 months.
- Frequency of reliever use per week.
- Absenteeism from work/school due to asthma in the last 12 months.
- Receipt of influenza vaccine last year.
- Spirometry measurement.
- Possession of an Asthma Attack Card.
- Patient's ACT score.

A significant relationship was observed with one item referring to the receipt of written information/education about asthma.

1) Receipt of written information/education about asthma.

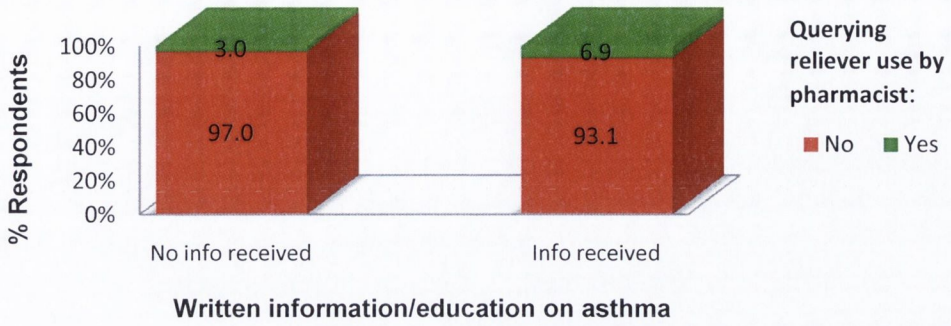


Figure 3.11: Querying patients' reliever use by the pharmacist classified according to whether or not the patient ever received written information/education on asthma (N = 911, p =0.006, χ^2 test.)

A significantly greater proportion of patients who received written information or education on asthma have had their reliever use queried by the pharmacist than those who have not.

3.4.6.2. Second/subsequent appointment data

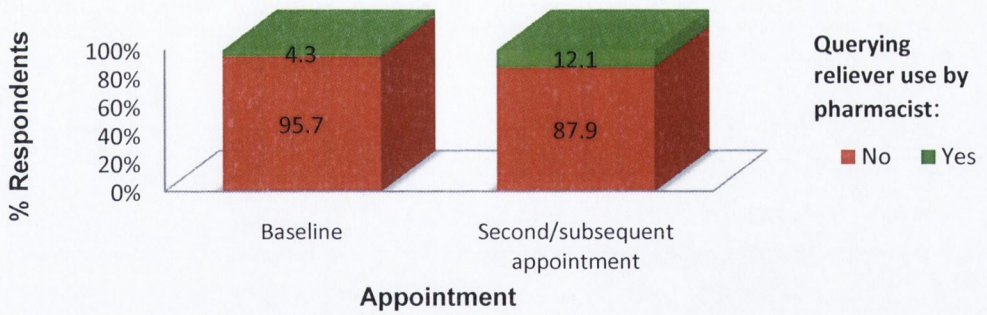


Figure 3.12: Querying of patients' reliever use by the pharmacist classified according to appointment number (N = 1159, p <0.001, χ^2 test).

A significantly greater proportion of patients had their reliever use queried by their pharmacist by the time of the second/subsequent GP appointment (*i.e.* once the Demonstration Project commenced) than prior to its initiation.

No significant relationship was observed between this item and patients' demographic data or any of the other items in the patient questionnaire.

3.4.7. Counselling by any health-care professional on inhaler technique

3.4.7.1. Baseline data

The data were analysed to investigate if there were any patients who indicated that they had not received counselling on inhaler technique from either their GP/practice nurse or their pharmacist before the Demonstration Project commenced.

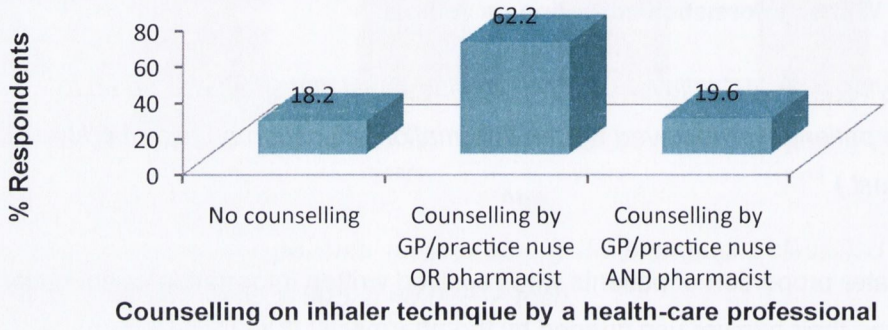


Figure 3.13: Proportion of patients who had/had not received counselling on inhaler technique from a health-care professional (N = 851).

A more in-depth analysis was conducted in conjunction with patients' demographic data. No significant relationship was observed with the number of years with diagnosed asthma, but a significant link was observed with patients' age range.

1) Age range

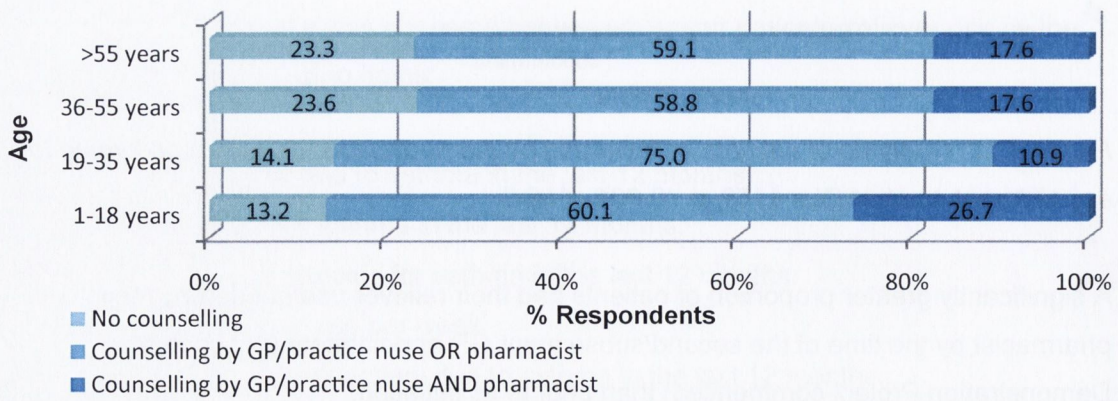


Figure 3.14: Counselling of patients on inhaler technique by a health-care professional classified according to age range of patients (N = 846, p <0.001, χ^2 test).

As the age range of patients increases the proportion of patients who received no counselling from a health-care professional on inhaler technique increases and the differences between the groups are statistically significant. Furthermore, significantly more patients aged 1-18 years have received counselling on inhaler technique from both their GP/practice nurse AND their pharmacist than have older patients.

No significant relationship was observed between counselling by a health-care professional on inhaler technique and the following items:

- Number of GP visits due to asthma in the last 12 months.
- Number of ED visits to asthma in the last 12 months.
- Hospitalisation due to asthma in the last 12 months.
- Prescription of oral steroids for asthma in the last 12 months.
- Receipt of influenza vaccine last year.
- Spirometry measurement.
- Possession of an Asthma Attack Card.

A significant relationship was observed with a number of items outlined in Table 3.5 below.

Table 3.5: Level of counselling by health-care professionals on inhaler technique received by patients classified according to different actions for/due to asthma (N = 851).

	Action for/due to asthma	Level of counselling			χ^2 test
		No counselling	GP/practice nurse OR pharmacist	GP/practice nurse AND pharmacist	
1.	Use of a nebuliser for asthma in last 12 months	**Used nebuliser: 22.6%**	**Used nebuliser: 22.1%**	**Used nebuliser: 32.9%**	**p=0.015**
2.	Absent from work/school due to asthma in last 12 months	**Absent: 19.4%**	**Absent: 27.8%**	**Absent: 36.5%**	**p=0.003**
3.	Possession of a personal, written asthma action plan	**Possess plan: 3.2%**	**Possess plan: 8.1%**	**Possess plan: 12%**	**p=0.015**
4.	Received written information/education on asthma	**Received information: 14.8%**	**Received information: 35%**	**Received information: 47.3%**	**p<0.001**

The table illustrates a number of findings. Firstly, a significantly greater proportion of patients who were counselled by both their GP/practice nurse AND their pharmacist on inhaler technique were nebulised over the last 12 months than those who were counselled by one health-care professional or not at all *(p = 0.015).* In addition, a significantly greater proportion of patients who received counselling from a health-care professional on inhaler technique had been absent due to asthma, or had been given a written asthma action plan, or had been given written information on asthma than those who received no such counselling. Furthermore, a significantly greater proportion of patients who received counselling from both their GP/practice nurse AND their pharmacist were absent due to asthma, or received an asthma action plan, or received written information on asthma than those who were counselled by only their GP/practice nurse OR their pharmacist.

There was no significant relationship between counselling by a health-care professional on inhaler technique and either patients' weekly reliever usage or patients' ACT scores. However, when these relationships were analysed by comparing patients who had received any counselling on inhaler technique (by combining the group 'counselling by GP/practice nurse OR pharmacist' and 'counselling by GP/practice nurse AND pharmacist) with patients who had not received counselling on inhaler technique from any health-care professional, one significant relationship was detected.

1) Patients' ACT scores.

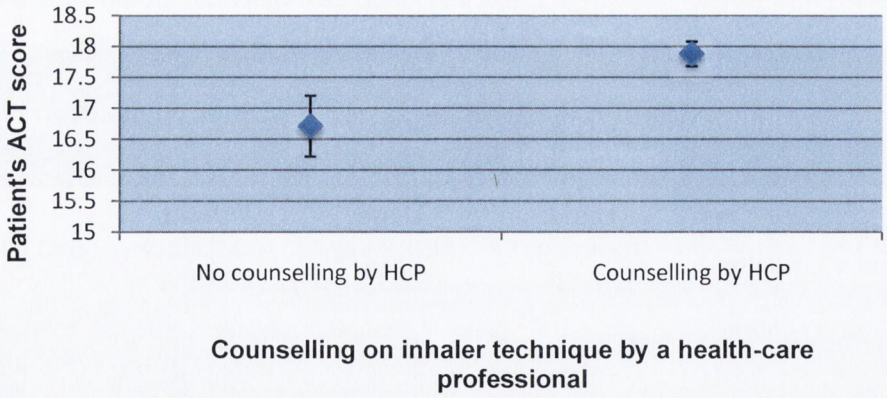


Figure 3.15: Counselling on inhaler technique by any health-care professional classified by patients' mean ACT scores (± S.E.) (N = 696, p = 0.018, ANOVA).

Patients who received counselling from any health-care professional on inhaler technique had significantly higher ACT scores than those who did not receive any such counselling.

3.4.7.2. Second/subsequent appointment data

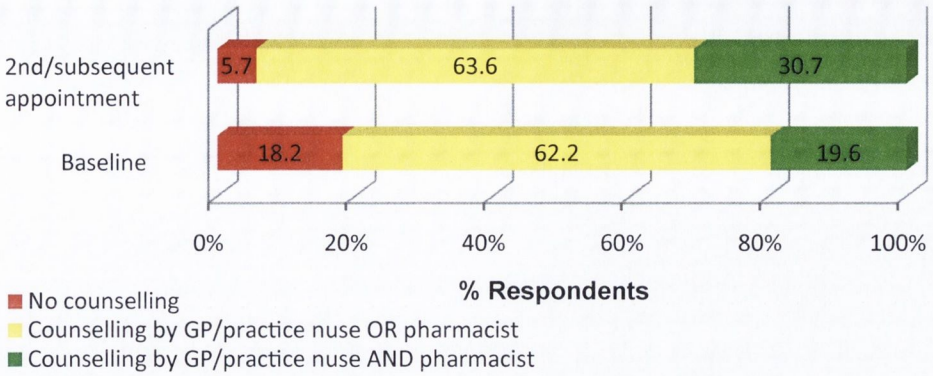


Figure 3.16: Patient counselling on inhaler technique by a health-care professional classified according to appointment number (N = 1159, p = 0.003, χ^2 test).

The proportion of patients who had never received counselling on inhaler technique from a health-care professional decreased significantly following the commencement of the Demonstration Project. In addition, there was a significant increase in the number of patients who were advised on inhaler technique by both their GP/practice nurse AND pharmacist after the project was initiated.

In-depth analysis with other items in the patient questionnaire was conducted and no significant relationships were observed with any of the items.

3.4.8. Counselling by any health-care professional on the peak flow meter

3.4.8.1. Baseline data

The data were analysed to investigate if there were any patients who indicated that they had not received counselling on the peak flow meter from either their GP/practice nurse or their pharmacist at baseline.

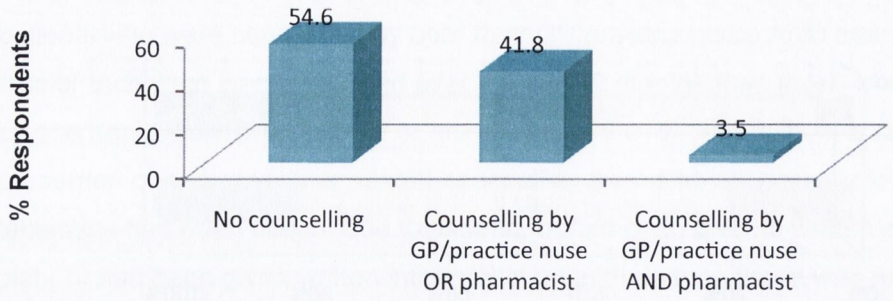


Figure 3.17: Proportion of patients who had/had not received counselling on the peak flow meter from a health-care professional (N = 851).

This data were analysed in conjunction with patients' demographic data. Significant relationships were observed with patients' age range and the number of years with which they had diagnosed asthma.

1) Age range

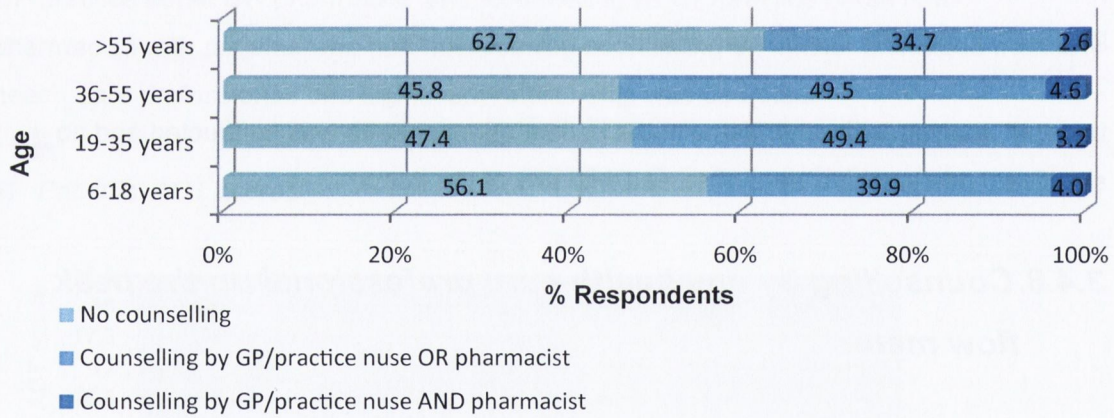


Figure 3.18: Counselling by health-care professionals on the peak flow meter classified according to age range (N = 856, p = 0.005, χ^2 test).

The graph illustrates that a significantly greater proportion of the youngest (6-18 years) and oldest (>55 years) patients received no counselling on the peak flow meter than patients of 19-55 years.

No significant relationship was observed between counselling by a health-care professional on the peak flow meter and the following items:

- Number of GP visits due to asthma in the last 12 months.
- Number of ED visits due to asthma in the last 12 months.
- Hospitalisation due to asthma in the last 12 months.
- Use of a nebuliser due to asthma in the last 12 months.
- Prescription of oral steroids for asthma in the last 12 months.
- Absenteeism from work/school due to asthma in the last 12 months.
- Frequency of reliever use per week.
- Patient's ACT score.

However, a significant relationship was observed with a number of items tabulated below.

Table 3.6: Level of counselling by health-care professionals on the peak flow meter received by patients classified according to different actions for/due to asthma (N = 851).

Action for/due to asthma	Level of counselling			χ^2 test
	No counselling	GP/practice nurse OR pharmacist	GP/practice nurse AND pharmacist	
Receipt of the influenza vaccine last year	**Vaccinated: 41.7%**	**Vaccinated: 47.5%**	**Vaccinated: 63.3%**	**p=0.031**
Spirometry measurement	**Had spirometry: 25.6%**	**Had spirometry: 39.3%**	**Had spirometry: 56.7%**	**p<0.001**
Received written information/education on asthma	**Received information: 21.5%**	**Received information: 46.9%**	**Received information: 66.7%**	**p<0.001**

The table above illustrates similar findings: Firstly, a significantly greater proportion of patients who have received counselling from either their GP/practice nurse OR pharmacist or their GP/practice nurse AND pharmacist have had spirometry, received the influenza vaccine, or received written information about asthma than those who have received no such counselling. Furthermore, a significantly greater proportion of patients who received counselling from two health-care professionals (*i.e.* GP/practice nurse AND pharmacist) have had spirometry, received the 'influenza vaccine', or received written information about asthma than those who have only received counselling on the peak flow meter from one health-care professional.

In order to conduct an in-depth analysis on items referring to the possession of an asthma action plan and an Asthma Attack card the results of the category referring to counselling by the GP/practice nurse AND pharmacist and that referring to the GP/practice nurse OR pharmacist had to be pooled into one category. This was due to the small number of responses in some response categories.

Table 3.7: Counselling by any health-care professional on the peak flow meter classified according to different actions for/due to asthma (N = 851).

	Action for/due to asthma	No counselling	Counselling by any HCP	χ^2 test
1.	Possession of an asthma action plan	**Possess plan: 4.3%**	**Possess plan: 12.4%**	**p<0.001**
2.	Possession of an Asthma Attack card	**Possess card: 2.8%**	**Possess card: 8.5%**	**p<0.001**

HCP = health-care professional

A significantly greater proportion of patients who received a written asthma action plan or an Asthma Attack card have received counselling from a health-care professional on the peak flow meter than those who do not.

3.4.8.2. Second/subsequent appointment data

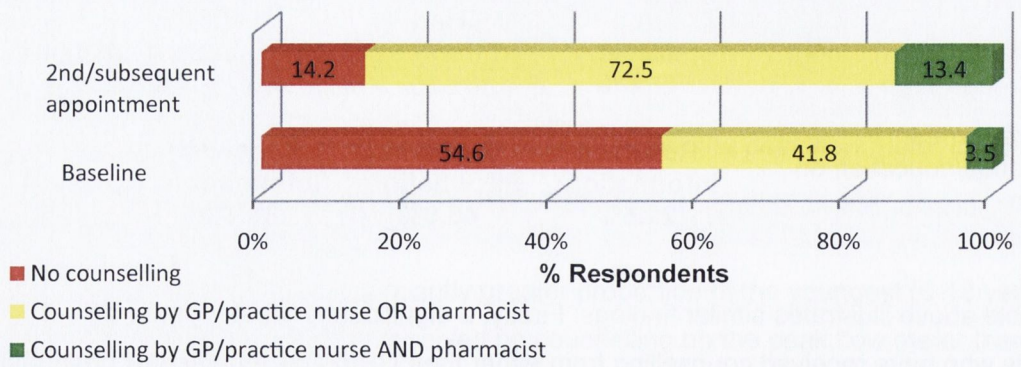


Figure 3.19: Proportion of patients who have received counselling on the peak flow meter from a health-care professional classified according to appointment number (N = 1098, p < 0.001, χ^2 test).

A significantly greater proportion of patients were counselled on the peak flow meter by their GP/practice nurse OR pharmacist, or by their GP/practice nurse AND pharmacist by the time of the second/subsequent GP appointment than at baseline.

Indeed the proportion of patients who never received counselling from a health-care professional on the peak flow meter dropped by ~40%.

This data were analysed in conjunction with patients' demographic data. No significant relationship was observed between this item and the number of years with diagnosed asthma. In addition, no significant relationship was observed between counselling by a health-care professional on the peak flow meter and the following items:

- Use of a nebuliser due to asthma in the last 12 months.
- Prescription of oral steroids for asthma in the last 12 months.
- Absenteeism from work/school due to asthma in the last 12 months.
- Frequency of reliever use per week.
- Possession of a personal, written asthma action plan.
- Receipt of the influenza vaccine last year.
- Spirometry measurement.
- Possession of an Asthma Attack card.
- Receipt of written information/education about asthma.

A significant relationship was observed with two items:

1) *Prescription of oral steroids for asthma in the last 12 months.*

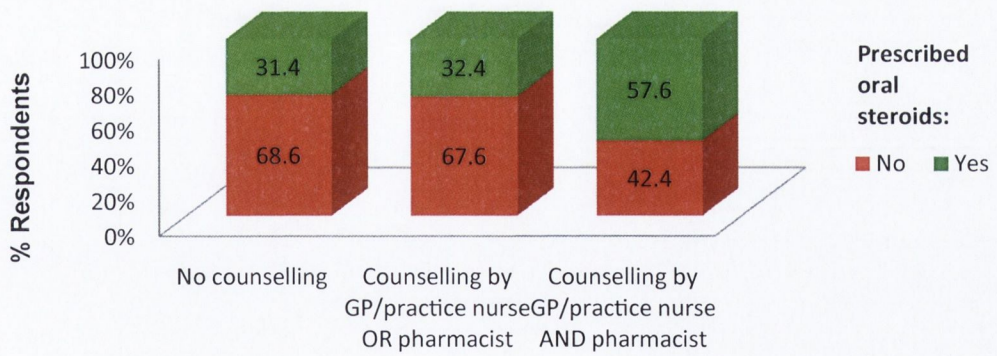


Figure 3.20: Counselling by a health-care professional on the peak flow meter classified according to whether or not a patient was prescribed oral steroids for asthma in the last 12 months (N = 247, p = 0.018, χ^2 test).

A significantly greater proportion of patients who were prescribed oral steroids for their asthma were counselled by their GP/practice nurse AND their pharmacist on the peak

flow meter than those who were counselled by only one health-care professional or not at all.

2) *Patient's ACT score.*

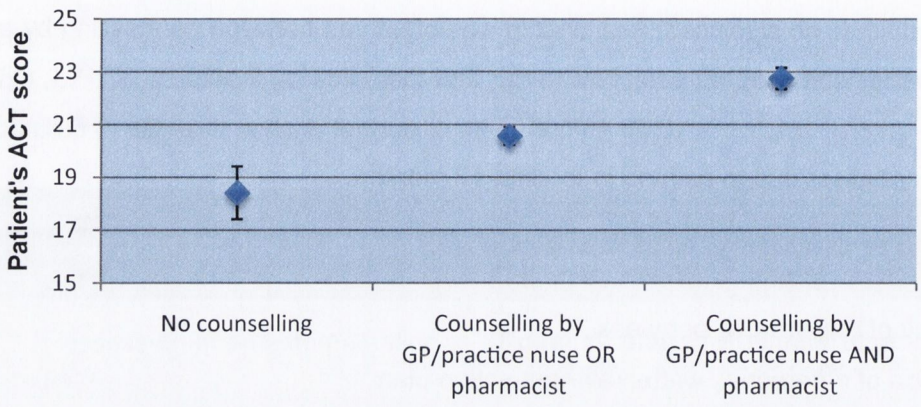


Figure 3.21: Counselling on the peak flow meter by a health-care professional classified by patients' mean ACT scores (±S.E.) (N = 198, p = 0.001, ANOVA).

The graph illustrates two points: Firstly, patients who never received any counselling from a health-care professional on the peak flow meter had a significantly lower ACT score than those who did receive such counselling. In addition, patients who received counselling on the peak flow meter from both their GP/practice nurse AND pharmacist had a significantly higher ACT score than those who only received such counselling from one health-care professional.

3.5. Results: Evaluation Project

Completed data collection forms for the Evaluation Project were only been received for one patient. Repeated communication with the participating pharmacists revealed a number of points: Firstly, the majority of the pharmacists did not encounter any patients who had been newly recruited to the Demonstration Project by their GPs and had consented to participate in the Evaluation Project. There may be a number of reasons for this: To start with, the Demonstration Project was launched and GPs started recruiting patients to the programme on October 12th 2009. However, due to a delay in getting ethical approval for the Evaluation Project, the researcher was unable to start recruiting patients until May. By this time, many of the GPs had exhausted their pool of asthma patients who were willing to participate in the Demonstration Project so recruitment rates for new patients were very low. In addition, while every attempt was made to recruit pharmacists in community pharmacies neighbouring a GP practice participating in the Demonstration Project a number of the GP practices served a large catchment area and so many of their patients may not have frequented the neighbouring community pharmacies that were recruited. As a result, even if asthma patients were recruited by the GP, if their community pharmacist was not participating in the study they could not be involved. Secondly, two pharmacists stated that patients who had been recruited by their GPs to the Evaluation Project had not been properly informed about the project, despite the provision of detailed patient information leaflets to the GP for this purpose. Accordingly, when the pharmacist provided the patients with the questionnaires for completion they refused to complete them due to time constraints.

3.5.1. Exit interview with community pharmacists participating in Demonstration Project

3.5.1.1. Demographic characteristics

Thirty-three community pharmacists were telephoned at their place of work and twenty-four interviews were completed. Two pharmacists did not consent to the interview and the remaining seven either were on maternity leave or were no longer employed at that community pharmacy. The overall response rate was 73%. 67% of the respondents were female. The average number of years practising as a community pharmacist was 12.9 years. The maximum and minimum number of years was 2 years and 30 years respectively. 50% of the respondents worked in pharmacies situated in towns, 29% worked in suburban pharmacies, 13% worked in rural pharmacies and the remaining 8% worked in city pharmacies. 46% of respondents worked in independently owned

pharmacies, 33% worked in large chain pharmacies (> 10 shops), 13% worked in medium chain pharmacies (4-10 shops) and the remaining 8% worked in small chains (2-3 shops).

71% of respondents were employee pharmacists and the remainder were pharmacy owners. 58% of respondents did not work with another pharmacist on an average day and the remaining 42% usually worked with one other pharmacist daily. The mean number of hours worked per week was 39 hours. The maximum and minimum number of hours was 27 hours and 55 hours respectively. The mean number of items dispensed daily was 277. The maximum and minimum number of items was 600 items and 60 items respectively *(N = 24)*. The respondents' age range is displayed below.

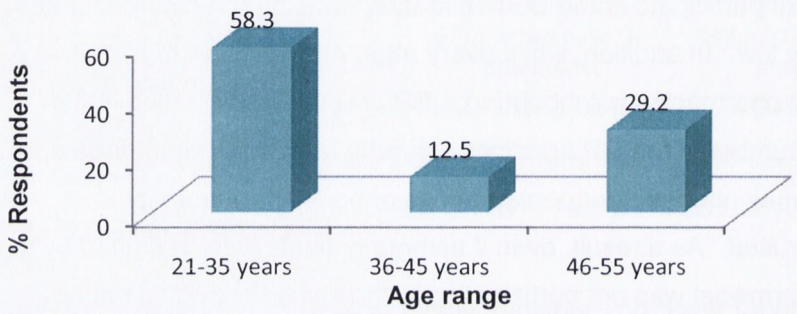


Figure 3.22: Age range of respondent community pharmacists (N = 24).

3.5.1.2. Time commitment and communication with asthma patients

1) Counselling of patients enrolled in Demonstration Project.

Only 21% of respondents had counselled asthma patients who were enrolled by their GPs in the Demonstration Project. However, of the five respondents who did counsel patients who were enrolled in the project, two of them stated that they had only counselled 1-3 enrolled patients. The remaining 79% had not counselled any patient who was officially enrolled in the Demonstration Project.

2) *Time needed to provide sufficient counselling to an asthma patient.*

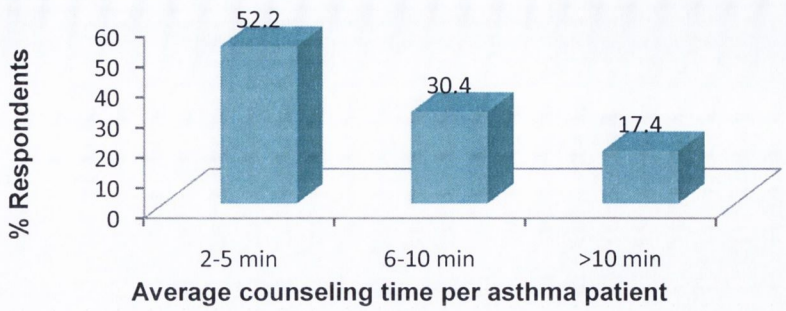


Figure 3.23: Average amount of time needed to counsel an asthma patient effectively (N = 23).

The average amount of time needed to counsel an asthma patient on his/her condition and the relevant medication was 8 minutes. The minimum and maximum recorded times were 2 minutes and 20 minutes respectively.

No significant difference was observed between the average amount of time spent counselling an asthma patient who was enrolled in the Demonstration Project compared with the amount of time spent counselling an asthma patient who was not officially enrolled *(N = 23, p = 0.11, ANOVA).*

3) *Acceptability of time needed to provide sufficient counselling to an asthma patient*

70% of respondents felt that the average amount of time needed to provide adequate counselling to an asthma patient was *acceptable* and 30% stated that it was *moderately acceptable.* None of the respondents felt that the amount of time needed was *unacceptable.*

No significant difference was observed when the item on the level of acceptability of the time needed for counselling was analysed in conjunction with the item on the average amount of time needed to provide sufficient counselling *(N = 23, p = 0.78, ANOVA).*

4) *Feasibility of incorporating counselling into daily practice*

78% of respondents believed that this level of counselling could be routinely incorporated into daily practice. Only 22% did not believe that this would be possible. This result was independent of the average amount of time needed by respondents to provide sufficient counselling to an asthma patient *(N = 23, p = 0.13, ANOVA).*

5) Percentage of asthma patients counselled following launch of Demonstration Project

The mean percentage of asthma patients that respondents counselled in detail, following the launch of the Demonstration Project was 40%. The minimum and maximum percentages were 0% and 100% respectively (*N = 19).* Four respondents were not able to provide a percentage estimate.

6) Patients' receptiveness to counselling

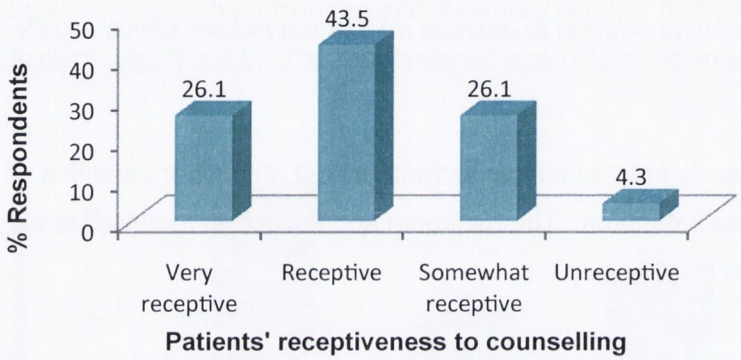


Figure 3.24: Patients' degree of receptiveness to asthma counselling provided by the pharmacist (N = 23).

7) Patients' understanding of their medications prior to counselling

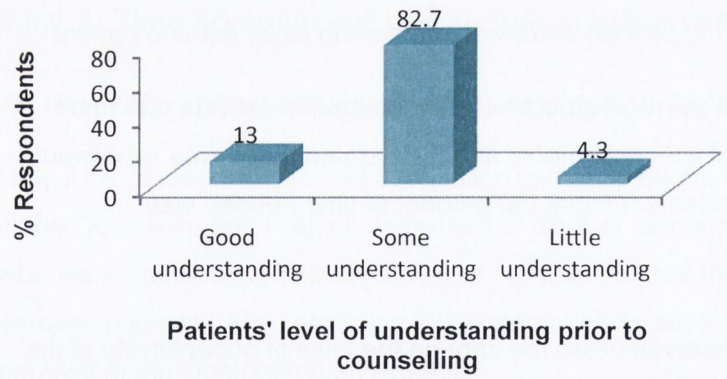


Figure 3.25: Patients' level of understanding of their asthma medications prior to counselling (N = 23).

8) Patients' ability to use their inhalers prior to counselling

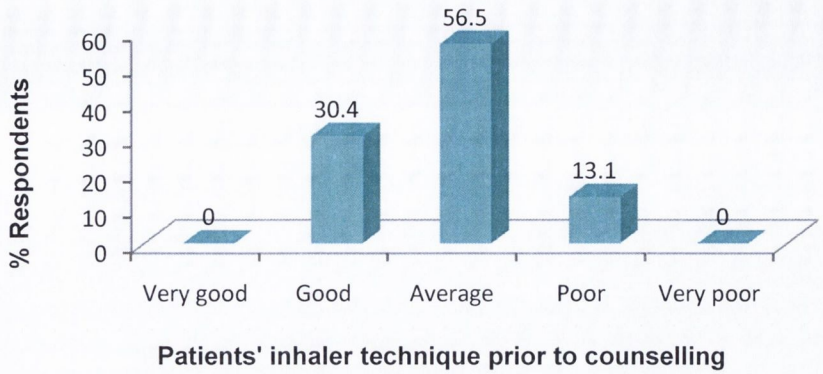


Figure 3.26: Patients' ability to use their inhalers properly prior to counselling (N = 23).

9) Need for placebo inhalers, demonstration spacers and demonstration peak flow meters when counselling asthma patients

Respondents were asked to rate the necessity of having placebo inhalers, demonstration spacer devices and demonstration peak flow meters available when counselling their asthma patients and their responses are outlined in the table below.

Table 3.8 Need for placebo inhalers, demonstration spacers and demonstration peak flow meters when counselling asthma patients

Device	Not essential (%)	Quite essential (%)	Neutral (%)	Essential (%)	Totally essential (%)
Placebo inhalers	**0.0**	**8.7**	**8.7**	**26.1**	**56.5**
Demonstration peak flow meters	**4.3**	**13.0**	**21.7**	**30.4**	**30.4**
Demonstration spacers	**0.0**	**13.0**	**13.0**	**30.4**	**43.5**

3.5.1.3. Interprofessional communication with GPs and practice nurses

1) Frequency of communication relation to Demonstration Project

Respondents were asked to rate the frequency with which the communicated with the GP and the practice nurse about the Demonstration Project and the results are outlined in the table below.

Table 3.9 Frequency of interprofessional communication

Health-care professional	Once or twice a week (%)	Once a month (%)	Less than once a month (%)	Not at all (%)
GP	13.0	26.1	26.1	34.8
Practice nurse	13.6	22.7	9.1	54.5

2) Level of satisfaction with frequency and method of communication

Respondents were asked to rate their satisfaction with the frequency and method of communication with the GP and the practice nurse and their responses are outlined below

Table 3.10 Satisfaction with frequency and method of interprofessional communication

	Satisfactory (%)	Fairly satisfactory (%)	Unsatisfactory (%)	N/A (%)
Method of communication: GP	52.2	17.4	4.3	26.1
Method of communication: Nurse	36.4	18.2	4.5	40.9
Frequency of communication: GP	52.2	17.4	30.4	-
Frequency of communication: Nurse	54.5	13.6	31.8	-

N/A: Not applicable due to absence of interprofessional communication

3.5.1.4. Success and feasibility of the project

Respondents were asked if they thought the Demonstration Project was a success and whether a similar project would be feasible on a national scale. The results are outlined below.

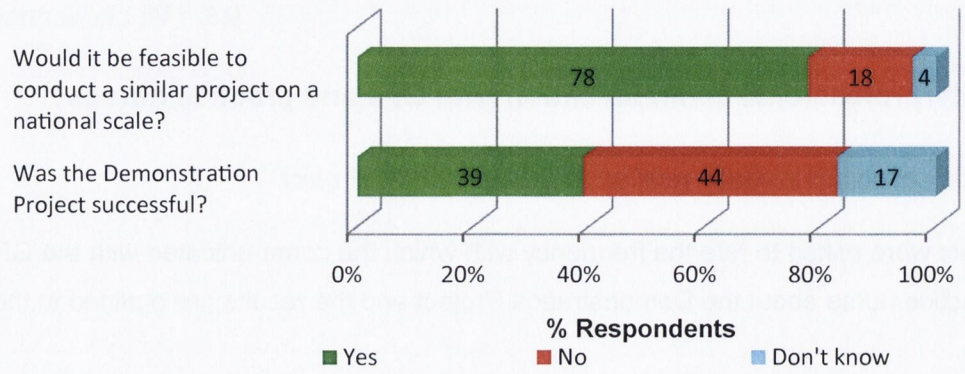


Figure 3.27: Respondents' opinions on the success and feasibility of this project (N = 23).

3.6. Discussion: Demonstration Project

3.6.1. Baseline data on asthma management

It is evident that, at baseline, a significant proportion of patients did not have well controlled asthma as the mean ACT score was 17.7 and an ACT score of <20 is an indication that asthma is not well controlled and the patient may need an evaluation to determine methods to improve control[386]. In addition, at least one quarter of patients were absent from work/school or were nebulised due to asthma and >40% were prescribed oral steroids for an asthma exacerbation in the last 12 months. In the majority of patients, it is possible to attain and maintain asthma control[387] with the appropriate pharmacological regimen developed in partnership between the patient/carer and the doctor[1]. Thus, it is possible that a sizeable proportion of these patients were not being treated according to best practice guidelines for asthma management at baseline.

3.6.2. Provision of advice by the pharmacist on inhaler technique

3.6.2.1. Baseline data

Prior to the commencement of the Demonstration Project, only ~23% of patients indicated that they had ever received advice from their pharmacist on inhaler technique. Similarly poor results were observed in the literature: 8-13% of patients indicated that they had received counselling from their pharmacist on inhaler technique[48,175]. Indeed, 54-72% of patients reported that they received no counselling from pharmacists on presenting a new prescription[388,389].

Incorrect inhaler technique is associated with poor asthma control and increased risk of hospitalisation, emergency department visits, and courses of oral steroids[9,10]. In addition, incorrect use of inhalers can reinforce poor medication adherence arising from a belief that the medication is ineffective[150]. Incorrect inhaler technique is very common across all types of inhalation devices. In a meta-analysis of randomised control trials, the percentage of patients who performed the inhaler technique correctly prior to an intervention was 59% (DPI) and 43% (pMDI) [280].

It was observed that a greater proportion of younger patients (1-18 years) than adults received advice on inhaler technique. Paediatric counselling on inhaler technique is a vital component of appropriate asthma management in children. In a recent study[70] of ~300 asthmatic children; 9-22% of them had incorrect inhaler technique highlighting the importance of paediatric training on inhaler technique. In a study[75] investigating the

determinants of correct paediatric inhaler technique, it was concluded that repeated education on inhalation technique was the key factor essential to correct technique achievement and maintenance.

The mean number of years with asthma was 15.25 years, thus it is possible that some of these patients did receive training on inhaler technique when the device was initially prescribed but have forgotten due to the time lag. However, irrespective of this point, it is clear that the majority of pharmacists are not counselling their patients on inhaler technique routinely or reinforcing correct technique.

This point is reinforced by the results of the QAM-CP (Chapter 2). 89% of respondents indicated that they *always/often* demonstrate the use of a newly prescribed inhalation device to an asthma patient, but only 10% stated that they *always/often* routinely check a patient's inhalation technique. Erickson and colleagues[136] reported similar findings: Prior to an educational intervention, 85% of pharmacists surveyed stated that they educate patients on inhaler technique when they are prescribed a pMDI initially, but only 21% indicated that they educate and assess patients on inhaler technique if they have been using an pMDI device for an extended period. Similarly, Ovchinikova and colleagues[48] reported that 78% of asthma patients surveyed indicated that they had never received reinforcement on inhaler technique from any health-care professional. Research has shown that in order to maintain correct inhalation technique, education on technique must be repeated regularly[41]. In addition, Takemura and colleagues[238] demonstrated that repeated education on inhaler technique was significantly and positively related to good adherence to the patient's therapeutic regimen.

The fact that pharmacists do not appear to be regularly reinforcing correct inhaler technique may be due to a number of factors. Firstly, it may be due to a lack of knowledge about the decline in inhaler technique over time in the absence of repeated education. A recent study[136] assessed pharmacists' attitudes, knowledge and beliefs about educating patients on MDI technique. Following a four hour educational intervention, the percentage of pharmacists who strongly agreed with the statement *it is important to frequently assess patients' MDI technique* significantly increased from 5% to 31%.

It may also be due to time constraints in a busy pharmacy, in particular where there is only one pharmacist working on any given day. In the aforementioned QAM-CP, ~85% *strongly agreed/agreed* that time is a major factor that influences their ability to counsel. This was supported by a survey of community pharmacists in New Zealand where 87% of

respondents agreed that time was a major barrier to the implementation of pharmaceutical care[207].

A significantly greater proportion of patients who visited their GP >4 times, or who used a nebuliser, or who were absent from school, due to asthma in the last 12 months, received advice from their pharmacist on inhaler technique than those who did not. From these results, it would appear that a greater proportion of patients with poor asthma control received advice on inhaler technique than those patients with controlled asthma. While it is encouraging to see patients with poorly controlled asthma receiving advice on inhaler technique, it does suggest that the majority of pharmacists are not proactively counselling patients on correct technique; rather they appear to be reacting when patients' asthma control deteriorates.

In addition, a greater proportion of patients who had spirometry measurement or who received written information/education about asthma, received advice from their pharmacist on inhaler technique, than those who did not. It is possible that patients informed about their lung function, or who have received written information about their disease may have a greater interest in asthma self-management and may be better equipped to do so. Indeed, knowledge about asthma is essential for effective self-management of the disease[222]. Consequently, these patients may have actively sought inhaler technique instruction from their pharmacist or they may have been more open to such counselling than patients without such interest/knowledge about their disease or its management.

3.6.2.2. Second/subsequent appointment data

Following the initiation of the Demonstration Project the proportion of patients who received advice from their pharmacist on inhaler technique increased by ~9%. The possible reasons for this small increase will be discussed in detail in 3.7. However, in brief, 79% of pharmacists who participated in the Exit Interview stated that they had not knowingly counselled any asthma patients who were officially enrolled in the project *(N = 29)*. There may be a number of reasons for this. Firstly, there were 23 GPs and 73 pharmacies enrolled in the project. Of these pharmacies, only 36 were located in close proximity to a participating GP practice; it was not possible to recruit every pharmacy in the locality. Consequently, a proportion of patients may have frequented pharmacies that were not involved in the project. In addition, a number of pharmacists stated that it was difficult to identify the patients that were involved in the project as none of the pharmacists surveyed encountered patients who identified themselves with the official Demonstration Project enrolment card. Furthermore, participating pharmacists were not provided with a

clearly defined protocol for patient counselling, or any supporting documentation on the procedure for conducting such counselling. The limited communication between the GP and/or practice nurse and the pharmacist may also have contributed to this poor result.

3.6.3. Provision of advice by the pharmacist on the peak flow meter

3.6.3.1. Baseline data

Only 4.2% of patients stated that had ever received advice from their pharmacist on the peak flow meter. This result was independent of patients' demographic data. One of the key reasons for this may be the small number of asthma patients who have a peak flow meter that they use regularly to monitor their asthma. Results of the QAM-CP, QAM-GP and QAM-PN (Chapter 2) revealed that, the mean percentage of asthma patients estimated to have a peak flow meter that they used regularly was 11%-18%. Similarly, in the literature, regular peak flow meter use among asthma patients ranged from 0-13%[151,390].

Best practice guidelines indicate that peak flow measurements can be an important support in monitoring asthma control[1]. Peak flow measurements can provide an early indication of deteriorating asthma before the patient experiences any physical symptoms. Consequently, a peak flow meter should be considered an essential tool in monitoring one's level of asthma control.

There are a number of possible reasons for the infrequent use of peak flow meters: patient-related factors and health-care professional factors. For patients, cost may be a factor prohibiting use. The average cost of an adult peak flow meter is ~€25 and it is not reimbursable by any of the PCRS schemes. In addition, patient preference may be an issue. Harver and colleagues[227] conducted a survey on patient preference and they discovered that those surveyed preferred to monitor their asthma symptoms than peak flow rate to detect deteriorating asthma control. The authors concluded that the reason for this preference might be explained by the degree of effort required for both practices. Measuring peak flow rate requires significantly more patient effort than symptom monitoring, a task that that simply requires attention to be focused on breathing[227]. However, the use of peak flow rate measurement to monitor asthma has been proven to be a more accurate tool than symptom self-monitoring which tends to lead to the underestimation of asthma severity and inappropriate medication usage[179].

For health-care professionals, insufficient knowledge or skill on the correct use of the peak flow meter may prevent them from counselling patients. Infrequent counselling on the peak flow meter may also be related to beliefs about poor patient compliance in using the devices regularly and effectively. In this instance, health-care professionals may believe that recommending their patients to use a peak flow meter to monitor their asthma will have little or no impact and so they rarely make such recommendations. Cabana and colleagues investigated barriers to adherence to asthma guidelines among paediatricians using focus groups[249] and a cross-sectional survey[231]. One of the guidelines investigated was the instruction of patients on regular use of the peak flow meter. The reasons for nonadherence recorded from both investigations were a lack of confidence in their skills and a belief that recommending the device would be ineffective[231,249].

A significantly greater proportion of patients with a personal written asthma action plan received advice from their pharmacist on the peak flow meter. This result is logical as an asthma action plan is devised using a patient's personal peak flow rate or symptoms, thus use of a peak flow meter is often essential for its appropriate usage. Consequently, as more of these patients were using peak flow meters, a greater proportion of them received advice on their appropriate use than patients who did not have an asthma action plan.

A greater proportion of patients who had spirometry measurement or who received written information/education about asthma, received advice from their pharmacist on the peak flow meter, than those who did not. A similar result was observed in 3.6.2.1 and the same possible reasons are applicable, *i.e.* these patients may be more concerned about their health and more proactive in seeking advice on the peak flow meter or more receptive to such counselling, than patients who have not had spirometry measurement or received written education on their asthma.

3.6.3.2. Second/subsequent appointment data

The proportion of patients who received advice from their pharmacist on the peak flow meter increased by 9.5%, following the commencement of the Demonstration Project. The possible reasons for such a minimal improvement, discussed in 3.6.2.2, are also valid in this instance.

A significantly greater proportion of patients who received a prescription for oral steroids for their asthma over the last 12 months received advice from their pharmacist on the peak flow meter than patients who did not need oral steroids. From this result, it would appear that pharmacists are more frequently advising patients about the peak flow meter as a monitoring tool following an exacerbation rather than promoting its use as a

preventative tool when a patient's asthma is well controlled. However, consideration must also be given to the fact that patients may be more receptive to advice when they are ill rather than when they feel well.

Patients who received advice from their pharmacist on the peak flow meter had significantly higher ACT scores, indicating better-controlled asthma, than patients who did not receive such advice. This result is promising as it indicates that advising patients on the use of a peak flow meter as a monitoring tool may contribute to improved asthma control.

3.6.4. Pharmacist-patient discussion on a patient's asthma medications

3.6.4.1. Baseline data

Only ~24% of patients indicated that their pharmacist had ever discussed their asthma medications with them. This result was independent of patients' demographic data. As discussed in 3.6.2.1 above, it is possible that some patients may have received counselling on their asthma medications when they were prescribed initially but due to the long intervening period, this may have been forgotten. This is supported by results from the QAM-CP (Chapter 2) where ~90% of respondent pharmacists indicated that they *always/often* provide their patients with verbal information on new asthma medications. However, regardless of this possibility, the results of this survey highlight the fact that few pharmacists are having routine discussions with their patients about their asthma medications.

This result is quite concerning as pharmacists are trained in pharmacology and so should be an invaluable source of information and advice on all aspects of medication. However, from this result it would appear that patients are not benefiting from this knowledge.

Patient adherence to therapeutic regimens for chronic diseases is poor. According to a WHO report[391] ~50% of patients with a chronic illness do not use their medications as prescribed. Adherence rates for asthma are particularly problematic, generally ranging from 30-70%[392].

Horne and Weinman[196] conducted a survey of asthma patients in primary care to investigate the role of patient beliefs about asthma and its treatments on adherence to ICS. They concluded that patients with the greatest doubts about the need for ICS,

together with concerns about possible side effects, had the highest nonadherence rates. The converse was also true. Consequently, to improve adherence to ICS all health-care professionals need to educate patients on the importance of ICS in the treatment of asthma and address patients' concerns about the side effects of ICS[237]. Pharmacists, in particular, could play a key role in addressing the necessity/concerns barrier to adherence for a number of reasons: Firstly, they see asthma patients more frequently than any other health-care professional in primary care, due to the need for prescription refills. In addition, information from PMRs provides them with a unique insight into patient adherence. Finally, they are equipped with an in-depth knowledge of pharmacology that would benefit their patients and help allay any fears/concerns they may have about their medication. Thus, an increase in pharmacist-patient discussions about their asthma medications is essential to improve adherence to therapeutic regimens.

A number of studies[157,171,217,218,374,393] have demonstrated that community pharmacy-led interventions have resulted in improved therapeutic outcomes for asthma patients. These interventions included education on asthma as a disease, education on the prescribed medications, addressing any medication adherence issues, education on lifestyle issues such as trigger factors, and training on correct inhaler technique. Outcomes included an increase in adherence to preventative therapies[171,374,393] and a reduction in reliever usage[171,217,218], a reduction in asthma severity[157,171,217,218,393], an increase in health-related quality of life[171,218] and a reduction in health-care utilisation[218]. The majority of the more successful studies[171,217,393] were based on a collaborative goal setting process between the pharmacist and the patient, to encourage asthma self-management. Personally relevant and specific goals encourage the patient to invest more energy into addressing the problems and resulting behavioural change is more likely[171].

A significantly greater proportion of patients who were absent from work/school due to asthma had a discussion with their pharmacist about their asthma medications than those who were not absent. A similar result was observed in 3.6.2.1 above and further reinforces the theory that pharmacists appear to be counselling patients reactively when asthma control deteriorates, rather than proactively when their asthma is well controlled.

In addition, a significantly greater proportion of patients who received written information/education on asthma or who received a personal written asthma action plan had a discussion with their pharmacist about their asthma medications than those who did not receive such information/plans. A similar result was observed in 3.6.2.1 and 3.6.3.1 and the same possible reasons are also valid in this situation.

3.6.4.2. Second/subsequent appointment data

No significant difference in the proportion of patients who discussed their asthma medications with their pharmacist was observed following the initiation of the Demonstration Project.

As observed in 3.6.2.1 and 3.6.3.1 a significantly greater proportion of patients who received written information/education on asthma or who received a personal written asthma action plan had a discussion with their pharmacist about their asthma medications than those who did not receive such information/plans. The same possible reasons for this are applicable here.

3.6.5. Querying use of reliever inhaler by the pharmacist

3.6.5.1. Baseline data

Only ~4% of patients indicated that they had ever had their reliever use queried by their pharmacist. This result is very concerning as ~54% of patients reported using their reliever inhaler at least 3 times per week and, of these, ~18% indicated usage of at least 2 puffs daily. Reliever usage >2 times/week is one of the indicators of inadequate asthma control and signifies the need for an evaluation of preventative therapy[1,394]. Excessive reliever use has been associated with an increased risk of an asthma exacerbation, demonstrated by an increased likelihood of hospitalisation or ED visit due to asthma[395].

As discussed in 3.6.4.1, pharmacists are the only health-care professionals in primary care with access to information on patient adherence to prescribed medication via the PMRs. This information provides them with a unique insight into patient reliever use, and consequently their level of asthma control, facilitating their ability to intervene and counsel the patient appropriately. The PMR can provide an indication of medication overuse, for example frequent dispensing of reliever inhalers, but if a patient verbally chooses not to get a medication dispensed, this information is only obtainable directly from the prescription. In addition, it is important to note that medication dispensed does not necessarily indicate patient adherence. A patient may decide not to take the dispensed medication at all (in particular if he/she obtains the medication free of charge) or may take it in a manner other than that prescribed.

Data from PMRs were successfully used by community pharmacists in Australia to identify patients whose asthma was not believed to be well managed due to evidence of excessive reliever use[180]. These patients were advised to undergo an asthma

management review with their GPs. The intervention resulted in a threefold increase in preventer-to-reliever ratio in the intervention group compared with the control group and a higher proportion of ICS therapy usage among the intervention group compared with the control group.

Furthermore, a community pharmacist-led intervention targeting excessive SABA dispensing resulted in a 67% reduction in the number of patients who received >1 SABA MDI per month[396]. The intervention involved a written or verbal request to the prescriber to reduce the number of SABA pMDIs prescribed to < 1 per month if deemed appropriate, by the prescriber, for optimum patient care. Thus, pharmacists, in conjunction with prescribers, can have a positive impact on the over-dispensing of SABA inhalers by querying excessive reliever prescribing.

A significantly greater proportion of patients aged 19-35 years had their reliever use queried by their community pharmacist than older or younger patients. When patients' reliever use was analysed according to their age range, it was observed that patients aged 19-35 and 36-55 years used their reliever inhalers significantly more frequently than patients in the youngest or oldest age range categories. This high reliever usage may explain why patients aged 19-35 years had their reliever use queried more frequently than older or younger patients. However, as patients aged 36-55 years also used their reliever inhalers more frequently than younger/older patients; one would have expected that their usage would have been queried as frequently as those aged 19-35 years.

As observed in 3.6.2.1 and 3.6.3.1, a significantly greater proportion of patients who received written information/education about asthma had their reliever use queried by their pharmacist than those who did not receive such written information. It is possible that in this situation patients were provided with educational materials on asthma in an effort to demonstrate to them that patients with well controlled asthma do not need to use their reliever inhaler >2 times/week. The Living and Breathing study[241] illustrated that the majority of asthma patients surveyed had low expectations of disease management. Prior to being shown the asthma symptom management goals outlined in the GINA guidelines[1], 58% of patients stated that they were satisfied with their level of asthma care. However, this dropped to 33% when patients were shown the symptom management goals. These results indicate that many patients are not aware of the level of asthma control that is achievable for many asthmatics when treated according to best practice guidelines[1].

3.6.5.2. Second/subsequent appointment data

Following the commencement of the Demonstration Project the proportion of patients who had their reliever use queried by their pharmacist increased by ~8%. This result corresponds with the increases observed in 3.6.2.2 and 3.6.3.2. The same possible reasons for such a small increase are also valid in this instance.

3.6.6. Counselling by any health-care professional on inhaler technique

3.6.6.1. Baseline data

Approximately 18% of patients indicated that they had never received any counselling from a health-care professional on inhaler technique. As discussed in 3.6.2.1, a proportion of these patients may have received, and forgotten about, counselling on inhaler technique when the device was prescribed and dispensed initially, but the fundamental point is that a significant proportion of patients had not received routine counselling on inhaler technique.

The results from the literature on receipt of inhaler technique instruction from health-care professionals varied considerably. A large multi-centre Italian study[9] reported that one third of patients reported receiving no previous education on inhaler technique. Conversely, studies in Korea[34] and Australia[48] reported that 96-100% of patients had received previous instruction on inhaler technique from a health-care professional.

Melani and colleagues[9] highlighted the importance of providing instruction on inhaler technique by demonstrating that lack of education on inhaler technique increased the risk of a patient performing a 'critical error' (an error that would make inhalation therapy ineffective) in inhalation technique. Furthermore, patients who had their inhalation technique checked at least once had a lower risk of performing a critical error than those who had no technique reinforcement[9].

Counselling on inhaler technique varied according to age range. A significantly greater proportion of patients > 35 years had never received counselling on inhaler technique compared to patients < 35 years. To ensure correct inhaler technique in children, individual education with repeated practical demonstration is necessary when a new device is prescribed initially[397]. Thus, the fact that the majority of children had received counselling on inhaler technique from at least one health-care professional is encouraging. However, it has been widely reported that increasing age is associated with

an increased risk of incorrect inhaler technique[9,16,398]. Thus, it is concerning that ~23% of patients > 55 years reported that they never received counselling on inhaler technique from any health-care professional.

A significantly greater proportion of patients who experienced an asthma exacerbation or deterioration in their asthma control, evidenced by the need for nebulisation or absenteeism from work/school, received counselling on inhaler technique from both their GP/practice nurse AND their pharmacist, than those with better asthma control. A similar situation was observed in 3.6.2.1 and 3.6.4.1, and as discussed above, it is evident that counselling on inhaler technique is predominantly occurring reactively rather proactively among all three groups of health-care professionals.

Similarly to 3.6.2.1 and 3.6.3.1, a significantly greater proportion of patients who received an asthma action plan or who received written information on asthma received counselling from a health-care professional on inhaler technique than those who did not. The aforementioned possible reasons for this result are also valid in this situation.

A significantly greater proportion of patients who received counselling from any health-care professional on inhaler technique had a higher ACT score (indicating better asthma control) than patients who did not receive such counselling. This result highlights the importance of correct inhaler technique in asthma control and illustrates how health-care professionals can positively influence disease control. Basheti and colleagues[104] demonstrated that a simple pharmacist-led intervention on inhaler technique repeated at 1, 2, 3, and 6 month intervals improved perceived asthma control[399] of test patients compared to control patients.

3.6.6.2. Second/subsequent appointment data

Following the commencement of the Demonstration Project only ~5% of patients indicated that they had never received counselling on inhaler technique from any health-care professional, an improvement of ~13%. This result is encouraging as it demonstrates the successful implementation of the project. However, as only 32% of patients indicated that they had received counselling from their pharmacist on inhaler technique following the commencement of the project, it is likely that a large proportion of the counselling that occurred after the second/subsequent GP appointment was conducted by GPs and/or practice nurses.

3.6.7. Counselling by any health-care professional on the peak flow meter

3.6.7.1. Baseline data

Approximately 55% of patients indicated that they had never received counselling from any health-care professional on the peak flow meter. Similar results were observed in the literature with 39%[231]-48%[199]% of physicians indicating that they instructed their patients to use a peak flow meter regularly to monitor their asthma control.

The possible reasons for the infrequent recommendation and use of peak flow meters are discussed in 3.6.3.1.

A relationship was observed between patients' age and counselling by a health-care professional on the peak flow meter. A significantly greater proportion of the oldest patients (>55 years) never received counselling by a health-care professional on the peak flow meter. This result is concerning because elderly patients frequently have a reduced ability to recognise asthma symptoms and deteriorating control[400,401]; consequently, use of an objective measure such as peak flow rate would be beneficial in aiding the identification of airway obstruction.

A significantly greater proportion of patients who appear to have an interest in their asthma and its management (*i.e.* those who have received the influenza vaccine, had spirometry measurement, received written information about asthma, possess an asthma action plan, or have an Asthma Attack card) were counselled by a health-care professional on the peak flow meter. This result is logical especially as one of the barriers mentioned to recommending the regular use of a peak flow meter was poor patient compliance[231]. It is likely that patients with an interest in asthma self-management will be more compliant in using a peak flow meter than those with less interest.

3.6.7.2. Second/subsequent appointment data

Following the initiation of the Demonstration Project the proportion of patients who had never received counselling from any health-care professional decreased by ~40%. This is a substantial decrease and highlights the successful implementation of this aspect of the project. However, it is likely that a large proportion of the counselling that occurred after the second/subsequent GP appointment was conducted by GPs and/or practice nurses as the proportion of patients who received advice from their pharmacist on the peak flow meter only increased by 9.5% at the follow-up consultations.

A significantly greater proportion of patients who received oral steroids for their asthma were counselled by both their GP/practice nurse AND their pharmacist than those who did not need a prescription for oral steroids. This result illustrates the possibility that all three groups of health-care professionals may still be counselling their patients reactively, on deteriorating asthma control, rather than proactively, despite the initiation of this project.

Patients' ACT scores differed significantly according to the absence/presence of counselling on the peak flow meter and the degree of counselling. Patients who were counselled by both their GP/practice nurse AND their pharmacist had the highest mean ACT score, followed by those who were counselled by one health-care professional. Patients who received no counselling on the peak flow meter had the lowest mean ACT score, indicating a lower degree of asthma control. Furthermore, patients who received no counselling on use of the peak flow meter had a mean ACT score of 18.4 $\pm$ 1 (S.E), whereas patients who received such counselling had a score of >20. An ACT score of <20 is an indication that asthma is not well controlled and the patient may need an evaluation to determine methods to improve control[386]. A multi-disciplinary approach to asthma self-management in Switzerland, involving physicians, pharmacists and specialised nursing staff, has been shown to improve asthma control, reduce patients' need for emergency health-care utilisation, and reduce absenteeism due to asthma[355].

3.6.8. Limitations of the study

This study has a number of limitations. Firstly, the participating GPs were not randomly selected to participate in the study, they either expressed an interest in the study following an announcement in the medical press, the practice was an ICGP Research practice, or it had an established Primary Care Team. As a result, the participating GPs might have had a greater interest in asthma or chronic disease management than the overall GP population in Ireland and thus, their asthma patients might have received better asthma care prior to the commencement of the study than asthma patients in the general population. Consequently, the baseline results obtained might not be reflective of the overall asthma population; it is likely that at least a proportion of the general asthma population are receiving a lower standard of asthma care than that reflected in the baseline results. Secondly, the four questions relating to the provision of asthma care by the pharmacist were reliant on participants' recall ability. As the mean duration of asthma was ~15 years it is possible that a proportion of participants might have incorrectly recalled whether their pharmacist *ever* provided them with advice on an asthma-related issue, thus leading to the possible introduction of recall bias[402].

3.7. Discussion: Evaluation Project

3.7.1. Time commitment and communication with asthma patients

3.7.1.1. Counselling of patients enrolled in Demonstration Project

All of the twenty-two pharmacists interviewed were working in community pharmacies in the same locality as a GP who was participating in the Demonstration Project but only five of these had knowingly counselled asthma patients who were enrolled in the project. There may be a number of reasons for this finding. Firstly, according to the PSI Annual Report 2010 there are currently 1728 retail pharmacy businesses on the PSI register in Ireland[403], However, every pharmacy that was located within the proximity of a participating GP did not express an interest in participating in the project, in response to a memorandum circulated by the IPU. Thus, it is possible in some instances that asthma patients who were enrolled in the project did not frequent one of the participating pharmacies and this may have contributed to the low rates of counselling observed.

In addition, it is plausible that patients, who were participating in the project, did attend a participating community pharmacy and were simply not identified as participating patients. This may have been due to patient-related or pharmacist-related factors. The patients themselves may not have identified themselves as participants in the Demonstration Project despite the fact that each patient was provided with a 'membership card' on enrolment. Indeed, personal communication with a number of the participating pharmacists revealed that none of them had ever encountered this card. However, it is also possible that the pharmacists themselves were not proactive in seeking out participating patients, thus if the patients did not identify themselves they may have been overlooked. In late 2009, the PSI commissioned a study on community pharmacy practice in Ireland that consisted of a nationwide survey of community pharmacists and follow-up qualitative interviews with approximately 40 community pharmacists across the country[404]. One of the areas investigated in the survey was the time that community pharmacists spent on various pharmacy activities in a typical week. They discovered that >80% of respondents spent ***most*** *of the time on most days* dispensing prescriptions whereas only ~43% of respondents spent ***some*** *of the time on most days* providing patients with advice on long-term conditions. Furthermore, results from the qualitative interviews revealed that many believed that the workload in pharmacy had increased in comparison with the preceding years and an increase in administration and paperwork was identified as one of the contributing factors in conjunction with an increase in the range and complexity of pharmacological therapies available[404]. In addition, the absence of a clearly defined protocol for patient counselling may have contributed to the low rates of counselling.

Participating pharmacists were provided with a pack containing inhaler technique checklists and a booklet of carbon copies of a checklist for completion following a patient consultation. This checklist contained 4 items and accompanying tick-boxes, but there was no accompanying documentation on the procedure for conducting each aspect of patient counselling identified in the checklist and so it was open to interpretation by the participating pharmacists. Consequently, insufficient time due to the increased workload and the amount of time spent on dispensing prescriptions, in addition to the lack of a clearly defined protocol on patient counselling, may have contributed to pharmacists' failure to identify and counsel patients who were enrolled in the project and who attended their community pharmacy.

Insufficient interprofessional communication may also have contributed to the low counselling rates of enrolled patients and this will be discussed in 3.7.2 below.

3.7.1.2. Time needed for counselling, it's acceptability and feasibility in daily practice

A considerable variation was observed in the amount of time needed to provide sufficient counselling to asthma patients. This is likely to be due to the lack of provision of a clearly defined protocol for patient counselling to the participating pharmacists. As discussed in 3.7.1.1 above, the procedure for conducting patient counselling was not outlined to the participating pharmacists, thus it was subject to their own interpretation. Indeed, in a comparison study conducted by McLean and MacKeigan[376] on four community pharmacy-based studies of pharmaceutical care for asthma patients, one of the factors associated with optimal health outcomes for patients was the existence of a comprehensive pharmaceutical care protocol. As the majority of participating pharmacists did not counsel any enrolled patients, they were asked to answer the questions in this section about counselling their asthma patients overall. However, as no significant difference was observed in the amount of time spent counselling enrolled patients versus those who were not believed to be enrolled; the results of this section were treated as a single group.

Despite the variation in the time needed for the provision of adequate patient counselling none of the respondents believed that the amount of time needed was *unacceptable* and ~80% felt that this level of patient counselling could be feasibly incorporated into routine practice. These results are quite surprising in comparison with the published literature in this area and may be reflective of the absence of a clearly defined protocol for the provision of enhanced counselling to asthma patients beyond that routinely provided in conjunction with the medications dispensed. Berbatis and colleagues[405] investigated the

barriers and facilitators to the provision of enhanced services in community pharmacies in Australia using data from Australia's National Pharmacy Database Project. The enhanced services were defined as *health-related services provided in pharmacies other than the routine provision of prescribed and non-prescribed therapeutic agents*[405]. The greatest barrier to the provision of enhanced services was insufficient time, >90% of respondents agreed/strongly agreed that this was a barrier. Shortage of pharmacists and lack of remuneration were also identified by 78% and 63% respectively as representing significant barriers to providing enhanced services. Blenkinsopp and colleagues[406] conducted a national evaluation of the community pharmacy contractual framework (CPCF), introduced in the UK in April 2005, by surveying a stratified random 10% sample of Primary Care Organisations in England and Wales. The CPCF introduced three levels of pharmacy services; essential, advanced and enhanced pharmacy-based services with the underlying aim of providing remuneration to community pharmacists for the quality rather than the volume of service provided[406]. One of the items in the survey was an open question that asked respondents to identify the barriers they perceived to the implementation of the CPCF. Similarly to the results of the aforementioned Australian study[405], insufficient time was the most frequently identified barrier (55%), followed by financial reimbursement (25.5%) and funding to employ the additional staff needed (19%)[406].

3.7.1.3. Asthma patients and counselling

Approximately 70% of respondents thought that, on average, their asthma patients were *very receptive/receptive* to counselling. This result is accordance with the results of the QAM-CP (Chapter 2) where 78% of respondents *strongly agreed/agreed* that their asthma patients were receptive to counselling. Conversely, an exploration into the perceptions of health-care professionals and patients on asthma management in New South Wales revealed that pharmacists considered the patient to be the most significant barrier to asthma management due to their attitude towards both asthma and a lack of understanding of the potential role of the pharmacist in asthma management[182].

Greater than 80% of respondents stated that, on average, the asthma patients whom they counselled only had *some understanding* of the indications for their asthma medications prior to counselling. Saini and colleagues[144] conducted a community pharmacy-based educational intervention on asthma patients and they administered the Consumer Asthma Knowledge Questionnaire[383] to the enrolled patients prior to the commencement of the study. Many of the items in this questionnaire relate to knowledge about asthma medications and the results at baseline revealed that many patients had a limited understanding of their asthma medications. 36% of respondents believed that asthma

medications were addictive if used all the time, 46% believed that one should use 'preventer medication' in the event of an asthma attack and ~30% believed that irregular use of preventative medication was not a problem[144].

Only ~30% stated that their patients' inhaler technique was *good* prior to counselling and this result is in accordance with the published literature[148,280].

Greater than 82% of respondents stated that placebo inhalers were *totally essential/essential* when counselling asthma patients. This result is encouraging, as research has demonstrated the importance of providing a physical demonstration when counselling on inhaler technique. Basheti and colleagues[175] conducted a pilot study to compare the effectiveness of three different approaches to counselling on Turbohaler technique. The three methods were: (1) verbal counselling with the aid of printed patient information leaflets on inhaler technique, (2) augmented verbal counselling that consisted of verbal counselling as in (1) with additional emphasis on the four steps considered essential for correct use of a Turbohaler, and (3) augmented verbal counselling in conjunction with a physical demonstration using a placebo inhaler. Two weeks after the initial visit, patients' inhaler technique was assessed and the patients in group (3) had significantly higher inhaler technique scores that those in groups (1) and (2) signifying the importance of providing a physical demonstration when counselling patients on inhaler technique[175].

3.7.2. Interprofessional communication

3.7.2.1. Frequency of communication with other health-care professionals

Communication between pharmacists and both GPs and practice nurses who were participating in the Demonstration Project was very infrequent. Indeed >60% of respondents communicated with both GPs and nurses either *less than once a month* or *not at all*. Interestingly, following the launch of the CPCF in the UK 80% of pharmacists surveyed stated that their contact with local GPs had not increased despite the fact that the medicines use review , an advanced service, requires the pharmacist to send a copy of the medicines use review report to the GP including any recommended medication changes[406].

The infrequent communication between participating pharmacists and both GPs and nurses may also have contributed to the small numbers of enrolled asthma patients who were counselled by participating pharmacists. Communication between the respondent and either the participating GP or nurse about the identities of the enrolled patients could

have facilitated their detection when they attended the community pharmacy and thus may have increasing the counselling rates of these patients. It is also possible that the participating GPs and practice nurses were not adequately informed of the role of the community pharmacist in this study and consequently may not have advised their patients to identify themselves to their community pharmacists when they collected their prescriptions. However, communication initiation by pharmacists with both GPs and nurses could have facilitated an increased awareness about the role of the pharmacist in the project thus possibly leading to an increase in the rate of counselling of enrolled patients by pharmacists.

Many studies suggest that collaborative patient care between pharmacists and physicians can improve patient outcomes in a range of areas such as hypertension[351,353,407], diabetes[347,348], hyperlipidaemia[354,408], and depression[356]. Consequently, it is vital that the barriers and facilitators to inter-professional collaboration are identified and addressed. McDonough and Doucette developed a theoretical framework for the collaborative working relationships between physicians and pharmacists[267]. They identified three types of variables that can affect the development of a collaborative working relationship: participant, context and exchange characteristics. Participant variables relate to the characteristics of the individual practitioners and include demographics, education/training and psychological traits. Context variables refer to the practice environment and include the practice setting and the professional interaction between the physician and pharmacist. Exchange variables encompass the nature of social exchanges and the extent of the relationship between the two professionals (*e.g.* trust, role specification)[267].

Two exchange variables, trustworthiness and role specification, and one context variable, professional interaction, were identified by both pharmacists[209] and primary care physicians[210] as being significantly associated with collaborative care. Trustworthiness is essential to the development of any relationship, not just collaborative relationships[409-411]. As time progresses, the consistent demonstration of the pharmacist's competency through useful recommendations stimulates the development of trust by the physician in his/her abilities[209,210]. The same is true for the pharmacist's trust in the physician. As trust develops, communication between the two professionals improves and becomes more open. Indeed the performance of health-care teams has been shown to be enhanced by communication and trust[412,413]. In order to enhance trust in other health-care professionals an awareness about their skills, education and training is essential. A lack of awareness among GPs about pharmacists' training and contribution to patient care has been suggested[211,214]. This could be addressed by the combined education of both professions at undergraduate and postgraduate level.

Role specification was also highlighted as a vital component in the development of a collaborative relationship. Collaboration appears to be associated with the joint determination of specific roles and responsibilities by both professionals[209]. This leads to interdependence and an improved collaborative working relationship[210]. The importance of role specification is further emphasized by the results of a study on the barriers to improved inter-professional relationships between GPs and community pharmacists[214]. Both GPs and pharmacists expressed strong views on their professional roles and standing in primary care. GPs were concerned that an extension of the role of the pharmacist would encroach on the realm of general practice. Pharmacists also stated their belief that an extension of their role would be viewed in this light. Many also stated that GPs considered them professionally inferior. Thus, the initial demarcation of individual roles through open communication is imperative in founding a collaborative working relationship.

Professional interaction was the only context variable related to the successful establishment of pharmacist/physician collaboration[209,210]. This association is logical as it indicates that the greater the frequency of bidirectional communication the greater the extent of collaboration between the two parties. Indeed such bidirectional communication has been demonstrated in effective multi-disciplinary teams[414]. It is likely that an increase in interdependence would lead to an increase in the frequency of communication[209,211].

The two main variables that may have been neglected by a significant number of pharmacists involved in the Demonstration Project were relationship initiation and role specification.

Concerning practice nurses, 86% of respondents to the survey of community pharmacists indicated that they had no communication with practice nurses about asthma patients. It must be considered that not all GP surgeries employ a practice nurse but this does not explain such low levels of communication among the majority of respondents. The main barriers indicated by respondents to communication with the practice nurses were a lack of knowledge about their identity and a means of contacting them.

Similarly, in the literature, a survey[215] aimed at exploring the views of community pharmacists about nurse prescribing and collaborative care discovered that approximately two-thirds of pharmacists had contact with a nurse prescriber less than once every three months. However, the study revealed an enthusiasm among pharmacists to actively engage with nurse prescribers and develop an inter-professional working relationship.

Indeed, there is evidence in the literature to support the collaboration of community pharmacists and practice nurses in the improvement of patient outcomes[318,321].

3.7.2.2. Satisfaction with communication

Despite the fact that only ~13% of respondents had regular communication with the participating GP or nurse >50% were satisfied with the current frequency of communication. The aforementioned PSI commissioned study[404] on baseline community pharmacy practice also revealed that ~60% of respondents were very satisfied/satisfied with their relationships with the local doctors, but no information was sought on the nature of these relationships. Dey and colleagues[208] investigated the opinions and expectations of GPs and community pharmacists working in Western Sydney, on collaborative care for asthma management, using semi-structured interviews. They discovered that while most pharmacists and GPs believed that they had good working relationships with the other health-care professionals a more in-depth discussion revealed that minimal collaboration existed between the two groups, the relationship that existed was basic in nature[208]. Thus, it is possible that the reason the majority of pharmacists are satisfied with the infrequent communication with GPs is because they have not experienced collaborative relationships and so are unaware of the benefits that such collaboration can provide[271].

3.7.3. Success and feasibility of the project

The majority of respondents thought that the Demonstration Project was unsuccessful or they were unable to provide an opinion about its level of success. This result is unsurprising due to the minimal engagement that the majority of respondents had with the project. Interestingly, despite the minimal involvement of most respondents in the project ~80% did believe that it was feasible to roll out this asthma management programme on a national scale. This result can be interpreted in two different ways. Firstly, the respondents may believe that engaging in a programme on asthma management that involves collaboration with other health-care professionals in an effort to improve patients' asthma care should be embraced regardless of the work involved, as it would represent one of the first efforts at interprofessional collaboration in Ireland. Indeed, the results of the qualitative interviews, conducted as part of the aforementioned study commissioned by the PSI, revealed that one issue that arose in almost every interview was the feeling among pharmacists that as a profession they are being consistently *undervalued, underestimated and under-recognised* in the current healthcare system in Ireland[404]. Therefore, it is possible that respondents are keen to alter this view of pharmacy by collaborating with other health-care professionals in an attempt to improve patient care. A second interpretation of the result may be that, due to their minimal involvement in the

Demonstration Project they may not be aware of the time and effort involved, at least initially, around collaboration in chronic disease management. In the afore-mentioned study by Dey and colleagues[208] while both the pharmacists and GPs interviewed believed that collaboration between the two professions would benefit patient care, significant differences were evident in their expectations of each other, their perceptions of the needs of the asthma patient, in addition they also appeared to have a limited understanding of each other's knowledge and expertise. These issues would all need to be addressed to facilitate successful interprofessional collaboration.

3.7.4. Limitations of the study

The main limitation of the study was that the survey was conducted as an interview thus prohibiting respondent anonymity. As a result, the responses might have been biased by social desirability. However, prior to the commencement of the interview the researcher emphasized the fact that she was not affiliated with the ASI and that all responses would be confidential and recorded anonymously. Secondly, all of the participating pharmacists volunteered to participate in the Demonstration Project following the circulation of a memorandum from the IPU thus, it is likely that they had a greater interest in asthma care and interprofessional collaboration than the overall community pharmacist population. Consequently, their responses, particularly, in relation to the feasibility of implementing a nationwide asthma management programme might not be representative of the overall community pharmacist population. The participating pharmacists might have a greater interest in expanding the professional role of the pharmacist than a proportion of their colleagues and this might be reflected in their responses to this aspect of the interview. In addition, it is possible that they provide their asthma patients with more counselling on asthma than a proportion of their colleagues in general population and so their patients might not be representative of the overall asthma population.

3.8. Conclusion: Demonstration Project

It is evident from the results of the Demonstration Project that a significant proportion of asthma patients have never received advice from any health-care professional on inhaler technique. Community pharmacists do not appear to be regularly assessing and reinforcing correct inhaler technique. Indeed, much of the counselling on inhaler technique appears to be conducted as a result of deteriorating asthma control, *i.e.* pharmacists are not counselling patients on inhaler technique proactively. The provision of a physical demonstration of correct inhaler technique when counselling patients has proven to be more effective than verbal or written instructions[9,175]. Studies[41,43,104] have shown that the repeated provision of practical education on inhaler technique by community pharmacists has led to an improvement in patients' inhaler technique, a reduction in asthma severity and an improvement in clinical outcomes.

Pharmacists should be educated on correct inhaler technique prior to educating patients as studies have shown that health-care professionals often perform the same errors in inhaler technique as their patients[42,176,177]. In addition, the education needs to include the importance of repeated reinforcement of inhaler technique due to its deterioration over time[148].

Pharmacists have frequently indicated that insufficient time is a major barrier to effective patient counselling[136,174,207]. However, inhaler technique education of patients has been reported to take an average of just 2.5-5 minutes[41,104], thus facilitating its inclusion in daily practice.

The majority of patients do not appear to have received counselling from any health-care professional on the peak flow meter. This is particularly marked among community pharmacists. Once again, education is essential; pharmacists should be educated about the importance of the peak flow meter as an objective monitoring tool for asthma. GINA guidelines recommend guided self-management of asthma[1]. A key component of self-management is the personalised written asthma management plan where patients adjust their medication in response to changes in their asthma control, as evidenced by symptoms and/or peak expiratory flow, according to written predetermined guidelines[168,169,415]. Education on self-management involving self-monitoring of asthma control, using peak expiratory flow or symptoms, in conjunction with regular review and the use of personal written asthma action plan resulted in a one-third to two-thirds reduction in hospitalisations, emergency room visits, unscheduled GP visits, absenteeism

and nocturnal wakening[170]. Thus, the peak flow meter is an important component in asthma self-management.

Cost appears to be an importance issue with peak flow meters. If the device was reimbursable under the PCRS, it is likely that a greater proportion of patients would be willing to obtain it.

As discussed, patients' adherence to their therapeutic regimen for asthma is poor. Much of the nonadherent behaviour may be driven by a lack of belief about necessity for ICS and fears over possible side-effects to long-term treatment[196]. The PMR and verbal engagement with patients at the point when prescriptions are presented for dispensing can provide pharmacists with a unique insight into nonadherent patients and they are optimally placed to discuss asthma medications with patients, to allay fears and emphasize the importance of chronic treatment. The evidence[157,171,217,218,374,393] for the successful implementation of pharmaceutical care models for asthma treatment in community pharmacies is extensive and emphasizes the potential impact that pharmacists could have on asthma management in Ireland.

A number of significant relationships were observed between counselling by pharmacists and other factors, but it is important to note that these associations may not be causative; they may be due to an underlying unidentified reason.

Following the commencement of the Demonstration Project, little improvement in counselling patients by community pharmacists was observed. One of the key reasons for this appeared to be a lack of communication between pharmacists and both GPs and practice nurses. Team-based patient care has been identified as a vital means of improving patient health in primary care, particularly due to the lack of physician time[264]. A systematic review and meta-analyses of the effect of pharmacist-provided patient care concluded that pharmacist-provided care resulted in favourable effects on therapeutic and safety outcomes[416]. This result supports the inclusion of pharmacists as members of the primary health-care team. To conclude, there is significant scope for the improvement of asthma management in primary care by pharmacists in collaboration with both GPs and practice nurses.

3.9. Conclusion: Evaluation Project

It is evident from the results of this study that, overall, community pharmacists who expressed an interest in participating in the Demonstration Project as their local GP was involved, had minimal involvement in the project. It is possible that the predominant reason for this lack of involvement was the infrequent communication between the two groups and lack of a pre-defined role for pharmacists. The establishment of a collaborative working relationship between GPs and practice nurses and community pharmacists is positively associated with the establishment of trust, consistent bidirectional communication and a comprehensible specification of individual roles[209,210]. Prior to fostering collaboration in primary care, there is a need to increase communication between pharmacists and both GPs and practice nurses. The absence of sustained reciprocal communication is likely to impede the development of collaborative working relationships[211] to the detriment of patient care[264]. Furthermore, as the pharmacists did not appear to encounter enrolled patients it was their responsibility to initiate communication with the GP in order to begin collaboration on this project. However, it is possible that pharmacists did attempt to establish communication with their local GPs and were not successful. Indeed, one of the barriers to successful collaboration identified by pharmacists was their difficulty in contacting the local GPs[214]. A detailed description of the many potential barriers to pharmacist-GP and pharmacist-nurse collaboration has been discussed in Chapter 2 and it is possible that these may also have contributed to pharmacists' minimal involvement in the project. Patients' limited understanding of their asthma medications and inadequate inhaler technique illustrate that the current health-care system in Ireland, where minimal collaboration exists, is inadequate but hopefully the National Asthma Project, which focuses on interprofessional collaboration and is currently in development (discussed in Chapter 6) will help to improve asthma management nationwide. In addition, respondents appear to be receptive to such a nationwide project on asthma management.

4. Review of Asthma-specific Quality of Life instruments for adults

4.1. Introduction

The availability of disease-specific health related quality of life instruments has grown exponentially over the last twenty years. There are numerous possible reasons for this: Firstly, it has been recognised that focusing solely on the anatomical and pathophysiological parameters of chronic disease provides an incomplete understanding of a patient's experience[417]. In addition, research has consistently highlighted a discrepancy between physician and patient ratings of quality of life, functional status and emotional well being, whereby physicians tended to overestimate a patient's physical and emotional well-being[418-420]. The prevalence of asthma is increasing as urbanisation and the adoption of the western lifestyle increases[421]. This, in combination with the fact that many chronic diseases cannot be cured, has elevated the importance of quality of life measurements as a vital outcome variable[422].

There is an abundance of asthma-specific health related quality of life instruments currently available. However, there is a paucity of information comparing the quality of these instruments among the adult population. The two most recent studies reviewing asthma-specific quality of life instruments are either lacking in the comprehensiveness of the instruments included for review[423] or do not provide guidance to researchers on the most appropriate instrument for a particular type of study[424]. In contrast, this review provides a comprehensive review of the characteristics and psychometric properties of nine asthma-specific quality of life instruments for adults and provides guidance on selecting the most suitable instrument for a particular application.

4.2. Methods

A detailed literature review was performed using the MEDLINE, EMBASE and Web of Science electronic databases to facilitate the preliminary identification of the quality of life instruments. Keyword searches included 'asthma-specific quality of life', 'disease specific quality of life', 'disease-specific health status measures', 'asthma-specific health status instruments',' respiratory disease specific health status instruments',' asthma' and 'quality of life'. The resulting instruments were subsequently analysed and excluded if they did not fulfil the following criteria: (1) the instrument must be specific for asthma; it may also be used in patients with COPD but such an instrument must have been designed

specifically for use in both asthma and COPD patients and not COPD patients alone or for the general population (*e.g.* the Chronic Respiratory Disease questionnaire[425] was designed specifically for patients with chronic airflow limitation, not asthmatic patients and so was excluded from this study) ; (2) it must be designed for use in adults; (3) it must be developed and published originally in the English language, either UK or US English.

Following the identification of the instruments for inclusion in the study, additional searches were conducted using the aforementioned electronic databases. The full name or appropriate abbreviation of the instrument was used in a keyword search in the case of each instrument. In addition, a search was also performed using the first and/or corresponding author of each instrument in conjunction with keywords such as the name of the instrument, 'asthma', 'quality of life', 'health status'. A hand search of the cited references in the individual articles retrieved from the preliminary search was also conducted. Relevant journal articles were included in the analysis of the instrument if they were available in the English language.

4.3. Evaluation and review criteria

A framework for assessing and evaluating the quality of life instruments was designed following an analysis of the available literature on the subject[426-431]. The criteria employed in the evaluation are collated into nine categories as follows:

4.3.1. Basic features

4.3.1.1. Health related quality of life domains

The WHO defines health as 'a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity'[432]. Consequently, each instrument has been evaluated to determine if it encompasses the three health-related quality of life (HRQL) domains: physical, mental and social functioning.

4.3.1.2. Breadth of health

Description of the specific dimensions measured by the instrument, and the number of questions.

4.3.1.3. Response measures

The number of response options available for each question.

4.3.1.4. Recall period

The period of time over which respondents are asked to recall events. This recall period may vary throughout the instrument.

4.3.1.5. Descriptive statistics

The presence of ceiling and floor effects, and missing data following administration.

4.3.1.6. Respondent burden

The average time taken to complete the instrument, and whether it is a self-administered or interviewer-administered instrument.

4.3.1.7. Administrator burden

For interviewer-administered instruments, the average time taken to administer the instrument, the level of training required to administer it appropriately, any requirement for additional personnel or resources to score or analyse the results.

4.3.1.8. Setting(s) in which the instrument can be used

4.3.1.9. Scoring of results

Basic definition of the results, *i.e.* does a higher score mean better or poorer quality of life? Is the resulting quality of life score defined as a single overall score or are there domain scores? The absence/presence of weighting.

4.3.2. Reliability

4.3.2.1. Internal consistency

A measure of the extent to which all aspects of the instrument are measuring the same underlying concept[427]. This is usually measured by Cronbach's coefficient α. Minimum acceptable standards are >0.7 for group comparisons and >0.9 for individual comparisons. For instruments with dichotomous response options the Kuder-Richardson formula 20 (KR-20) is utilised[426].

4.3.2.2. Test-retest reproducibility

This is assessed among respondents who are assumed to have remained stable on the domains being assessed[426] and is usually quantified with the Interclass Correlation Coefficient (ICC).

4.3.3. Validity

The validity of an instrument is defined as the extent to which an instrument measures what it claims to measure[426]. Validity is quantified by two different measures:

4.3.3.3. Content validity

Evidence that the content domain of the instrument encompasses, yet is restricted to, its intended use. Content validity is assessed by analysing the protocol used in developing the instrument.

4.3.3.4. Construct validity

Evidence that the proposed interpretation of the instrument scores accord with theoretical expectations. Construct validity is assessed by analysing the absence/presence of correlations between the instrument and other measures, such as markers of disease severity.

Criterion *validity* is usually also used as to measure validity. However due to the absence of a 'gold standard' instrument to measure asthma-specific health-related quality of life, this measure is not applicable in this case.

4.3.4. Responsiveness

Due to the absence of a 'gold standard', evidence for responsiveness includes analysis of the associations between changes in instrument scores and changes in other disease-specific measures and/or comparison with an external criterion, such as the views of the patient or expert practitioner, that a significant change has occurred[428].

4.3.5. Interpretability

Interpretability is defined as the extent to which an instrument's scores can be translated into qualitative results. Evidence for interpretability includes the development of the

minimum clinically important difference (MID), or the existence of comparative data on the distribution of scores derived from a health population.

4.3.6. Sensitivity

Sensitivity is defined as the ability of the instrument to detect differences between populations with varying degrees of disease severity.

4.3.7. Alternative forms

Alternative forms refers to the presence of modified versions of the original questionnaire. Evidence of comparability with the original instrument should be provided.

4.3.8. Cultural and language adaptations

An instrument that has been adapted for use in a different culture from that for which it was originally developed must be conceptually and linguistically equivalent to the original instrument. Information must be provided on the methods employed to achieve such equivalence. Linguistic equivalence is generally achieved using the standard 'forward-backward' method of translation.

4.3.9. Comparisons

Information on any comparative studies conducted on the instrument in question and other asthma-specific quality of life instruments and/or generic quality of life instruments.

4.4. Results

4.4.1. Asthma Quality of Life Questionnaire: E. F. Juniper (AQLQ-J).

The AQLQ-J was developed by E.F. Juniper *et al.* at the McMaster University, Hamilton Ontario, Canada and first published in 1992[433].

1. BASIC FEATURES		
(a)	**HRQL domains**	
	(i) Physical	✓
	(ii)Mental	✓
	(iii)Social functioning	✓
(b)	**Breadth of health**	
	(i) Dimensions measured[433]	• Activity limitation (AL): 11 Qs including 5 individualised Qs • Symptoms (S): 12 Qs • Emotional function (EF): 5 Qs • Exposure to environmental stimuli (ES): 4 Qs
	(ii) No. of questions	32
(c)	**Response measures**	7 point Likert scale
(d)	**Recall period**	Preceding 2 weeks
(e)	**Descriptive statistics**	
	(i) Ceiling effects	0[434] -72.1%[435]
	(ii) Floor effects	0.4%[435]
	(iii) Missing data • Overall instrument • AL subscale (overall) • AL subscale (5 individualised Qs only)	 • 3-7%[435]to 19.8%[436] • 15.5%[436] • 29.1%[437]
(f)	**Respondent burden**	
	(i) Self-administered	✓
	(ii) Interviewer-administered	✓
	(iii) Time for completion	Avg. time: 5-10 min[433,438]
(g)	**Administrator burden**	
	(i) Level of training	Not specified
	(ii) Additional resources	Not required
(h)	**Setting(s)**	Clinical trials[433]
(i)	**Quality of life score**	Higher score = better quality of life
	(i) Scoring:	Overall score and 4 individual subscale scores
	(ii) Weighting	x

2. RELIABILITY		
(a)	**Internal consistency** (Cronbach's α)	
	• AL • S • EF • ES	• 0.88-0.95[435,439,440] • 0.91-0.93[435,439-441] • 0.84-0.87[435,439,440] • 0.67-0.80[435,439,440]
(b)	**Test-retest reproducibility**	
	(i) Time period	1 - 4 weeks
	(ii) ICC overall	0.82 - 0.94[438-442]
3. VALIDITY		
(a)	**Content validity**	
	(i) Item selection sources	• Generic QOL instruments[443,444] • Work by Kinsman *et al.*[445] on severe asthmatic patients • Patient experiences of asthma[446] • Consultations with chest physicians[442] • Unstructured interviews with asthma patients[442]
	(ii) Item reduction process	• Items with highest frequency-importance product[447] chosen • Repeated pre-testing on asthmatic patients
(b)	**Construct validity**	
	(i) FEV_1 % predicted	Correlation: weak - moderate *Weak*: S = 0.02-0.21[439,441,442], P = 0.09- 0.41[438,440] *Moderate*: S = 0.37-0.42[435]
	(ii) PEFR	Correlation: weak S = 0.04-0.16[442]
	(iii) PC_{20}	Correlation: no correlation - weak S = 0.00-0.14[442]
	(iv) FEF_{25-75}	Correlation: weak P = 0.21-0.31[435]
	(v) Asthma control[448]	Correlation: weak - strong S = 0.31-0.69[442]
	(vi) ADSS	Correlation: weak - moderate/strong S = -0.31 to -0.53[439,441] P = -0.52 to -0.85[440]
	(vii) Respiratory symptoms	Correlation: moderate - strong P = 0.55-0.77 (excluding the ES domain which was weak in magnitude)[438] S = -0.55 to -0.67[435]
	(viii) SIP • Physical • Psychological • Overall	• Correlation: weak - moderate S = 0.28-0.52[442], P = 0.43-0.58[438] • Correlation: weak S = 0.30-0.40[442], P = 0.19-0.23[438] • Correlation: moderate S = -0.48[449]

	(ix) SF-36 (PCS)	Strongest correlation with AL: moderate in strength S = 0.56[439], P = 0.51[435]
	(x) HUI	Correlation: weak - moderate Weak: S = 0.13-0.26[441] Moderate: P = 0.40 - 0.53[439]
	(xi) EQ-5D summary index	Correlation: moderate P = 0.40-0.57[440]
	(xii) RGHS	Strongest correlation between AL and Physical domain of RGHS: strong in magnitude, S = 0.81[442]
	(xiii) Cantril's Ladder[450]	Correlation: weak S = 0.15-0.26[439]
4. RESPONSIVENESS		
	(i) FEV_1% predicted Time period: 4 weeks	Correlation: weak - moderate S = 0.27-0.43[442]
	(ii) PC_{20} Time period: 4 weeks	Correlation: weak S = 0.26-0.30[442]
	(iii) PEFR Time period: 4 weeks	Correlation: weak - moderate S = 0.33-0.4[442]
	(iv) Asthma control Time period: 4 weeks	Correlation: moderate - strong S = 0.40-0.67[442]
	(v) Medication requirements Time period: 4 weeks	Correlation: weak - moderate S = 0.30-0.50[442]
	(vi) SIP (Time period: 4 weeks) • Physical • Psychosocial • Overall	• Correlation: weak S = 0.17-0.24[442] • Correlation: no correlation - weak S = 0.00-0.27[442] • Correlation: weak S = -0.31[449]
	(vii) RGHS (Time period: 4 weeks) • Physical domain • Emotional domain	• Correlation: weak - moderate S = 0.36-0.51[442] • Correlation: weak, S = 0.30-0.37[442]
	(viii) Global rating of change Time period: 7-10 days	Correlation: moderate - strong P = 0.44-0.77[438]

5. INTERPRETABILITY		
(a)	**Interpretability data**	✓
(b)	**Form of interpretability data**	MID = 0.5[451]
6. SENSITIVITY		
	(i) Ability to discriminate between asthma severity groups using ADSS	Yes[440,441]
	(ii) Ability to discriminate between asthma severity groups using PSRS	Yes[441]
7. ALTERNATIVE FORMS		
(a)	Standardised AQLQ-J (AQLQ(S)-J)[452]	• Measures same construct as AQLQ-J • Five individualised activities are replaced by five generic activities • Recall period and response options remain the same as AQLQ-J
(b)	Mini AQLQ-J[384]	• Measures same construct as AQLQ-J • 15 item questionnaire which retains the four domains of the AQLQ-J • No individualised questions • Recall period and response options remain the same as AQLQ-J
(c)	Acute AQLQ-J[453]	• Measures QOL in patients with acute severe asthma requiring hospitalisation • 11 item questionnaire divided into 2 domains; S and EF • Recall period = previous half hour • Response options remain the same as AQLQ-J
8. CULTURAL AND LANGUAGE ADAPTATIONS		
(a)	**Languages available**	26
(b)	**Countries in which it has been utilised**	61
	Linguistic equivalence was established using the standard 'forward-backward' translation method[454-456]. Little, if any reference, was made to attempts to establish conceptual equivalence with the original instrument[454-456], with the exception of one study[457].	

Q = question; QOL = quality of life; FEV1% predicted = Forced Expiratory Volume in one second % predicted; S = Spearman's rank order correlation coefficient; P = Pearson's product moment correlation coefficient; PEFR = peak expiratory flow rate; PC_{20} = airway responsiveness to methacholine; FEF = Forced Expiratory Flow from 25%-75% of vital capacity; ADSS = Asthma Disease Severity Scale; SIP = Sickness Impact Profile; SF-36 = Medical Outcomes Study Short-Form 36; PCS Physical Component Summary; HUI = Health Utilities Index; EQ-5D = European Quality of Life-5 Dimensions; RGHS = Rand General Health Survey; MID = minimum clinically important difference; PSRS = Physician Severity Rating scheme

4.4.2. The Asthma Quality of Life Questionnaire G.B. Marks: (AQLQ-Mks)

The AQLQ-Mks was developed by Marks *et al.* in the University of Sydney and first published in 1992[458].

1. BASIC FEATURES		
(a)	**HRQL domains**	
	(i) Physical	✓
	(ii)Mental	✓
	(iii)Social functioning	✓
(b)	**Breadth of health**	
	(i) Dimensions measured[458]:	• Breathlessness and physical restrictions (B): 5 Qs • Mood disturbance (M): 5 Qs • Social disruption (S): 7 Qs • Concerns for health (C): 7 Qs A number of questions fall into two subscales
	(ii) No. of questions	20
(c)	**Response measures**	5-point Likert scale
(d)	**Recall period**	Preceding 4 weeks
(e)	**Descriptive statistics**	
	(i) Ceiling effects	No published data identified
	(ii) Floor effects	
	(iii) Missing data	
(f)	**Respondent burden**	
	(i) Self-administered	✓
	(ii) Interviewer-administered	✗
	(iii) Time for completion	< 5 min[458]
(g)	**Administrator burden**	
	(i) Level of training	Not applicable
	(ii) Additional resources	None required
(h)	**Setting(s)**	Clinical trials, clinical setting
(i)	**Quality of life score**	Higher score = poorer quality of life[458]
	(i) Scoring:	Overall score and 4 individual subscale scores
	(ii) Weighting	✗

2. RELIABILITY		
(a)	**Internal consistency** (Cronbach's α)	
	(i) B	0.83-0.89[458-460]
	(ii) M	0.82-0.84[458-460]
	(iii) S	0.88-0.92[458-460]
	(iv) C	0.78-0.87[458-460]
	(v) Total	0.92-0.94[458-460]
(b)	**Test-retest reproducibility**[458]	
	Time period	Mean 24.0 days, SD 8.9
	ICC Total	0.80
3. VALIDITY		
(a)	**Content validity**	
	(i) Item selection sources[458]	• Focus group of 8 asthma patients • Interviews with asthma nurse educators • Personal clinical experience of the authors
	(ii) Item reduction process[458]	• Preliminary administration of draft questionnaire to 18 asthma patients • Principal component analysis
(b)	**Construct validity**	
	(i) FEV_1% predicted	Correlation: none[458]/none - weak[460] Weak: P = -0.14 to -0.17 (Total, S and C subscales only)
	(ii) $PD_{20}FEV_1$	Correlation: none
	(iii) No. of asthma medications	Correlation: weak[459]/weak - moderate[458] Weak: S = 0.19 - 0.23 Weak-moderate: S = 0. 37-0.43 (no correlation with M subscale)
	(iv) SF-36 • PCS • MCS	• Correlation: moderate - strong[460] P = -0.43 to -0.66 • Correlation: weak - moderate[460] P = -0.22 to - 0.60
4. RESPONSIVENESS		
	(i) Asthma symptoms Time period: mean 4.0 (SD 1.8) months	Correlation: only observed with S subscale, moderate in strength P = 0.52[461]
	(ii) PEFR Time period: mean 4.0 (SD 1.8) months	Correlation: only observed with S subscale, moderate in strength P = 0.51[461]
	(iii) SIP • Total • Psychosocial Time period: mean 4.0 (SD 1.8) months	• Correlation: none[461] • Correlation: none[461]
	(iv) $Log_{10}DRR$	Correlation: only observed with total score and S

	Time period: mean 4.0 (SD 1.8) months	subscale, weak to moderate in strength P = 0.38-0.47[461]
	(v) Sleep disturbance Time period: 6 months	Correlation: weak - moderate S = 0.39-0.43 (results published for total score and B subscale only)[462]
	(vi) β-agonist use	Correlation: weak - moderate S = 0.38-0.43(results published for total score and B subscale only)[462]
	(vii) Activity limitation	Correlation: weak - moderate S = 0.36-0.57(results published for total score and B subscale only)[462]
5.	**INTERPRETABILITY**	
(a)	**Interpretability data**	x
(b)	**Form of interpretability data**	x
6. SENSITIVITY		
(a)	Ability to distinguish between varying degrees of disease severity	Yes[460,461]
7. ALTERNATIVE FORMS		
(a)	Modified AQLQ-Mks (MAQLQ-Mks)[463]	• Measures same construct as AQLQ-Mks • Modified to increase reliability and responsiveness • 22 item questionnaire; 2 combined activities items separated into 4 individual items • Response options modified to 7-point Likert scale • Recall period same as original
8. CULTURAL AND LANGUAGE ADAPTATIONS		
(a)	**Languages available**	Exact data not evident from published literature
(b)	**Countries in which it has been utilised**	Exact data not evident from published literature
	Gupchup *et al.*[464]adapted the questionnaire for the Native American population and considerable effort was taken to establish both conceptual and linguistic equivalence with the original instrument. For many of the adaptations of the original instrument little published data are evident on attempts to establish conceptual equivalence[465,466]. There is evidence of linguistic equivalence in most cases[465,466].	

$PD_{20}FEV_1$ = Bronchial responsiveness; MCS = Mental component summary; DRR = dose-response ratio.

4.4.3. Living with Asthma Questionnaire: M. E. Hyland (LWAQ)

The LWAQ was developed by M.E. Hyland *et al.* at the University of Plymouth (then named Polytechnic South West) and first published in 1991[467].

1. BASIC FEATURES		
(a)	**HRQL domains**	
	(i) Physical	✓
	(ii)Mental	✓
	(iii)Social functioning	✓
(b)	**Breadth of health**	
	(i) Dimensions measured	• Social/leisure: 6 Qs • Sport: 3 Qs • Holidays: 3 Qs • Sleep: 4 Qs • Work and other activities: 6 Qs • Colds: 5 Qs • Mobility: 6 Qs • Effects on others: 5 Qs • Medication usage: 5 Qs • Sex: 1 Q • Dysphoric states and attitudes: 23 Qs
	(ii) No. of questions	68
(c)	**Response measures**	4 response options: • Untrue of me • Slightly true of me • Very true of me • Not applicable
(d)	**Recall period**	Not specified
(e)	**Descriptive statistics**	
	(i) Ceiling effects	No published data identified
	(ii) Floor effects	
	(iii) Missing data	
(f)	**Respondent burden**	
	(i) Self-administered	✓
	(ii) Interviewer-administered	✓
	(iii) Time for completion	15-20 min
(g)	**Administrator burden**	
	(i) Level of training	None specified
	(ii) Additional resources	None required
(h)	**Setting(s)**	Clinical trials, out-patient management[467]
(i)	**Quality of life score**	Higher score = poorer quality of life
	(i) Scoring	Overall score, 11 domain scores, 2 construct scores (physical and mental)
	(ii) Weighting	✗

2. RELIABILITY		
(a)	**Internal consistency** (Cronbach's α)	
	(i) Total	0.94[468]
	(ii) Constructs	0.90-0.94[469]
	(iii) Domains (excluding sex domain)	0.57-0.91[469]
(b)	Test-retest reproducibility	
	(i) Time period: 2 months	0.95[467]
3. VALIDITY		
(a)	**Content validity**	
	(i) Item selection sources[467]	• 6 focus groups of asthma patients facilitated by the researcher • Contribution by the researchers
	(ii) Item reduction process[467]	Principal component analysis
(b)	**Construct validity**	
	(i) Morning PEFR	Correlation: none - weak[470]/weak[468] None- weak: correlation observed with the Activities and Avoidance constructs only, weak in magnitude P = -0.21 to -0.33 Weak: P = 0.26-0.36
	(ii) Asthma symptoms	Correlation: weak-moderate[468] P = 0.26-0.41
	(iii) β-agonist use	Correlation: none-weak[468] P = 0.24-0.27 (No correlation with mental construct)
	(iv) FEV_1	Correlation: weak [468] P = 0.21-0.23
	(v) PC_{20}	Correlation: weak [468] P = 0.22-0.35
	(vi) SIP	Correlation: moderate[449] S = 0.56 (total score)

4. RESPONSIVENESS		
	(i) PEFR	Correlation: none[449]/none-moderate [470,471] Correlation observed with Activities and Avoidance constructs only, P = 0.35 to 0.43[470] Correlation observed with physical construct only, P = 0.50-0.54[471]
	(ii) Asthma symptoms	Correlation: none-moderate/moderate None-moderate: P = 0.46-0.47 (no correlation observed with mental construct)[471] Moderate: S = 0.42[449]
	(iii) β-agonist use	Correlation: weak P = 0.25-0.32[471]
	(iv) FEV_1% pred.	Correlation: none[449]/none - weak[471] P = -0.30 (no correlation observed with mental construct)
	(v) SIP	Correlation: weak S = 0.31[449]
5. INTERPRETABILITY		
(a)	**Interpretability data**	x
(b)	**Form of interpretability data**	x
6. SENSITIVITY		
	Ability to distinguish between varying degrees of disease severity	Yes[472]
7. ALTERNATIVE FORMS		
(a)	Modified LWAQ (ms-LWAQ)[473]	Modified to reduce respondent burden and increase validity 27 item questionnaire consisting of 5 subscales: Consequences, Affect, Leisure, Seriousness and Drugs Response options are modified to three possible options: 0 = 'not at all true' 1 = 'somewhat true' 2 = 'very true'
8. CULTURAL AND LANGUAGE ADAPTATIONS		
(a)	**Languages available**	Exact data not evident from published literature
(b)	**Countries in which it has been utilised**	Exact data not evident from published literature
	There are little published data on attempts to establish conceptual equivalence with the original instrument[474]. There are limited data available on establishment of linguistic equivalence, but one such translation does not make reference to the 'forward-backward' method of translation or any equivalent method so it is not possible to determine whether linguistic equivalence was satisfactorily established[474].	

4.4.4. St. George's Respiratory Questionnaire: P.W. Jones (SGRQ)

The SGRQ was developed by P.W. Jones *et al.* in St. George's Hospital Medical School in London and was first published in 1991[475].

1. BASIC FEATURES		
(a)	**HRQL domains**	
	(i) Physical	✓
	(ii)Mental	✓
	(iii)Social functioning	✓
(b)	**Breadth of health**	
	(i) Dimensions measured	• Symptoms (S) • Activity (A) • Impacts (I)
	(ii) No. of questions	50
(c)	**Response measures**	• Symptoms: multiple response options that vary from question to question • Activity, Impacts: Yes/No
(d)	**Recall period**	These days, over the last 3 months/over the last year
(e)	**Descriptive statistics**	
	(i) Ceiling effects	0-4%[476]
	(ii) Floor effects	2-9%[476]
	(iii) Missing data	Instrument overall: 6.0%[436] 18.6 - 30.0% for question on 'playing sports causing shortness of breath'[477,478]
(f)	**Respondent burden**	
	(i) Self-administered	✓ (supervised)
	(ii) Interviewer-administered	✓
	(iii) Time for completion	10 minutes
(g)	**Administrator burden**	
	(i) Level of training	No published data identified
	(ii) Additional resources	Method and means to compute results due to weighting system
(h)	**Setting(s)**	Clinical trials
(i)	**Quality of life score**	Higher score = poorer quality of life
	(i) Scoring	Overall score, 3 domain scores
	(ii) Weighting	✓

2. RELIABILITY		
(a)	**Internal consistency** (Cronbach's α)	
	(i) Domain scales	>0.7[479]
	(ii) Total	>0.9[479]
(b)	**Test-retest reproducibility**	
	(i) Time period	2 weeks
	(ii) ICC total	0.91[480]
3. VALIDITY		
(a)	**Content validity**	
	(i) Item selection sources	• Source of items not clearly evident from published literature • Use of distress ratings to ensure the absence of confounding variables[481]
	(ii) Item reduction process[480]	Principal component analysis
(b)	**Construct validity**	
	(i) MRC RSQ • Cough • Sputum • Wheeze	• Correlation: weak R^2 = 0.03-0.35 • Correlation: none - weak R^2 = 0.06-0.24 (no correlation with A domain) • Correlation: weak R^2 = 0.12-0.32[480]
	(ii) FEV_1% pred.	Correlation: none - weak[480]/weak[436] None-weak: R^2 = 0.07-0.08 (no correlation with S domain)[480] Weak: S = ~0.1 to ~0.3[436]
	(ii) FVC% pred.	Correlation: weak R^2 = 0.06-0.20[480]
	(iii)Dyspnoea	Correlation: weak - moderate R^2 = 0.13-0.50[480] S = ~0.4 to ~0.55[436]
	(iv) 6-MWD	Correlation: weak R^2 = 0.07-0.35[480]
	(v) SIP • Total • Physical • Psychosocial	• Correlation: weak - moderate R^2 = 0.11-0.54 • Correlation: weak - moderate R^2 = 0.12-0.48 • Correlation: weak - moderate R^2 = 0.07-0.42[480] [Weakest correlation in each instance with S domain]
	(vi) HAD scale	Correlation: weak - moderate R^2 = 0.12 - 0.50[480]

4. RESPONSIVENESS		
	(i) FEV_1% pred.	Correlation: none[436]/weak[480] R^2 = 0.05 (total)
	(ii) FVC% pred.	Correlation: weak R^2 = 0.07 (total)[480]
	(iii)Dyspnoea	Correlation: weak[480]/none-moderate[436] R^2 = 0.22 (total) S = ~0.35 to ~0.45[436]
	(iv) 6-MWD	Correlation: weak R^2 = 0.22 (total)[480]
	(v) SIP Total Physical Psychosocial	• Correlation: weak R^2 = 0.10 (total) • Correlation: weak R^2 = 0.02 (total) • Correlation: weak R^2 = 0.02 (total)[480]
	(vi) HAD scale	Correlation: weak R^2 = 0.03-0.12[480]
5. INTERPRETABILITY		
(a)	**Interpretability data**	✓
(b)	**Form of interpretability data**	• General population reference norms stratified according to gender and age[479] • MID: 4.0[482]
6. SENSITIVITY		
	Ability to distinguish between varying degrees of disease severity	Yes[479,480]
7. ALTERNATIVE FORMS		
(a)	Modified SGRQ (MSGRQ)[478]	• Measures the same construct as SGRQ • Recall period for the S domain modified to 1 month to improve reliability and detection of clinical changes
8. CULTURAL AND LANGUAGE ADAPTATIONS		
(a)	**Languages available**	Exact data not evident from published literature
(b)	**Countries in which it has been utilised**	54 to date
	A number of research groups have published detailed accounts of their efforts to establish both conceptual and linguistic equivalence[476-478,483].	

FVC = Forced vital capacity; MRC RSQ = Medical Research Council Respiratory Symptoms Questionnaire; R^2 *= proportion of variance shared between the 2 variables; 6-MWD = 6 min. walking distance; HAD scale = Hospital Anxiety and Depression scale.*

4.4.5. The Asthma Bother Profile: M. E. Hyland.

The Asthma Bother Profile (ABP) was developed by Hyland *et al.* in the University of Plymouth in the UK and was first published in 1995[484].

1. BASIC FEATURES		
(a)	**HRQL domains**	
	(i) Physical	✓
	(ii)Mental	✓
	(iii)Social functioning	✓
(b)	**Breadth of health**	
	(i) Dimensions measured	• 'Asthma bother': 15 Qs • 'Management': 7 Qs
	(ii) No. of questions	22
(c)	**Response measures**	7- point Likert scale
(d)	**Recall period**	At present
(e)	**Descriptive statistics**	
	(i) Ceiling effects	No published data identified
	(ii) Floor effects	
	(iii) Missing data	
(f)	**Respondent burden**	
	(i) Self-administered	✓
	(ii) Interviewer-administered	×
	(iii) Time for completion	Not reported
(g)	**Administrator burden**	
	(i) Level of training	None specified
	(ii) Additional resources	Not relevant
(h)	**Setting(s)**	Out-patient setting
(i)	**Quality of life score**	Higher score = poorer quality of life
	(i) Scoring	Not specified
	(ii) Weighting	×
2. RELIABILITY		
(a)	**Internal consistency** (Cronbach's α)	
	(i) Asthma bother items	0.92[472,484]
(b)	**Test-retest reproducibility**	
	(i) Time period: 3-6 weeks	
	(ii) ICC Asthma bother items	0.88[472]

3. VALIDITY		
(a)	**Content validity**	
	(i) Item selection sources	• Five existing disease-specific QOL questionnaires: CRQ[446], LWAQ[467], SGRQ[480], AQLQ-J[433], AQLQ-Mks[458] • Content of focus groups of asthma patients conducted as part of an earlier study[467] • Questionnaire by Sibbald[485] on patient evaluation of self-management
	(ii) Item reduction process	Focus groups of asthma patients whose aim was to develop a 'patient-friendly' instrument[484].
(b)	**Construct validity**	
	(i) FEV_1% pred.	Correlation: none[472,486]
	(ii) Log(PD_{20}-FEV_1)	Correlation: none[486]
	(iii) 6-MWD	Correlation: moderate P = -0.54 ('asthma bother items')[472]
	(iv) MRC dyspnoea scale	Correlation: weak S = 0.28 ('asthma bother items')[486]
	(v) HADS • Anxiety • Depression	 • Correlation: strong S = 0.62 • Correlation: moderate S = 0.58[486]
	(vi) STAI • State • Trait	 • Correlation: moderate P = 0.59 • Correlation: moderate P = 0.57[472]
	(vii) SF-36	Correlation: significant with each of the eight domains, strongest correlation with the 'Physical functioning' and 'General health perceptions' domains. S = -0.30 to -0.64[486]
	(viii) LWAQ	Correlation: strong P = 0.85[472] S = 0.79[486]
	(ix) AQLQ-J	Correlation: weak- moderate S = -0.35 to -0.41[486]
3. RESPONSIVENESS: No published data identified		
4. INTERPRETABILITY: No published data identified		
5. SENSITIVITY		
	Ability to distinguish between varying degrees of disease severity	Yes[472]
7. ALTERNATIVE FORMS: No published data identified		

8. CULTURAL AND LANGUAGE ADAPTATIONS		
(a)	**Languages available**	2 identified
(b)	**Countries in which it has been utilised**	2
	Japanese and Norwegian adaptations of the instrument were identified in the published literature. However, no data on attempts to establish conceptual equivalence were evident[472,486]. Linguistic equivalence was referenced in the Norwegian adaptation [472].	

CRQ: Chronic respiratory disease questionnaire; PD_{20}-FEV_1 = dose of methacholine required to produce a 20% fall in FEV_1; STAI = Speilberger state and trait anxiety inventory

4.4.6. The Asthma Impact Survey: M. Schatz

The Asthma Impact Survey (AIS) was developed by Schatz *et al.* in the Kaiser Permanente Medical Centre, San Diego, U.S.A. and the Quality Metric Corporation, Lincoln, U.S.A. and was first published in 2007[487].

1. BASIC FEATURES		
(a)	**HRQL domains**	
	(i) Physical	✓
	(ii)Mental	✓
	(iii)Social functioning	✓
(b)	**Breadth of health**	
	(i) Dimensions measured	Daily living limitations
	(ii) No. of questions	6
(c)	**Response measures**	5-point Likert scale
(d)	**Recall period**	Past 4 weeks
(e)	**Descriptive statistics**	
	(i) Ceiling effects	No published data identified
	(ii) Floor effects	
	(iii) Missing data	
(f)	**Respondent burden**	
	(i) Self-administered	✓
	(ii) Interviewer-administered	x
	(iii) Time for completion	Not specified
(g)	**Administrator burden**	
	(i) Level of training	Not relevant
	(ii) Additional resources	None specified
(h)	**Setting(s)**	Outpatient setting
(i)	**Quality of life score**	Higher score = poorer quality of life
	(i) Scoring	Overall score
	(ii) Weighting	x
2. RELIABILITY		
(a)	**Internal consistency** (Cronbach's α)	0.95[487]
(b)	**Test-retest reproducibility**	No published data identified

3. VALIDITY		
(a)	**Content validity**	
	Item selection sources[487]	Bank of 52 items developed for computerised adaptive evaluation of asthma impact.
	Item reduction process[487]	Generalised partial credit item response theory model
(b)	**Construct validity**[487]	
	(i) Mini-AQLQ-J total	Correlation: strong S = -0.84
	(ii) ATAQ[488]	Correlation: strong S = 0.67
	(iii) AOMS[489]	Correlation: moderate S = 0.57
	(iv) Self assessment of general health	Correlation: moderate S = 0.52
4. RESPONSIVENESS: No published data identified		
5. INTERPRETABILITY: No published data identified		
6. SENSITIVITY: No published data identified		
7. ALTERNATIVE FORMS: No published data identified		
8. CULTURAL AND LANGUAGE ADAPTATIONS		
(a)	**Languages available**	Reference made to a Spanish adaptation however, no published data on this adaptation were identified.
(b)	**Countries in which it has been utilised**	Not evident

ATAQ = Asthma Therapy Assessment Questionnaire™; AOMS = Asthma Outcomes Monitoring System asthma symptoms severity tool

4.4.7. The Airways Questionnaire 20 items & the Airways Questionnaire 30 items: F. H. Quirk and P. W. Jones.

The Asthma Questionnaire 20 items (AQ20) and the Asthma Questionnaire 30 items (AQ30) were developed by Quirk and Jones in St. George's Hospital Medical School, London and they were first published in 1997[490]. This review will focus on the AQ20 as no advantage of the AQ30 over the AQ20 was found[491].

1. BASIC FEATURES		
(a)	**HRQL domains**	
	(i) Physical	✓
	(ii)Mental	✓
	(iii)Social functioning	✓
(b)	**Breadth of health**	
	(i) Dimensions measured	• Respiratory symptoms • Social/activity limitation • Emotional distress
	(ii) No. of questions	20
(c)	**Response measures**	Dichotomous: Yes/No/Not applicable
(d)	**Recall period**	Everyday life
(e)	**Descriptive statistics**	
	(i) Ceiling effects	None[491]
	(ii) Floor effects	At baseline, 3 months and 6 months: 3.7%, 18.3% and 30.3% respectively[492] Skewing towards the milder end also observed by Nishimura *et al.*[486]
	(iii) Missing data	No published data identified
(f)	**Respondent burden**	
	(i) Self-administered	✓
	(ii) Interviewer-administered	✓
	(iii) Time for completion	≤ 3 minutes
(g)	**Administrator burden**	
	(i) Level of training	None specified
	(ii) Additional resources	Not relevant
(h)	**Setting(s)**	Clinical trials, primary care setting, medical audits
(i)	**Quality of life score**	Higher score = poorer quality of life
	(i) Scoring	Overall score
	(ii) Weighting	✗

2. RELIABILITY		
(a)	**Internal consistency**	No published data identified
(b)	**Test-retest reproducibility**	
	(i) Time period	2 weeks
	(ii) P value between repeated administrations	0.93
	(iii) ICC	No published data identified
3. VALIDITY		
(a)	**Content validity**	
	(i) Item selection sources[493]	Six existing questionnaires: CRQ[425], AQLQ-J[433], LWAQ[467], SGRQ[480], MIMIC health index[494], Questionnaire on patients' attitudes and beliefs[495]
	(ii) Item reduction process [493]	Investigation of relationship with DS-5 and CH-5 Presence of confounding variables *e.g.* sex, age *etc.* Principal component analysis
(b)	**Construct validity**	
	(i) FEV_1% pred.	Correlation: none[486,491]
	(ii) FVC % pred.	Correlation: none[491]
	(iii) Log(PD_{20}-FEV_1)	Correlation: none[486]
	(iv) PEFR	Correlation: weak P = 0.23[491]
	(v) MRC dyspnoea scale	Correlation: weak S = 0.40[486]
	(vi) HADS	Correlation: moderate S = 0.42-0.44[486]
	(vii) β-agonist use	Correlation: weak P = 0.32[491]
	(viii) Diary card measures of asthma severity and impact	Correlation: moderate - strong P = 0.57-0.64[491]
	(ix) Sleep disturbance	Correlation: moderate P = 0.51[491]
	(x) LWAQ total	Correlation: strong S = 0.62[486]
	(xi) AQLQ total	Correlation: strong P = -0.80[491]
	(xii) SGRQ total	Correlation: strong P = 0.86[491]
	(xiii) SF-36	Significant correlation with 7 of the 8 domains, strongest correlation with the 'Physical functioning' domain S = -0.29 to -0.48[486]

4. RESPONSIVENESS		
	(i) FEV_1% pred. Time period: 12 weeks	Correlation: weak S = -0.40[486]
	(ii) AQLQ-J Time period: 12 weeks	Correlation: weak[491]/strong[492] Weak: P = -0.40 Strong: S = -0.62
	(iii) SGRQ Time period: 12 weeks	Correlation: moderate P = 0.46[491]
	(iv) LWAQ Time period: 12 weeks	Correlation: moderate S = 0.60[492]
5. INTERPRETABILITY: No published data identified		
6. SENSITIVITY		
	Ability to distinguish between varying degrees of disease severity	Yes[496]
7. ALTERNATIVE FORMS		
(a)	Modified AQ20 (MAQ20)[497]	• Measures same construct as AQ20 • Response options modified to include the response option 'unable' which was scored as '1'. • Modification undergone to reduce potential underestimation of patient's impairment
8. CULTURAL AND LANGUAGE ADAPTATIONS		
(a)	**Languages available**	Exact number not evident from published literature; in 2002 there were 8 adaptations.
(b)	**Countries in which it has been utilised**	Exact number not evident from published literature.
	Little published data available on efforts to establish conceptual and linguistic equivalence as information on such adaptations was frequently not published in English.	

CRQ =Chronic respiratory disease questionnaire; MIMIC = Multiple Indicators/Multiple Causes health index; DS-5 = Disease Severity; CH-5 = Current Health

4.4.8. The Asthma Life Impact Scale: D. M. Meads.

The Asthma Life Impact Scale (ALIS) was developed by Meads *et al.* in Galen Research Ltd., Manchester, U.K. and was first published in May 2010[498].

1. BASIC FEATURES		
(a)	**HRQL domains**	
	(i) Physical	✓
	(ii)Mental	✓
	(iii)Social functioning	✓
(b)	**Breadth of health**	
	(i) Dimensions measured	• Self-actualisation needs • Safety and security needs • Independence needs • Self-esteem needs • Control needs • Social and relationship needs
	(ii) No. of questions	22
(c)	**Response measures**	Dichotomous: True/Not true
(d)	**Recall period**	At present
(e)	**Descriptive statistics**	
	(i) Ceiling effects	No published data identified
	(ii) Floor effects	
	(iii) Missing data	
(f)	**Respondent burden**	
	(i) Self-administered	✓
	(ii) Interviewer-administered	x
	(iii) Time for completion	Not reported
(g)	**Administrator burden**	
	(i) Level of training	None specified
	(ii) Additional resources	Not relevant
(h)	**Setting(s)**	Outpatient/clinical setting
(i)	**Quality of life score**	Higher score = poorer quality of life
	(i) Scoring	Overall score
	(ii) Weighting	x

2. RELIABILITY		
(a)	**Internal consistency** (Cronbach's α)	0.92-0.94[498]
(b)	**Test-retest reproducibility**	
	Time period	2 weeks
	ICC	0.82-0.92[498]
3. VALIDITY		
(a)	**Content validity**	
	(i) Item selection sources	• Unstructured individual interviews with asthma patients in UK • Focus groups of asthma patients in US • Needs-based quality of life model[499-501]
	(ii) Item reduction process	• Cognitive debriefing interviews with asthma patients • Rasch analysis using the Rasch Uni-dimensional Measurement Model
(b)	**Construct validity**	
	(i) AQLQ-J total	Correlation: strong S = 0.78-0.79[498]
4. RESPONSIVENESS: No published data identified		
5. INTERPRETABILITY: No published data identified		
6. SENSITIVITY		
	Ability to distinguish between varying degrees of disease severity	Yes[498]
7. ALTERNATIVE FORMS: No published data identified		
8. CULTURAL AND LANGUAGE ADAPTATIONS: No published data identified		

4.4.9. The Integrated Therapeutics Group Asthma Short Form: M.S. Bayliss.

The Integrated Therapeutics Group Asthma Short Form (ITG-ASF) was developed by Bayliss *et al.* and was first published in 2000[502].

1. BASIC FEATURES		
(a)	**HRQL domains**	
	(i) Physical	✓
	(ii)Mental	✓
	(iii)Social functioning	✓
(b)	**Breadth of health**	
	(i) Dimensions measured	• Asthma symptoms (AS): 5 Qs • Functioning with asthma (FWI): 5 Qs • Psychosocial impact of asthma (PIA): 3 Qs • Asthma: confidence in health (ACH): 1 Q • Asthma: energy (AE): 1 Q
	(ii) No. of questions	15
(c)	**Response measures**	5-point Likert scale
(d)	**Recall period**	Past 4 weeks
(e)	**Descriptive statistics**[502]	
	(i) Ceiling effects	• ACH: 34.6% - 51.8% • AE: 15.1% - 28.2% • PIA: 14.9 - 35.9% • FWI: 16.0% - 35.9% • AS: 1.7-8.5%
	(ii) Floor effects	Negligible
	(iii) Missing data	Negligible
(f)	**Respondent burden**	
	(i) Self-administered	✓
	(ii) Interviewer-administered	✗
	(iii) Time for completion	Not specified
(g)	**Administrator burden**	
	(i) Level of training	Not relevant
	(ii) Additional resources	None specified
(h)	**Setting(s)**	Clinical setting
(i)	**Quality of life score**	Higher score = better quality of life
	(i) Scoring	Overall score, 5 subscale scores
	(ii) Weighting	✗

2. RELIABILITY		
(a)	**Internal consistency** (Cronbach's α)[502]	
	(i) AS	0.78-0.84
	(ii) FWI	0.85-0.90
	(iii) PIA	0.79-0.90
	(iv) Total	0.88-0.93
(b)	**Test-retest reproducibility**	No published data identified
3. VALIDITY		
(a)	**Content validity**	
	(i) Item selection sources	• AQLQ-Mks[458] • ITG Physical symptom/side effect battery[503] • ITG Psychosocial symptom/side effect battery[503]
	(ii) Item reduction process	Principal component analysis
(b)	**Construct validity**	No published data on absence/presence of correlations with other relevant measures
	(i) Predictor of validity criterion; patient rated asthma severity, using one-way ANOVA	F (total) = 46.65% - 75.56%[502]
	(ii) Predictor of validity criterion; NHLBI severity classification, using one-way ANOVA	F (total) = 34.79%[502]
	(iii) Predictor of validity criterion; absenteeism, using one-way ANOVA	F (total) = 31.48% - 37.95%[502]
4. RESPONSIVENESS: No published data evident on associations with changes in relevant variables or comparisons with external criteria		
	Relative validity analyses compared the ITG-ASF to the AQLQ-Mks on responsiveness to changes in absenteeism, NHLBI severity classification, patient rated asthma severity, and FEV_1% predicted.	ITG-ASF total comparable to AQLQ-Mks total in all 4 categories[502]
5. INTERPRETABILITY: No published data identified		
6. SENSITIVITY: No published data identified		
7. ALTERNATIVE FORMS: No published data identified		
8. CULTURAL AND LANGUAGE ADAPTATIONS		
(a)	**Languages available**	No published data identified
(b)	**Countries in which it has been utilised**	No published data identified
	According to Bayliss *et al.*[502] a Spanish language adaptation of the ITG-ASF is available and a Chinese-American version was in development in 2000; however neither adaptation was identified in the published literature.	

NAEPP = National Asthma Education and Prevention Programme; NHLBI = National Heart Blood and Lung Institute.

4.5. Discussion:

Nine disease-specific health-related quality of life instruments have been discussed in detail above. Some of these questionnaires are specific to asthma (AQLQ-J, AQLQ-Mks, LWAQ, ABP, AIS, ALIS and ITG-ASF) whereas others are applicable to both asthma and other chronic non-specific lung diseases such as COPD (SGRQ and AQ20). These instruments vary widely in their basic features (*e.g.* item count, recall period, completion time, response options, administration setting), their instrument construction, and their psychometric properties.

4.5.1. Basic Features

4.5.1.1. Health related quality of life domains

Each of the nine instruments discussed encompasses physical, mental and social functioning domains.

4.5.1.2. Breadth of health

The breadth of health measured by each instrument varies considerably. Obviously, shorter instruments generally encompass fewer aspects of quality of life; but the instruments differ in the emphasis placed on distinct facets of quality of life. The focus in the AQLQ-J is on the effects of Activity Limitation and presence of respiratory Symptoms, due to asthma, on quality of life. There are over twice as many questions in each of these domains compared with the Emotional Function and Environmental Stimuli domains. There are no questions that refer to limitations in social activities or relationships[433]. Unlike the other eight instruments, the AQLQ-J is the only instrument that includes five individualised questions on physical activity. Individualisation was included so that the questionnaire would be applicable to all adult asthmatic patients irrespective of their demographic characteristics[433]. Quality of life instruments with individualised questions can often have good responsiveness[504]. However, the lack of standardisation between patients makes comparability between different studies and different populations more complicated[480]. In fact, the AQLQ-J was specifically designed as an evaluative instrument[433].

In contrast, the LWAQ places the most emphasis on measuring the effect of asthma on one's emotional state; there are 23 items out of a total of 68 in this domain. However, the LWAQ also measures the greatest range of quality of life; it comprises 11 different domains ranging from Holidays to Sex.

The overall focus of the AQLQ-Mks is on the effect of asthma on emotional functioning and social activities, and less so on respiratory symptoms. Only one of the domains, Breathlessness, contains items referring to symptoms of asthma and physical limitations, while the predominant focus of the remaining three domains is on social restrictions and emotions.

With 50 items, the SGRQ is a broad-ranging instrument. However, unlike the LWAQ, the items in the SGRQ are classified into three domains: Symptoms, Activities and Impacts. The emphasis is placed on the Symptoms and Impacts domains equally. The Impacts domain is very comprehensive. It includes items on emotions, activities, relationships, medication, sleep, and mobility, which all contribute to the measurement of the overall impact of asthma on a patient's daily quality of life. Thus, the SGRQ is useful if one wishes to gain a comprehensive insight into the general impact of asthma on daily functioning.

The ABP was specifically designed to evaluate psychological interventions, thus the 15 Bother items are phrased specifically to assess the emotional impact/distress caused by a range of situations from social activities to illness. The seven Management items focus on the level of care a patient perceives he has received or is receiving. However, the Management items may not be relevant to all cultures [486]. Nishimura *et al.*[486] omitted the Management items due to lack of relevance but, data on the validity of the instrument in the absence of the Management domain have not been identified in the published literature and would need to be investigated further before proceeding with the use of this shortened version of the instrument.

The AQ20 is a broad instrument encompassing a wide range of scenarios but it lacks depth. It was developed by two of the researchers (Jones and Quirk) involved in the development of the SGRQ, and it could crudely be considered a shortened version of that instrument.

The ITG-ASF does not focus on one particular aspect of quality of life; two of the domains contain only one item each but the remaining three domains (Symptom-Free Index, Functioning with Asthma and Psychosocial Impact of Asthma) each contain 3-5 items.

As the AIS consists of only six items it obviously lacks breadth and depth and should only be used where there are significant time constraints. Such a brief instrument could only provide a general overview of quality of life due to the multi-faceted nature of the quality of life concept.

The ALIS differs significantly from all of the other instruments under evaluation as it was designed using the needs-based quality of life model[499,500] as its conceptual framework[498]. Consequently, unlike the other instruments, there are no items on respiratory symptoms; instead, there are items on loss of independence and autonomy and self-actualisation needs, which are unique to this instrument. There are also items on social and activity limitations and relationships, which can be found in other instruments.

The choice of instrument will be influenced by the desired outcome of the intervention. For example, if the intervention is expected to influence respiratory symptoms, an instrument like the AQLQ-J would be more suitable than the AQLQ-Mks. However, if one wished to evaluate the effect of the intervention on emotional functioning the ABP or the LWAQ would be an appropriate instrument.

4.5.1.3. Response measures

The response options employed by each instrument are quite varied. If an instrument is being utilised to measure within-subject changes it must demonstrate responsiveness, *i.e.* it must be able to detect small changes for each item, should they arise. The use of dichotomous response options limits the ability of the instrument to detect these changes, thus an instrument that uses a Likert scale with multiple response options is recommended for measuring longitudinal changes[447]. The is particularly relevant in the case of shorter instruments[504]. Consequently, the ALIS, the AQ20, the LWAQ (3 response options), and the SGRQ would be less suitable than the other instruments in measuring within-subject changes. Conversely, binary or tertiary response options, in conjunction with an instrument of 20-100 items, are recommended for detecting cross-sectional changes[504]. Thus, the LWAQ and the SGRQ, which have 68 and 50 items respectively, would be more suited to studies of this kind.

4.5.1.4. Recall period

It is evident from the published data that a recall period of 12 months or longer is sub-optimal. The recall period of the original SGRQ varied across the instrument; the recall period of the Symptoms domain was 'over the last year', whereas the recall period for the remainder of the instrument was 'these days'. In the comparative study of the AQLQ-J and the SGRQ conducted by Sanjuas *et al.*[436] (discussed in more detail in 4.5.9.5(b) below) the Symptoms domain of the SGRQ performed consistently worse than the other two domains of the SGRQ and all domains of the AQLQ-J in tests for cross-sectional validity, longitudinal validity and sensitivity. As mentioned previously, Barr *et al.*[478] modified the SGRQ such that the recall period for the Symptoms domain was reduced to

the 'past month'. On comparing the results of the '1 year' versus '1 month' recall period Symptoms domain scores, the 1 month modification produced consistently better results in terms of internal reliability, test-retest repeatability, sensitivity, construct and subjective discriminate validity. In addition, in unstructured interviews conducted by the researchers, COPD patients reported that they felt they could accurately describe symptoms only over a period of 4-6 weeks[478]. However, whether this is true of other respiratory illnesses is not clearly evident.

The authors of the original SGRQ instrument have subsequently modified the recall period of the Symptoms domain so that is now available with either a 1 year or a 3 month recall period. This modified version was utilised in a comparative study conducted by Barley and Jones[505], and the Symptoms domain performed in a comparable manner to the other domains of the instrument in all evaluative tests. From the available data, the instrument with the three-month recall period for the Symptoms domain appears to have superior psychometric properties and so would be more suitable for use in most studies.

4.5.1.5. Descriptive statistics

For the majority of the instruments evaluated, the presence of missing data and ceiling and floor effects was not problematic. However, significant floor effects, indicating best possible health, were reported for both the AQ20 in two studies[486,492] and the ABP in one study[486]. In both studies, the patients surveyed had mild to moderate asthma; thus, the disease severity of the study population should be considered before either of these instruments is employed as an outcome measure. Puhan *et al.*[435] reported significant ceiling effects, indicating best possible health, for the AQLQ-J. However, 55.4% of patients studied did not use any asthma medication in the three months preceding the study and there was no formal diagnosis of asthma by a health professional; thus, it is possible that a proportion of these patients were not asthma sufferers.

Information on occurrence of 'missing items' is sparse. In relation to the SGRQ, data on 'missing items' relate predominantly to COPD patients not asthma patients. Two separate research groups who administered the SGRQ to COPD patients reported that one question on whether playing sport made them short of breath had a very poor response rate[477,478]. This may be because many COPD patients are no longer capable of such physical activities. Sensitivity testing was conducted by the original investigators and it indicated that the random omission of up to 10 items would only cause the total score to differ by <2%. However, it is unclear what consequences the non-random omission of items (*e.g.* omission of items on activities that are no longer possible due to COPD) would have on the SGRQ score[478]. In contrast, the administration of the questionnaire to a

sample of asthma patients produced a much lower occurrence of missing data[436]. Consequently, one should be vigilant when administering the SGRQ to COPD patients, particularly those with severe disease, due to the possibility of omission of irrelevant items, which may affect the validity of the resultant scores. Bayliss et al.[502] reported that the presence of 'missing items' for the ITG-ASF was negligible. However, further studies are necessary to substantiate this finding. The occurrence of 'missing items' in the AQLQ-J is discussed in detail below in 4.5.1.7.

4.5.1.6. Respondent burden

As discussed, the number of items per instrument ranges from 6 items in the AIS to 68 items in the LWAQ. This also translates into a significant variation in the time required for instrument completion. It is reported that the LWAQ requires 15-20 min for completion[467]. No such data have been reported for the AIS but approximately 1-2 min would be a good estimate of the time needed for the completion of 6 questions. The setting in which the instrument is to be utilised and the frequency with which it is to be used will help determine the choice of instrument. Briefer instruments are more appropriate for routine use especially in the clinical practice setting where the average physician consultation is 9-17 minutes. Longer instruments are more difficult to assimilate and incorporate into clinical decision-making[428]. However, choosing a shorter instrument may mean a reduction in instrument reliability and responsiveness and a decline in the breadth and depth of quality of life measurement[417,428].

4.5.1.7. Administrator burden

The choice of instrument will also be influenced by the method of administration. The SGRQ is the only instrument for which close monitoring is recommended with self-administration necessitating additional resources. None of the instruments must be interviewer-administered but the AQLQ-J, LWAQ, SGRQ and AQ20 have all been designed for both self- and interviewer-administration. No published data were identified on the level of training required for appropriate administration.

The AQLQ-J was designed to be both interviewer and self-administered. However, a number of studies have reported significant rates of missing data in the individualised activities domain when the questionnaire is self-completed. Sanjuas *et al.*[436] report that 15.5% of patients had missing data due to problems in completing the 'individualised activities' items. Similarly, Garratt *et al.*[437] stated that only 72.9% of patients completed all of the individualised activities items. Conversely, Puhan *et al.*[435] reported that the percentage of missing data per item was below 3% for 31 of the 32 items; but it is unclear

whether the questionnaire was interviewer or self-administered. Consequently, to ensure an optimum response rate, the use of an interviewer would be recommended when administering the AQLQ-J.

The SGRQ is the only instrument for which additional resources are required to score the instrument due to the presence of weighting. The authors of the instrument advocate the use of a Microsoft Office Excel spreadsheet, the 'SGRQ calculator', with pre-programmed calculation formulae for item weights, to calculate the total and component scores. (This is available to download on their website www.healthstatus.sgul.ac.uk).

Accordingly, the need for additional resources must be considered when choosing an appropriate instrument.

4.5.1.8. Setting(s)

Some instruments were designed specifically for certain settings. The AQLQ-J was designed specifically for use in the clinical trial setting[433] and was validated in such a setting, thus its validity in the outpatient setting, for example, would need to be demonstrated prior to such use.

Conversely, the AQ20 was designed specifically for routine use in the clinical setting[491]. The AQLQ-Mks, the LWAQ, the SGRQ and the AQ20 were designed for use in both clinical trials and other clinical settings[458,467,475,493]. The authors of the ALIS and AIS do not specifically state the appropriate setting for use of these instruments. However, validation studies for both instruments are conducted in the clinical setting so it may be assumed they would perform optimally in such settings[487,498]. Similarly, ITG-ASF is validated in patient samples from both clinical trials and outpatient clinics so it may be assumed that it can be used in both settings[502].

The ABP differs from the other eight instruments as it was specifically designed for use in the evaluation of psychological treatments for asthma[484] and so would not be ideally used as the primary quality of life instrument in the appraisal of pharmacological asthma treatments. However, it may provide additional information on a patient's distress as an adjunct measure in such studies.

4.5.1.9. Scoring of results

The result of each instrument is presented as an overall score representing quality of life. However, a number of instruments are designed to produce individual subscale/domain

scores that provide additional insight into a patient's quality of life in these areas. The results of the AQLQ-J, AQLQ-Mks, LWAQ and the ITG-ASF can all be presented as subscale scores. The LWAQ can also be analysed by calculating the score for two constructs: the 49-item Problem construct and the 19-item Evaluation construct[469].

As mentioned above, the SGRQ is the only instrument in which the responses are weighted. The aforementioned 'SGRQ calculator' has limited tolerability for missing items. To ensure the calculation of each component score, a maximum of two, four and six items are tolerated for the Symptoms, Activity, and Impacts components respectively. In each case, the weight for the missing item is subtracted from the total possible weight for the component in question and from the total weight. This further necessitates the need for supervised administration of this instrument to ensure a valid result.

4.5.2. Reliability

As discussed previously the minimum acceptable Cronbach's α value of internal consistency reliability for individual comparisons is >0.9 and for group comparisons is >0.7[506]. In general, the Cronbach's α value for the overall instruments is >0.9. However, the reported values for the instruments' domains are frequently > 0.7 but <0.9. Consequently, for individual comparisons, the overall instrument scores should be used and the domain scores should only be used for group comparisons. The available ICC values for the instruments were also consistently high: The majority of the ICC values for the overall instruments were ~0.9, indicating excellent reproducibility.

4.5.3. Validity

4.5.3.1. Content validity: Item selection

The procedures used in the development of a disease-specific health-related quality of life questionnaire varied considerably from instrument to instrument. In terms of item selection protocols they can be broadly divided into two categories: (1) those that used existing instruments as the sole source of items for questionnaire development such as the AQ20, and the ITG-ASF and (2) those that used information garnered from patient interviews/focus groups as the primary source of items, as was done in the development of the AQLQ-J, the AQLQ-Mks, the LWAQ and the ALIS. Literature reviews and/or consultations with relevant health-care professionals were also used as sources of information in the development of the AQLQ-J and the AQLQ-Mks.

The ABP also used existing questionnaires as the original item source, but unlike category (1) instruments, the initial draft of the questionnaire was discussed in focus groups and the content of the focus groups contributed significantly to the final version of the instrument[484].

There is insufficient information on the development of the SGRQ to determine the source of the items.

The source of items for the AIS was a computerised item bank (source unknown) developed in an attempt to regulate the evaluation of disease impact across a range of diseases[487].

It is evident that the item selection process employed by category (2) instruments has superior content validity than that used in the development of category (1) instruments, as patients' personal experiences are the fundamental sources of the items. Furthermore, the contribution of previous research and/or the experience of health-care professionals used in the development of the AQLQ-J and the AQLQ-Mks should have further enhanced the content validity of these instruments.

Considerable variation was seen between instruments within category (2) in relation to the quality and quantity of patient input. In the development of both the AQLQ-J and the AQLQ-Mks six and eight patients respectively were interviewed or participated in a focus group[433,458]. However, in the development of the LWAQ, Hyland *et al.*[467] conducted eight focus groups of three to ten people and Meads *et al.*[498] held both unstructured interviews with 39 UK patients and focus groups with 16 US patients in order to develop a pool of potential items for the ALIS. In addition, both of these research groups specified that the original wording of the patients' comments was used as much as possible, which should have enhanced content validity.

4.5.3.2. Content validity: Item reduction

The item reduction procedure used in the development of the majority of instruments was principal component analysis, a statistical psychometric technique. However, in the development of the AQLQ-J Juniper *et al.* used the 'impact method' whereby the items with the highest frequency-importance product are chosen. In this method, it is the items that are of greatest importance to patients, and identified most frequently by them, which are retained. Juniper *et al.* compared the 'impact method' with the factor analysis method in the construction of the AQLQ-J[507]. It was discovered that while 20 of the items in the original AQLQ-J would have been included based on factor analysis, items of moderate

importance to patients would also have been included and three items of greatest importance to patients would have been omitted. Thus, the item reduction method chosen has a significant impact on the resulting questionnaire.

An alternative method of item reduction was employed in the construction of the ALIS; final item reduction was achieved using the Rasch Uni-dimensional Measurement Model, a one-parameter logistic item-response theory model. The Rasch model tests the uni-dimensionality of the instrument, *i.e.* that all items are measuring the same underlying construct. A number of studies have compared the factor analysis method with the Rasch model with mixed results; some studies have indicated that the Rasch model has several advantages over the factor analysis method[508,509] whereas other studies have failed to find a significant difference between the two approaches[510,511]. In order to determine which method is superior one would have to test the psychometric properties of the instrument developed by the three different methods.

The demographic characteristics of the patient sample used to perform item reduction and subsequent creation of the instrument are very important. In order for an instrument to be widely applicable, the patient sample used in its creation must include patients from the entire spectrum of disease severity as well as patients with a broad age range, patients of both sexes, and those whose duration of disease varies considerably[447].

No published data have been identified that includes any information about the patient sample used in the creation of the AQ20 or the SGRQ. In relation to both the ABP and the LWAQ, no data are included on the patients' degree of disease severity nor is there any information on an attempt to include patients across the severity spectrum. Three separate patient samples were used in the creation of the ITG-ASF[502]. A total of 584 patients were included, and at least one of the groups sampled patients from across the severity spectrum. There are insufficient data about the range of severity of the patients in the other two groups. Marks *et al*[458] specified that a patient would be considered to suffer from more severe asthma if he/she had been admitted to hospital for asthma in the preceding 12 months and/or had received a course of oral corticosteroid. Consequently, the researchers decided that more than 45% of the patient sample used in instrument development suffered from more severe asthma.

Only the researchers responsible for the development of the AQLQ-J outlined specific inclusion and exclusion criteria for the patient sample and classified patients according to degree of disease severity using specific lung function measures, thus ensuring the adequate representation of all degrees of disease severity[433]. The researchers involved in

the creation of the ALIS also specified exclusion criteria for the patient sample, and patients recruited in the US were classified according to disease severity by their physician. Overall both the UK and the US samples combined included patients across the complete spectrum of disease severity[498]. In summary, only the patient samples used to develop both the AQLQ-J and the ALIS adequately represent the full spectrum of disease severity and consequently can be considered broadly applicable.

4.5.3.3. Construct validity

Demonstration of the validity of a quality of life instrument is complicated by the absence of a 'gold standard' or criterion measure that is widely accepted as a valid measure of quality of life[426]. Consequently, instruments must provide evidence of construct validity. Precise accordance with other measures is not necessary as this would render quality of life instruments redundant, but demonstration of logical relations that should exist with other measures is vital. However, due to the absence of a criterion measure, the instruments and measures to which the quality of life instruments are compared vary hugely. Consequently, it is difficult to determine which instrument has the greatest validity as they are frequently being compared to different measures. In addition, newer instruments such as the ALIS, the AIS and the ITG-ASF have limited validity data to date and so it is not possible to draw concrete conclusions about their performance.

With the exception of the ALIS, AIS and ITG-ASF, the quality of life instruments under evaluation all investigated the existence of a relationship between the instrument and pulmonary function measures such as FEV_1 % predicted, FVC, FEV_1, $PD_{20}FEV_1$ or PC_{20}. From the published data identified, the majority of the studies reported very weak or not significant relationships between the instruments and these lung function measures. The strongest correlations identified were reported for the SGRQ and the LWAQ. Barley *et al.*[505] and Barr *et al.*[478] recorded a Pearson's r value of -0.38 ($p < 0.001$) and -0.30 ($p \leq 0.01$) respectively for the relationship between the SGRQ total score and the FEV_1% predicted. However, in the study conducted by Barley *et al.,* the recall period for the Symptoms domain of the SGRQ was shortened to 3 months and in the study conducted by Barr *et. al* a modified American version of the SGRQ was utilised in the study, and the patient sample was COPD sufferers. Van der Molen *et al.*[468] reported a Pearson's r value of 0.35 ($p < 0.05$) for the relationship between the LWAQ total score and PC_{20}.
Marks and colleagues[458] and Rowe and Oxman[438] have suggested that the reason for such weak, often not significant correlations is that quality of life measurements represent a distinct aspect of asthma. Furthermore, a single measure of pulmonary function may not be representative of lung function over a longer period and asthma patients may often be unable to assess accurately their own degree of airflow obstruction.

In addition to spirometry, the existence of a relationship between the quality of life instruments and PEFR measurements was also evaluated in an attempt to establish construct validity. Only the AQLQ-J, the LWAQ, the SGRQ and the AQ20 have been evaluated in terms of their relationship with PEFR measures to date. As was observed with spirometry, in general only weak correlations were observed with the instruments and PEFR measures. The strongest relationship was observed between both morning and evening PEFR and the SGRQ total score (Pearson's r = -0.41 to -0.45[491]). The magnitude of the correlations between PEFR and both the AQLQ-J and the LWAQ varied from exceedingly weak and occasionally not significant to weak (Pearson's r = 0.2 - ~0.3[468,491,512], Spearman's r = ~0.1- ~0.3[442,449,505]). Consequently, based on the results of both PEFR and spirometry evaluations, the SGRQ appears to have the strongest relationship with lung function measures.

The existence of a relationship between each of the AQLQ-J, the AQLQ-Mks, the LWAQ, the SGRQ, the ABP, the AIS, the AQ20 and the ITG-ASF, and various measures of disease severity (*e.g.* β-agonist use, sleep disturbance, ADSS, AOMS, number of asthma medications) and/or presence or severity of respiratory symptoms was evaluated. The magnitude of the relationship varied from instrument to instrument and depended on the measure used in the investigation. The strength of the correlation with the AQLQ-J and the AQ20 varied from weak to strong depending on the outcome being evaluated [435,439-441,486,491]. A weak correlation was observed between the SGRQ and the ABP, and the MRC RSQ and the MRC dyspnoea scale respectively[480,486]. Weak/weak to moderate relationships were observed for the AQLQ-Mks[458,459], the LWAQ[468] and the ITG-ASF[502]. A moderate correlation was observed between the AIS and the AOMS[487].

It is not possible to draw any concrete conclusions from the results as each instrument was compared with a different measure. Some of the measures were patient subjective (*e.g.* diary cards used to measure disease severity and impact[491]) while others were objective measures (e.g. asthma control questionnaire[442]). Some were validated disease severity instruments (*e.g.* MRC RSQ[480]) while others were created by the authors specifically for the study and were not validated (*e.g.* measurements of sleep disturbance[491]). In addition, the statistical analyses performed on the studies varied, further impeding comparison of results.

A number of studies evaluated the relationship between the disease-specific quality of life instruments and generic quality of life instruments. The relationship between the AQLQ-J, the AQLQ-Mks, the ABP, and the AQ20, and the generic SF-36 instrument was

investigated[435,439,460,486]. The physical component summary (PCS) and mental component summary (MCS) scores of the SF-36 were compared with both the AQLQ-J and the AQLQ-Mks domain and total scores. A slightly stronger correlation was observed between the AQLQ-Mks domain scores and the SF-36 PCS score than with the AQLQ-J domain scores (Pearson's r = -0.45 to -0.66 AQLQ-Mks [460]; r = 0.36-0.56 AQLQ-J [439]. The magnitude of the correlations between both instruments and the SF-36 MCS was broadly similar.

The ABP and AQ20 total scores were compared with each of the eight domains of the SF-36 and a stronger correlation was observed between the ABP and each of the SF-36 subscales than the AQ20 (Spearman's r = -0.30 to -0.63 ABP; r = -0.17 to -0.48 AQ20)[486].

The magnitude of the relationship between the AQLQ-J, the LWAQ and the SGRQ, and the generic SIP instrument was evaluated[438,442,449,480]. However, the results from each of the investigations are reported either using different statistical tests or different instrument total/domain scores so it is not possible make direct comparisons.

The relationship between the AQ20 and the ABP, and the HADs Anxiety and Depression scales was evaluated[486]. A stronger relationship was observed between both HADs scales and the ABP than with the AQ20. This result was expected as the ABP was designed specifically to measure psychological distress. No published data were identified evaluating the relationship between the ITG-ASF, the AIS or the ALIS and any generic health-related quality of life instruments. The greatest number of evaluations with generic quality of life instruments exists for the AQLQ-J. In general, a moderate relationship was observed between the AQLQ-J and generic quality of life instruments[438-440,442].

A number of the more recent quality of life instruments (ABP, AQ20 and ALIS) have endeavoured to demonstrate the existence of a relationship with one or more of the more established instruments, such as the AQLQ-J, the LWAQ or the SGRQ, as evidence of construct validity[472,486,491,498]. However, as the item pool for the ABP and the AQ20 included these established questionnaires, caution should be exercised in drawing conclusions about the construct validity of these instruments based on these data alone. Overall, there is insufficient evidence to establish firmly the construct validity of the ITG-ASF, the AIS and the ALIS, as only one published study for each instrument has been identified to date[487,498,502].

4.5.4. Responsiveness

Published evidence of responsiveness has not been identified for the ABP, the AIS and the ALIS to date. The AQLQ-J was designed primarily as an evaluative instrument; thus, it is unsurprising that it appears to be the most responsive instrument on analysis of the available published data[438,442,449]. However, it should be noted that fewer studies have been identified that evaluated the responsiveness of the other instruments and this deficit of information has made it difficult to draw definitive conclusions about these questionnaires.

The relationship between changes in instrument scores (changes in quality of life) and changes in pulmonary function measures was investigated for the AQLQ-J, the AQLQ-Mks, the LWAQ and the SGRQ. The strongest and most consistent relationship was observed between the AQLQ-J and clinical measures of disease severity such as FEV_1 % predicted, PC_{20}, PEFR *etc.*[442]. These correlations were weak to moderate in magnitude but they were much stronger than similar relationships used in the establishment of construct validity.

A significant relationship was only observed between the Symptom domain of the AQLQ-Mks and both PEFR and a measure of bronchial hyperresponsiveness[461]. A significant correlation was also reported between the AQLQ-Mks total score and a measure of bronchial hyperresponsiveness[461].

Conflicting results were observed between the LWAQ and pulmonary function measures. Rutten-van Molken and colleagues recorded no significant correlations between the LWAQ total score and FEV_1 % predicted or PEFR a.m. /p.m[449]. Conversely, van der Molen and colleagues recorded a weak significant correlation between the LWAQ total score and FEV_1% predicted and a moderate significant correlation with PEFR (r = -0.30 and -0.50 respectively[471]).

In relation to the SGRQ, Sanjuas *et al.* reported that there was no significant relationship between the instrument and FEV_1 % predicted and Jones and colleagues recorded a very weak relationship between the two measures[436,480]. In both studies, the strongest relationship was observed with a measure of dyspnoea. However, the relationship was weak to moderate in strength. Overall, from the studies identified, the SGRQ demonstrated a very weak ability to distinguish within subject changes. Both studies that evaluated responsiveness did so using a one year recall period for the Symptoms domain. Sanjuas and colleagues observed not significant relationships between changes in the

Symptoms scores and changes in both FEV_1 % predicted and changes in dyspnoea scores[436]. As discussed previously, the instrument is now available with a recall period of three months for the Symptoms domain and this may improve the responsiveness of the instrument, but published data on responsiveness have not been identified for this modification of the SGRQ to date.

Non-clinical measures were also used in the evaluation of the responsiveness of the quality of life instruments. Changes in AQLQ-J, AQLQ-Mks and LWAQ scores were compared with changes in SIP scores. A weak not significant correlation was observed between the SIP score and the AQLQ-Mks[461]. Weak significant correlations of approximately equal magnitude were observed between the SIP and both the LWAQ and the AQLQ-J[442,449]. The relationships between changes in symptom scores, changes in β-agonist use, and changes in quality of life scores were also evaluated in an attempt to demonstrate responsiveness. Weak to moderate correlations of similar magnitude were observed between changes in β-agonist use and changes in the quality of life scores of the AQLQ-J, the LWAQ and the AQLQ-Mks (Spearman's r = ~0.2 - ~0.4[462,471]). Symptom scores were obtained in each case from patient recordings in diary cards over a period of two weeks. The symptoms recorded and the severity scale varied from study to study so direct comparison of the results would not be appropriate. However, from the data published for the AQLQ-J, the AQLQ-Mks and the LWAQ, the strongest relationship was observed between changes in symptom scores and changes in AQLQ-J scores.

The responsiveness of the AQLQ-J was also evaluated in terms of the correlation between changes in the instrument scores and changes in patient-assessed global ratings of change measures. Both Rowe and colleagues[438] and Juniper and colleagues[442] reported a strong correlation between the global, activities and symptoms ratings of change and the corresponding domains of the AQLQ-J. In both studies, the weakest correlations were those observed with the Environmental Stimuli domain of the AQLQ-J. Kheir *et al.* reported similar findings, but in this study a not significant correlation was observed with the Environmental Stimuli domain of the AQLQ-J[513]. Kheir and colleagues[513] proposed two possible reasons for the lack of responsiveness of the Environmental Stimuli domain: Firstly, the items in this domain assume exposure to asthma triggers, consequently the responses may be skewed towards 'no limitation' due to lack of exposure not due to absence of limitations as a consequence of exposure. The second reason is the difficulty in impacting on asthma symptoms arising from trigger exposure especially if the interventions being initiated are largely behavioural. This applies more so to the study conducted by Kheir and colleagues and less so to those conducted by Rowe *et al.* and Juniper *et al.*

The responsiveness of the AQ20 was only evaluated in terms of the relationship between the change in AQ20 scores and the change in AQLQ-J, LWAQ and SGRQ scores[491,492]. Further studies are needed before a definitive conclusion can be made about the responsiveness of this instrument.

4.5.5. Interpretability

At present, only the AQLQ-J and the SGRQ have interpretability data that contextualises the quality of life scores in a meaningful manner for health-care professionals. Consequently, these instruments would be more favourable for use in studies where a clinically significant result is important.

A statistically significant effect does not necessarily translate into a clinically relevant effect due to its partial dependency on sample size. The term statistically significant simply means that the result is unlikely to have occurred by chance. A clinically relevant effect, however, refers to the beneficial effect of an intervention on a patient's quality of life and it has implications for the patient's clinical management[514,515]. The minimum clinically important difference (MID) is the measurement used in health status instruments to assign clinical relevance. There are two main approaches used to determine the MID; anchor based methods and distribution based methods[516,517]. In brief, distribution based methods are based on the statistical characteristics of the sample in question and their major disadvantage is that they do not provide any indication of the significance of the perceived change[518]. Anchor-based methods compare changes in health status scores to other measures that have clinical relevance, *i.e.* the anchor[516]. In contrast to distribution based methods, a significant disadvantage of these methods is that they do not take the measurement precision of the health status instrument into account[516,517].

Juniper *et al.* used the anchor-based approach in determining the MID for within-patient changes for the AQLQ-J[451]. However, a small sample size of thirty-seven adults was used to determine the MID. Furthermore, there was no clinician input incorporated into quantifying relevant HRQL change; asthma patients were the only participants in determining clinical relevance. A mean value of 0.5 was chosen as the MID, but on analysis of the results it is evident that there was considerable scatter around this value, so 0.5 is clearly an estimate by the authors. A value of 1.0 was deemed to represent a moderate change in quality of life; but on analysis of the changes in quality of life scores across the three domains and the overall score, this value ranged from 0.87-1.51 with considerable deviation around this range, as before. The authors also investigated

whether the MID of 0.5 was representative of both an improvement and a deterioration. They concluded that this was the case, however closer inspection of the results indicated that this should also be accepted with caution. The scope of values for improvement ranged from 0.40-0.73 and those for deterioration ranged from -0.37 to -0.62 with considerable deviation as before. In a study by Metz and colleagues comparing the use of tradition and Rasch cut points for assessing the MID in HRQL in asthmatic patients it was concluded that improvements and declines in HRQL are not equal in magnitude[519]. This study further emphasizes the need to exercise caution when using the MID of 0.5 to assess both clinically important deterioration and improvement.

Wywich and colleagues sought to establish a link between the MID and the standard error of measurement (SEM) and they concluded that one SEM identified the MID in the AQLQ-J[520]. Once again, the SEM per item values ranged considerably from 0.35 for the Symptoms domain to 0.61 for the Emotional Function domain. However, on cross-tabulation of each patient's classification by the MID standards with the classification using the one-SEM criterion, weighted κ values of 0.88-0.93 were observed indicating high consistency between the two methods. The authors acknowledged that there were a number of limitations to the study; namely the limited age range of the patients (18-44) and the lack of disease severity classifications, both of which limit the generalisability of the results to the larger asthmatic population[520].

Juniper and colleagues used global transition ratings as the anchor in the determination of the MID for the AQLQ-J[451]. One of the major limitations of this method, especially when the transition ratings have an extended recall period, is that it is susceptible to a number of well-documented recall biases[521]. Furthermore, recall has been demonstrated to be influenced by a patient's current or more recent health state, thus global transition ratings may not accurately reflect the actual or 'true' change in a patient's health state[517,522]. In an attempt to address these limitations Guyatt *et al.* investigated the relationship between the AQLQ-J and transition ratings corresponding to the instrument's responsive domains[522]. They observed that the correlations between the initial AQLQ-J scores and the transition ratings were much lower than the correlations between the follow-up AQLQ-J scores and the transition ratings, suggesting that patients are indeed disproportionately influenced by their current health state when they complete transition ratings. In addition, the magnitude of the correlations rarely exceeded 0.5, the threshold set by the authors to demonstrate validity of the transition rating. Thus, this study questions the overall validity of employing global transition ratings to determine the MID of a health status measurement. Conversely, Wyrwich and colleagues investigated the test-retest reliability of global transition ratings used in the assessment of domain changes in a number of generic and

disease-specific health-related quality of life instruments including the AQLQ-J. A moderate-to-substantial agreement was observed between teat and retest scores providing some evidence of their validity as anchors in determining MIDs[523].

Consequently, the existence of an MID for the AQLQ-J, which allows a clinician or researcher to draw meaningful conclusions about the clinical effects of an intervention is very advantageous. However, due to the considerable scatter around the MID value and the questions surrounding the symmetry of quality of life improvement versus deterioration, it should not be considered an absolute cut-off point for clinical significance but simply a reference source. Jones suggested an alternative method for assessing clinical relevance that uses both the MID mean value and its confidence intervals (CIs) thus addressing some of the limitations mentioned above[482]. Full details of this method will not be discussed here but, for example, he suggests that if the treatment effect lies between zero and the MID value and its upper CI includes the MID, the treatment effect should be considered 'small but clinically significant.'

As discussed above, there are currently two methods available for interpreting quality of life scores obtained using the SGRQ[475,479]. Clinicians are very familiar with the use of reference norms, as they are available, for example, to compare one's spirometry results with healthy group-based norms. Due to this familiarity with their use, general population based norms for the SGRQ should facilitate its use in the clinical setting by providing information to the clinician on the amount of impairment in quality of life of the patient when the score obtained is compared with the distribution of scores of the corresponding population[479,524]. In addition, the reference norms can be used to contextualise the size of the score differences observed in a patient over time or between patients[479].

However, caution should be exercised if one is using the general population norms obtained by Ferrer and colleagues outside Spain, where they were obtained. The SGRQ Symptoms domain scores obtained from a study of English patients with no history of respiratory disease were significantly higher than those obtained for the corresponding Spanish population[525]. This could be representative of a true difference in respiratory symptoms from country to country, which would make the general population norms invalid outside Spain. In addition, it should be noted that a considerable ceiling effect of 41.2%-59.5% was observed for all three domains of the SGRQ in the general population sample so the reference norms may not be entirely accurate. The reference norms are only valid for patients with a diagnosis of COPD, not asthma, and for those aged from 40-69 years, as these were the characteristics of the patients used in obtaining the reference norms.

In contrast to the use of a single method to obtain the MID for the AQLQ-J, Jones and colleagues used three methods to obtain and validate the MID for the SGRQ incorporating clinician input, patient input and comparison to an external criterion of health. All three methods resulted in an MID of approximately four units. Employing different methods to validate the result ensures an increased confidence in the resultant MID value. However, the MID value should still be used with care as regardless of the method employed to obtain this value, it could not be obtained without measurement error[482].

4.5.6. Sensitivity

Published data on sensitivity was identified for six of the nine instruments under evaluation; the AQLQ-J, the AQLQ-Mks, the LWAQ, the SGRQ, the ABP and the AQ20. Extensive data are available on the ability of the AQLQ-J to distinguish between populations of differing disease severity classified using the ADSS, the Physician Severity Rating Scale, daily and nocturnal symptom frequency and FEV_1 % predicted. It can be concluded that the AQLQ-J is a sensitive instrument. Only one study has been identified for each of the LWAQ, the ABP and the AQ20. These studies concluded that the questionnaires could distinguish between groups of asthma patients that differed in asthma severity, but additional studies are needed to confirm this. Slightly contradictory findings were observed in evaluating the sensitivity of the SGRQ. Jones and colleagues reported that the SGRQ could distinguish between asthma patients whose wheezing symptoms increased in frequency and those whose symptoms did not change, but it failed to distinguish between patients whose wheezing symptoms became less frequent and those whose symptoms did not change[480]. Conversely, Sanjuas and colleagues reported that the SGRQ could distinguish between patients whose daily and nocturnal symptoms varied in frequency from none to frequent[436]. Additional studies are needed to evaluate the sensitivity of the SGRQ.

4.5.7. Alternative forms

Evidence of modification has been identified for five of the nine instruments being evaluated. These modifications vary considerably from modification of a few of items, modification of recall periods or modification of response options, to modification of the entire instrument.

The AQLQ-J is the only instrument that has been substantially modified to result in the production of three separate instruments. The Mini-AQLQ-J[384] was developed for use in

large clinical trials and long-term studies where measurement precision may be reduced in favour of ease of completion and convenience. The AQLQ-J(S)[452] was created for use in cross sectional studies where generic activities are preferable for comparisons between individuals, and long-term trials where activities can vary seasonally. In addition, if the instrument is to be self-administered the AQLQ-J(S) should be considered due to the occasional recorded occurrences of missing data in the individualised questions when the AQLQ-J has been self-administered. The Acute AQLQ-J[453] was developed specifically for patients with acute severe asthma requiring hospital treatment. Each of these instruments demonstrated comparable measurement properties to the AQLQ-J and both the AQLQ-J(S) and the Mini-AQLQ were strongly correlated with the AQLQ-J (P = 0.99 AQLQ-J(S) overall[452], P = 0.99 Mini-AQLQ-J[384]). The advantage of the availability of these modified instruments is that it allows the researcher to choose the most appropriate instrument for the population and assessment criteria.

The performances of the modified versions of the AQLQ-Mks and the LWAQ (the MAQLQ-Mks and the ms-LWAQ) could not be directly compared to the original instruments as they were not administered in parallel in the respective studies, therefore it is not possible to definitively conclude whether the modified instruments are superior to the originals[463,473]. However, with regard to the MAQLQ-Mks, the internal validity (measured by Cronbach's α) and the test-retest reproducibility were superior to the values reported for the original AQLQ-Mks[463]. Direct comparison studies are necessary to confirm this.

As discussed previously, the modification of the recall period of the SGRQ from 1 year to 1 month for the Symptoms domain resulted in an instrument with superior psychometric properties to the original[478]. As discussed in 4.4.7, the AQ20 was modified to include the response option 'unable' which was scored as '1' as the researchers considered that there was the potential for ambiguity among items that the respondent avoids or is unable to perform due to his/her respiratory condition. In such a scenario, the respondent may chose the 'not applicable' response option that has a score of 0, resulting in a possible underestimation of the patient's impairment. In a sample of 352 patients with chronic obstructive airways disease the 'unable' response option was chosen 39 times, 21 subjects chose this option once and 7 respondents chose it twice[497]. The study sample in question was classified as having mild-moderate disease, consequently little impact was observed as a result of the modification. However, the researchers anticipated that a more significant difference would be observed in a population with greater disease severity. If the researchers' theory is valid, *i.e.* that patients may choose the 'not applicable' response if they are too impaired to partake in a particular activity and may

subsequently be misclassified with a falsely higher quality of life, then the modification must be tested on patients with moderate to severe disease.

4.5.8. Cultural and language adaptations

To date, there are numerous cultural and language adaptations of eight of the nine instruments under evaluation. The ALIS is the only instrument that has not undergone adaptation. However, as this instrument is newly developed it is surely only a matter of time before it is adapted for use in countries other than its countries of origin. A unique feature of the ALIS is that it was developed in both the UK and the US in parallel and subsequently demonstrated reliability and validity in both countries[498] without necessitating further adaptation. There are numerous reasons for the increasing demand for cross-cultural measures of health-related quality of life, but perhaps the most prevalent is the need for the aggregation or comparison of results in multinational clinical trials[526,527]. In addition, from an economic and health-policy perspective, cross-cultural measures facilitate the extrapolation of effective and cost-effective interventions and studies from one country to another[528].

It is insufficient simply to translate the original instrument into the language of the target culture and assume that it will accurately measure the quality of life of the population due to differences in language and culture[529], the perception of quality of life and the expression of health problems in different cultures[530]. This approach, referred to by Berry and colleagues as an absolutist approach[531], assumes that 'culture' plays a negligible role in the concept being evaluated and consequently these concepts will be predominantly invariant across cultures. At present, research outcomes both within the health-related quality of life area[532,533] and outside it[530,534,535] have provided sufficient evidence to question the validity of this approach. However, Herdman and colleagues reported that this approach has been adopted in much of the cross-cultural research being conducted as indicated by the absence of an initial investigation into the relevance of health-related quality of life to the target culture[536]. To allow the valid comparison of cross-cultural results, the equivalence of the translated and original questionnaire must be demonstrated[536]. Hui and Trandis suggest that conceptual equivalence should be the first type of equivalence examined and other forms of equivalence should only be assessed when it has been demonstrated[537]. Conceptual equivalence refers to the existence, relevance and acceptability of the concept and its domains across cultures[538]. Thus, determining conceptual equivalence is vital to minimise the risk of imposing an irrelevant concept on the target culture or perhaps missing domains that more accurately capture the concept in that culture[539].

The evaluation of the cross-cultural adaptations of the instruments in question was conducted on a selection of adaptations chosen at random based on their accessibility and their availability in the English language. On analysis of the adaptations, it is apparent that considerable variation exists between the methods used to adapt the original instruments for use in the target culture. With regard to the adaptation of the AQLQ-J, Stahl and colleagues[457] adapted the AQLQ-J for use in Sweden, Norway, the Netherlands and Greece. The researchers recognised the need to adjust the instrument to 'take into account cultural differences in patient-perceived impairments'. Accordingly, for each adaptation, following the established forward-backward translation procedure[540-542], the final draft version was pre-tested on 10 asthmatic patients to assess comprehensibility, validity and acceptability of the adaptation. Conversely, no apparent attempt was made to determine conceptual equivalence in the adaptation of the AQLQ-J into Serbian[455], French[454] or Chinese for Hong Kong[456]. Tan and colleagues investigated the suitability of the English version of AQLQ-J(S) in a heterogeneous multi-ethnic population comprising Indians, Malays and Chinese where English is not the mother tongue but is used as *lingua franca*[543]. Patient feedback reports indicated that while none of the subjects considered any of the items to be irrelevant from a cultural aspect, 12.6% felt some questions were ambiguous and 15% felt that they needed assistance in completing the questionnaire mainly due to lack of understanding of certain terms or the response options scale.

The methods used in the adaptation of the AQLQ-Mks also varied widely. Gupchup and colleagues[464] modified the instrument for use in the Native American population. Recognising the possibility of culturally irrelevant items the researchers conducted a focus group of adult asthmatics from different Pueblo communities to assess the relevance and comprehensibility of each item to the population and they used this information to modify the questionnaire. However, only three patients participated in a single 2-hour focus group so there was insufficient gender and age representation. In addition, the opinions of one person per community cannot be assumed representative of the views of the community as a whole. Overall, while a considerable attempt was made to establish conceptual equivalence the incomplete representation of the Pueblo communities due to poor participation means that conceptual equivalence of the instrument in the Native American population is unlikely. The researchers involved in the adaptation of the AQLQ-Mks into Spanish[466] and German[465] both refer to an article by Chwalow and colleagues on the cross-cultural adaptation of the SIP into French[544] as a reference source for the translation of the original instrument. However, it is no clear whether any attempt was made to establish conceptual equivalence in addition to simply translating the instrument.

In relation to the Norwegian[472] and Japanese translations[474] of the LWAQ there is no published evidence of any attempt to establish conceptual equivalence.

Ferrer and colleagues[476] and Barr and colleagues[478] adapted the SGRQ into Spanish and American English respectively and both research groups sought conceptual equivalence through the use of patient focus groups and draft questionnaire pre-testing to ensure relevance, comprehensibility and ease of completion. The Swedish[545], French-Canadian[483], and Moroccan-Arabic[477] adaptations of the SGRQ all pre-tested an adapted version of the instrument on a patient sample from the target culture to evaluate ease of completion and understanding. While this is not sufficient to demonstrate conceptual equivalence, it is superior to simply translating the instrument without any regard for the difference in language and culture of the target population.

With regard to the AQ20, information on the methods used to adapt the instrument for use in Spain and Brazil were published in detail in those native languages. The AQ20 was also adapted for use in Japan, but no reference was made to any effort to establish conceptual equivalence[546].

The published data on the Japanese and Norwegian versions of the ABP do not refer to any endeavour to establish conceptual equivalence[472,486].

No articles published in the English language could be identified with regard to the cultural adaptation of either the AIS or the ITG-ASF.

It is evident from the vast differences in methodologies used in the cultural adaptation of health-related quality of life instruments that a standardised procedure, such as that suggested by Sidani and colleagues[538] is needed to ensure that the instrument is valid for use in the target population. While the psychometric properties of the adapted instrument might appear comparable to the original instrument, the diversity of cultural backgrounds may lead patients to respond to items from their own perspective, an outlook that may be inconsistent with the underlying objective, leading to an invalid or inaccurate health assessment[538]. Consequently, one must initially demonstrate conceptual equivalence between the original and adapted instrument to ensure valid and reliable cross-cultural comparisons.

4.5.9. Comparative studies

Although there are a significant number of asthma/COPD-specific health-related quality of life instruments available, only a limited number of studies have directly compared them in terms of their psychometric properties, validity and responsiveness. There are also few studies that compare these disease-specific instruments with generic health-related quality of life instruments.

4.5.9.4. Comparisons with generic instruments

Generic health-related quality of life instruments are designed to measure the burden of illness across a range of medical conditions. Consequently, they can be used to compare health status across a range of diagnoses. However, they may lack sufficient depth to detect small but significant changes that can occur over the course of an illness[512]. In addition, a disease-specific scale is advantageous in that the exclusivity of the items to the disease will enhance the sensitivity of the scale as variance from irrelevant items is excluded [467].

a) AQLQ-J

A few studies have compared the performance of the AQLQ-J[433] with a number of generic health-related quality of life instruments, in particular the Medical Outcome Survey short-form 36 (SF-36)[444]. In all but one study the AQLQ-J[433] was found to perform better than the SF-36. Juniper *et al.*[512] and van der Molen *et al.*[468] compared the two instruments in terms of cross-sectional validity. Both research teams found the AQLQ-J to have better cross-sectional validity than the SF-36, particularly in relation to correlations with symptom scores[468] and asthma control[512]. However, correlations with lung function measures yielded correlation coefficients of broadly similar magnitude for both instruments.

Oga *et al.*[547] compared the responsiveness of the AQLQ-J and the SF-36 over 3 and 6 months using effect size and standardised response means. They observed that the three domains of the AQLQ-J (excluding the Environmental Stimuli domain) and the total score showed responsiveness of >0.8. In contrast, the mean effect size of the eight subscales of the SF-36 after 3 and 6 months was 0.42 and 0.53 respectively.

Van der Molen *et al.*[471] and Juniper *et al.*[512] also compared the responsiveness of the AQLQ-J and the SF-36. Both research groups found that the AQLQ-J was more responsive than the SF-36 when evaluating correlations with change in symptom scores,

change in asthma control, changes in β-agonist use and changes in lung function measures.

The above mentioned studies involved patients with a clinical diagnosis of asthma according to the definition of the American Thoracic Society[468,471,547] and/or confirmation of asthma with a lung function test[512]. In addition, the majority of these patients were recruited from outpatient clinics or from patients who had participated in previous studies. Puhan *et al.*[435] compared the AQLQ-J and the SF-36 in asthmatic patients from the general population. In this study the diagnosis of asthma was based on two questions; 'Do you have asthma?' and 'Has your asthma been diagnosed by a doctor?' 55.4% of asthma patients reported that they had not used any asthma medication in the three months preceding the study. Puhan *et al.* compared the construct validity of the AQLQ-J and the SF-36. Correlations of similar magnitude were observed between all domains of the AQLQ-J and domains assessing physical impairment of the SF-36, and measures of 'asthma severity', 'respiratory symptoms', 'exercise limitation', and 'professional or leisure limitation'. However, while the SF-36 domains assessing mental impairment correlated with the 'depression' measure to a greater extent than the physical domains, the Emotional Function domain of the AQLQ-J showed very weak correlation with this measure. In addition, the Emotional Function domain of the AQLQ-J showed correlations of similar magnitude to the other domains of the AQLQ-J with the validation measures for physical impairment. Consequently, the SF-36 was considered better at discriminating between different aspects of quality of life in the general population.

In addition, to the SF-36, a small number of studies compared the AQLQ-J to alternative generic health-related quality of life questionnaires: the Psychological and General Well-Being scale (PGWB)[468,471], the Nottingham Health Profile (NHP)[547], the Sickness Impact Profile (SIP)[449], the Medical Outcomes Survey short-form 12 (SF-12)[437] and the EuroQol (EQ5D)[437,547]. The PGWB was found to have lower construct validity[468] and responsiveness[471] than the AQLQ-J. Garratt *et al.*[437] reported that the SF-12 and the EQ5D were both significantly less responsive to changes in health status than the AQLQ-J. Similarly, Oga *et al.*[547] found the AQLQ-J to be more responsive to health status changes than either the EQ5D or the NHP. The SIP was compared with the AQLQ-J in the context of construct validity and responsiveness[449]. Only the SIP was observed to correlate with measures of lung function on analysis of construct validity, although the magnitude of the correlations was very weak ($r = -0.26$- -0.29, $p \leq 0.001$-0.01). In contrast, the AQLQ-J correlated more strongly with the 'symptoms' measures than the SIP. Conversely, the SIP only correlated significantly with the PEFR p.m. measure of responsiveness whereas the AQLQ-J correlated with all but one of the lung function

measures in addition to the 'symptoms' measures. Consequently, with the possible exception of the construct validity of the SIP, the AQLQ-J was found to be superior to the aforementioned generic instruments in measuring health-related quality of life in asthma patients.

b) LWAQ

A small number of studies have compared the LWAQ with the SF-36[468,471], the PGWB[468,471], and the SIP[449] with mixed results. Van der Molen *et al.*[468] observed that the SF-36 and the LWAQ were approximately equal in relation to construct validity. In terms of responsiveness, the LWAQ was observed to be superior to the SF-36 in detecting changes in health status following treatment with formoterol, a long-acting β-agonist[471].

Rutten-van Molken compared the performance of the LWAQ with the SIP in a clinical trial evaluating the effects of salmeterol on health-related quality of life[449]. Although, both questionnaires showed an improvement in quality of life in favour of salmeterol treatment neither showed a statistically significant greater improvement on salmeterol. However, on analysis of the effect sizes, it was observed that the LWAQ was more responsive than the SIP. In terms of construct validity, the SIP was found to correlate significantly with four of the lung function measures whereas a correlation was only observed between the LWAQ and two such measures. A weak-moderate correlation was observed between both instruments and the 'symptoms' measure. The responsiveness of both instruments was observed to be poor; changes in SIP values correlated significantly with changes in PEFR p.m. only and changes in LWAQ correlated with changes in daytime symptoms only.

In both studies that compared the performances of the PGWB and the LWAQ, the LWAQ was observed to be superior in terms of construct validity[468] and responsiveness[471].

c) AQLQ-Mks

Ware *et al.*[503] compared the responsiveness of the AQLQ-Mks and the SF-36 in discriminating between groups that did and did not change in terms of asthma severity. They observed that the AQLQ-Mks was more responsive than the SF-36 in all of the outcome measures evaluated.

4.5.9.5. Comparisons between disease-specific instruments

a) AQLQ-J and LWAQ

Three studies were identified that compared the AQLQ-J and the LWAQ in terms of responsiveness and construct validity with contradictory results. Van der Molen *et al.*[468,471] compared the performance of the AQLQ-J and the LWAQ in evaluating the effects of formoterol on quality of life. At baseline, they observed that the AQLQ-J had greater construct validity than the LWAQ, especially in relation to 'symptom scores' and 'β-agonist use'. Only the physical domains of both instruments showed evidence of correlations with lung function measures and these were much weaker in magnitude for both instruments. Treatment with formoterol resulted in statistically significant changes in clinical outcome measures such as mean FEV_1, mean use of reliever medication and so forth. However, only the LWAQ total score and LWAQ physical domain improved significantly ($p < 0.05$). No statistically significant change was observed for the AQLQ-J total score or any of its four domains. The effect size (ES) of the LWAQ total and LWAQ physical construct and that of the AQLQ-J symptoms domain were broadly similar in magnitude (ES = 0.394, 0.407 and 0.316 respectively). The responsiveness of the AQLQ-J and the LWAQ were observed to be broadly similar, with the exception of the 'symptoms' measure where a stronger correlation was observed with the AQLQ-J total score and three of its four domains.

Rutten-van Molken *et al.*[449] compared the two health status measures in investigating the effects of salmeterol on quality of life. The AQLQ-J had greater construct validity than the LWAQ in terms of the 'symptoms' measure, but both instruments only correlated weakly with one of the 'lung function' measures. Following treatment with salmeterol or salbutamol, a statistically significant improvement was observed in all but one of the lung function measures, PEFR p.m. While both the AQLQ-J and the LWAQ were responsive to within-patient improvements following salmeterol treatment, only the AQLQ-J total and Activity Limitations domain showed a statistically significant improvement in quality of life with salmeterol over salbutamol. In addition the effect sizes of the AQLQ-J total and Activity Limitations domain were larger in magnitude than those of the LWAQ total and Health Knowledge domain (ES = 0.820, 0.860 versus 0.696, 0.625 respectively). Furthermore, the responsiveness of the AQLQ-J was superior to that of the LWAQ in relation to both 'lung function' measures and 'symptom' measures.

Oga *et al.*[492] compared the performance of the AQLQ-J, the LWAQ and the AQ20 in a sample of newly diagnosed asthma patients over a 6 month period. It was observed that the AQLQ-J was the most responsive instrument in detecting changes in health status, followed by the AQ20 and then the LWAQ. The responsiveness index/effect size for the AQLQ-J total and its four domains from baseline to 6 months ranged from 0.91-1.53. The effect size of the AQ20 and LWAQ for the equivalent period ranged from 1.06-1.13 and

0.55-0.76 respectively. In addition, the longitudinal validity of both the AQLQ-J total and AQ20 was superior to that of the LWAQ total in terms of correlation with changes in FEV_1 (Spearman's correlation coefficients = -0.40 [AQ20], 0.38 [AQLQ-J], -0.23 [LWAQ]). The researchers also evaluated the score distribution of the three instruments. They observed that at 3 months and 6 months 18.8% and 30.3% of patients had the best possible score in the AQ20, whereas no patient reached the best possible score in the LWAQ after 6 months and only 9.1% of patients rated the best score in the AQLQ-J after 6 months.

b) AQLQ-J and SGRQ:

Two studies that compared the performance of the AQLQ-J and the SGRQ, directly[436] and indirectly[505], have been identified in the published literature. Both studies concluded that the two instruments are comparatively equal in their ability to measure asthma-specific health related quality of life. Sanjuas *et al.*[436] and Barley *et al.*[505] compared the cross-sectional validity and responsiveness of the two instruments. Sanjuas *et al.*[436] investigated the existence of a relationship between each instrument and both dyspnoea and $\%FEV_1$. It was observed that all domains of the AQLQ-J and the SGRQ correlated strongly with dyspnoea (Spearman's correlation coefficients (r) > 0.5), with the exception of the Symptoms domain of the SGRQ which showed a moderate correlation. Weaker relationships were recorded between both instruments and $\%FEV_1$. Only the Symptoms and Activity Limitations domains, the AQLQ-J total score and the Activities and Impacts domains of the SGRQ and the total score had low to moderate statistically significant correlations with $\%FEV_1$. Barley *et al.*[505] also examined the possible relationship between the two instruments and lung function measures in their evaluation of cross-sectional validity. It was observed that all domains of the SGRQ and the total score correlated weakly to moderately with $\%FEV_1$, morning PEFR and evening PEFR (r = -0.35 to -0.49). Only the Activity Limitations and Symptoms domains of the AQLQ-J correlated with all three lung function measures; the total score failed to correlate with $\%FEV_1$. For each measured variable the magnitude of the correlation was smaller than that with the SGRQ (r = 0.23 - 0.40). In addition, this study also explored the possible relationship between the health status instruments and two global questions, one estimating asthma severity and the other estimating the impact of asthma on daily living. Each instrument correlated strongly with both global questions. The weakest correlations observed were those with the Emotional Functioning and Environmental Stimuli domains of the AQLQ-J (r = -0.52 to -0.56).

As mentioned above, both studies also compared the responsiveness of the two instruments. Both Barley *et al.*[505] and Sanjuas *et al.*[436] found both instruments to be equal in their ability to distinguish between groups of asthma patients with varying degrees of disease severity.

Sanjuas *et al.*[436] also compared the AQLQ-J and the SGRQ in terms of sensitivity and longitudinal validity. The AQLQ-J was superior in its ability to distinguish between populations of asthma patients according to recruitment group (which translated into asthma severity) and frequency of daily and nocturnal symptoms. Conversely, the SGRQ showed a greater discriminatory capacity than the AQLQ-J among patients with differing levels of airflow limitation. In terms of longitudinal validity, moderate correlations were observed between all domain and total scores of the AQLQ-J and SGRQ and changes in dyspnoea, with the exception of the Symptoms domain of the SGRQ which failed to correlate significantly with changes in dyspnoea. Only the Symptoms and Emotions domains of the AQLQ-J and the total score correlated significantly with changes in $\%FEV_1$. No significant correlations were observed between $\%FEV_1$ and any of the domains of the SGRQ.

Sanjuas *et al.*[436] also compared the AQLQ-J and the SGRQ in terms of score distribution and reliability. In general, the percentage of missing items in each domain was low for both questionnaires with the exception of the Activity Limitations domain of the AQLQ-J (15.5%). With regard to reliability both questionnaires showed Cronbach's α values of ≥ 0.7 and ICC values of between 0.82(AQLQ-J Symptoms) and 0.94 (SGRQ overall).

c) AQ20 and ABP:

Nishimura *et al.*[486]compared the ability of the AQ20 and ABP to evaluate health-related quality of life in asthma patients. The researchers compared the cross-sectional validity of the two instruments with regard to the existence of a correlation between the two questionnaires and both the HADS scale and the MRC dyspnoea scale. It was observed that the ABP had a stronger correlation with the Anxiety and Depression scales of the HADS than the AQ20 ($r = 0.58$-0.62 ABP; $r = 0.42$-0.44 AQ20, $p < 0.01$) but the AQ20 had a stronger relationship with the MRC dyspnoea scale than the ABP ($r = 0.40$ AQ20; $r = 0.28$ ABP, $p < 0.01$).

4.6. Conclusion

In conclusion, there is no one instrument that is superior to the others in all contexts. However, due to the dearth of information on the AIS, ITG-ASF and ALIS, additional studies are needed to draw definitive conclusions on their psychometric properties. The choice of instrument depends greatly on the characteristics of the study. As discussed, the focus of the item content varies between instruments and so it is vital to choose an instrument with items that reflect the desired outcome measure for the study. In addition, for convenience and patient participation, shorter instruments are more suited to long-term studies or those conducted in the clinical setting where there are significant time constraints. A recall period of one year has been demonstrated to be too long and so if using the SGRQ, a one- or three-month recall period for the Symptoms domain is advisable. The population studied will also influence the choice of instrument in some instances as the AQ20 and the ABP have been demonstrated to be more suited to patients with more severe disease. Concerning using the instruments to assess individual versus group comparisons, only the overall instrument scores have proven suitable for individual level comparisons. The domain scores should only be used for group comparisons as evidenced by the Cronbach's α coefficient values.

The choice of instrument will also vary depending on whether the study is measuring longitudinal or cross-sectional outcomes. The only instrument of the nine evaluated with individualised questions was the AQLQ-J, thus the use of this instrument would not be recommended for cross-sectional studies, but for evaluative or longitudinal studies. In addition, to minimise instances of missing data for the individualised questions, the use of the interviewer-administered version of the questionnaire would be recommended. Conversely, the SGRQ and the LWAQ would be more suitable for cross-sectional studies than evaluative studies as longer instruments covering the entire range of quality of life limitations with fewer response options are more appropriate in these instances. In addition, studies evaluating the responsiveness of the SGRQ have produced poor results. However, in cross-sectional studies the greatest correlation between lung function/PEFR was observed with the SGRQ.

From the published data identified, to date interpretability data are only available for the SGRQ and the AQLQ-J. The availability of this data is essential if one wishes to contextualise the study outcomes into clinically meaningful results. This is extremely valuable in both clinical trials and studies conducted in the clinical setting and should be a major consideration when choosing an appropriate instrument. In conclusion, the AQLQ-J would be recommended for evaluative studies and the SGRQ for longitudinal studies if the item content of both is appropriate to the studies.

5. Brief Intervention

5.1. Introduction

Numerous community pharmacy-based pharmaceutical care interventions on asthma management have been conducted to date[140,171,217,218,344,375,393,548-551]. The interventions involved in many of these studies have necessitated significant deviations from normal practice and the time requirements for the patient consultations have been considerable[217,218,393,171,344]. However, insufficient time has been frequently mentioned by pharmacists in the published literature as a potential barrier to the provision of enhanced pharmacy services[404-406]. In addition, the results of the QAM-CP revealed that 85% of respondents *agreed/strongly agreed* that insufficient time is a major barrier to the provision of patient counselling on asthma. In Ireland, there is a 'fee per item' culture in community pharmacy as, with the exception of the seasonal influenza vaccination scheme and the provision of emergency hormonal contraception, dispensing prescription medications is the main source of revenue. Unlike in the UK, where community pharmacists are paid for the provision of professional services such as providing the Chronic Ailment Service[552], in Ireland, to date, there is no such fee structure. The 'Baseline Study of Community Pharmacy Practice in Ireland' commissioned by the PSI revealed that 17.5 % of respondents dispensed >4,000 - 5,000 prescriptions per month and 26.5% dispensed >5,000 prescriptions per month. In addition, > 80% of respondents indicated that they spent 'most of the time on most days' dispensing prescriptions[553]. This 'fee per item culture' is further exacerbated by the predominance of pharmacies with only one community pharmacist working each day and limited qualified support staff. Indeed, 80% of the QAM-CP respondents indicated that only one pharmacist was on duty each day and >44% of respondents worked in pharmacies where there was no pharmaceutical technician employed. Consequently, to maximise pharmacist and patient involvement, this intervention was designed to be brief to facilitate its incorporation into daily practice where limited professional staff and qualified support staff, and the 'fee per item' culture imply that time is a priceless commodity in community pharmacy.

The Demonstration Project, discussed in Chapter 3, was designed to assess the barriers and facilitators to implementing a national asthma programme and it failed to achieve and sustain pharmacist involvement. The Demonstration Project provided a clear indication that a pilot project, which focused solely on community pharmacy, was essential to determine the feasibility of implementing an asthma intervention in community pharmacy in Ireland and to investigate the presence of any barriers and facilitators that were unique to this environment. As discussed above, the community pharmacy environment in

Ireland is a unique setting where considerable emphasis is placed on dispensing prescriptions, thus considerably reducing the amount of time available for patient counselling. In addition, in the absence of a national asthma programme, regular checking of patients' inhaler technique is unlikely to be routine practice for the majority of community pharmacists. Indeed the results of the QAM-CP illustrated <10% of respondents *always/often* routinely assess and educate their patients on inhaler technique. Consequently, the combination of poor pharmacist involvement in the Demonstration Project, the unique 'fee per item' culture in community pharmacy in Ireland, and the absence of a national asthma programme signified the urgent need to design and implement a community pharmacist-led pilot project on asthma. The inclusion of an Exit Questionnaire (outlined in 5.2.2 below) provided participating pharmacists with an opportunity to outline clearly any barriers and facilitators to the implementation of this project from their own personal experiences. Outcome measures to assess participants' experiences with an educational intervention are infrequently included in pharmacy-based studies, but they are invaluable to the provision of a comprehensive understanding of a pilot project.

The results of the QAM-CP (see Chapter 2) revealed that community pharmacists believed that, on average, only ~56% of their asthma patients used their inhalers properly and only ~11% had a peak flow meter that they used regularly. Inhaler technique can affect the amount of drug delivered to the lungs. Newman and colleagues[2] demonstrated a difference of ~33% in the amount of drug deposited in the lungs between patients who failed to coordinate actuation and inhalation using a pMDI and good coordinators. Furthermore, incorrect inhaler technique has been associated with poor asthma control, increased asthma instability and increased unscheduled health-care visits compared to patients with optimal technique[9,10]. Therefore, assessing and training patients on inhaler technique was considered an essential component of this brief intervention (BI). In addition, a community pharmacy-based intervention on inhaler technique was reported to take just 5.0 ±2 minutes (median ± inter-quartile range) per education/assessment cycle[41].

The GINA guidelines[1] recommend the use of peak flow measurements in monitoring asthma control. Using peak flow rates to monitor asthma control provides an objective measure of lung function and it has been shown to provide a more accurate measure of asthma severity than symptom monitoring[179]. The availability of an objective measure of asthma control is particularly important given the extensive reporting of patients' poor perceptions of asthma control in the published literature both in Ireland and worldwide[151,172]. Thus, peak flow meter assessment and training was also included in the

BI due to the apparently limited use of peak flow meters nationwide and also as peak flow rate measurements would provide an objective measure of patients' degree of asthma control.

5.2. Methods

5.2.1. Design of the study protocol

Ethical approval for the study was obtained from the Faculty of Health Sciences Research Ethics Committee (see Appendix 11). The study was designed as a single-blind randomised parallel group design. Extensive research was conducted on the published literature with a particular emphasis on community pharmacy-based interventions on asthma care[140,171,217,218,344,375,393,548-551] and those that focused primarily on inhaler technique interventions[6,41,104,175] in order to devise appropriate protocols for the Test and Control parts of the study (see Appendices 26 and 27 respectively). Figure 5.1 provides an overview of the study design.

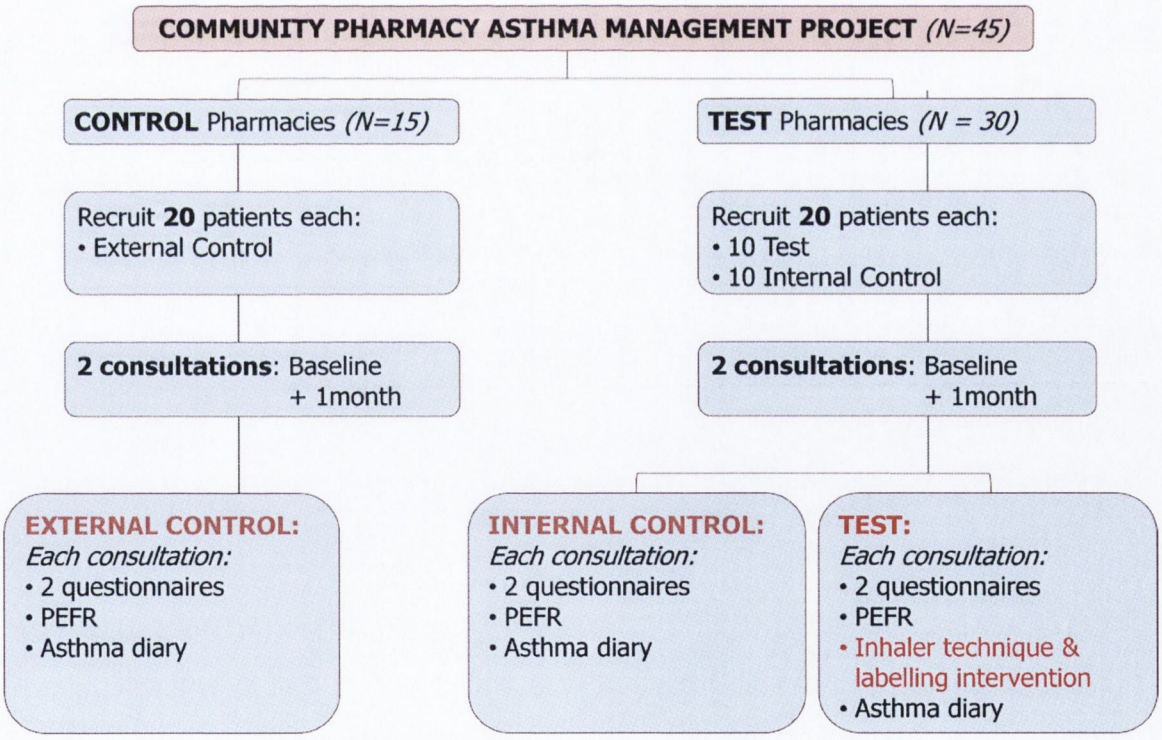


Figure 5.1: Overview of the design of the Brief Intervention

As discussed in 5.1 above, the key component of the educational intervention for test patients was assessment and training on inhaler technique. A recent study by Basheti and colleagues[175] demonstrated that when counselling on inhaler technique, verbal counselling augmented with a physical demonstration of the correct technique appears to

be necessary for the achievement of optimal technique in the majority of asthma patients. Thus, the 'Show and Tell' protocol designed by Basheti and colleagues[175] and outlined in Figure 5.2, was adopted into the Test protocol. This consisted of assessing the patient's inhaler technique using the appropriate placebo and technique checklist then educating the patient (if necessary) by going through each step on the technique checklist and demonstrating it correctly using the placebo inhaler. This cycle of assessment and training could be repeated a further two times if necessary.

In an attempt to address 'contrivance' whereby an individual deliberately uses his/her inhaler device in a manner that he/she knows to be sub-optimal[554] Basheti and colleagues used novel inhaler technique labels in an intervention that was well received by both participating patients and pharmacists alike[41]. The use of inhaler technique reminder labels was also used in this study (see Appendix 33) in conjunction with the 'Show and Tell' protocol. The text and format of the labels were designed with Microsoft Office Word 2007 using the label specifications as a guide. The Microsoft Word document was then printed directly onto laser labels (64 mm x 33.9mm).

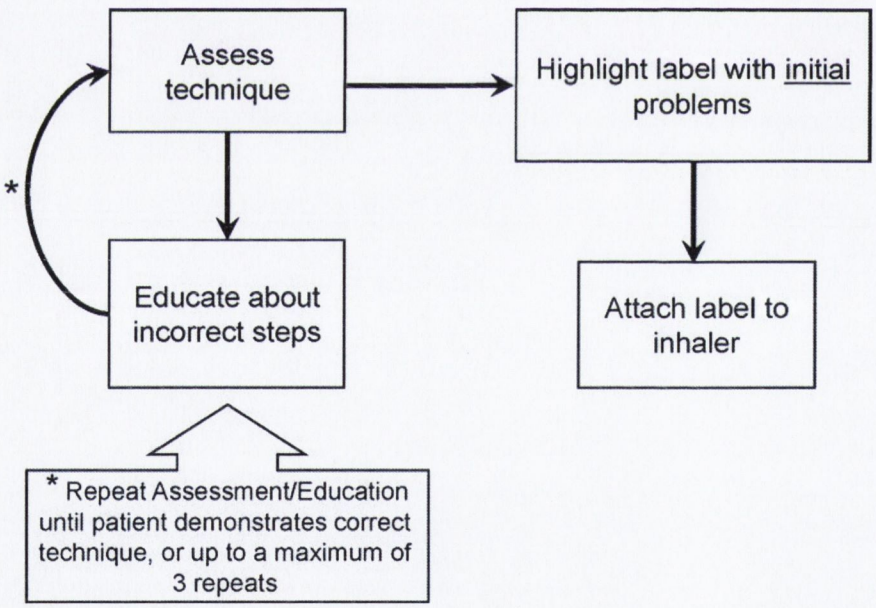


Figure 5.2: Protocol for inhaler technique assessment and education (taken from Basheti and colleagues[41]). (Following initial assessment and education, assessment and education could be repeated twice if necessary until correct technique was observed)

5.2.2. Design of outcome measures

Two separate questionnaires were designed following an analysis of the outcome measures used in the published literature on community pharmacy-based interventions on asthma management[6,104,140,171,217,218,344,374]. The first questionnaire, identified as the

Control, Knowledge and Adherence questionnaire (CKAQ) was a one-page questionnaire printed on both sides and it was divided into four subsections. The first subsection consisted of items on the demographic characteristics of the patient to facilitate the contextualisation of the results. The second section consisted of the ACT[555]. This measure of asthma control was chosen because it has good psychometric properties[386] and it is short and easy to score as it consists of only five questions. In addition, unlike the Asthma Control Questionnaire[8] it does not require FEV_1 measurements, which are unlikely to be available in a typical community pharmacy. The ACT is scored by summing the responses for each of the five questions to yield a score of 5 to 25 where higher scores indicate better control[555]. A score of 20 or more has been identified as indicative of controlled asthma and score of ≤ 15 indicates uncontrolled asthma[386].

The third part of the questionnaire consisted of the Consumer Asthma Knowledge Questionnaire (CQ)[383] but one minor adjustment was made to the final item in the questionnaire. This item in the original CQ read as follows: *Blue puffer (Ventolin), Brown puffer (Flixotide) and Green puffer (Serevent) are called "preventer medications," so they should be used everyday although you are well.* This was altered to: *Blue puffer (Ventolin/Salamol/Bricanyl/Gerivent) is called a "preventer medication," so it should be used everyday although you are well.* This modification was made due to the number of trade names of preventative medications that would need to be included in this item to ensure that all of those currently available in Ireland were incorporated. Each correctly answered item scored one point and if the answer was incorrect or unanswered, a score of zero was provided for the question. The final score was expressed as a mean value by dividing each participant's score by the maximum score.

The final subsection consisted of a modified version of the 8-item self-report Morisky Medication Adherence Scale (MMAS)[382]. The MMAS was developed to assess medication adherence in patients with hypertension, thus five of the eight items needed to be modified for asthma patients. The MMAS scores can range from 0-8 and they have been divided into three levels of adherence in the literature: 8 = high adherence, 6-7 = medium adherence, < 6 = low adherence[382].

The second questionnaire was on asthma-specific quality of life and the Mini Asthma Quality of Life questionnaire (Mini-AQLQ)[384], developed by Juniper and colleagues was used. This version of the asthma-specific quality of life questionnaire, developed by Juniper and colleagues, was chosen because it is short, it consists of 15 items, but it still demonstrated good psychometric properties[384,385]. An overall mean quality of life score was calculated with higher scores indicating better asthma-specific quality of life. In

addition, four mean domain scores (Activity Limitation, Environmental Stimuli, Emotional Function and Symptoms) were calculated using the scores of the items that represent these four domains.

An adult and a paediatric version of the CQAK (see Appendix 28: adult and Appendix 29: child) and the Mini-AQLQ (see Appendix 30: adult and Appendix 31: child) questionnaires were developed. The wording of the CQAK was modified in the paediatric version from *you, your asthma* to *your child, your child's asthma*. A paediatric version of the Mini-AQLQ is available on the author's website (*http://www.qoltech.co.uk/minipaqlq.html*) and it has also demonstrated good validity, reliability and responsiveness[385].

The peak flow meter technique checklist and the inhaler technique checklists (available in Appendix 34 and 32 respectively) were designed with reference to those prepared by Mrs. Cicely Roche, Senior Lecturer in the School of Pharmacy and Pharmaceutical Sciences and those promoted by the ASI and GINA. The GINA guidelines recommend that PEFR measurements should preferably be compared to a patient's own personal best measurement obtained when he/she is clinically well due to the wide range of predicted values[1]. However, as the results of the QAM-CP revealed that, on average, only ~11% of patients are estimated to possess a peak flow meter that they use regularly it was predicted that a significant proportion of patients would not be aware of their personal best peak flow rate measurement. Consequently, a peak expiratory flow reference chart[556] was provided as a support tool to each participating pharmacist (available in Appendix 35).

An *asthma diary* was also developed as an outcome measure that patients would complete at home over the two-weeks following each consultation with the pharmacist (available in Appendix 36). The *asthma diary* developed for the Evaluation Project was modified slightly, with reference to those used in the published literature[41,140,344,374], to produce a diary that was easy to use and comprehend. The patients was asked to record their peak flow readings morning and evening, their daily reliever usage and any absenteeism from work/school due to asthma over a two-week period.

In order to determine test pharmacists' opinions about the educational intervention on inhaler technique and their experiences with patient recruitment and follow-up an *Exit Questionnaire* was designed with reference to relevant published studies[221,405,557-559] (see Appendix 38). The questionnaire was a single page document printed on both sides and it consisted of four subsections. The first subsection consisted of items on the demographic characteristics of the test pharmacists to facilitate the contextualisation of

the results. The second subsection consisted of questions about the initial patient consultations and included items on patient receptiveness to participation, barriers to participation and the average time required to complete an initial consultation. The third subsection was based on the follow-up consultation and included items on receptiveness to engaging in a follow-up consultation, barriers to engagement and the average time needed to complete a follow-up consultation. The last subsection investigated respondents' perceptions of the project and included items on the usefulness of the study materials, the effect of the study on pharmacist-patient relationships and pharmacists' knowledge, and any desirable/undesirable factors about the project. The questionnaire was designed as an anonymous postal questionnaire to be completed by participating pharmacists on the conclusion of the project.

5.2.3. Pharmacist recruitment

In order to recruit community pharmacists to the Demonstration Project (see Chapter 3), Ms. Pamela Logan, Director of Pharmacy Services for the IPU, circulated a memorandum on behalf of the ASI, to community pharmacists nationwide. Only community pharmacists who were located in the catchment area of a GP who was enrolled in the Demonstration Project could participate in the project, but a considerable number of pharmacists who were not eligible also expressed an interest. This list of pharmacists who had expressed an interest in the Demonstration Project, but who were ineligible for participation, was obtained from Ms. Logan as it was considered that these pharmacists had an interest in asthma and might agree to participate in the BI. The list consisted of pharmacists working in community pharmacies located in twenty-one of the twenty-six counties in Ireland, in rural, suburban, town and city locations. This pool of pharmacists was randomised into a list of potential Test participants and one of potential Control participants using the randomised number generator in Microsoft Office Excel 2007.

Each potential participant was telephoned at the community pharmacy in which they worked in a sequential manner according to the randomised lists until the quota of 15 Control pharmacists and 30 Test pharmacists was reached. The original list provided by Ms. Pamela Logan consisted of 107 community pharmacists. As numerous barriers to participation in practice-based research have been identified in the literature[560,561], it was considered unlikely that >50% of those invited to participate would agree. As a result, a quota of 45 pharmacists was considered a realistic number with which to conduct this pilot study. Each telephone call was conducted in a similar manner and commenced with a brief introduction outlining the researcher's interest in asthma followed by an enquiry about whether or not the potential participant wished to hear a description of the BI for

which the researcher was currently recruiting participants. If the pharmacist did not wish to hear about the BI, he/she was thanked for the time and the telephone call was terminated. However, if the pharmacist did express an interest he/she was provided with explanation of the BI and a description of the relevant intervention protocol (Test or Control) and asked if he/she would like to participate. In most instances, additional information was provided to the potential participant by email and an arrangement was made to conduct a follow-up telephone call a few days later. The additional information included the *pharmacist information leaflet* (see Appendix 13: Test and Appendix 16: Control) and the relevant *intervention protocol*. If the pharmacist ultimately agreed to participate in the BI a face-to-face meeting was arranged in the community pharmacy in which he/she worked, at a suitable time in the following 7-10 days.

At each face-to-face meeting, the participating pharmacist was provided with the *pharmacist information leaflet*, the *pharmacist informed consent form* and a Study Pack (Test or Control version). Each Test Study Pack consisted of an expandable file with separate indexed sections that contained the following documents: the Test intervention protocol, adult and paediatric information leaflets and informed consent forms, adult and paediatric CKAQs, adult and paediatric Mini-AQLQs, peak flow meter checklists, peak flow reference charts, inhaler technique checklists for nine different types of inhalation device, inhaler technique reminder labels for each type of inhalation device, asthma diaries, and postage paid envelopes. Twenty copies of each document were provided in each pack and they were colour coded for ease of identification. Test pharmacists were also provided with a selection of placebo inhalers, the relevant contact details to obtain a greater supply and sufficient peak flow meters for each recruited patient and the pharmacist.

The Control Study Pack differed from the Test Study Pack in the content of the patient and pharmacist information leaflets, informed consent forms and the intervention protocol. It did not contain the inhaler technique checklists or reminder labels but the peak flow meter checklists and patient questionnaires were identical to those provided in the Test Study Pack except that they differed in colour for ease of differentiation by the researcher on receipt of the completed forms. The Control pharmacists did not receive any placebo inhalers but they did receive a supply of peak flow meters. The documentation included in both the Control and Test Study Packs is available in Appendices 12-36.

At each face-to-face meeting, the researcher carefully outlined the intervention protocol, explained the various documents that needed to be completed and identified the support material available in the Study Pack as well as reliable reference websites if further

information was needed. The correct procedure for assessing and scoring patients' inhaler technique was emphasized to each Test pharmacist in order to ensure inter-rater reliability. The researcher's contact details were also provided to each participating pharmacist if further clarification on any issue was required over the course of the study.

All patients and all Control pharmacists were blinded to their group allocation. This was achieved by instructing Test and Control pharmacists to educate all participating patients on peak flow meter technique, thus providing a plausible 'intervention' for the Control pharmacists and the patients in the internal and external control groups[41].

5.2.4. Patient recruitment

Pharmacists were asked to approach consecutive patients for inclusion in the study who had a diagnosis of asthma, were currently using at least one inhalation device, were regular customers at the pharmacy and were ≥ 7years. Exclusion criteria included those who suffered from dementia and/or had severe learning or communication difficulties as it was considered that conducting consultations with these patients might be difficult.

Participating pharmacists were requested to recruit 20 patients each. In the case of Test pharmacists, these 20 patients were divided into 10 test patients and 10 internal control patients. Pharmacists were told to recruit patients to each group in an alternate manner. The patients recruited by the Control pharmacists were all external control patients.

5.2.5. Test patient consultations

Following the provision of informed consent by the patient, each consultation (both initial and follow-up) adhered to the same format, which is outlined below:

1) Administration of the relevant CKAQ and Mini-AQLQ for self-completion by the patient in the pharmacy.
2) Assessment and training (if needed) on peak flow meter technique and measurement of peak expiratory flow rate.
3) *Assessment and training (if needed) on inhaler technique according to Figure 5.2.*
4) Provision of an asthma diary for self-completion by the patient over the ensuing two weeks.

5.2.6. Control patient consultations

The format for the control patient consultations is outlined below. This was adhered to for consultations with both internal and external control patients at every consultation once informed consent had been obtained at initial recruitment.

1) Administration of the relevant CKAQ and Mini-AQLQ for self-completion by the patient in the pharmacy.
2) Assessment and training (if needed) on peak flow meter technique and measurement of peak expiratory flow rate.
3) Provision of an asthma diary for self-completion by the patient over the ensuing two weeks.

5.2.7. Statistical analysis

The results of the outcome measures were coded, inputted into SPSS version 16 and analysed with probabilities of ≤ 0.05 considered statistically significant. For discrete variables, comparisons between groups were conducted using the Chi-square test and one-way ANOVA was used to evaluate differences between groups of continuous variables. The paired-samples t-test was used to compare differences within groups between baseline and follow-up consultations.

5.3. Results

At baseline, test patients and both internal and external control patients completed the relevant CKAQs and Mini-AQLQs, they were assessed and trained on the peak flow meter and their peak expiratory flow rates were measured, and they were asked to complete an asthma diary. Identical data collection forms were used to gather this information, therefore the Results section is divided into two parts. The first section presents the baseline data of all recruited patients (excluding inhaler technique data) as an observation study. In the second section, an analysis of any impact(s) of the inhaler technique intervention on the test patients will be conducted and the results will be compared with those of both internal and external control patients.

5.3.1. Results: Observational study

5.3.1.1. Baseline characteristics

Twenty-two pharmacists recruited a total of 147 participants for the baseline consultation. The number of participants recruited by each pharmacist ranged from one to thirteen and the mean number of recruited participants per pharmacist was seven.

a) Gender

52.4% of the participants were male *(N = 147).*

b) Age

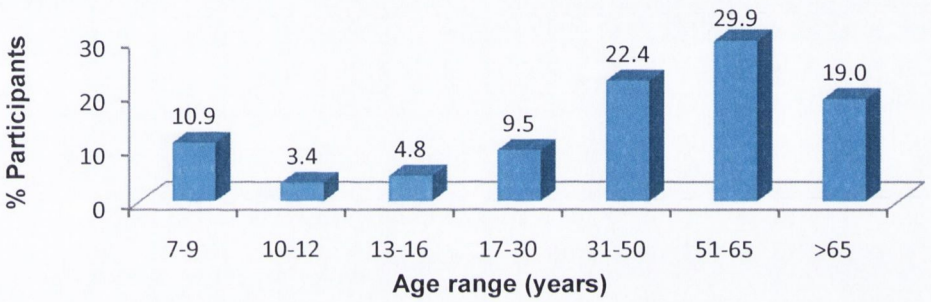


Figure 5.3: Age range of participants (N = 147).

c) Smoking status

49.2% of the participants were non-smokers, 31.7% were ex-smokers and 19.1% were current smokers *(N = 126).* Participants aged 7-12 years were excluded from this evaluation. The average number of cigarettes smoked daily ranged from two to forty and the mean number was twelve cigarettes (SD = 8.5) *(N = 23).*

d) Possession of a medical card or Drug Payment Scheme card

38% of participants had a medical card, 49% had a DPS card and the remaining 13% had neither.

e) Possession of an asthma management plan

Only 6.2% of participants reported that they possessed an asthma management plan *(N = 146).*

f) Number of GP visits for asthma in the past 12 months

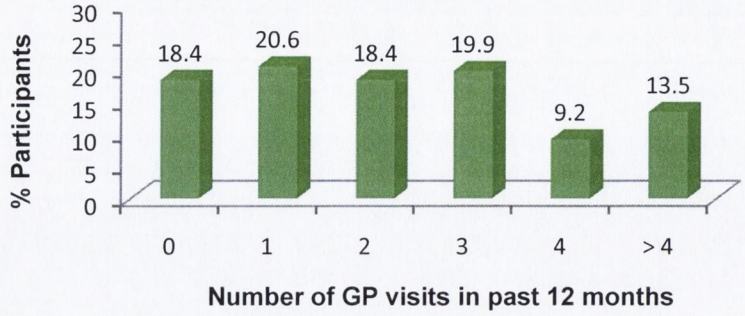


Figure 5.4: Number of times each participant attended his/her GP for asthma in the preceding 12 months (N = 141).

The maximum number of visits in the past 12 months was twelve and the mean number of visits was 2.5 (SD = 2.4).

g) Inhaler technique education on initial prescription

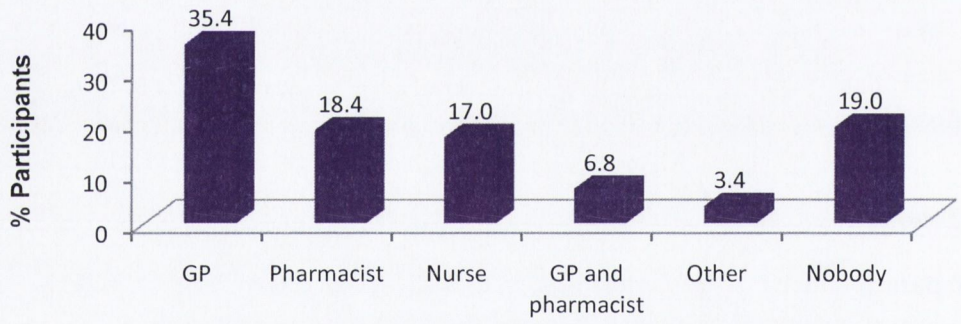


Figure 5.5 The health-care professional(s) who demonstrated inhaler technique to the participants when an inhaler was first prescribed (N = 147).

5.3.1.2. Asthma control status

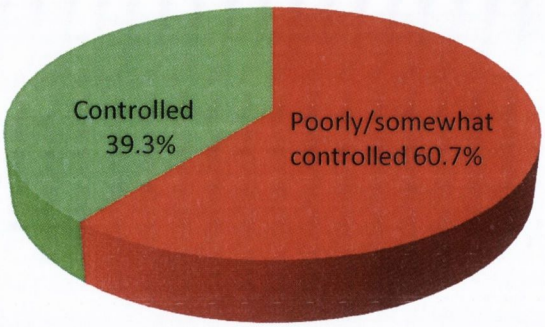


Figure 5.6: Asthma control status of participants according to their ACT scores (N = 145). Controlled = ≥ 20, poorly/somewhat controlled = < 20 poorly/somewhat controlled.

Neither age, possession of a medical/DPS card, possession of an asthma management plan nor initial inhaler technique education by a health-care professional had any influence on this result. However, significant differences were observed between participants depending on their smoking status and the number of times they attended their GP for asthma in the past 12 months.

a) Smoking status and asthma control status

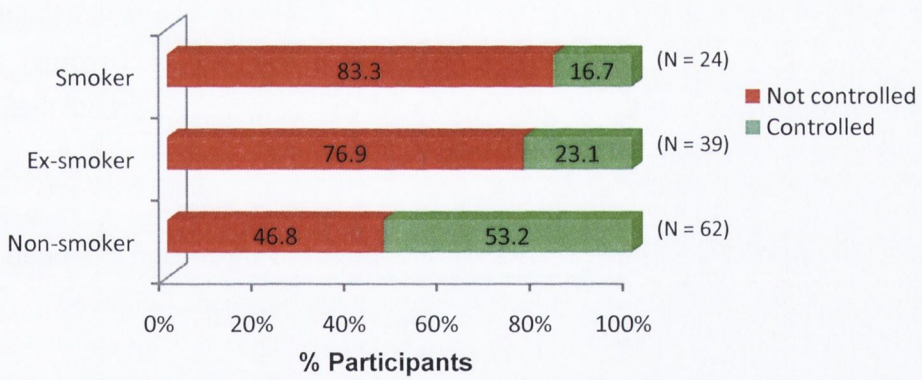


Figure 5.7: Participants' smoking status classified according to whether or not their asthma was controlled (p = 0.001, χ^2 test).

A significantly greater proportion of smokers and ex-smokers had uncontrolled asthma compared to non-smokers. A significantly greater proportion of non-smokers had controlled asthma compared to smokers and ex-smokers.

b) GP visits for asthma and asthma control status

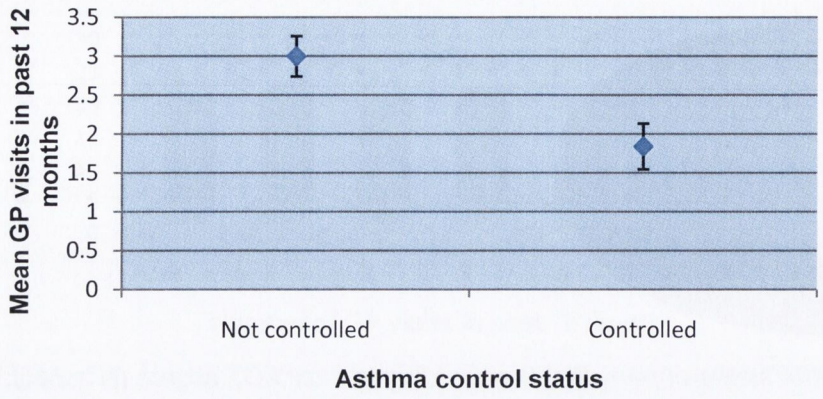


Figure 5.8: Participants' asthma control status classified according to their mean number of GP visits for asthma in the preceding 12 months (±SE) (N = 145, p = 0.004, ANOVA).

Participants with uncontrolled asthma reported a significantly higher mean number of GP visits for asthma in the past 12 months than participants with controlled asthma.

5.3.1.3. Asthma Knowledge

Item (h) in the CQ, *You should use "preventer medication" when you have an asthma attack* was excluded from the analysis because it was considered ambiguous due to the introduction of the Symbicort SMART (Symbicort Maintenance and Reliever Therapy) regime for asthma. Patients under this regime use their Symbicort inhaler as both their preventer and reliever medication.

The mean CQ score was 7.36 (SD = 2.1) out of a maximum of 11 points and the mean percentage score was 66.9% (SD = 19.2) but considerable variation was observed between participants' scores as outlined in Figure 5.9 below.

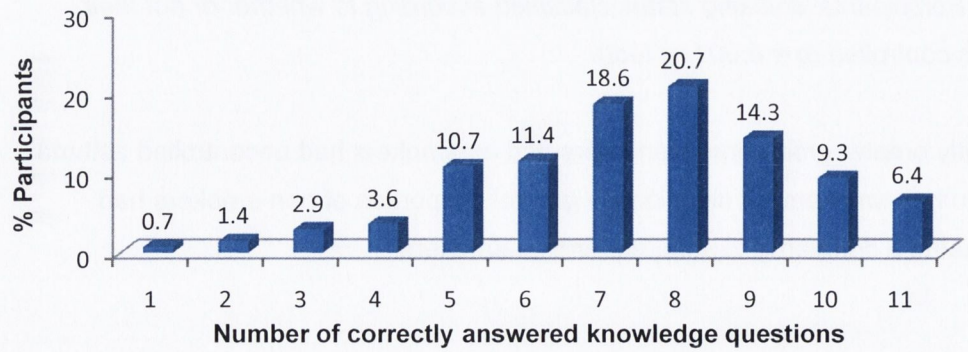


Figure 5.9: Participants' Consumer Asthma Knowledge Questionnaire scores (N = 140).

Only a minority of participants correctly answered all of the questions on asthma-related issues.

The mean CQ scores were not influenced by participants' age, smoking status, or the possession of an asthma management plan. However, they were influenced by whether or not a participant received an inhaler technique demonstration from a health-care professional at the initial prescription.

a) Initial demonstration of inhaler technique by a health-care professional and CQ scores

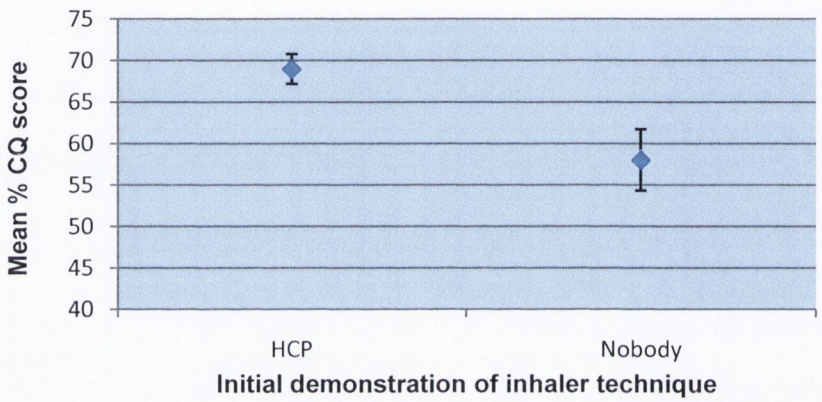
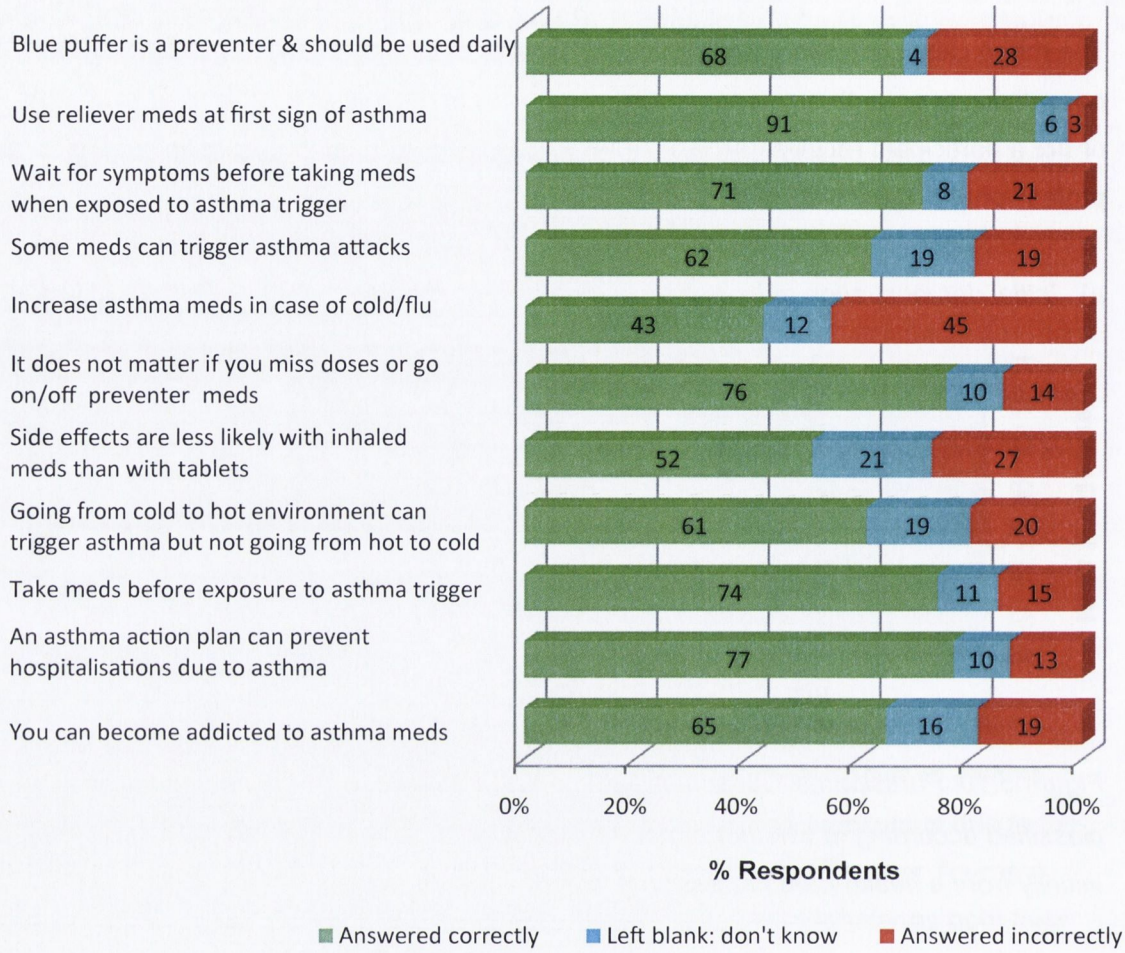


Figure 5.10: Participants' Consumer Asthma Knowledge Questionnaire scores (±SE) classified according to whether or not they received a demonstration of inhaler technique initially from a health-care professional (N = 135, p = 0.008, ANOVA).

Participants who received a demonstration of inhaler technique from a health-care professional initially had significantly higher mean CQ scores than those who did not receive a demonstration of inhaler technique on initial prescription.

A detailed analysis of the results obtained for each item in the CQ is outlined below:



Meds = medicines

Figure 5.11: Participants' knowledge about a range of asthma-related issues (N = 140).

Each item included in the CQ was analysed individually to evaluate whether participants' demographic characteristics influenced the results obtained. To facilitate this analysis the 'incorrect' and 'don't know' responses were combined into one category. Participants' age range and the initial demonstration of inhaler technique by a health-care professional influenced a number of the CQ items.

a) Influence of participants' age range on CQ results

Four of the items included in the CQ were influenced by participants' age range. In each instance, a significantly greater proportion of participants > 50 years answered this question incorrectly compared to the younger participants. The items influenced by age were:

- You can become addicted to asthma medications if you use them all the time *(N = 140, p = 0.008, χ^2 test).*
- Going from a cold to hot environment can trigger asthma, but going from a hot to cold environment does not trigger asthma *(N = 140, p = 0.004, χ^2 test).*
- Some medications can trigger asthma attacks *(N = 140, p = 0.045, χ^2 test).*
- Blue puffer is called "a preventer medication" and should be used every day although you are well *(N = 140, p = 0.032, χ^2 test).*

b) Influence of initial demonstration of inhaler technique by a health-care professional on CQ results

Only one item in the CQ was influenced by the initial demonstration of inhaler technique by a health-care professional and that was *You should take "reliever medication" as soon as you recognise the first sign of asthma.* A significantly greater proportion of participants who received an initial demonstration of inhaler technique from a health-care professional answered this question correctly compared to those who did not receive any initial demonstration of inhaler technique *(N = 140, p = 0.047, χ^2 test).*

5.3.1.4. Medication Adherence

Five participants indicated that they were not prescribed preventative medication for their asthma at the time of the consultations therefore their responses were not included in the analysis of items (a), (e), (f), (g) and (h) or in determining participants' overall level of medication adherence.

a) Overall medication adherence

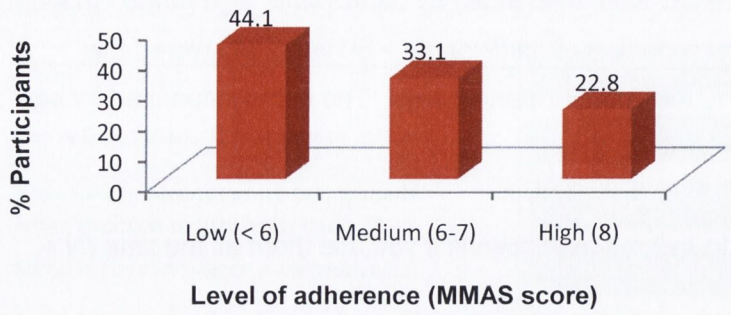


Figure 5.12: Participants' overall level of asthma medication adherence (N = 136).

A detailed analysis of participants' overall level of adherence was conducted and it was discovered that neither participants' smoking status, possession of a medical card, possession of an asthma management plan, number of GP visits for asthma, initial demonstration of inhaler technique by a health-care professional, ACT score or total CQ score influenced this result. However, participants' age range and their responses to two of the relevant CQ items were influential and these are outlined below.

- *Age range*

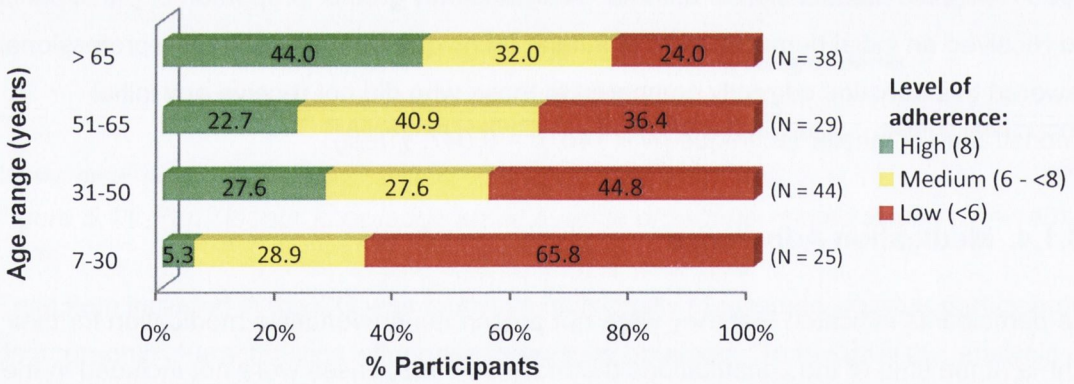


Figure 5.13: Participants' level of medication adherence classified according to their age range (p = 0.005, χ^2 test).

A significantly greater proportion of participants aged 7 - 30 years had low medication adherence compared to those > 30 years. A significantly greater proportion of the oldest participants (> 65 years) had high medication adherence compared to those ≤ 65 years. A significantly greater proportion of participants aged 51-65 years had a medium level of medication adherence compared to the younger and older participants.

- *Side effects are less likely with inhaled medications than with tablets*

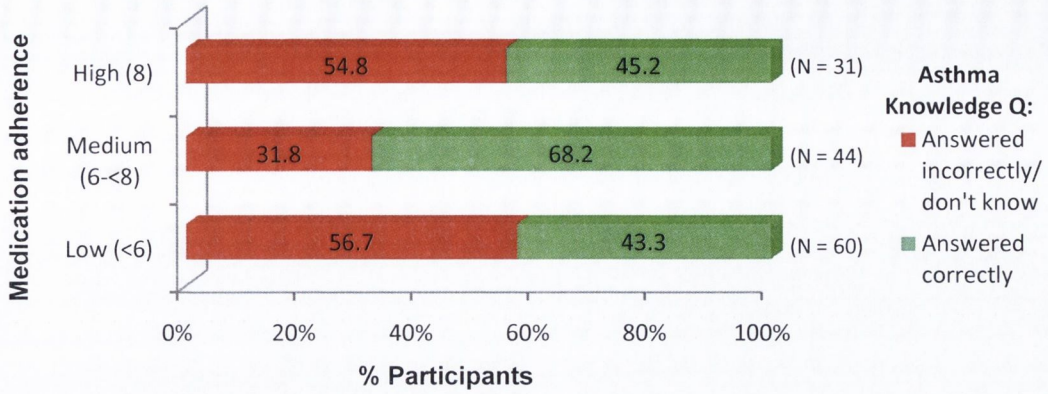


Figure 5.14: Participants' level of medication adherence classified according to their responses to the question on whether or not side effects are less likely with inhaled medications than with tablets ($p = 0.03$, χ^2 test).

A significantly greater proportion of participants with high and low adherence answered this question incorrectly compared to those with medium adherence. In addition, a significantly greater proportion of participants with medium adherence answered this question correctly compared to those with both low and high adherence.

- *With "preventer medications", it does not matter if some doses are missed or if you go on and off them*

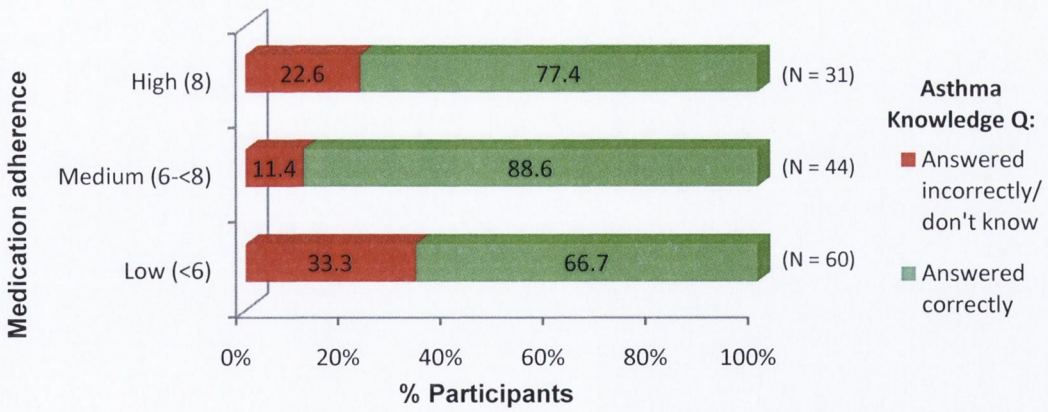


Figure 5.15: Participants' level of medication adherence classified according to their responses to the question on whether or not it matters if you miss doses or go on and off preventer medications ($p = 0.03$, χ^2 test).

A significantly greater proportion of participants with medium adherence answered with question correctly compared to those with high and low adherence. Additionally, a significantly greater proportion of participants with low adherence answered this question incorrectly compared to those with higher levels of medication adherence.

A detailed description of participants' responses to seven of the eight MMAS questions is outlined in Figure 5.16 below. The results of the eighth question are outlined in a separate graph in Figure 5.17.

a) Participants' responses to Medication Adherence questions (excluding item h)

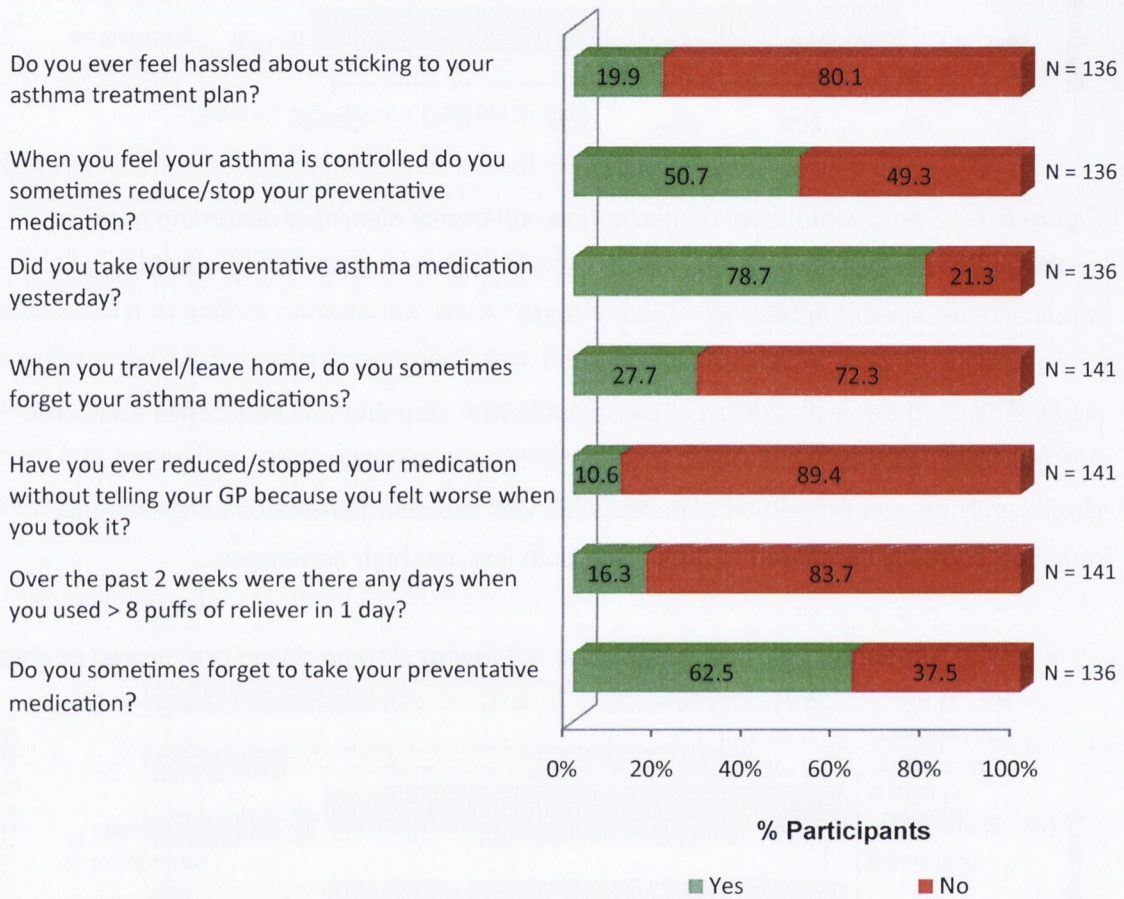


Figure 5.16: Participants' responses to questions on medication adherence

b) *Participants responses to the frequency with which they have difficulty remembering their preventative medications*

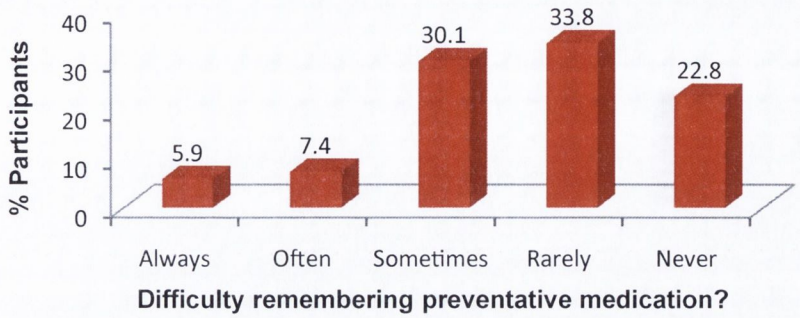


Figure 5.17: The frequency with which participants have difficulty remembering to take their preventative medication (N = 136).

Each of the items in the MMAS was analysed to investigate if the results were influenced by the participants' baseline characteristics and/or their asthma control status. It was discovered that participants' age range, number of GP visits in the preceding 12 months and participants' asthma control status influenced a number of the MMAS items and these are outlined below.

a) *Influence of participants' age range on their medication adherence.*

Participants' age range influenced the responses to three of the MMAS items. In each case, a significantly greater proportion of the youngest participants (7-30 years) provided responses indicative of poor medication adherence compared to the older participants. In addition, a significantly greater proportion of the oldest participants (> 50 years) provided responses indicative of good medication adherence compared to the younger participants. Indeed, in each case as participants' age range increased the percentage of those who provided responses indicating good medication adherence also increased and the differences between the groups were significant. The thee items influenced by age range were:

- Do you sometimes forget to take your preventative asthma medication? *(N = 136, p = 0.003, χ^2 test).*
- Did you take your preventative medication yesterday? *(N = 136, p = 0.014, χ^2 test).*
- When you feel your asthma is under control, do you sometimes reduce or stop taking your preventative asthma medication? *(N = 136, p = 0.015, χ^2 test).*

b) Influence of the number of GP visits in the preceding 12 months on their medication adherence

Participants' number of GP visits in the preceding 12 months influenced two of the MMAS items: (1) *Do you sometimes forget to take your preventative asthma medication?* and (2) *Over the past two weeks, were there any days where you used more than eight puffs of your reliever inhaler in one day?*

Participants who claimed to occasionally forgot their preventative asthma medication had a significantly lower mean number of GP visits in the preceding 12 months than those who claimed to be more adherent to their preventative medication regime *(N = 130, p = 0.007, ANOVA).* However, participants who claimed to have used more than eight puffs of their reliever inhalers in one day in the preceding two weeks had a significantly higher mean number of GP visits for asthma in the preceding 12 months than those who did not use such large quantities of their reliever medication *(N = 135, p = 0.018, ANOVA).*

c) Influence of participants' asthma control status and their medication adherence

Participants' asthma control status influenced one of the items in the MMAS: *Over the past two weeks, were there any days where you used more than eight puffs of your reliever inhaler in one day?* A significantly greater proportion of participants with uncontrolled asthma indicated that they used > 8 puffs of their reliever medication on one day in the preceding 2 weeks than those with controlled asthma *(N = 140, p = 0.001, χ^2 test).*

5.3.1.5. Asthma-specific quality of life: Participants > 12 years

The overall mean quality of life score and the mean scores for each of the four domains are provided in the table below.

Table 5.1 Mean asthma-specific quality of life scores (participants > 12 years) (N = 124).

Domain	Mean±SD	Minimum	Maximum
OVERALL	5.0±1.2	2.5	7.0
Activity Limitation	5.6±1.3	2.5	7.0
Symptoms	4.8±1.3	1.8	7.0
Emotional Function	4.8±1.7	1.0	7.0
Environmental Stimuli	4.8±1.6	1.3	7.0

The overall asthma-specific quality of life score and those of each of the four domains were analysed in detail and the results are outlined below. As discussed in Chapter 4, a statistically significant result does not necessarily translate into a clinically relevant effect for quality of life scores due to its partial dependence on sample size[514]. In health status instruments the MID is used to assign clinical relevance and Juniper and colleagues determined that a MID of 0.5 was clinically relevant for the original asthma-specific quality of life questionnaire[451]. Thus, this measure of clinical relevance will be used in the analysis below.

Neither participants' age, possession of a medical card, possession of an asthma management plan, nor initial demonstration of inhaler technique by a health-care professional influenced the overall quality of life scores or the domain scores. However, participants' asthma control status, smoking status and their medication adherence influenced one or more of the domain scores and/or the overall quality of life scores.

a) Smoking status and quality of life.

Table 5.2 Mean quality of life scores and participants' smoking status (> 12 years) (N = 124)

Domain	Non-smoker Mean±SD	Ex-smoker Mean±SD	Current smoker Mean±SD	Significance
OVERALL	5.3±1.2	4.8±1.2	4.6±1.0	0.016
Activity Limitation	5.9±1.2	5.4±1.4	5.4±1.4	NS
Symptoms	5.1±1.3	4.6±1.2	4.2±1.0	0.003
Emotional Function	5.3±1.6	4.6±1.6	4.0±1.5	0.003
Environmental Stimuli	4.9±1.6	4.4±1.6	5.0±1.5	NS

NS = Not significant

Non-smokers had significantly higher, and clinically relevant, mean overall quality of life scores compared to both smokers and ex-smokers. In addition, non-smokers had significantly higher mean Symptoms and Emotional Function domain scores than current smokers.

b) Asthma control and quality of life

Table 5.3 Mean quality of life scores and participants' asthma control status (> 12 years) (N = 124)

Domain	Controlled Mean±SD	Not controlled Mean±SD	Significance
OVERALL	5.9±0.8	4.5±1.0	< 0.001
Activity Limitation	6.4±0.8	5.2±1.4	< 0.001
Symptoms	5.8±0.9	4.2±1.0	< 0.001
Emotional Function	5.8±1.4	4.3±1.5	< 0.001
Environmental Stimuli	5.5±1.2	4.3±1.6	< 0.001

Participants with controlled asthma had significantly higher mean overall quality of life scores and mean domain scores than participants with uncontrolled asthma and the differences between the mean scores were clinically relevant.

c) Medication adherence and quality of life

Participants' level of medication adherence only influenced the Symptoms domain scores and the results are outlined below.

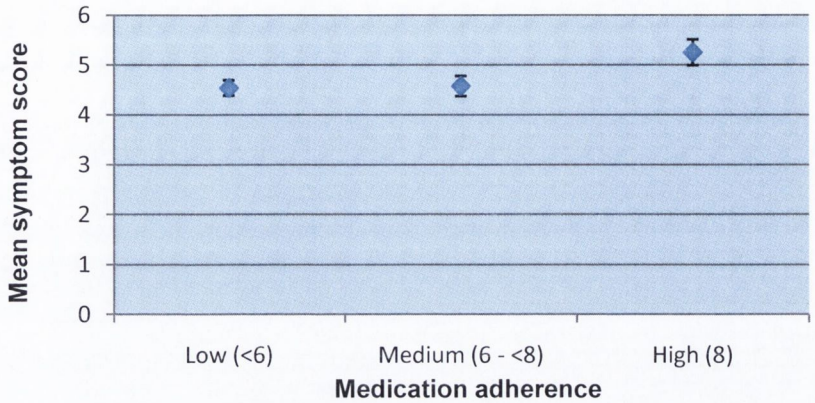


Figure 5.18: Participants' mean Symptom scores classified according to their level of medication adherence (N = 116, p =0 .03, ANOVA).

Participants with high medication adherence had significantly higher mean Symptoms domain scores than participants with medium or low adherence.

5.3.1.6. Asthma-specific quality of life: Participants 7-12 years

The overall mean quality of life scores and the mean scores for each of the three domains are provided below (the Environmental Stimuli domain is not included in the paediatric Mini-AQLQ).

Table 5.4: Mean asthma-specific quality of life scores (participants 7-12 years) (N = 21)

Domain	Mean±SD	Minimum	Maximum
OVERALL	5.9±1.0	3.5	7.0
Activity Limitation	5.9±1.1	3.7	7.0
Symptoms	5.7±1.3	2.2	7.0
Emotional Function	6.2±0.9	4.3	7.0

Neither participants' age, possession of a medical card, possession of an asthma management plan, initial demonstration of inhaler technique by a health-care professional nor level of medication adherence had any influence on either the overall quality of life score or the domain scores. However, participants' asthma control status did influence this result and the results are outlined in Table 5.5 below.

Table 5.5 Mean quality of life scores and participants' asthma control status (7-12 years)

Domain	Controlled Mean±SD	Not controlled Mean±SD	Significance
OVERALL	6.5±0.5	5.0±0.9	< 0.001
Activity Limitation	6.5±0.7	5.1±1.0	0.002
Symptoms	6.4±0.6	4.6±1.2	< 0.001
Emotional Function	6.6±0.5	5.6±1.0	0.01

Participants with controlled asthma had significantly higher mean overall quality of life scores and mean domain scores than those with uncontrolled asthma.

5.3.1.7. Participants' ability to use a peak flow meter

Each participant was assessed on his/her ability to use a peak flow meter without the provision of any additional training and the results are presented below.

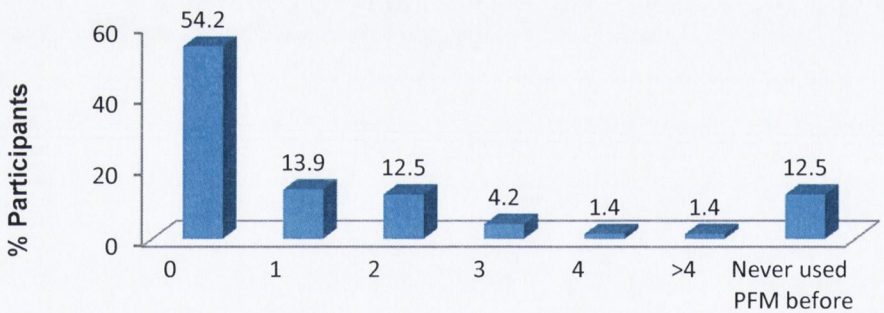


Figure 5.19: The percentage of participants who made 0 - >4 peak flow meter technique errors (N = 144).

Over half of the participants performed the peak flow meter technique without making any technique errors. Forty-eight participants made at least one technique error and the frequency with which each error was committed is outlined in Figure 5.20 below.

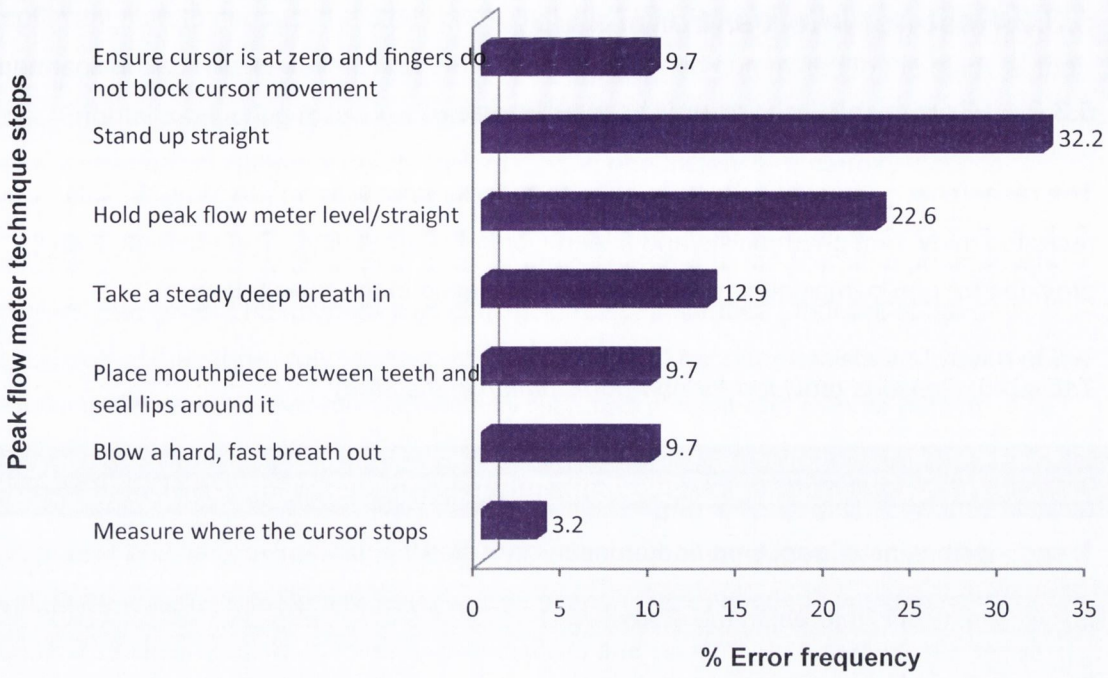


Figure 5.20: Frequency with which each peak flow meter technique error was performed (N = 48).

None of the participants' baseline characteristics, their asthma control status or their level of medication adherence had any influence on whether or not the participants' correctly performed all peak flow meter technique steps correctly.

5.3.2. Results: Interventional study

5.3.2.1. Community pharmacist recruitment

The researcher contacted seventy-eight pharmacists from May 11th to May 30th 2011 and recruited thirty Test pharmacists and fifteen Control pharmacists. The reasons, if any, provided for non-participation varied and are displayed in the table below.

Table 5.6: Reasons provided for non-participation in the study

	N	Reason for non-participation in study
1.	14	Insufficient time and/or insufficient staff
2.	4	No interest in the study
3.	3	No reason provided
4.	3	Pharmacist with asthma interest on maternity leave
5.	2	Pharmacist with asthma interest on holidays
6.	2	Insufficient asthma patients to participate
7.	1	New pharmacy, not enough regular asthma patients
8.	1	Pharmacist with asthma interest no longer working full-time
9.	1	Pharmacist with asthma interest no longer working in the pharmacy
10.	1	Pharmacy closed down
11.	1	Pharmacy moving premises in near future

Unfortunately, between May 11th and mid-June 2011 one Control pharmacist and three Test pharmacists withdrew from the study. The reasons provided were 'insufficient time', 'loss of the pharmaceutical technician', 'pharmacist was changing jobs' and 'pharmacy was raided'. As the remaining pharmacists were still recruiting participants for the baseline consultation it was decided to attempt to replace these pharmacists. This was completed successfully by June 28th 2011. However, between September 5th and October 17th 2011 one additional Control pharmacist and three further Test pharmacists withdrew from the study. The Control pharmacist withdrew due to an inability to recruit any asthma patients despite repeated attempts to do so. Two of the three Test pharmacists also withdrew as they were unable to recruit any patients and the third Test pharmacist withdrew as he had opened a new community pharmacy and consequently had

insufficient staff to conduct the study consultations. The remaining fourteen Control pharmacists and twenty-seven Test pharmacists remained committed to the study at that time. Prior to conducting follow-up consultations, two more Test pharmacists and one Control pharmacist withdrew due to lack of time in one instance, maternity leave in another and personal circumstances in the third instance. However, as the study progressed, the monthly telephone calls by the researcher to the recruited pharmacists revealed that patient recruitment was difficult in many instances. Indeed, at the conclusion of the study, only fourteen of the remaining Test pharmacists and seven of the remaining Control pharmacists successfully recruited at least one asthma patient. The reasons provided by the majority of pharmacists, when contacted monthly by the researcher, for their inability to recruit patients were 'insufficient time' on the part of the pharmacist and 'lack of interest in the study' on the part of the patients. In addition, one Test pharmacist took maternity leave and so was unable to continue with the study. Figure 5.21 illustrates the number of pharmacists and patients recruited initially, those who withdrew and those who completed the study.

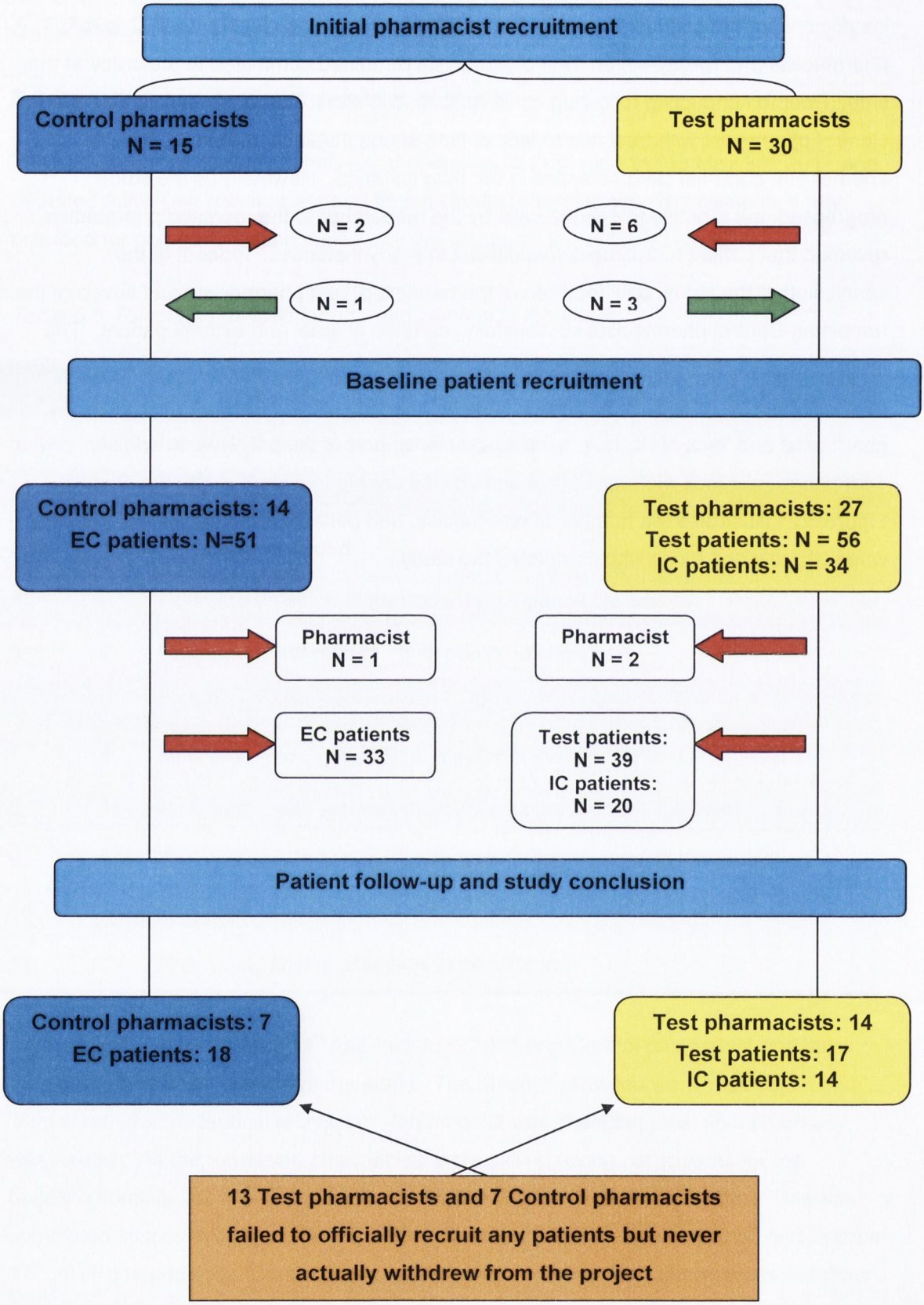


Figure 5.21: Flow chart of pharmacist and patient recruitment and withdrawal

EC = external control, IC = internal control.

5.3.2.2. Asthma patient recruitment

Table 5.7 outlines the test, internal control, and external control patients recruited by each community pharmacist initially and those who returned for their second consultations.

Table 5.7: Participant recruitment by community pharmacists nationwide

Pharmacist ID	Pharmacy location	Patients recruited for 1st consult		Patients who returned for 2nd consult	
A	Westmeath	T: 5	IC: 2	T: 0	IC: 0
B	Meath	T: 7	IC: 2	T: 2	IC: 1
C	Waterford	T: 3	IC: 3	T: 2	IC: 3
D	Mayo	T: 4	IC: 3	T: 0	IC: 0
E	Galway	T: 7	IC: 5	T: 4	IC: 2
F	Dublin	T:1	IC: 0	T: 0	IC: 0
G	Cork	T:3	IC: 2	T: 1	IC: 1
H	Cork	T: 1	IC: 0	T: 0	IC: 0
I	Tipperary	T: 7	IC: 0	T: 0	IC: 0
J	Limerick	T:4	IC:1	T: 0	IC: 0
K	Kilkenny	T: 2	IC: 3	T:1	IC: 0
L	Waterford	T: 6	IC: 0	T: 6	IC: 0
M	Meath	T: 5	IC: 3	T: 0	IC: 0
N	Dublin	T:1	IC: 10	T:1	IC: 7
O	Cork	EC: 6		EC: 2	
P	Dublin	EC: 7		EC: 3	
Q	Tipperary	EC: 10		EC: 6	
R	Kilkenny	EC: 2		EC: 0	
S	Waterford	EC: 11		EC: 0	
T	Dublin	EC: 13		EC: 7	
U	Longford	EC: 2		EC: 0	

T = Test patient; IC = Internal control patient, EC = External control patient.

5.3.2.3. Baseline characteristics of participants who completed the study

a) Age

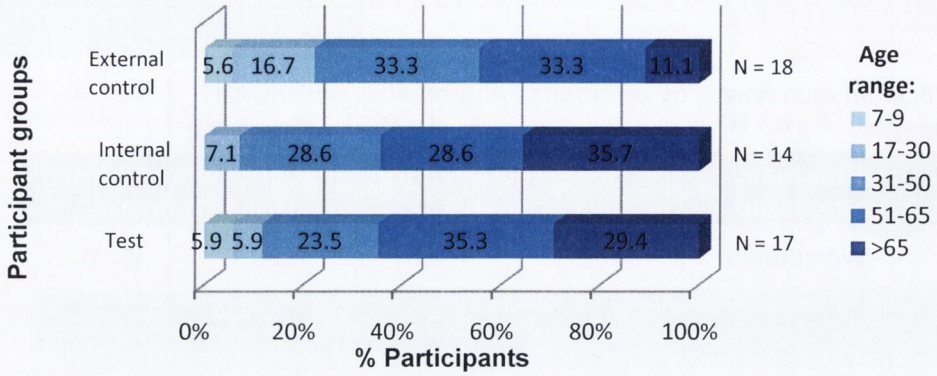


Figure 5.22: Age range of participants classified according to their study groups

b) Smoking status

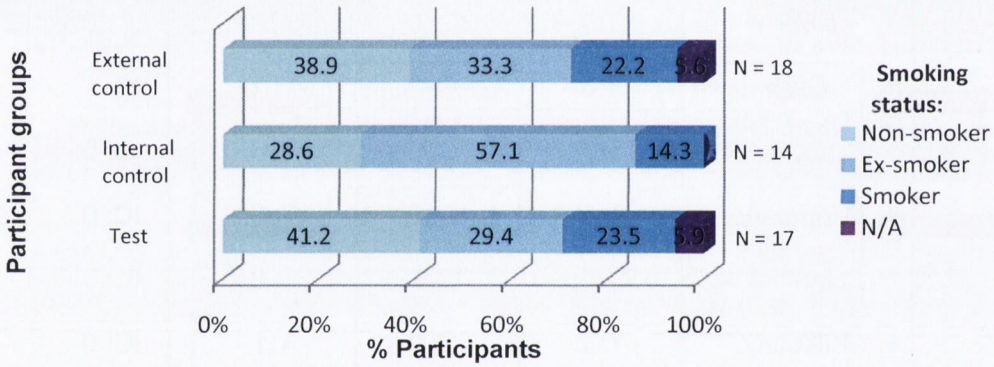


Figure 5.23: Participants' smoking status classified according to their study groups. N/A refers to participants aged 7-12 years.

The mean number of cigarettes smoked daily by the test patients was 5±0.8 (N = 4; test patients who smoked). Internal control patients smoked a mean number of 5.5±0.7 cigarettes daily (N = 2; internal control patients who smoked). The external control patients smoked a mean number of 20±13.5 cigarettes daily (N = 4; external control patients who smoked).

c) *Possession of a medical card*

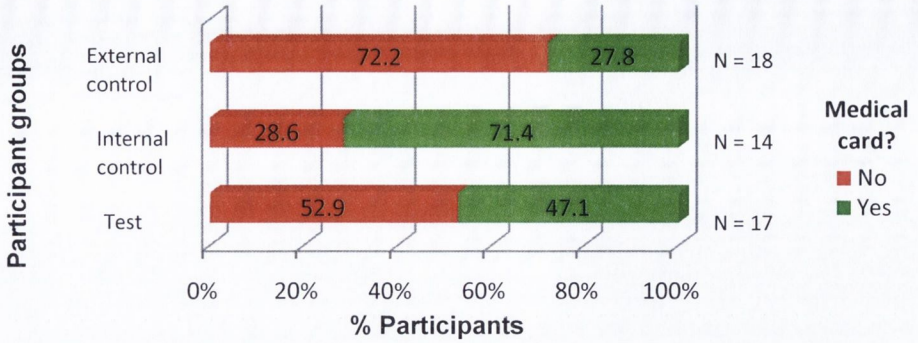


Figure 5.24: Proportion of participants who possessed a medical card classified according to their study groups.

A significantly greater number of internal control participants possessed a medical card and a significantly greater proportion of external control participants did not (p = 0.049, χ^2 test).

d) *Possession of an asthma management plan*

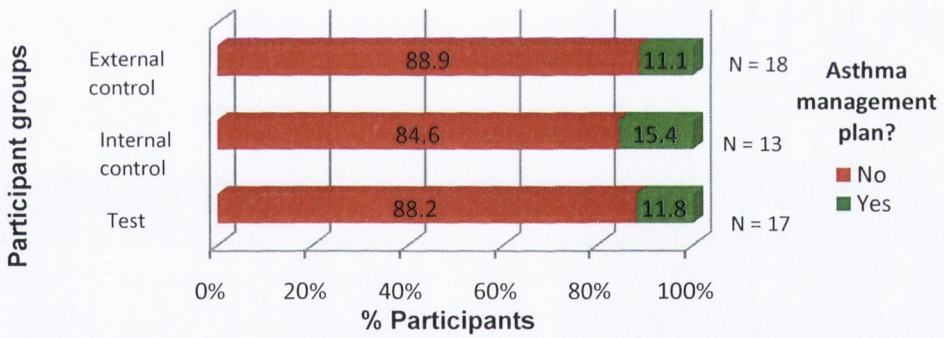


Figure 5.25: Proportion of participants who possessed an asthma management plan classified according to their study groups

e) *Demonstration of inhaler technique on initial prescription*

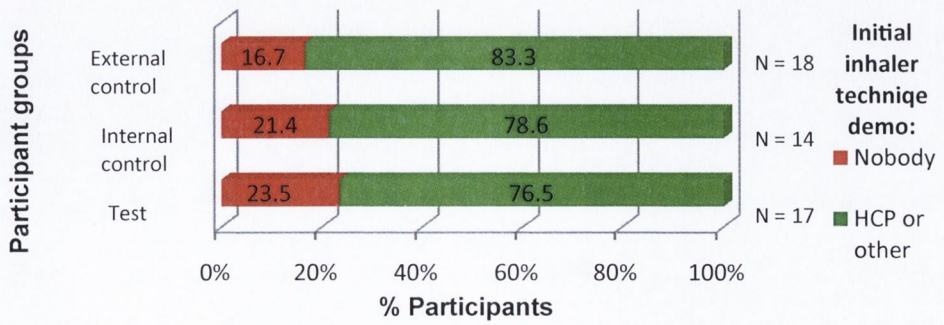


Figure 5.26: Proportion of participants who received an initial inhaler technique demonstration from a health-care professional classified according to their study groups.

f) Mean number of GP visits in the preceding 12 months

The test participants made an average of 2.4±3.1 visits to the GP in the preceding 12 months. The internal control participants attended the GP 2.2±1.5 times in the preceding 12 months. The external control participants attended the GP 2.8±1.8 times in the preceding year.

5.3.2.4. Peak flow meter technique: differences between study groups

One-way ANOVA was used to compare the peak flow meter technique scores between the three study groups at the initial consultations and at follow-up. No significant differences were observed between the groups at either consultation.

5.3.2.5. Peak flow meter technique: differences within study groups

The paired-samples t-test was used to determine if there were significant differences between the peak flow meter technique scores obtained at the initial visits compared to those obtained at the follow-up visits, for all three study groups. The results are displayed in the table below.

Table 5.8 Peak flow meter technique scores obtained at baseline and at follow-up

Study group	N	Baseline: Mean±SD	Follow-up: Mean±SD	Significance (2-tailed)
Test	20	5.75±1.8	6.9±0.3	0.01
Internal control	14	5.7±1.9	6.8±0.6-	0.026
External control	16	5.8±1.3	6.9±0.3	0.002

The table illustrates that a significant improvement in peak flow meter technique scores was observed for all three study groups between the initial and the follow-up consultations.

5.3.2.6. Peak flow meter technique: differences between those who completed the study and those who did not

Eighteen participants who did not return for the follow-up consultations had never used a peak flow meter before, thus they were not included in this analysis. One-way ANOVA was conducted to compare the initial peak flow meter technique scores between those who completed the study and those who dropped out. Those who completed the study

had an initial mean peak flow meter technique score of 5.9±1.4 (N = 47) and those who dropped out had a mean peak flow meter technique score of 6.4±1.0 (N = 79). These scores were significantly different, p = 0.022.

5.3.2.7. Inhaler technique: baseline

a) Baseline characteristics

Only the test participants were assessed and educated on inhaler technique. Eleven participants used one type of inhalation device and the remaining six used two device types. The proportion of participants per device type is outlined below.

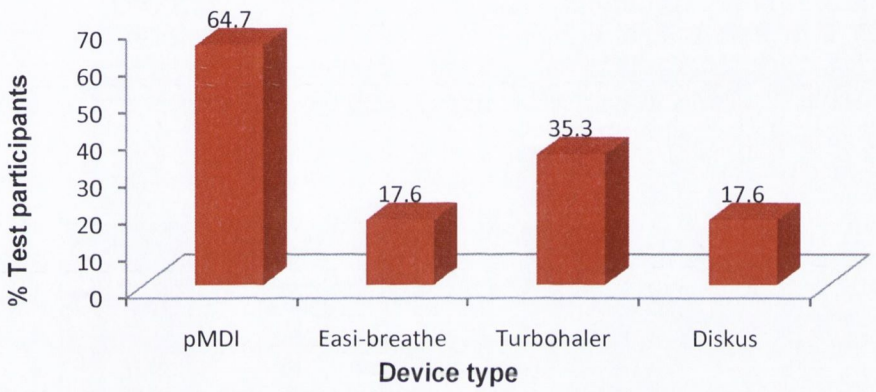


Figure 5.27: Proportion of test participants using each of the four inhalation devices (N = 17).

The percentages do not add up to 100% as six participants used two different device types.

b) Mean technique errors

There were no significant differences between the numbers of mistakes in inhaler technique performed according to device type. The results are displayed in the table below.

Table 5.9 Mean number of technique errors according to inhalation device recorded at baseline

Device type	N	Errors: Mean±SD	Minimum Errors	Maximum Errors
pMDI	11	2.2±1.0	1	4
Easi-breathe	3	2.3±3.2	0	6
Turbohaler	6	1.3±0.5	1	2
Diskus	3	1.3±1.2	0	2

However, when mean technique errors for the DS and TH were combined (both dry-powder inhalers) and compared with the mean technique errors for the pMDI a significant difference was observed. The mean number of technique errors obtained using a pMDI was 2.1±1.2 and this was significantly higher than 1.3±0.7, the mean number of technique errors obtained using a DPI *(N = 20, ANOVA, p =0.04).*

c) Essential and non-essential technique steps

The essential and non-essential technique steps performed by the participants using a pMDI, the Turbohaler and the Diskus are outlined below. As only three participants used the Easi-breathe inhaler and one of these performed all the technique steps correctly, it was omitted from this analysis. The Turbohaler and the Diskus were once again combined in this analysis.

- pMDI.

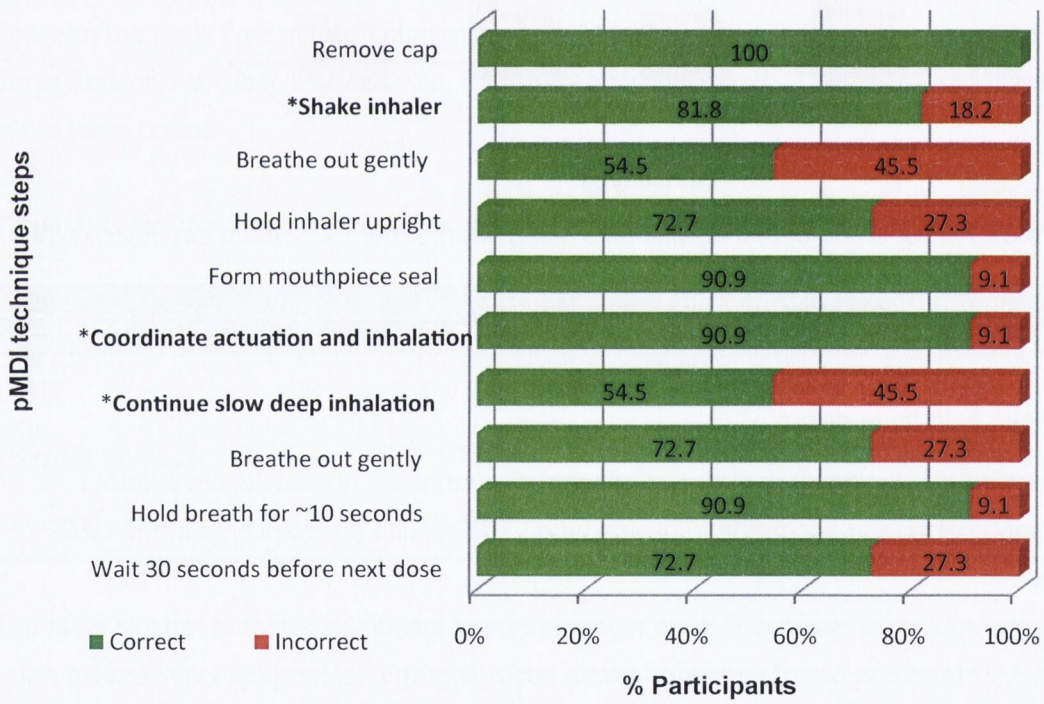


Figure 5.28: The proportion of participants using a pMDI who correctly/incorrectly performed each of the technique steps at baseline (N = 11).

The steps in bold and marked with an asterisk are those, which if incorrectly performed significantly reduce pulmonary drug deposition[2,3,64].

- *Turbohaler and Diskus*

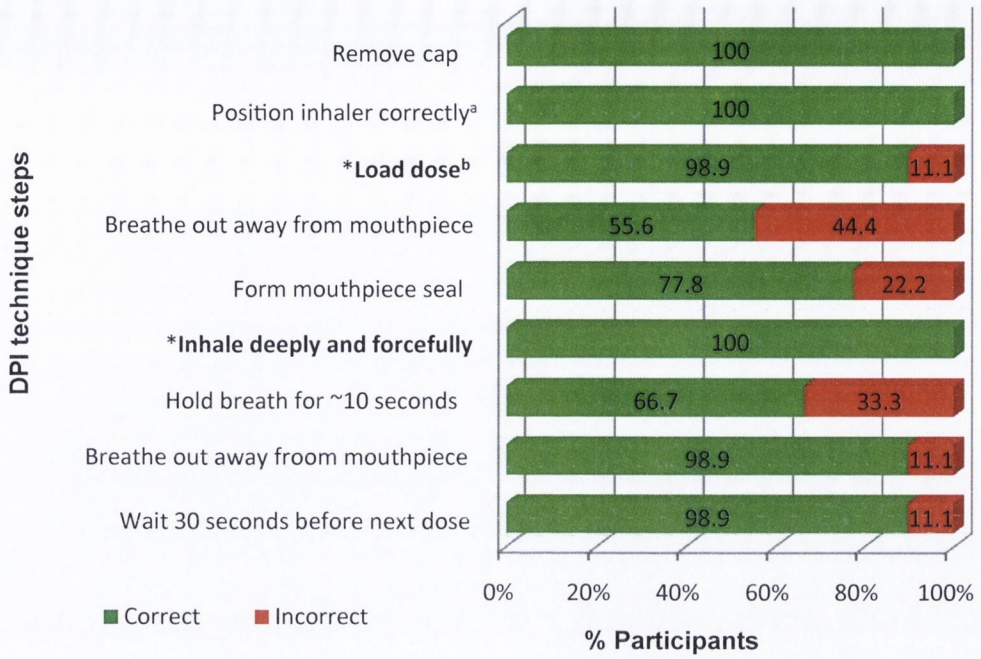


Figure 5.29: The proportion of participants using a DPI (Diskus/Turbohaler) who correctly/incorrectly performed each of the technique steps at baseline (N = 9).

[a] 'Position *inhaler correctly' refers to the upright position (with tolerance of ±45°) for TH on loading and to horizontal position for DS.*

[b] *'Load dose' refers to refers to twisting grip forward and backward until it clicks for TH and to sliding the lever away until it clicks for DS.*

The technique steps in bold and marked with an asterisk are essential steps, which if incorrectly performed significantly reduce drug deposition in the lungs[5,66,67].

Three steps in the pMDI technique and two in both the DS and TH techniques are considered critical to optimum pulmonary drug deposition and these are outlined in Figure 5.28 and 5.29 above.

The mean number of critical technique errors performed using either a pMDI or a DPI was compared using one-way ANOVA. Participants using a DPI performed 0.1±0.3 critical errors, significantly less than 0.7±0.8 critical errors recorded for a pMDI *(N = 20, ANOVA, p = 0.04).*

The percentages of test participants performing critical and non-critical technique errors are outlined in the table below.

Table 5.10: Participants performing critical and non-critical errors at baseline

Device type	N	% (n) ≥ 1 critical error	% ≥ 1 non-critical error
pMDI	11	54.5% (6)	81.8% (9)
DPI	9	11.1% (1)	88.9% (8)

5.3.2.8. Inhaler technique: follow-up

a) Mean technique errors

The mean number of technique errors performed according to device type is outlined in the table below. There were no significant differences in the mean number of errors performed between the types of inhalation devices.

Table 5.11: Mean number of technique errors according to inhalation device recorded at follow-up

Device type	N	Errors: Mean±SD	Minimum Errors	Maximum errors
pMDI	11	1.0±1.3	0	4
Easi-breathe	3	0.3±0.6	0	1
Turbohaler	6	0.3±0.5	0	1
Diskus	3	0.3±0.6	0	1

When the mean number of technique errors for the DS and TH were combined and compared with the mean number of errors recorded for the pMDI, no significant difference was observed.

b) Essential and non-essential technique steps

At the follow-up visits, none of the participants using either the DS or TH incorrectly performed any essential step. Three participants failed to *breathe out gently away from mouthpiece* after dose inhalation, one of these participants was using a DS and the other two were using a TH. No other technique errors were recorded. The essential and non-essential pMDI technique steps incorrectly performed by the participants varied considerably and so are displayed graphically below.

- *pMDI*

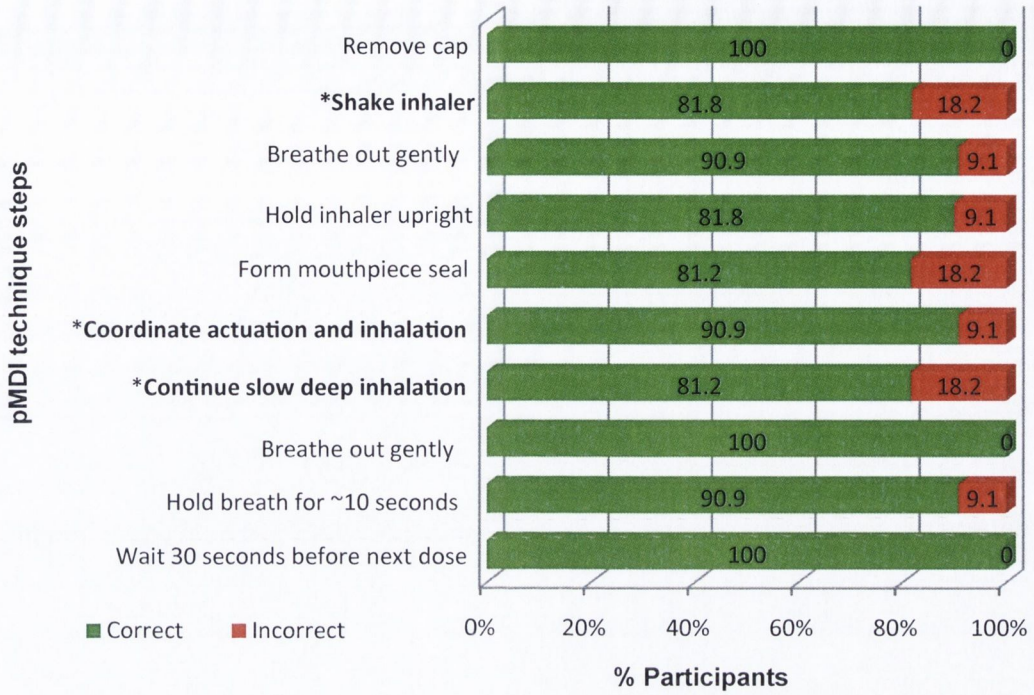


Figure 5.30: The proportion of participants using a pMDI who correctly/incorrectly performed each of the technique steps at follow-up (N = 11).

As outlined in 5.3.2.7, the technique steps in bold and marked with an asterisk are essential steps.

The percentage of test participants performing critical and non-critical errors at follow-up are outlined in the table below.

Table 5.12: Participants performing critical and non-critical errors at follow-up

Device type	N	% (n) ≥ 1 critical error	% ≥ 1 non-critical error
pMDI	14	14.3% (2)	28.6% (4)
DPI	9	0% (0)	33.3% (3)

5.3.2.9. Inhaler technique: comparison between baseline and follow-up

The mean number of technique errors and critical technique errors per device at the initial and follow-up visits were compared using paired-samples t-tests and the results are displayed in the table below.

Table 5.13: Mean errors and critical errors performed at baseline and follow-up visits

Device type	N	Errors	Baseline Mean±SD	Follow-up Mean±SD	Significance (2-tailed)
pMDI	11	Critical and non-critical	2.2±1.0	1.0±1.3	< 0.001
		Critical only	0.7±0.8	0.5±1.0	NS
DPI	9	Critical and non-critical	1.3±0.7	0.3±0.5	0.009
		Critical only	0.1±0.4	0.0	NS
All devices	20	Critical and non-critical	1.9±1.3	0.6±1.0	< 0.001

NS = Not significant

The table illustrates that following inhaler technique education and training the mean number of technique errors decreased significantly for all devices but the mean number of critical errors did not.

5.3.2.10. Inhaler technique: differences between those who completed the study and those who did not

Forty-four test participants failed to complete the study and eleven of these used two different inhaler devices on which they were assessed. The mean number of technique errors was compared between those who completed the study and those who did not using one-way ANOVA. The mean number of technique errors per group was 1.9±1.3 and 2.6±2.3 respectively and they were not significantly different.

5.3.2.11. Asthma control: differences between study groups

The ACT scores for the test, internal control and external control participants, obtained at the initial and the follow-up consultations, were compared using one-way ANOVA. No significant differences were recorded been each of the three groups at the initial visits. However, at the follow-up consultations the mean ACT score obtained by the test participants was significantly higher than that obtained by the external control participants. The results are outlined in the table below.

Table 5.14: Asthma Control Test scores at initial and follow-up consultations

Study group	N	Mean ACT score: Initial visit	Sig.	N	Mean ACT score: Follow-up visit	Sig.
Test	17	19.7±3.2	0.15 (NS)	14	20.1±3.6	0.04
Internal control	14	18.2±4.8		14	18.5±4.7	
External control	18	16.8±4.9		18	16.1±4.9	

NS = Not significant

5.3.2.12. Asthma control: differences within study groups

a) Test participants

The mean ACT score recorded at baseline was 19.3±3.3, indicating that, on average, the test participants were partly controlled. At follow-up, the mean ACT score was 20.1±3.6, indicating that on average the participants had controlled asthma. A paired-samples t-test was conducted to test the significance of this change and the significance value obtained was 0.08, indicating that a significant improvement was not obtained, but the improvement did approach significance.

b) Internal control participants

The mean ACT score at initial recruitment was 18.2±4.8, corresponding to partly controlled asthma. At the follow-up consultation the mean ACT score was 18.5±4.7. A paired-samples t-test indicated that this improvement was not significant *(p value = 0.77).*

c) External control participants

The average ACT score recorded at the initial consultations was 16.8±4.9 and the mean value obtained at the follow-up visits was 16.1±4.9. Both values are indicative of partly controlled asthma. A paired-samples t-test indicated that this deterioration was not significant *(p value = 0.41).*

5.3.2.13. Asthma control: differences between those who completed the study and those who did not

Baseline ACT scores were available for 98 participants who did not attend the pharmacy for the follow-up consultations (drop-outs). The one-way ANOVA test was used to compare the ACT scores of this group with the initial scores of the participants who

completed the study (completed). No significant difference was observed between the two groups *(drop-outs: 17.7±4.5 versus completed: 18.1±4.5, p = 0.63).*

5.3.2.14. Asthma knowledge: differences between study groups

The asthma knowledge scores for the test, internal control and external control participants, obtained at both the initial consultations and the follow-up consultations, were compared using the one way ANOVA-test and no significant differences were recorded been each of the three groups at either consultation.

5.3.2.15. Asthma knowledge: differences within study groups

a) Test participants: mean score

The mean asthma knowledge score at baseline was 67.9±17.4. This increased to 72.2±13.1 at the follow-up consultation. However, when a paired-samples t-test was conducted to test the significance of this change, this change was not significant *(N = 16).*

b) Test participants: individual knowledge questions.

McNemar's test was used to investigate if there were any significant changes in participants' knowledge in relation to each of the eleven asthma knowledge questions. The test revealed that there were no significant changes to participants' asthma knowledge after the intervention.

c) Internal control participants

The mean asthma knowledge score recorded at the initial consultations was 64.3±15.7 and the mean score at the follow-up consultations was 64.3±18.7. According to the paired-samples t-test, these results were not significantly different *(N = 14).*

d) External control participants

The mean asthma knowledge score recorded at the baseline consultations was 69.7±18.1. The paired-samples t-test indicated that this result was not significantly different from 69.7±17.7, the score obtained at the follow-up consultations *(N = 15).*

5.3.2.16. Asthma knowledge: differences between those who completed the study and those who did not

Mean asthma knowledge scores obtained at the initial consultations were available for 94 drop-outs. These were compared with the baseline mean asthma knowledge scores obtained for the 49 participants who attended their follow-up appointments using one-way ANOVA. No significant difference was observed between the two groups *(drop-outs: 67.0±19.1 versus completed: 64.1±19.7, p = 0.39).*

5.3.2.17. Medication adherence: differences between study groups

One-way ANOVA was used to compare the medication adherence scores of the test, internal control and external control participants at the initial visits and at the follow-up consultations. No significant differences were observed between the three groups at baseline or at follow-up.

5.3.2.18. Medication adherence: differences within study groups

a) Test participants

The medication adherence scores of the test participants recorded at the initial and follow-up visits were compared using the paired-samples t-test. No significant difference was observed between the mean medication adherence scores recorded on the two visits *(initial: 6.3±1.8 versus follow-up: 6.9±1.4, N = 14).*

b) Internal control participants

No significant difference was observed between the medication adherence scores of the internal control participants using the paired-samples t-test. *(Initial: 5.6±2.2 versus follow-up: 5.7±2.2, N = 14).*

c) External control participants

The medication adherence scores of the external control participants did not differ significantly between baseline and follow-up visits according to the paired-samples t-test *(initial: 5.1±2.5 versus follow-up: 5.6±2.0, N = 17).*

5.3.2.19. Medication adherence: differences between those who completed the study and those who did not

Medication adherence scores were available for ninety drop-outs. These were compared with the scores of the participants who finished the study using one-way ANOVA. No significant difference was observed between the medication adherence values of the two groups *(drop-outs: 5.2±2.1 versus completed: 5.7±2.3, N = 136).*

5.3.2.20. Asthma-specific quality of life: differences between study groups

Participants' overall asthma-specific quality of life scores and each of the four domain scores, obtained at the initial consultations and the follow-up visits, were compared according to their study groups using one-way ANOVA. No significant differences were observed between the three study groups at the baseline consultations. However, significant differences were observed in the mean overall scores, the mean Symptoms domain scores and the mean Emotional Function domain scores, at the follow-up consultations. These are outlined in the table below.

Table 5.15 Comparison of quality of life scores between groups at follow-up (N = 47)

Domain	Test Mean±SD	Internal control Mean±SD	External control Mean±SD	Significance
OVERALL	5.7±0.9	5.4±1.0	4.6±1.4	0.018
Activity Limitation	5.8±1.1	6.0±1.3	5.3±1.5	NS
Symptoms	5.7±0.9	5.2±1.1	4.5±1.6	0.02
Emotional Function	5.8±1.2	5.2±1.5	4.0±1.8	0.005
Environmental Stimuli	5.4±1.2	5.2±1.5	5.0±1.7	NS

NS = Not significant

Test participants had significantly higher mean overall quality of life scores and mean Symptoms and Emotional Function domain scores than external control participants at follow-up.

5.3.2.21. Asthma-specific quality of life: differences within study groups

a) Test participants

The paired-samples t-test was used to determine if there were any significant differences (and MIDs) between the asthma-specific quality of life scores obtained at the initial consultations and the follow-up consultations. The results are displayed in the table below.

Table 5.16 Comparison of quality of life scores recorded at baseline and follow-up for test participants

Domain	N	Baseline: Mean±SD	Follow-up: Mean±SD	Mean difference	Significance (2-tailed)
OVERALL	16	5.2±1.1	5.7±0.9	0.5	0.003
Activity Limitation	16	5.6±1.5	5.8±1.1-	0.3	NS
Symptoms	16	5.1±1.1	5.7±0.9	0.6	0.002
Emotional Function	16	5.01±.4	5.8±1.2	0.8	0.01
Environmental Stimuli	16	4.9±1.4	5.4±1.2	0.5	NS

NS = Not significant.

The table illustrates that test participants reported a significant increase in both the Symptoms and Emotional Function domains and in overall quality of life at the follow-up visits compared to baseline.

b) Internal control participants

No significant differences were observed between either the overall quality of life scores or the domain scores, recorded at the initial and the follow-up consultations, using the paired-samples t-test.

c) External control participants

A significant decrease was observed between the mean Emotional Function domain score recorded initially and that recorded at the follow-up consultation (4.8±1.6 versus 3.9±1.8, $p = 0.015$). No other significant changes were observed.

5.3.2.22. Asthma-specific quality of life: differences between those who completed the study and those who did not

One-way ANOVA was used to compare the overall quality of life scores and each of the domain scores obtained at baseline between the participants who completed the study and the drop-outs. No significant difference was observed between the two groups in all categories. *(Mean overall quality of life score drop-outs: 4.9±1.2 versus completed: 5.1±1.1, p = 0.36).*

5.3.2.23. Exit questionnaire for Test pharmacists

At the conclusion of the study, an anonymous Exit Questionnaire (EQ), together with a cover letter and a postage-paid envelope was mailed to twenty-seven Test pharmacists; the three pharmacists who had officially withdrawn prior to recruiting any patients were excluded. Even though only fourteen of these pharmacists had recruited at least one patient, the questionnaire was sent to all twenty-seven as it included items investigating the reasons for poor patient participation/recruitment. However, only seven completed questionnaires were received so each of the twenty-seven pharmacists were contacted by telephone and, if they had not already done so, they were asked to complete the questionnaire in interview format over the phone. These two methods resulted in twenty-one completed questionnaires (both partly and fully completed where relevant). In three instances, the intern pharmacists, who participated in the project under their tutor pharmacists' supervision, had completed their training and were no longer working in the community pharmacies. In one instance, the participating pharmacist was on maternity leave and the remaining two pharmacists admitted that they had never made a conscious effort to recruit patients and so they could not complete the questionnaire. Interestingly, while only fourteen pharmacists returned completed data collection forms for at least one patient, four additional pharmacists conducted the inhaler technique intervention on at least one patient initially and at a follow-up visit but failed to complete the accompanying data collection forms. In addition, three pharmacists failed to recruit any patients despite repeated efforts. The opinions and responses of all of these pharmacists were included in the EQ data analysis.

5.3.2.24. Exit questionnaire: initial consultation

1) Patients' receptiveness towards participating in the project initially

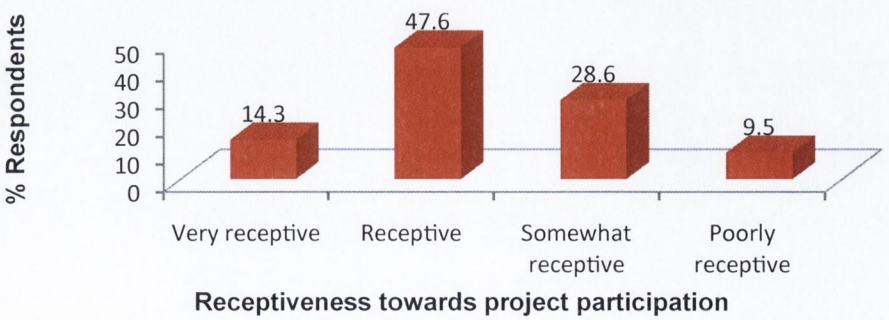


Figure 5.31: Respondents' opinions about patients' receptiveness towards participating in the project initially (N = 21)

2) Barriers to patient participation in the project initially

Respondents were asked to rate the impact that they believed a number of identified barriers had on patient participation in the project and the results are outlined in Figure 5.32 below.

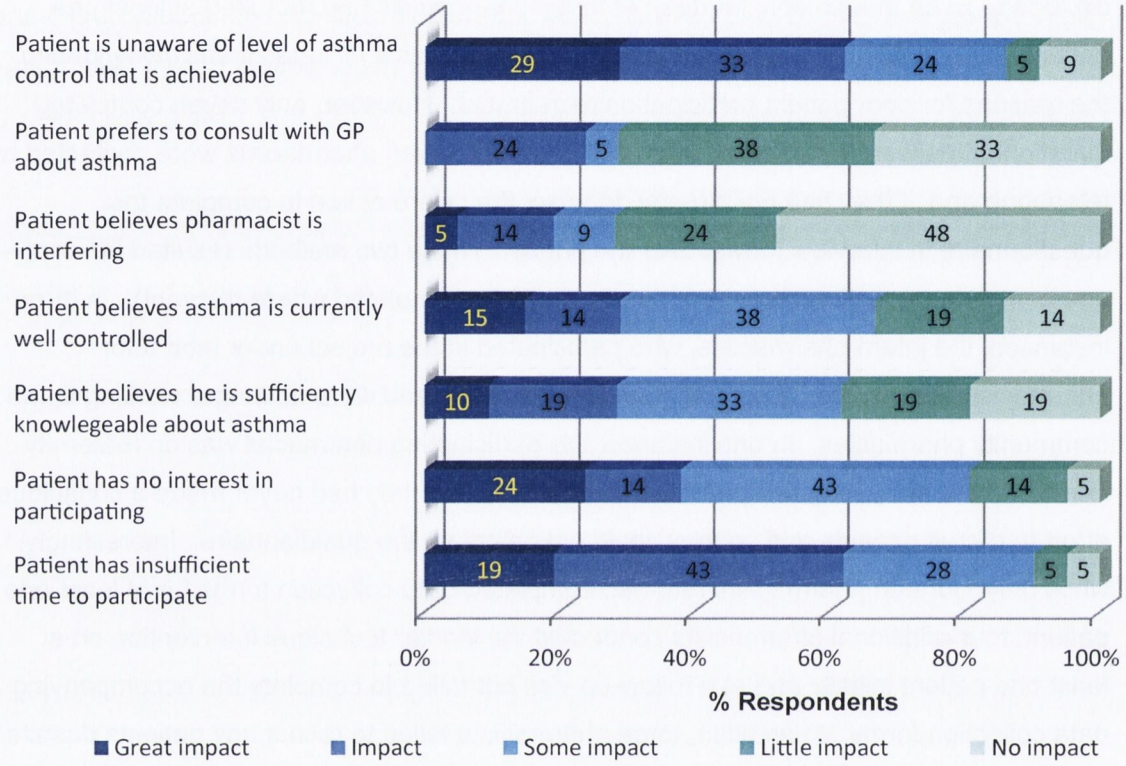


Figure 5.32: Pharmacists' opinions on the impact of various barriers on patients' participation in the project (N = 21).

The mean impact that each of the aforementioned barriers had on patient participation, according to the respondent community pharmacists, are outlined in Table 5.17 below.

Table 5.17 Mean impact of each proposed barrier on initial patient participation (N =21)

Proposed barrier	Mean Impact
Patient is unaware of level of asthma control that is achievable	Impact (2.3)
Patient prefers to consult with GP about asthma	Little impact (3.8)
Patient believes pharmacist is interfering	Little impact (4.0)
Patient believes asthma is currently well controlled	Some impact (3.1)
Patient believes he/she is sufficiently knowledgeable about asthma	Some impact (3.2)
Patient has no interest in participating	Some impact (2.6)
Patient has insufficient time to participate	Impact (2.3)

3) Average time needed to complete the initial consultation

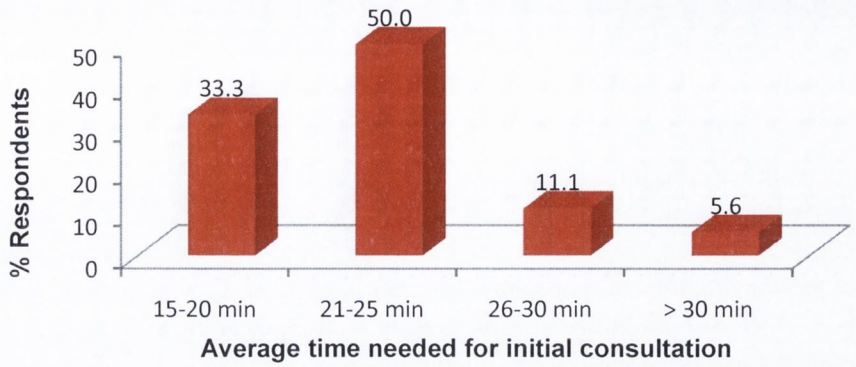


Figure 5.33: Average time needed to complete initial consultation (N = 18).

When asked whether or not this was an acceptable amount of time for the initial patient consultation, 37% stated that it was *very acceptable/acceptable*. However, 31.5% indicated that it was *somewhat acceptable* and 31.5% stated that it was *unacceptable.*

Respondents were asked if the paperwork required for the study was eliminated did they believe it would be feasible to incorporate this level of patient counselling and 90% believed that it would be feasible.

4) Payment for provision of counselling on inhaler technique and peak flow meter use

81% of the respondents believed that they should not charge patients for the provision of counselling on inhaler technique and peak flow meter use *(N = 21).* However, one of these respondents stated, in conversation with the researcher, that pharmacists should be paid by the Health Service Executive for this service.

When the four respondents who believed patients should be charged for this service were asked what this charge should be their responses varied considerably. A charge of €15 was proposed by one respondent, €5 was proposed by another, another suggested that a dispensing fee (€3-5) should be charged for provision of the service and the fourth respondent was unsure.

The pharmacists were asked whether or not they believed that their patients would be willing to pay for this service and none of the respondents believed that patients would be *very willing/willing* to pay. 24% believed that they would be *somewhat willing* and 78% believed that they would be *unwilling* to pay for this service *(N = 21).*

5.3.2.25. Exit questionnaire: second consultation

1) Patients' receptiveness towards engaging in the second consultation

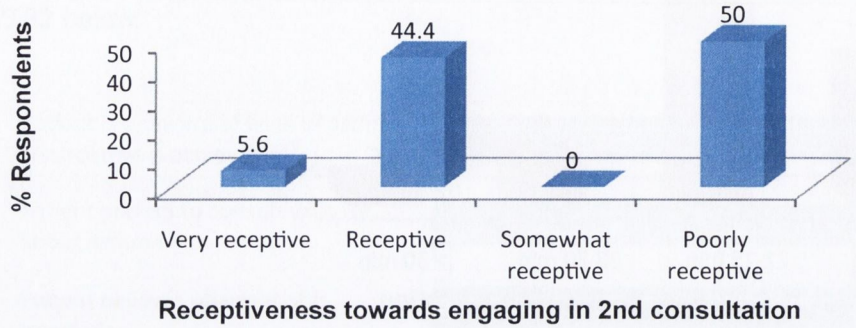


Figure 5.34: Respondents' opinions about patients' receptiveness towards engaging in a second consultation (N =18).

2) Barriers to patient engagement in the second consultation

Respondents were asked to rate the impact that they believed a number of identified barriers had on patients' engagement in the second consultations and the results are outlined below.

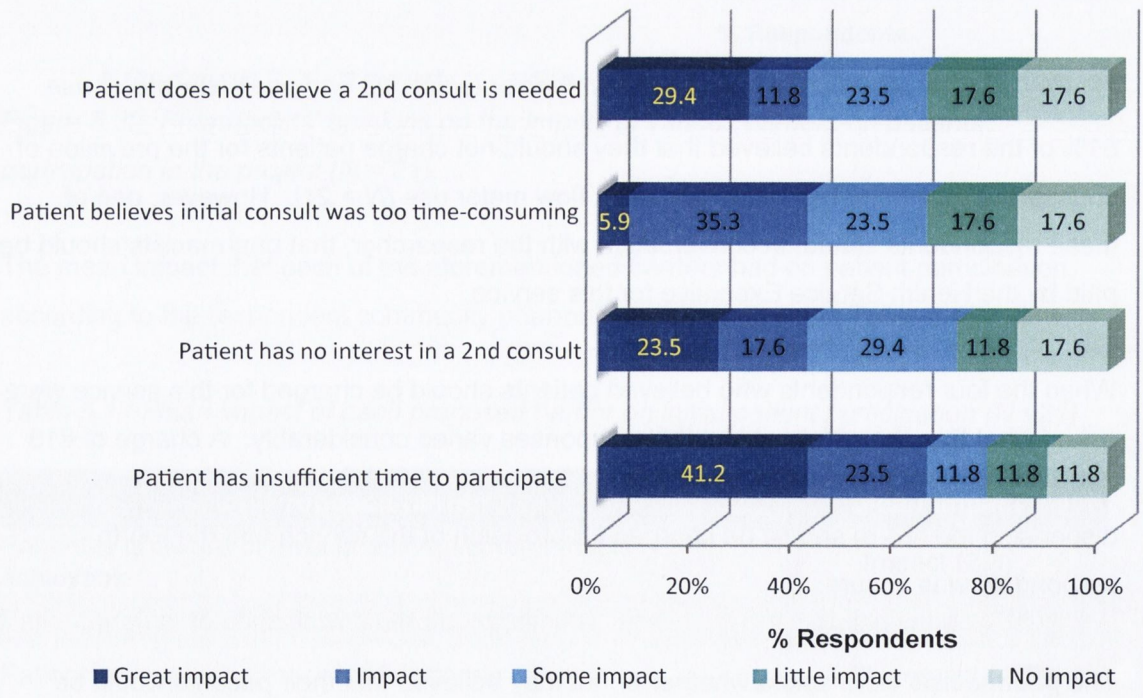


Figure 5.35: Pharmacists' opinions on the impact of various barriers on patients' engagement in a second consultation (N = 17).

The mean impact that each of the aforementioned barriers had on patient engagement in the second consultations, according to the respondent community pharmacists, are outlined in Table 5.18 below.

Table 5.18 Mean impact of each proposed barrier on patient participation in the second consultation (N =17)

Proposed barrier	Mean Impact
Patient does not believe a second consultation is needed	Some impact (2.8)
Patient believes initial consultation was too time-consuming	Some impact (3.1)
Patient has no interest in a second consultation	Some impact (2.8)
Patient has insufficient time to participate in a second consultation	Impact (2.3)

3) Average time needed to complete the second consultation

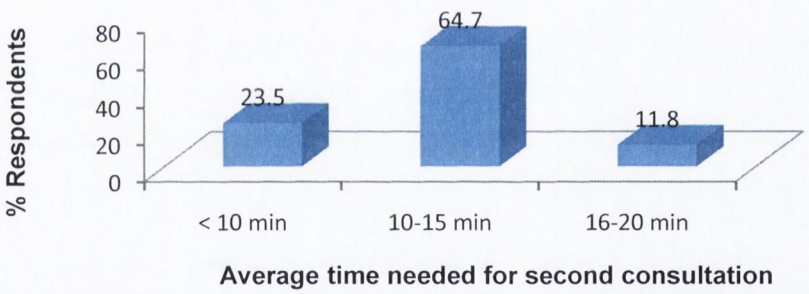


Figure 5.36: Average time needed to complete the second consultation.

5.3.2.26. Exit questionnaire: respondents' perceptions of the project

1) Benefit of the project for the participating patients

Respondents were asked whether they thought that the project was beneficial for their participating asthma patients and their responses are outlined below.

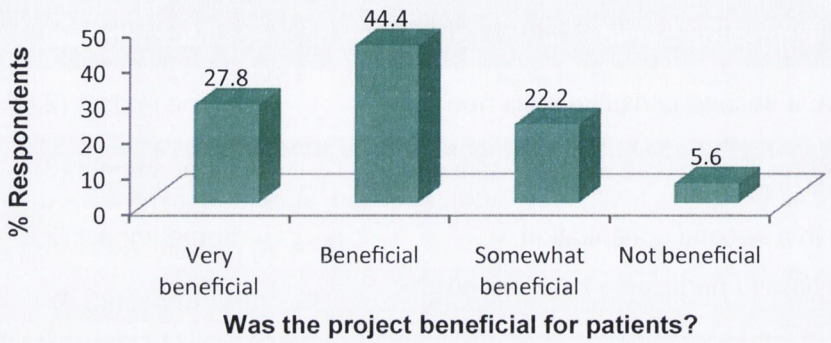


Figure 5.37: Respondents' opinions on the benefit that their patients gained from participating in the project (N = 18).

2) Level of appreciation of the participating patients

Respondents were asked to rate the level of appreciation of their participating patients for the counselling they received through the project and their opinions are illustrated below.

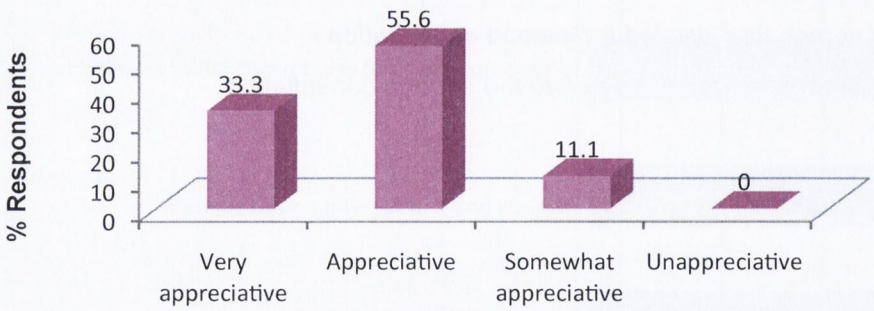


Figure 5.38: Respondents' opinions on the appreciation of their participating patients for the counselling they received (N = 18).

3) Usefulness of the provided project materials for the pharmacist

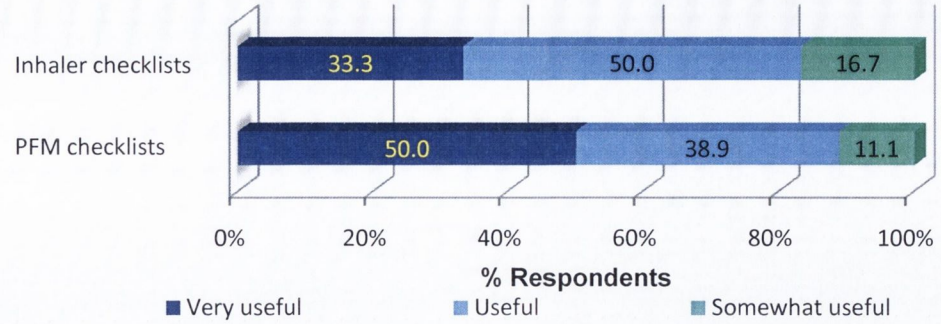


Figure 5.39: Respondents' opinions on the usefulness of the inhaler technique and peak flow meter technique checklists (N = 18).

4) Usefulness of the technique reminder labels for the participating patients

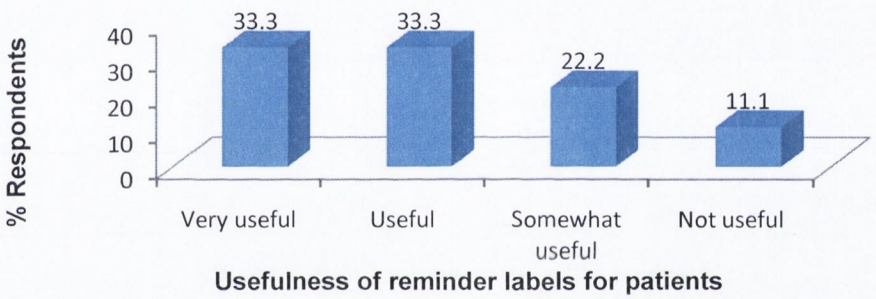


Figure 5.40: Respondents' opinions on the level of usefulness of the inhaler technique reminder labels for participating patients (N = 18).

5) Impact of the project on respondents' knowledge and their patient relationships

Respondents were asked about the impact that the project had on their relationships with the participating patients. 78% stated that it improved their relationships, 16.5% said that it had no impact on their relationships and only one respondent said that it had a negative impact on her relationships with the participating patients (*N = 18).* The respondent who stated that the project impacted negatively on her patient relationships was asked to elaborate. She stated that the reason for the negative impact was due to the difficulty ensuring that patients returned for their follow-up consultations. She felt she was 'badgering patients to get them to return for the second visit'.

Respondents were asked whether or not participating in the project had any impact on their knowledge of both inhaler technique and peak flow meter technique. 89% stated that it improved their knowledge of inhaler technique and 11% said that it had no impact on their knowledge. In addition, 94% stated that it improved their knowledge of peak flow meter technique and 6% said that it had no impact on their knowledge.

6) Desirable and undesirable factors about the project

Respondents were asked to write/answer freely about any factors that they found desirable and undesirable about the project. Many patients provided more than one response to each question and their responses are tabulated below.

Table 5.19 Desirable factors about the project (N = 21)

	Desirable factors	% Respondents
1.	Improved participating patients' asthma care	52%
2.	Improved pharmacist-patient relationships	14%
3.	Highlighted benefits of PEFR monitoring to patients	14%
4.	Inhaler technique reminder labels were excellent	19%
5.	Refreshed pharmacist's asthma knowledge	10%
6.	Informed pharmacist about patients' poor inhaler technique	5%
7.	Reason to have a structured consultation in consultation room	5%

(Percentages do not add up to 100% as some respondents provided more than one response)

PEFR = peak expiratory flow rate

Table 5.20 Undesirable factors about the project (N = 21)

	Undesirable factors	% Respondents
1.	The project was very time consuming	62%
2.	The paperwork was burdensome for the pharmacist and the patients	33%
3.	Patient recruitment and follow-up was difficult	29%
4.	No undesirable factors	10%
5.	Patients are unaccustomed to using the consultation room, some found it off-putting	5%

(Percentages do not add up to 100% as some respondents provided more than one response)

7) Changes needed to incorporate this level of patient counselling into routine practice

Respondents were asked to identify any changes to community pharmacy that would be needed to facilitate the incorporation of this increased level of patient counselling into routine practice. The responses were quite varied and they are outlined below.

Table 5.21 Changes needed for incorporation of more intensive counselling into routine practice (N = 21)

	Changes required for incorporation of intensive counselling	% Respondents
1.	Increased staff members (pharmacists ± pharmaceutical technicians)	38%
2.	Initiation of structured programmes on chronic diseases that are available from community pharmacies	33%
3.	Remuneration for provision of professional services	24%
4.	Improved training of dispensary staff members	19%
5.	Alteration of laws regarding sale of 'pharmacy-only medicines' to free up pharmacist's time for counselling	5%
6.	Overhaul of community pharmacy to facilitate the recognition of pharmacists as valuable health-care professionals	5%
7.	Facilitate the reimbursement of peak flow meters under State funded medicines reimbursement schemes	5%

(Percentages do not add up to 100% as some respondents provided more than one response)

5.4. Discussion

5.4.1. Observational study

5.4.1.1. Baseline characteristics

Interestingly, only ~19% of those recruited were 7-16 years old whereas almost 50% were > 50 years. This may have been because the younger patients did not collect their own medications as they were at school or at other extra-curricular activities whereas adult patients were probably more likely to frequent the pharmacy to pick up their own medications. Similarly, Savage and Goodyer[33] observed that the majority of the participants who were recruited to their study on pMDI technique education were > 50 years and Rootmensen and colleagues[13] reported that 57% of the participants recruited to their study on inhaler technique were ≥ 60 years.

Worryingly, almost 20% of those recruited admitted to being current smokers. However, this result is in accordance with the literature. Partridge and colleagues[155] conducted the INSPIRE study, a survey of ~3,400 asthma patients in eleven countries (10 European countries, Canada and USA) and they observed that 21% of respondents were current smokers. The results of the AIRI survey revealed that 19% of the adults surveyed were current smokers (N = 257)[151]. Asthma is a chronic inflammatory disease characterised by airway infiltration of inflammatory cells and mediators resulting in airway hyperresponsiveness and remodelling[1]. Chalmers and colleagues[562] investigated the effects of cigarette smoke on airway inflammation in asthmatic patients. They discovered that asthmatic smokers had significantly higher total sputum white blood cell counts, relative and absolute neutrophilia and interleukin-8 (a potent neutrophil chemoattractant) sputum levels than asthmatic non-smokers. Similarly, Boulet and colleagues[563] observed a significantly higher induced-sputum total cell count and neutrophil count in asthmatic smokers compared to asthmatic non-smokers. In addition, they reported significantly lower FEV_1/FVC ratios among asthmatic smokers compared to asthmatic non-smokers, suggestive of increased airway obstruction among the smokers. More emphysematous changes and a reduced airway lumen area were also reported among the asthmatic smokers compared to the non-smokers. Tsoumakidou and colleagues[564] investigated the effect of cigarette smoke on bronchial mucosal immunity in asthma. They discovered that asthmatic smokers had significantly less mature dendritic cells and B lymphocytes in the bronchial mucosa than asthmatic non-smokers, which may cause smokers to be more susceptible to respiratory infection and less responsive to ICS treatment[564].

Approximately 32% of participants claimed to be ex-smokers. As the long-term persistent abstinence rate from smoking for a given attempt at quitting unaided is very low[565] this result is encouraging. Tonnesen and colleagues[566] investigated the short-term effects of smoking cessation on asthma control and quality of life. They discovered that participants who had abstained from cigarettes for four months had significantly fewer daytime asthma symptoms, used significantly fewer puffs of their reliever medications daily and had significantly higher asthma-specific quality of life scores than asthmatic smokers. Similarly, To and colleagues[567] reported that asthma patients who had quit smoking over the 12 month study period had significantly lower incidences of wheezing, chest tightness and nocturnal asthma symptoms compared to the asthma participants who continued to smoke.

Only approximately 6% of the participants stated that they had an asthma management plan. While this result is very low it is unsurprising as the results of the QAM-CP, QAM-GP and QAM-PN revealed that the percentages of patients estimated by their community pharmacists, GPs and practice nurses to possess an asthma management plan were very low (See Chapter 2). Vermeire and colleagues[568] compared asthma management practices across seven European countries using data from AIRE study and they observed that the percentage of adults with an asthma management plan varied hugely between countries. In the UK 9.1% of respondents possessed an asthma action plan compared to ~49% in Spain. The GINA guidelines[1] recommend the development of a partnership between the asthma patient and their health-care professional(s) to encourage guided self-management of asthma. The provision of a personalised asthma management plan to the asthma patient forms an integral part of the self-management process as it advises the patient to make changes to their medication in response to changes in their level of asthma control as indicated by their asthma symptoms and/or peak flow readings, according to written predetermined guidelines[169,415].

Almost 20% of participants stated that had not attended their GP in relation to their asthma in the preceding 12 months. This result is concerning as best practice guidelines for asthma management recommend that patients' have regular follow-up consultations with their GP to monitor their asthma control, their degree of medication adherence and reinforce correct inhaler technique[1]. Schatz and colleagues[569] demonstrated that for patients with stable moderate persistent asthma who possessed a personalised asthma management plan a follow-up visit every six months was sufficient. However, for patients with asthma that is somewhat or poorly controlled and who do not possess an asthma management plan, more frequent GP consultations may be needed. Bellamy and Harris[173] surveyed > 800 asthma patients in five European countries, Canada and

Australia and they observed that 19% of respondents had not discussed their asthma with a health-care professional since their initial asthma diagnosis.

Approximately one in five participants stated that when they were prescribed their inhaler(s) initially they did not receive an inhaler technique demonstration from any health-care professional. Similarly, ~20% of participants in the Demonstration Project indicated that they had never received inhaler technique education from a health-care professional (see Chapter 3). Giraud and colleagues[6] surveyed > 700 asthma patients and discovered that ~ 30% had never been shown how to use their inhalers by a health-care professional. This result is concerning particularly as Melani and colleagues[12] found that inadequate inhaler technique positively correlated with the lack of education from a health-care professional at the initial prescription.

5.4.1.2. Asthma control

Less than 40% of participants had controlled asthma as evaluated by the ACT. This result is in accordance with the literature. Preito and colleagues[233] reported that only 33% of ~ 800 Spanish respondents had controlled asthma and Partridge and colleagues[155] stated that 28% of ~ 4000 respondents across eleven countries had 'well-controlled' asthma as assessed by the Asthma Control Questionnaire[8]. Unsurprisingly, a significantly greater proportion of non-smokers than smokers had controlled asthma. Prieto and colleagues[233] also observed that controlled asthma was significantly more frequent among non-smoking asthmatics than smokers. A number of studies[191,192,570,571] have demonstrated that smokers have an impaired responsiveness to both ICS and oral corticosteroids suggesting possible corticosteroid resistance among asthmatic smokers. This may be a contributory factor to the fact that a significantly greater proportion of smokers had uncontrolled asthma compared to non-smokers.

Participants with uncontrolled asthma had attended the GP significantly more frequently for asthma than those with controlled asthma, in the preceding 12 months. This result is unsurprising and is supported by the literature. Anis and colleagues[572] investigated the relationship between uncontrolled asthma, characterised by the excessive use of β_2-agonists and the underuse of ICS, and the use of health-care resources. They discovered that participants with inappropriate asthma medication use that is characteristic of uncontrolled asthma, had significantly more physician visits, more hospitalisations for asthma and more urgent hospital admissions for asthma than those with appropriate medication use. Furthermore, Sadatsafavi and collegaues[573] reported that patients with uncontrolled asthma who accounted for 64% of the population studied were responsible for 94% of health-care resource use attributed to asthma over the study period.

5.4.1.3. Asthma knowledge

a) Mean asthma knowledge score

The mean asthma knowledge score obtained was 7.36±2.1 out of a possible 11 points and this result is in accordance with the literature. Saini and colleagues[144] used the CQ to assess participants' asthma knowledge and the baseline scores of the two study groups, prior to any interventions, were 7.51±2.4 (N = 212) and 7.8±2.3 (N = 179). Similarly, Armour and colleagues[171] assessed the asthma knowledge of 205 control participants and 191 intervention participants at baseline and they recorded CQ scores of 7.68±2.3 and 7.8±2.2 respectively. Interestingly, participants who received an initial demonstration of inhaler technique from a health-care professional had significantly higher mean CQ scores than those who did not. Despite the fact that best practice guidelines on asthma management[1] recommend that education on asthma forms a fundamental part of all interactions between a patient and his/her health-care professional, it is evident from this study that a proportion of health-care professionals are not adhering to this recommendation. Health-care professionals who did not provide an initial demonstration of inhaler technique may also have failed to educate patients on other aspects such as asthma triggers, the differences between reliever and controller medications *etc.* and this may have lead to the significantly lower mean CQ scores observed among these patients. Indeed, the GAPP survey conducted on ~1700 adult asthmatics across sixteen countries revealed that only 25% of the physician visit was spent on asthma education[260]. Furthermore, a recent survey of pharmacists' perceptions on their role in asthma management revealed that < 50% believed their role included counselling on 'asthma control' and 'patient self-management' in addition to 'medication use'[574].

b) Awareness that asthma medications are not addictive

Only 65% of participants were aware that asthma medications are not addictive if used regularly. Horne and Weinman[575] reported that 37% of 100 respondents surveyed agreed that they 'sometimes worry about becoming too dependent on this (preventative) inhaler' and 25% of 233 respondents in a study conducted by Menckeberg and colleagues[576] had the same response, when questioned about their preventative medication. While medication dependence and addiction are not necessarily the same, both studies[575,576] demonstrated that participants' level of medication adherence was negatively correlated with concerns about becoming dependent on their preventative medication.

Significantly more older adults answered this question incorrectly compared to their younger counterparts and significantly more younger than older participants provided the correct answer to this question. Emtner and colleagues[577] conducted a study of ~ 160 asthma and COPD patients presenting at the ED. They discovered that while 80% of patients had received information on their disease from a health-care professional, patients with 'good knowledge' about their disease were significantly younger that those without this level of knowledge. Wolfenden and colleagues[578] evaluated the asthma care of older adults (N = ~300) and reported extensive deficiencies in their knowledge of asthma self-management, *e.g.* 34% were not aware that they should take their preventative medication prior to exposure to an asthma trigger and 32% reported that they did not increase their medication in the case of asthma worsening. One possible explanation for the differences in asthma knowledge between older and younger participants may be the differences in their desire for involvement in their asthma treatment. Schneider and colleagues[579] investigated patients' preferences for involvement in medical decision making in general practice. They discovered that older age was associated with a significantly lower preference for involvement in medical decision-making and a significantly lower preference for obtaining comprehensive information compared to younger age. Arora and McHorney[580] investigated the participation preference among ~2,200 participants with chronic diseases. They reported that age was a significant predictor of participation preference and participant preference for an active role in medical decision making decreased with increasing age. Caress and colleagues[581] investigated asthma patients' actual involvement and preferred involvement in medical decision making. They discovered a significant relationship between preferred involvement and age with older participants 'typically' preferring a more passive role in medical decision-making. These studies suggest that older patients typically prefer a more paternalistic form of communication with their physician(s) where they adopt a passive role. As a result, if the physician does not provide the patient with asthma education or the patient does not understand the information provided he/she is unlikely to question the physician. In addition, there is evidence of a declining trend in the provision of asthma education particularly among adult patients[582]. Thus, a combination of these two factors may result in a deficiency of asthma knowledge among the older asthma population.

c) Awareness that an asthma action plan can prevent hospitalisations

Interestingly, even though only ~6% of the participants possessed an asthma action plan 77% were aware that it could prevent hospitalisations. This may be due to GP and/or patient related-factors. As discussed in Chapter 2, GPs appear to infrequently provide their patients with asthma management plans[197-200]. However, this has been attributed to

a lack of self-efficacy and familiarity with asthma management plans on the part of the physician and a belief that patient adherence to such a plan would be poor[200,243,244]. This is supported by Adams and colleagues[583] who found that the majority of the asthma study participants would not alter their therapeutic regimen in response to a deterioration in asthma control without prior consultation with their physician. Conversely, Haughney and colleagues[241] reported that ~70% of >500 asthma patients surveyed in the Living and Breathing study stated that they would be comfortable in adjusting their asthma medication without first consulting a health-care professional.

d) Awareness about asthma triggers and that medication should be taken prior to exposure to an asthma trigger

Approximately 40% of participants were unaware that going from a hot to a cold environment can trigger asthma. Approximately one-quarter of the participants were not aware that they should take the relevant asthma medication prior to their exposure to an asthma trigger. In addition, ~30% believed that one should wait until symptoms develop before taking the relevant asthma medication after exposure to a trigger. Educating patients on the identification of trigger factors and management of exposure to trigger factors is a key component of asthma education[1]. It is possible that a proportion of the participants have not been educated on asthma triggers. Vainio and colleagues[139] investigated community pharmacists' beliefs about the importance of various asthma-related issues when counselling asthma patients and only ~30% believed that counselling asthma patients on 'lifestyle and triggers/environment' was an important issue. Similarly, Barton and colleagues[197] explored the provision of asthma care in ~ 250 Australian general practices. They found that only ~26% of the participating GPs educated > 80% of their patients with moderate to severe asthma on asthma triggers in the preceding 12 months. However, it is evident from the literature that asthma patients' desire information on asthma triggers. Caress and colleagues[584] conducted an exploratory study on the information requirements of adult asthmatics and they discovered that one of the core areas about which participants required additional information was asthma triggers. Smith and colleagues[375] conducted a study that focused on implementing an asthma self-management intervention. Participants identified problems, set goals and developed strategies to realise these goals. The most common type of goal/problem identified was related to asthma triggers; their identification, and avoidance and reduction of any nasal irritation caused by the triggers.

As observed in 5.4.1.3(b) above, a significantly greater proportion of older participants answered two of the three questions on asthma triggers incorrectly compared to the

younger participants. The possible reasons for this outlined in 5.4.1.3(b) are also valid in these instances.

e) Awareness that side effects are less likely with inhaled medications than with tablets

Almost half of the participants were not aware that side effects are less likely with inhaled medications than with tablets. This result is worrying as concerns about preventative medications have been shown to correlate negatively with medication adherence in both adults and children[575,576,585]. The GAPP survey[260] (outlined in 5.4.1.3(a) above) revealed that > 70% of asthma patient respondents stated that they 'rarely/never' discussed medication side effects with their physicians. Furthermore, ~20% of respondents reported that they key reason for discontinuing/switching their asthma medication was a fear of potential side effects. Similarly, Laforest and colleagues[163] investigated adherence to ICS among ~200 asthma patients in primary care. They reported that approximately one-quarter of participants believed that continuous use of respiratory drugs is 'unhealthy'. In addition, a significantly greater proportion of participants who believed such continuous use was unhealthy, intentionally or unintentionally interrupted their ICS treatment than those without this belief. It is evident, therefore that a proportion of the participants require further education on the benefits of inhaled medication, particularly because of the negative impact that incorrect beliefs about ICS can have on medication adherence.

f) Awareness that preventative medication should be taken daily and that the 'blue puffer' is not a preventative medication

Approximately one quarter of the participants were unaware that preventative medication should be taken daily and > 30% were unaware that the 'blue puffer' was not a preventative medication and so should not be taken daily. Saini and colleagues[144] reported similar levels of awareness about the need for regular use of ICS but 47% of their participants were not aware that the 'blue puffer' is not a preventative medication. The results of the INSPIRE study conducted by Partridge and colleagues[155] revealed that ~40% of those surveyed 'agreed somewhat/strongly' that there was no need for them to take their preventative medication daily when they felt well. Lee and colleagues[586] investigated patients' asthma knowledge when they presented to the ED with an exacerbation. They discovered that 60% of those interviewed could not differentiate between reliever and preventative asthma medications. Panettieri and colleauges[226] conducted the Asthma GAP II survey among ~2,000 adult asthmatics and found contradictory results. They reported that 92% of those surveyed were aware that preventative medications work optimally when taken daily and 94% could differentiate between reliever and preventative asthma medications.

Once again, older adults answered the question about the 'blue puffer' incorrectly significantly more frequently than their younger counterparts did and the same possible explanations outlined in 5.4.1.3(b) are valid in this case.

g) Awareness about increasing asthma medications in case of cold/flu and using reliever at first signs of asthma

Almost 50% of participants were unaware that they should increase their asthma medications in case of cold/flu. Upper respiratory viral infections are strongly associated with deterioration of asthma control and asthma exacerbations in both adults and children[587-591], indicating the need for an increase in asthma medications[1]. The proportion of incorrect responses to this question is unsurprising as > 95% of participants did not possess an asthma management plan, which provides patients with instructions on how to adjust their asthma medication in response to alterations in asthma control[1]. Similar results were observed in the literature. Results from the Living and Breathing study[241] revealed that only 50% of respondents increased their preventative medication with/without their reliever medications when their asthma worsened. Ulrik and colleagues[262] investigated patients' response to asthma variability among ~500 participants. They reported that only ~20% stated that they would increase both their reliever and preventative medication when their asthma control deteriorated.

Only 9% of participants were unaware that they should use their reliever at the first signs of asthma and this result is in accordance with the literature. Farber and colleagues[592] investigated paediatric patients' understanding of their asthma medications among ~600 patients aged 2-16 years. They reported that only 7% of respondents were unaware that the reliever inhaler was for use in case of asthma symptoms. A significantly greater proportion of respondents who received an initial demonstration of inhaler technique from a health-care professional answered this question correctly than those who did not receive an initial demonstration. The possible reasons for this are outlined in 5.4.1.3(a) above.

h) Awareness that some medications can trigger asthma attacks

Only 62% of participants were aware that asthma exacerbations can be triggered by some medications. Saini and colleagues[144] reported the same level of awareness among study participants at baseline. Sensitivity to aspirin and NSAIDs has a prevalence rate of 21% in asthmatic adults and 5% in children when determined by oral provocation testing[252]. Consequently, asthma patients, particularly those with adult onset asthma should be advised to avoid NSAIDs[1].

5.4.1.4. Asthma medication adherence

a) *Overall level of medication adherence*

Only ~23% of participants had high medication adherence according to self-reporting measured by the MMAS. The proportion of participants with high medication adherence may be even lower than that calculated, as patients have been show to overestimate their level of adherence compared to objective adherence measures[593]. This result is unsurprising as low rates of medication adherence to preventative asthma medications are frequently reported in the literature[161,163,593-597]. A number of studies evaluated the impact of poor adherence to preventative medications on asthma morbidity with perturbing results. Williams and colleagues[597] concluded that a preventative medication adherence rate of > 75% was associated with a significant reduction in asthma exacerbations. Similarly, Lasmar and colleagues[598] demonstrated that an adherence rate to preventative medications of > 80% was necessary to ensure optimal asthma control and Ulrik and colleagues[162] reported that decreasing nonadherence to ICS was significantly associated with increasing self-perceived asthma severity. Similarly, Williams and colleagues[599] demonstrated that nonadherence to preventative asthma medication was significantly associated with asthma-related hospitalisations and with prescriptions of oral steroids indicative of asthma exacerbations.

As participants' age increased, the proportion of participants with low rates of medication adherence decreased significantly and participants > 65 years had significantly lower proportions of low medication adherence than their younger counterparts did. Once again, this result is in accordance with the literature. Laforest and colleagues[163] reported that participants > 65 years were significantly less likely to intentionally or accidentally not adhere to their ICS medications compared to those < 45 years. Similarly, Bender and colleagues[594] demonstrated that participants aged 13-35 years had significantly fewer preventative medication prescription refills than those > 35 years. Lacasse and colleagues[593] reported that adherence rates increased significantly with increasing age.

The results of two of the CQ items influenced participants' overall level of medication adherence. A significantly greater proportion of respondents with low medication adherence were unaware that side effects were less likely with inhaled medications than with tablets than participants with medium medication adherence were. This result was unsurprising, as a negative correlation has been demonstrated between concerns about preventative asthma medication and medication adherence[196,576,585]. However, a significantly greater proportion of respondents with high medication adherence answered this question incorrectly compared to those with medium medication adherence. This

result is unexpected given the aforementioned association. One possible explanation may be that a proportion of the participants, consciously or subconsciously, reported a degree of medication adherence that was higher than the reality. Evidence of this has been reported in the literature[593].

A significantly greater proportion of respondents with low medication adherence were unaware that preventative medication should be taken daily than those with medium medication adherence. This result was expected and self-explanatory. However, once again, a significantly greater proportion of respondents with high medication adherence answered this question incorrectly compared to those with medium medication adherence. As discussed above, this may be due to an overestimation of medication adherence by the participants involved.

b) *Unintentional medication adherence*

Approximately 63% of participants indicated that they sometimes forget to take their preventative medication. Similarly, Franks and colleagues[161] reported that ~ 60% of the participants with poor medication adherence stated that forgetfulness was the most common reason for their non-adherence. Ulrik and colleagues[162] investigated the factors related to adherence. They discovered that greater than 50% of the respondents stated that the most important factors for adherence to ICS were the development of a fixed daily routine regarding their asthma medications and believing that 'it is best not to forget the ICS therapy'.

Participants who reported occasional unintentional nonadherence had significantly lower mean number of GP visits than those who did not report unintentional nonadherence. A possible explanation for this finding may be that frequent contact with the GP may facilitate ongoing reinforcement and patient education about the importance of ICS adherence. Indeed Ulrik and colleagues[162] reported that one quarter of the participants stated that their most important reason for ICS adherence was that their physician had told them about the importance of taking the medication. Unsurprisingly, as observed in 5.4.1.4 (a) above, a significantly greater proportion of respondents > 50 years did not report unintentional nonadherence compared to their younger counterparts.

c) *Excessive use of reliever medication*

Only ~16% of participants reported that they used > 8 puffs of their reliever medication in one day over the past two weeks. A significantly greater proportion of participants with uncontrolled asthma reported using > 8 puffs of their reliever in the preceding two weeks. This result is unsurprising, as according to the GINA guidelines[1] one of the criteria used in

the classification of asthma control is the use of reliever medication and patients with controlled asthma use their reliever medication ≤ twice per week. In addition, participants who reported excessive reliever medication in the preceding two weeks had significantly higher mean GP visits than those without such excessive use. This result is expected as patients with uncontrolled asthma have been shown to use significantly more health care resources than those with controlled asthma[572].

d) *Reduction or cessation of medication due to bad sensation(s)*

Approximately 11% of participants reported reducing or stopping their medication as they felt worse when they took it. It is important to educate patients on the potential short- and long-term side-effects of their medications and on measures to help prevent these side-effects. For example, rinsing with water after administering ICS is recommended to reduce the incidence of hoarseness and oral candidiasis. Results of the GAPP survey[260] revealed that 20% of the patients surveyed were unaware of potential short-term side effects even though only 3% of physicians believed their patients would be unaware of these potential side-effects. Furthermore, ~20% of participants stated that they discontinued/switched asthma medications as they experienced side effects.

e) *Medication forgotten when travelling/leaving home*

Approximately 28% of participants indicated that they sometimes forget their asthma medication when they travel or leave home. This is another example of unintentional nonadherence. It is possible that a proportion of these participants are unaware of the importance of regular adherence with ICS and thus do not consider that forgetting to bring their medications away with them is of any great concern. Jobin and colleagues[600] investigated the issues associated with the appropriate use of asthma medications among patients. They discovered that participants who were knowledgeable about both the indications and onset of action of their asthma drugs were significantly more likely to use them appropriately than those without such knowledge. Similarly, Farber and colleagues[592] determined that lower ICS adherence was associated with a misunderstanding about the role of ICS.

f) *Preventative medication taken the preceding day*

21% of participants indicated that they did not take their preventative medication the preceding day. Unfortunately, the determination of intentional or unintentional nonadherence is beyond the scope of this question. Ulrik and colleagues[162] reported similar results. 30% of those prescribed ICS stated that had not taken their medication regularly in the preceding week. Unsurprisingly, a significantly greater proportion of the

youngest participants did not take their preventative medication the preceding day compared to the older participants.

g) *Reduction or cessation of preventative medication when asthma is controlled*

Greater than 50% of participants indicated that they sometimes reduce or stop taking their medication when they feel that their asthma is under control. This result is very concerning as a medication adherence rate of > 75% has been proven necessary for optimal asthma control and the prevention of exacerbations[597,598]. However, similar results have been widely reported in the literature. Ulrik and colleagues[162] discovered that the most frequently reported factor relating to nonadherence among study participants was a lack of perceived asthma symptoms. Similarly, the results of the GAP II survey[226] revealed that 42% of respondents agreed that 'it is appropriate to take controller medication less regularly when symptoms decrease' and 39% of respondents in the INSPIRE study[155] agreed that it is not necessary to take asthma medication everyday when feeling well. Laforest and colleagues[163] reported that 31% of study participants reduced their ICS usage when they felt better and Ulrik and colleagues[262] discovered that > 50% of respondents reduced their asthma medication when their symptoms lessened. The results of this study and those in the literature indicate an urgent need for patient education on the chronic nature of asthma and the resultant need for regular preventative treatment to prevent deterioration of asthma control.

h) *Irritation about sticking to an asthma treatment plan*

20% of participants indicated that they felt hassled about sticking to their asthma treatment plans. Unfortunately, the medication regimens prescribed for these patients are not available as it would be interesting to investigate whether those with more complicated regimens and/or > 2 inhaler devices felt more hassled than those with less complicated regimens. Indeed results from the Living and Breathing Study[241] revealed that respondents with more complicated treatment regimens were more likely to adjust their own medications than those with simpler regimens.

i) *Difficulty remembering to take preventative asthma medication*

Only ~57% of participants stated that they *rarely/never* have difficulty remembering to take all of their preventative asthma medication. This result is expected > 60% indicated that they occasionally forget to take their preventative medication. As discussed in 5.4.1.4(b) above, forgetfulness is frequently mentioned as a reason for nonadherence[161] and developing a medication routine is instrumental in promoting adherence[162].

5.4.1.5. Asthma-specific quality of life

Patients' asthma health status is multi-factorial. It is composed of airway calibre, daytime clinical symptoms and β-agonist use, nocturnal symptoms and β-agonist use, and asthma-specific quality of life[601]. This is reinforced by the fact that measures of airflow limitation such as FEV_1 and FEV_1 % predicted have only demonstrated weak correlations with asthma-specific quality of life measures[441,442,460,468,602,603]. Consequently, an evaluation of the impact of asthma on a patient's daily life is essential in providing an overall assessment of their asthma health status.

Numerous studies have investigated the relationship between asthma-specific quality of life scores and other measures of asthma health status. Tierney and colleagues[604] and Lloyd and colleagues[605] determined that asthma patients who experienced an exacerbation in the preceding four weeks/three months had significantly lower asthma-specific quality of life scores than patients who did not. Furthermore, Siroux and colleagues[606] demonstrated that patients' asthma-specific quality of life scores were significant predictors of asthma exacerbations at four months and at twelve months. Similarly, Magid and colleagues[607] concluded that a patient's asthma-specific quality of life score was a significant predictor of future ED utilisation.

Chen and colleagues[608] demonstrated that patients with higher asthma-specific quality of life scores had significantly less work, school and activity impairment as measured by a modified version of the Work Productivity and Activity Impairment instrument[609] than those with lower asthma-specific quality of life scores. Pont and colleagues[610] investigated the relationship between asthma-specific quality of life scores and patients' medication regimens. They discovered that patients whose prescribed medication regimes were in accordance with asthma treatment guidelines had significantly higher asthma-specific quality of life scores than those whose medication regimes were not guideline concordant.

a) *Asthma-specific quality of life and asthma control*

The mean overall asthma-specific quality of life score was 5.0±1.2 for participants > 12 years and 5.9±1.0 for participants aged 7-12 years. However, participants with uncontrolled asthma, as determined by the ACT, had a significantly lower mean asthma-specific quality of life overall scores compared to those with controlled asthma (4.5±1.0 versus 5.9±0.8: participants > 12 years, 5.0±0.9 versus 6.5±0.5: participants 7-12 years). This result is in accordance with the literature. Bateman and colleagues[611], Siroux and colleagues[612] and Volbeda and colleagues[613] determined that participants with controlled asthma, as defined by the GINA guidelines[1], had significantly higher mean

overall asthma-specific quality of life scores compared to those with uncontrolled/not well controlled asthma. A number of studies investigated the existence of a relationship between asthma-specific quality of life, measured using the Mini-AQLQ[384], the AQLQ(S)-J[452] or the paediatric version[614], and asthma control. Chen and colleagues[615] demonstrated the existence of a significant association between asthma-specific quality of life and asthma control measure by the Asthma Therapy Assessment Questionnaire (ATAQ)[488]. They demonstrated that as the number of asthma control problems increased the mean asthma-specific quality of life score decreased significantly. Similarly, Schatz and colleagues[616] established the existence of a strong significant correlation between the Mini-AQLQ overall score and two measures of asthma control, the ACT and the ATAQ. In addition, Almada-Lobo and Almada-Lobo[617] discovered a strong negative correlation between the AQLQ(S)-J and the Asthma Control Questionnaire[8]. Nordlund and colleagues[603] reported that children with problematic severe asthma had significantly lower overall mean asthma-specific quality of life scores than children with controlled asthma. These results provide evidence of the importance of achieving and maintaining asthma control to facilitate optimal daily living.

In addition, participants with uncontrolled asthma had significantly lower mean scores across all four domains of the Mini-AQLQ and all three domains of the paediatric Mini-AQLQ compared to those with controlled asthma. Both Siroux and colleagues[612] and Volbeda and colleagues[613] observed similar results using the AQLQ(S)-J[452]. Lisspers and colleagues[618] investigated the relationship between asthma-specific quality of life and measures of asthma control *e.g.* using β-agonists more frequently than twice per week, nocturnal awakenings, oral steroid prescriptions and emergency consultations. They observed that participants who attained the asthma treatment goals indicating controlled asthma had significantly higher mean scores across all four Mini-AQLQ domains compared to those with uncontrolled asthma. Chen and colleagues[615] and Schatz and colleagues[616] evaluated the association between the Mini-AQLQ domains and asthma control measured using the ATAQ and/or the ACT. Schatz and colleagues[616] discovered significant correlations between both the ACT and the ATAQ and all four domains of the Mini-AQLQ. However, the strongest correlations were observed with the Activity Limitations and Symptoms domains and the weakest association was observed with the Environmental Function domain. Similarly, Chen and colleagues[615] reported the strongest association between the ATAQ and the Activity Limitations domain of the Mini-AQLQ and the weakest correlation with the Environmental Function domain.

b) *Asthma-specific quality of life and smoking status*

Non-smoking respondents had a significantly higher mean overall asthma-specific quality of life score compared to current smokers (5.3±1.2 versus 4.6±1.0). In addition, the mean Symptoms domain score and Emotional Function domain score were significantly higher in non-smokers compared to smokers. Similarly, Tan and colleagues[619] observed that non-smokers had significantly higher mean Symptoms domain scores and mean Emotional Function domain scores compared to smokers after adjusting for gender, age, and preventative medications. However, no significant difference was observed in the Activity Limitations and Environmental Stimuli domains. Lisspers and colleagues[618] also investigated the influence of smoking status on asthma-specific quality of life. They reported that while a significant difference was observed between the scores obtained by the smokers and non-smokers across each of the domain scores a MID was only observed for the Symptoms domain.

These results are predictable as a significantly greater proportion of smokers than non-smokers had uncontrolled asthma (see 5.4.1.2) and numerous studies[611-613,615-617] have demonstrated a significant relationship between asthma-specific quality of life and asthma control.

c) *Asthma-specific quality of life and medication adherence*

Participants with high medication adherence had significantly higher mean Symptom scores compared to those with low adherence (5.3±1.4 versus 4.5±1.1). Schatz and colleagues[620] investigated the existence of a relationship between asthma-specific quality of life and patients' medication adherence determined by the computerised pharmacy dispensing records. They discovered that patients with a ratio of preventative to total medication (*i.e.* preventative and reliever medication) of ≥ 0.5 (indicating good medication adherence) had significantly higher asthma-specific quality of life scores than those with score < 0.5. Furthermore, Lasmar and colleagues[598] demonstrated that an adherence rate of > 80% was necessary to ensure optimal asthma control and there is significant relationship between the Symptoms domain of the Mini-AQLQ and asthma control[615,616].

5.4.1.6. Ability to use a peak flow meter

Only approximately half of the participants were able to use the peak flow meter correctly prior to receiving any additional training and ~13% had never used a peak flow meter before. These results are unsurprising as the results of the QAM-CP, QAM-GP and QAM-PN revealed that all three groups of health-care professionals in primary care believed that only 11-17% of their asthma patients had a peak flow meter that they used regularly

(see Chapter 2). Infrequent used of a peak flow meter is likely to reduce a patient's familiarity with the correct technique. Vermeire and colleagues[568] investigated the asthma management practices across seven European countries and reported similar results. They discovered that the percentages of children and adults who used a peak flow meter at least once a week ranged from 1.9% - 12.5% and 1.6% - 13.1% respectively across the seven countries. There is widespread evidence in the literature about patients' poor perception of their level of asthma control[153,155,172,233,324,568,621]. Consequently, the peak flow meter is an essential device for asthma patients as it provides them with an objective measurement of airflow limitation[1].

5.4.1.7. Limitations of the study

There are a number of study limitations. Firstly, the pharmacists who recruited the study participants were drawn from a list of pharmacists who had all expressed an interest in participating in the Demonstration Project, a nationwide asthma study. Therefore, they might have had a greater interest in asthma management than the general pharmacist population and their patients might have received more counselling on asthma than the general asthma patient population. As a result, the results obtained might not be generalisable to the asthma population as a whole; in fact, it is possible that the overall asthma population might have poorer asthma control, less asthma knowledge, worse medication adherence and poorer quality of life than the study participants. Secondly, in an attempt to minimise the workload incurred by the participating pharmacist, he/she was not asked to randomly recruit patients, but to recruit consecutive eligible patients. Therefore, it is possible that selection bias was introduced during patient recruitment. Finally, the sample size of the study was quite modest, therefore in order to confirm the results of this study it would need to be repeated in a larger sample size and the participating pharmacists should be recruited from the national list of registered pharmacists.

5.4.2. Interventional study

5.4.2.1. Community pharmacist recruitment

The original response rate by community pharmacists to participation in the study was 53%, but the loss of seven pharmacists after initial recruitment reduced this to 49%. No financial incentive was provided to the pharmacists to encourage participation; the only incentive was the possibility of improving their patients' asthma care, so this response rate is very encouraging. However, it may not be representative of the community pharmacist population in Ireland as a whole, as these pharmacists were drawn from a list of those who had previously expressed an interest in participating in the Demonstration Project (see Chapter 3 for details). Consequently, these pharmacists may have had a greater interest in asthma and/or they may have been more interested in the provision of pharmaceutical care and expanding the role of the pharmacist than the general pharmacist population. Hughes and colleagues[205] investigated the provision of pharmaceutical care by community pharmacists in thirteen European countries. They discovered that the provision of pharmaceutical care was not considered routine practice across Europe, but it was highest in Ireland. Furthermore, community pharmacists appeared to engage infrequently in patient-centred activities such as the implementation of therapeutic goals and monitoring plans, but were routinely involved in more traditional activities such as screening patient records.

During recruitment, the reason most frequently provided by pharmacists for opting not to participate in the study was insufficient time. This was frequently, but not exclusively, due to insufficient staff. This reason was also frequently provided by participating pharmacists who failed to recruit asthma patients to the study. This outcome is unsurprising as the results of the QAM-CP (see Chapter 2) revealed that ~86% of respondents identified 'time' as a major impediment to the provision of patient counselling on asthma. Rene-Henri and colleagues[134] reported that >70% of community pharmacists surveyed in Quebec, Canada agreed that they were unable to effectively counsel their asthma patients due to insufficient time. In a similar study conducted by Kritikos and colleagues[574], the vast majority of respondents believed that insufficient time had a 'considerable impact on their ability to provide optimal asthma care to their patients'. A survey on the implementation of pharmaceutical care in New Zealand, conducted by Dunlop and Shaw[207], revealed 87% of the respondents agreed that insufficient time was a barrier to its successful implementation. Roberts and colleagues[622] investigated the facilitators to the provision of professional services by community pharmacists in Australia. They reported that one of the facilitators to practice change identified was having sufficient staff who were properly trained.

5.4.2.2. Peak flow meter technique

At the initial consultations, all three study groups underwent education about the use of the peak flow meter in monitoring asthma control and they were trained in the correct technique. At the follow-up consultations, a significant improvement was observed in participants' ability to use the peak flow meter correctly in all three groups. These results illustrate the ability of pharmacists to educate successfully their patients on the use of the peak flow meter. In addition, the majority of the patients were able to retain successfully the correct technique until the follow-up visit. The successful education and retention of correct technique may be due to the content of the training session during which the pharmacist demonstrated the correct technique and the patient then repeated the demonstration until the technique was perfected. The use of a physical demonstration when educating patients on inhaler technique has been shown to be more effective than the provision of written or verbal instructions alone[43]. Consequently, it is likely that this is also true for the provision of education on peak flow meter technique.

Interestingly, at the initial consultations, the participants who failed to return for their follow-up consultations had significantly higher mean peak flow meter technique scores than those who completed the study. Consequently, it is possible that one of the reasons for failing to return for the follow-up consultation was a belief that they did not need any further education. This is likely to be particularly true of both internal and external control participants who dropped out as they only intervention they received was education and training on the peak flow meter. Lemaigre and colleagues[557] investigated the determinants of patient participation in an asthma management programme. They discovered that asthma patients who perceived the programme to be personally beneficial were seven to eight times more likely to participate than those who did not perceive such personal benefits.

The limited ability of asthma patients to perceive poor asthma control has been widely documented[153,155,172,233,324,568,621], therefore it is essential that they have an objective measure of airflow limitation like that provided by the peak flow meter.

5.4.2.3. Inhaler technique : initial consultation

At the initial consultation, only 18.2% of participants using a DPI and 11.1% of those using a pMDI performed all of the technique steps correctly. These results are unsurprising as asthma patients' inability to use their inhaler devices correctly has been widely documented in the literature[9,15,16,18,19,22,23,34]. The coordination of actuation and inhalation

has been frequently identified as one of the pMDI technique steps that patients have the most difficulty performing[13,22,23,29,31]. However, only ~9% of the participants in this study performed this step incorrectly. In addition, the speed of the inhalation rate was not assessed. A slow inhalation rate provides better pulmonary drug deposition than a rate exceeding 60L/min[623,624], but a fast inhalation rate is a common error among pMDI users[625]. The two steps most frequently performed incorrectly were *breathe out gently before inhalation (*non-essential step) and *continue to breathe in slowly and deeply after dose actuation* (essential step). Similarly, in two large multi-centre trials conducted by Melani and colleagues[12] and Molimard and colleagues[11] failure to continue inhaling after inhaler actuation was the technique step most frequently performed incorrectly. Failing to exhale prior to inhalation was also the DPI technique step most frequently incorrectly performed in this study. While this step is not widely considered an essential step, failure to exhale prior to dose inhalation has been shown to reduce pulmonary drug delivery to the lungs[3]. Rootmensen and colleagues[13] reported that 59% of participants using a pMDI, 61% using a DS and 63% using a TH performed this step incorrectly. Similarly, van Beerendonk and colleagues[16] observed that > 65% of participants using a pMDI or a DPI performed this step incorrectly and Lee and colleagues[34] discovered that this was the step most frequently performed incorrectly among participants using a pMDI, DS or TH. None of the participants using a DPI in this study failed to inhale deeply and forcefully, a technique step essential to pulmonary drug delivery[5,67]. However, it is possible that this was an overestimation as the peak inspiratory flow rate through the DPIs was only assessed subjectively and not measured using an In-Check meter or other objective measurement device.

The mean number of technique errors and critical errors was significantly higher among participants using a pMDI compared to a DPI. Khassawneh and colleagues[23] and Rootmensen and colleagues[13] reported similar results with respect to critical technique errors. Conversely, Melani and colleagues[9] reported that a significantly greater proportion of participants using a DS or TH performed at least one critical error compared to those using a pMDI.

5.4.2.4. Inhaler technique: follow-up consultation

At the follow-up consultation, the mean number of technique errors for both pMDI users and DPI users decreased significantly. In addition, none of the participants using a DPI performed any essential steps incorrectly and only 18.2% of pMDI users made any critical technique errors. The percentage of participants performing at least one error decreased from 82% to 36% for pMDI users and from 89% to 33% for DPI users. These results indicate that community pharmacists can successfully educate their asthma patients on

inhaler technique and ensure that the correct technique is retained. It is likely that the success of the inhaler technique training was due to two factors. Firstly, participants were trained using the 'Show and Tell' inhaler technique counselling method published by Basheti and colleagues[41]. This counselling method consists of a cycle of counselling assessment that is repeated until the patient can demonstrate the correct technique, up to a maximum of three times. In addition, the participants were provided with technique reminder labels[41] attached to their inhaler devices on which any incorrectly performed technique steps were highlighted. These labels provided participants with a visual reminder of their technique errors between consultations and may have encouraged them to be more mindful of these steps when using their inhalers.

A number of community pharmacist-led interventions on inhaler technique have been published. Basheti and colleagues[41] used the aforementioned 'Show and Tell' technique intervention with inhaler technique reminder labels and they reported a significant improvement in mean DS and TH technique scores between the baseline and the follow-up visits. Ovchinikova and colleagues[48] used this 'Show and Tell' intervention with reminder labels when educating participants to use a pMDI, DS or TH. They reported that the percentage of participants using their inhalers correctly increased from 17% at baseline to 61% at follow-up. Bosnic-Anticevich and colleagues[43] demonstrated the importance of providing participants with a physical demonstration when counselling on inhaler technique. They reported that at the second follow-up visit 80% of the participants who received a physical demonstration of inhaler technique with written and verbal instructions during counselling demonstrated correct technique, compared to 10% of those who only received written and verbal counselling Both Hammerlein and colleagues[626] and Giraud and colleagues[6] reported that the percentage of participants with optimal inhaler technique increased from 21% to 72% and from 24% to 79% respectively, after pharmacist-led inhaler technique interventions.

5.4.2.5. Asthma control

The mean ACT score for the test participants was significantly higher than that obtained for the external control participants at the follow-up consultations. It is likely that this improvement in asthma control is attributable to the significant improvement in the test participants' inhaler technique scores and this theory is supported by the literature. Melani and colleagues[9] demonstrated a significant association between incorrect inhaler technique and reduced asthma control. The reported that performing at least one critical error in inhaler technique was significantly associated with an increased risk of hospitalisation or ED visits due to asthma and courses of oral corticosteroids. Similarly, Giraud and colleagues[10] demonstrated that incorrect pMDI technique, particularly poor

coordination of inhalation and actuation, was strongly associated with asthma instability. In a more recent study, Giraud and colleagues[6] investigated the existence of an association between inhaler technique and asthma control, assessed using the Asthma Control Questionnaire without lung function testing (ACQ6)[627]. They reported that, at baseline, participants with incorrect inhaler technique had significantly worse ACQ scores than those with optimal technique. At follow-up, the mean improvement in the ACQ scores was significantly greater for patients with optimal technique after training compared with those whose technique was sub-optimal.

No significant improvement in asthma control was observed for either the internal or external control participants. This result was expected, as they did not receive any intervention that could have impacted on their level of asthma control. The mean ACT value for the test participants increased from 19.3±3.3 to 20.1±3.6. This increase was not significant but it did approach significance. There may be a number of possible reasons for this. Firstly, while a significant improvement was observed in participants' inhaler technique scores, 10% still performed at least one critical error at the follow-up visits. Due to the small sample size this may have impacted on the ACT values obtained. In addition, optimal inhaler technique is only one factor essential for attaining asthma control, medication adherence is also very important[599]. At follow-up, participants' mean medication adherence scores indicated medium adherence and they had not improved significantly from baseline. However, Lasmar and colleagues[598] demonstrated that adherence rates of > 80% were necessary for attaining optimal asthma control.

5.4.2.6. Asthma knowledge

No significant improvement in participants' asthma knowledge was observed for any of the three study groups. As this intervention did not include an asthma education component, these results are unsurprising. However, interventions aimed at improving participants' asthma knowledge have demonstrated success. Kritikos and colleagues[628] compared the effects of small group interactive asthma education with usual care on adult participants, in the community pharmacy setting. They observed that participants who received the educational intervention demonstrated a significant improvement in asthma knowledge compared to those who received usual care. This improvement was sustained over a twelve-week period. Saini and colleagues[144] also conducted a community pharmacist-led intervention on asthma education. They observed that delivering individualised asthma education in three consultations over six months resulted in a significant and sustained improvement in participants' asthma knowledge. Watson and colleagues[629] also compared usual care with small group interactive education delivered by a nurse educator

and a respiratory therapist to children and their caregivers. They observed that children who received the educational intervention had significantly fewer ED visits and courses of oral steroids than those who received usual care.

5.4.2.7. Medication adherence

No significant improvement in medication adherence was observed in any of the three study groups. This result is unsurprising as the intervention did not focus on or address medication adherence. Community pharmacist-led interventions that did result in improvements in medication adherence consisted of multiple consultations with the participants over six - twelve-month periods[171,217,344,630]. The consultations addressed multiple issues such as asthma pathology, lifestyle issues, medication use and adherence and goal setting and review. They frequently required extensive time expenditure thus precluding their routine inclusion in daily practice.

5.4.2.8. Asthma-specific quality of life

No significant improvements in asthma-specific quality of life were observed between the initial and follow-up consultations for either of the control groups. However, significant and clinically important improvements were observed in test participants' overall asthma-specific quality of life scores and in the Symptoms and Emotional Function domain scores, between the initial and follow-up consultations. Similarly, Basheti and colleagues[41,104] observed significant and clinically relevant improvements in participants' asthma-specific quality of life scores following a community pharmacist-led intervention on inhaler technique. They demonstrated that the improvements in participants' inhaler technique scores were significantly correlated with the improvements in their asthma-specific quality of life scores. Similarly, Al-Showair and colleagues[625] investigated the potential of the 2Tone Trainer, a training aid, to improve participants' pMDI technique. They reported that at the follow-up visits all participants' trained using the 2Tone Trainer had an inhalation rate of < 90L/min. In addition, their overall asthma-specific quality of life scores and their Symptoms, Emotional Function and Environmental Stimuli domain scores had increased significantly from their baseline scores.

The existence of a strongly significant correlation between asthma control and asthma-specific quality of life is well established in the literature[615-617]. Consequently, it is likely that the clinically significant increase in asthma-specific quality of life observed in this study is due to the increase in asthma control.

5.4.2.9. Exit questionnaire for test pharmacists

The Exit Questionnaire provided a unique insight into participating pharmacists' experiences with the provision of more intensive patient counselling on asthma than appears to occur routinely. It also allowed participants to outline clearly the barriers and facilitators to such intensive counselling from their own personal experiences. This was a unique feature of this project, which appears to be lacking in many community pharmacy-based interventions on asthma.

1) Initial patient recruitment to the project

Participating pharmacists' experiences with patient recruitment were quite varied. 62% believed that their patients were *very receptive/receptive* towards participation but 38% experienced patients who were, on average, *somewhat/poorly receptive.* Experiencing difficulties in the recruitment of patients to practice-based research studies on asthma is documented in the literature[558,631-633] and appears particularly problematic among patients who have lived with asthma for a considerable time period[558].

When respondents were asked to rate the impact of a number of identified barriers on patient participation in the study, a number of issues emerged. The two largest barriers to patient participation were believed to be a patient's lack of time to participate and his/her lack of awareness about the level of asthma control achievable. In addition, a lack of perceived need among patients and a lack of interest in the service offered were also believed to have contributed to poor patient participation. These findings are in accordance with the published literature. Lemaigre and colleagues[557] investigated participation behaviour in an asthma self-management programme using the Attitude, Social-Influence and Self-Efficacy model. They discovered that the two main predictors of participation were the existence of few structural barriers to participation (*e.g.* lack of time) and believing that the programme would be personally beneficial. Bereznicki and colleagues[221] conducted a qualitative follow-up study of participants who had been involved in a community pharmacy-based asthma study. The participant pharmacists stated that they felt their asthma patients were 'apathetic about asthma' and were unaware that regular use of reliever inhalers was indicative of poor control. This was confirmed by the patients themselves who stated that they perceived their asthma to be controlled despite the presence of wheezing symptoms and regular use of reliever medications. Similarly, a qualitative study on asthma management in New South Wales revealed that pharmacists believe that the patients' attitudes towards asthma, particularly their poor understanding of the condition, was the largest barrier to the provision of optimal asthma care[182]. Schneider and colleagues surveyed ~ 250 asthma patients

treated in primary care in eastern Germany. They discovered that while only ~30% had ever received education about asthma, the majority of the remainder did not want to receive asthma education. It is evident from the results of this study and those in the published literature that patients' lack of awareness about the level of asthma control that is achievable is a significant barrier to the implementation of measures aimed at improving their asthma care.

2) Average time needed to complete the initial consultation

50% of the respondent pharmacists stated that the initial consultation took 21-25 minutes to complete. The minimum amount of time needed was 15-20 minutes per consultation. The majority of the respondents stated that this amount of time was *somewhat acceptable* or *unacceptable* for them. This was unsurprising as the results of the QAM-CP revealed that ~85% of the respondents agreed that time was a major barrier to the provision of counselling on asthma.

This intervention was designed to be brief to facilitate its inclusion into the pharmacists' routine practice. Indeed, Basheti and colleagues[41] conducted a similar intervention on inhaler technique training and they concluded that the intervention was 'highly feasible' in terms of time expenditure. They stated that the inhaler technique training component of the initial visit took just 5±2min (median±inter-quartile range) per assessment and training cycle. It is likely that the completion of the patient questionnaires was the most time-consuming aspect of the study as 90% of those surveyed agreed that it would be feasible to incorporate this level of patient counselling into routine practice if the paperwork required was eliminated. However, the study paperwork was necessary to determine if counselling on inhaler technique resulted in any improvements in a patient's asthma health status. It was encouraging to discover that that vast majority of respondents were open to the inclusion of rigorous inhaler technique training into routine practice.

3) Payment for provision of counselling on inhaler technique

The majority of the respondents did not believe that they should charge patients for the provision of counselling on inhaler technique and peak flow meter use. It is possible that one of the predominant reasons for this was the fact that ~80% believed that patients would be unwilling to pay for this service. Interestingly, Naik-Panvelkar and colleagues[634] used a discrete choice experiment to investigate willingness-to-pay for specified aspects of a community-pharmacy based asthma service among patients who had participated in a specialised asthma service provided by community pharmacists in New South Wales. They discovered that patients were willing to pay AUS$22.80 (~€18) for the provision of

comprehensive advice on asthma compared to the provision of basic advice. They were also willing to pay AUS$9.18 (~€7) for a scheduled appointment with the pharmacist compared with a 'walk-in anytime' service. Older people and those with a higher education level were less price sensitive than younger people and those with a lower education level. This study reveals that patients value the provision of a specialised asthma service by community pharmacists and so may be willing to pay for such a service. This study was conducted on patients who had already experienced a specialised asthma service and so it may not reflect the opinions of the asthma population as a whole. Community pharmacy in Australia is similar to Ireland in that there is currently no provision for the remuneration of professional services provided by pharmacists by either the government or the patients. Therefore, this study is relevant to Ireland as patients in both countries are unaccustomed to paying their pharmacist for the provision of a professional service.

4) Patients' receptiveness towards engaging in the second consultation

Approximately 50% of the respondent pharmacists believed that their participating patients were *very receptive/receptive* towards engaging in the second consultation and the other 50% believed that their patients were *poorly receptive*. Emmerton and colleagues[633] investigated the opinions of community pharmacists involved in the provision of a specialised asthma service using focus groups and individual interviews and reported similar results. They discovered that participating pharmacists experienced a lack of commitment and persistence with the study among patients and this was extremely frustrating for them. Furthermore, Sarvis and colleagues[631] reported that only ~40% of the patients recruited to an community pharmacy-based educational intervention on inhaler technique returned for the follow-up visit.

Respondent pharmacists stated that insufficient time was the primary reason provided by patients for failing to engage in the second consultation. As the initial consultation took at least 15-20 minutes this result was unsurprising. A lack of interest among patients, a belief that they did not need a second consultation and feeling that the initial consultation was too time consuming were also considered to have impacted on participants' lack of participation in the second consultation. It is likely that the participants were unaware that correct inhaler technique declines over time[41,43,48] and this may have contributed to their belief that a second consultation was not required.

5) Perceptions of the project

The results indicate that overall the project was well received as the vast majority of respondent pharmacists believed that their patients benefited from their project and were appreciative of the increased counselling that they received. Outcome measures to

elucidate feedback from pharmacists and/or patients about a community pharmacy-based asthma service appear to be infrequently included in study protocols. However, qualitative feedback from both participating pharmacists and patients about specific studies in which they were involved revealed positive results about the benefits of the studies[41,144]. Furthermore, Naik-Panvelkar and colleagues[206] investigated patients' preferences for a community pharmacy-based asthma service. They discovered that patients who had already experienced a specialised pharmacy-based asthma service and those who had not would welcome their pharmacist taking a more active role in their asthma care.

Approximately 80% of the respondents believed that participating in the study had improved their relationships with the participating patients. In addition, the vast majority believed that the study had improved their knowledge of both inhaler technique and peak flow meter use. Peterson and colleagues[561] investigated Australian community pharmacists' opinions about practice based research. They discovered that 97% of those surveyed rated 'the opportunity to learn more about disease management' as a very important/important factor when considering whether to participate in practice based research. Paluck and colleagues[635] investigated the barriers and facilitators to pharmacist counselling. They discovered that one of the pre-disposing factors that received very strong support among those surveyed was the belief that counselling improves the relationship between the pharmacist and the patient.

6) Desirable and undesirable factors about the project

The desirable factor most frequently identified by the respondent pharmacists was the belief that participating in the project improved their patients' asthma care. The belief that the project was too time consuming was the most frequently identified undesirable factor, followed by the view that the paperwork was burdensome for both patients and pharmacists. Saini and colleagues[560] and Peterson and colleagues[561] investigated the factors that influenced community pharmacists' involvement in practice based research. A key facilitator to participating in practice based research, observed in both studies was the ability of the research to improve patient care. Saini and colleagues[560] reported that a key barrier to participation in research was time constraints within the community pharmacy. In addition, they observed that the chief factor that would motivate pharmacists to participate was research that was 'time-efficient and simple'. As discussed in 5.4.2.9(4) above, Emmerton and colleagues[633] investigated pharmacists' experiences of their involvement in a specialised asthma service. The participating pharmacists reported that participating in the asthma service improved the health status of the participating patients and improved pharmacist-patient relationships. Their key criticisms of the project were

the need to complete burdensome documentation and the time requirements for the provision of the asthma service.

7) Changes needed for incorporation of intensive counselling into routine practice

Respondents identified four key changes to facilitate the provision of an enhanced counselling service during daily practice. These were the need for increased staff members and improved training of the existing staff, remuneration for the provision of the service and the implementation of structured chronic disease programmes within the community pharmacy setting. These ideas will be explored in detail in Chapter 6. Other measures, not mentioned by the respondents, which might also facilitate the provision of an enhanced counselling service include reducing the amount of paperwork associated with the data collection aspect of the enhanced service and improving pharmacists' ability to delegate non-professional or semi-professional tasks to other staff members. Indeed, a study on community pharmacy practice in Northern Ireland[203] revealed that community pharmacists devoted almost one-quarter of their time each day to medication assembly and labelling, an activity that could be performed by appropriately trained pharmacy support staff. Therefore, appropriate delegation by pharmacists could increase the amount of time they have available for the provision of enhanced services.

5.4.2.10. Limitations of the study

The limitations outlined in 5.4.1.7 are obviously also applicable here, but there are also a number of additional limitations. Firstly, a considerable number of patient participants were lost to follow-up; as a result, the study would need to be repeated in a larger sample size to confirm the study results. However, the study has confirmed the feasibility of delivering an educational intervention on inhaler technique within the constraints of the community pharmacy setting. Secondly, participating pharmacists allocated the patients to the study groups and this was not conducted randomly, to limit the pharmacist's study workload. As a result, selection bias may have been introduced to the study. The study was also limited by the fact that the inhaler technique assessments were conducted by an unblinded pharmacist whose subjective judgement determined the incidences of technique errors. However, only one pharmacist in each study centre/pharmacy conducted all of the technique assessments and the potential for bias was limited by the used of standardised checklists and the provision of comprehensive instructions on the technique scoring methods by the researcher prior to the commencement of the study. Finally, there are no validated inhaler technique checklists available and the number of technique steps varied between each inhalation device. This limits the validity of comparing the scores obtained for each device. Consequently, the outcome measure

used to determine the impact of the educational intervention was the assessment of any changes in inhaler technique scores from baseline to follow-up within each device type.

5.5. Conclusion

5.5.1. Observational study

The baseline results of this Brief Intervention revealed a number of concerning issues. Firstly, > 60% of the participants had partly controlled or uncontrolled asthma and this sub-optimal asthma control appeared to be impacting negatively on all aspects of their daily lives. This was evidenced by their significantly lower asthma-specific quality of life scores compared to those recorded by participants with controlled asthma. Furthermore, poorly controlled asthma was even more prevalent among current smokers than non-smoking participants. As a result, asthma seemed to have an even greater negative influence on their quality of life than on that of non-smokers.

The study also illustrated considerable gaps in participants' knowledge of asthma-related issues, particularly in areas that could have a negative impact on their medication adherence. Almost half of the participants were unaware that side-effects are less likely with inhaled medications than with oral medications and greater than one-third did not know that asthma medications are not addictive. Studies[196,576,585] have demonstrated a negative correlation between fears/concerns about preventative medications and patients' medication adherence. In addition, older participants appeared to be even less informed about many of the asthma-related issues than their younger counterparts. Consequently, it is evident that there is an urgent requirement for an increase in patient education on asthma, especially in relation to older patients. The education should focus particularly on patients' fears and beliefs about their prescribed medications.

Less than one-quarter to the participants were highly adherent to their asthma medications and poor adherence was especially evident among younger participants (< 30 years). One of the primary contributors to poor adherence was a lack of understanding about the chronic nature of asthma as > 50% of participants stated that they reduced or stopped their preventative medication when they felt their asthma was controlled. These results provide further evidence for the vital need for patient education on asthma.

The baseline results of this study portray an asthma population that, predominantly, has sub-optimal asthma control, low levels of medication adherence and a lack of knowledge on key asthma-related issues. As a result, asthma appears to be exerting a negative impact on their lives. However, the study would need to be repeated in a larger sample size to determine if these results are representative of the general asthma population. Patient education on the pathology of asthma, asthma medications, lifestyle issues and the importance of adherence is vital to improve the quality of life of these patients.

5.5.2. Interventional study

Implementing this Brief Intervention in community pharmacies nationwide revealed that insufficient time is a major impediment to the expansion of the role of the pharmacist to include the routine provision of pharmaceutical care in Ireland. In order to address this issue, pharmacists may have to learn to delegate certain activities to ancillary staff to increase their availability for the provision of pharmaceutical care. However, this may necessitate the employment and training of additional staff[622], which will require a substantial investment of time and money[205]. It is unlikely that such an investment would occur without the implementation of a reimbursement system for the provision of professional pharmaceutical services.

Patient recruitment and follow-up was difficult for a substantial proportion of the participating pharmacists due to a professed lack of time on the part of the patient and a lack of understanding about the potential benefits of the study on their level of asthma control. It is evident, therefore, that patients need to educated on the degree of asthma control that is achievable and about the impact that correct inhaler technique can have on their asthma control.

The initial assessments of participants' inhaler technique demonstrated that < 20% performed all the technique steps correctly, prior to any additional training. Regular reinforcement of inhaler technique is essential to ensure patients' maintain the correct technique[41,43]. The results of the QAM-CP, QAM-GP and QAM-PN revealed that the majority of health-care professionals in primary care infrequently check their patients' ability to use their inhalers on a routine basis, therefore these results are unsurprising. However, following the provision of inhaler technique training by their community pharmacists, these participants demonstrated a significant improvement in inhaler technique at the follow-up consultations. Furthermore, the improvement in inhaler technique seemed to result in an improvement in participants' asthma control and this translated into an improvement in their quality of life.

In conclusion, recruiting pharmacists and engaging asthma patients in interventions aimed at improving their asthma care is difficult and requires the implementation of a patient education programme on the importance of inhaler technique in asthma control and an overhaul of the current reimbursement system in community pharmacy. While the study needs to be repeated with a larger sample size, this study illustrates the feasibility and clinically effectiveness of an inhaler technique intervention conducted within the constraints of the community pharmacy environment.

6. Pharmacoeconomic evaluation of R03A and R03B medicines licensed for asthma

6.1. Introduction

The Irish healthcare system is described in detail in Chapter 1, but of relevance to this chapter is the fact that all Category I patients (those with a full medical card) receive their medication free of charge (subject to €1.50 levy per item) under the General Medical Services (GMS) scheme. Category II patients can obtain a DPS card, which ensures that the family unit only pays a maximum of €144 each month for their medication under the DP scheme. LTI patients receive all of their medication/appliances related to specified long-term illnesses (which do not include asthma) free of charge. Each item that is reimbursable under the GMS, DP or LTI scheme is assigned a 5 digit code known as a GMS code. At the end of every month community pharmacists electronically submit information on all prescription items dispensed under the GMS, DP, LTI schemes (and other community drug schemes) to the PCRS for payment. Information on prescription items that are not dispensed under a community drug scheme (*i.e.* those dispensed to private patients) are not included in this electronic submission. This information is submitted to the PCRS pharmacy claims database held by the HSE. The PCRS database contains each patient's demographic details (age and gender), information on the prescription item dispensed including the proprietary and non-proprietary name of the item, the strength of the drug and the pack size, details of the manufacturer and both the associated cost and the pharmacy dispensing fee. However, no identifiable patient information is available. While the PCRS population cannot be considered representative of the entire Irish population, due to the overrepresentation of the elderly and the socially disadvantaged, it is still estimated to account for 70% of all medicines dispensed in primary care[636].

The PCRS Statistical Analysis of Claims and Payments Report 2011[637] reported that €113.35 million or 9.39% of total GMS expenditure and €33.44 million or 12.05% of total DPS expenditure on drugs, medicines and appliances was spent on respiratory medicines in 2011. Furthermore, medicines in the WHO anatomical therapeutic classification (ATC) class R03AK, 'adrendergics and other drugs for obstructive airways disease' was the 4th highest category of GMS expenditure and the 3rd highest category of DPS expenditure in 2011. However, due to the absence of patient diagnosis linked to the prescription items in the PCRS pharmacy claims database it is not possible to distinguish between the medicines prescribed for asthma versus those prescribed for COPD or other respiratory

illness, particularly as there is considerable overlap between the medicines prescribed for both asthma and COPD. An age cut-off point was used in conducting the European Community Respiratory Health Survey[638](ECRHS) and in conducting the World Health Survey[639] (WHS) to distinguish between asthma and COPD. Both surveys were conducted on adults and the ECRHS included patients aged 20-44 years whereas the WHS included those aged 18-45 years. The PCRS pharmacy claims database distinguishes patients according to age range not discrete age and the age ranges including 44 years and 45 years are 35-44 years and 45-55 years respectively. Consequently, following personal communication with the HSE National Asthma Programme working group, it was decided to use an age cut-off point of 45 years, whereby those < 45 years were considered likely to have asthma and those ≥ 45 years were more likely to have COPD. Obviously, this method of discrimination is not completely accurate, but it does help in achieving a number of broad objectives outlined below.

1. To determine the cost and quantity of each R03A and R03B medication, licensed for asthma that was dispensed to all patients and those < 45 years in the identified 12 month period and to identify any areas where savings could be made.
2. To determine the proportions of preparations and device types dispensed in the 12 month period according to age range.
3. To estimate asthma patients' adherence through the determination of the median weekly dose of each inhaled preventative drug dispensed and the proportion of monthly dispensings where only a reliever medication was dispensed without a concurrent R03A or R03B preventative medication.
4. To estimate patients' asthma control through the determination of the proportion of patients with excessive salbutamol dispensings.

6.2. Methods

The PCRS pharmacy claims database holds all of the prescription claims data and supplies the data to the National Centre for Pharmacoeconomics (NCPE) in Dublin. The data for this analysis were obtained from the NCPE. All prescription items held on the PCRS pharmacy claims database are coded using the WHO ATC classification system. The statistical software package, SAS, version 9.2, was used to extract all prescription items with the ATC codes R03A and R03B for the 12 month period from April 1st 2012 to March 1st 2013 from the database held in the NCPE. As described in 1.6.3.3, R is the ATC code for respiratory drugs, R03 is the code for obstructive airways diseases drugs, R03A is the code for 'adrenergics, inhalants' and R03B is the code for 'other drugs or

obstructive airways diseases, inhalants'. This data were exported as a csv file and imported into SPSS version 16. The data were analysed with probabilities of ≤ 0.05 considered statistically significant. The Kolmogrov-Smirnov test was used to investigate normality. For discrete variables, comparisons between groups were conducted using the Chi-square test and one-way ANOVA was used to evaluate differences between groups of continuous variables. As discussed in 6.1, age range of < 45 years was considered an indicator of patients with asthma versus COPD. Consequently, most of the results are presented for the entire R03A and R03B population and for those patients < 45 years.

6.3. Results

6.3.1. Demographic data

385,297 unique patients had at least one R03A or R03B prescription item, dispensed in the 12 month period from April 1st 2012 - March 31st 2013. 84.1% of these patients were full medical card holders, 15.2% were DPS card holders and 0.7% were LTI card holders. The age range was not available for 3,081 patients; the age range of the remaining patients is displayed in the graph below. Of the 382,217 patients for whom age range was available, 182,230 or 47.7% were < 45 years.

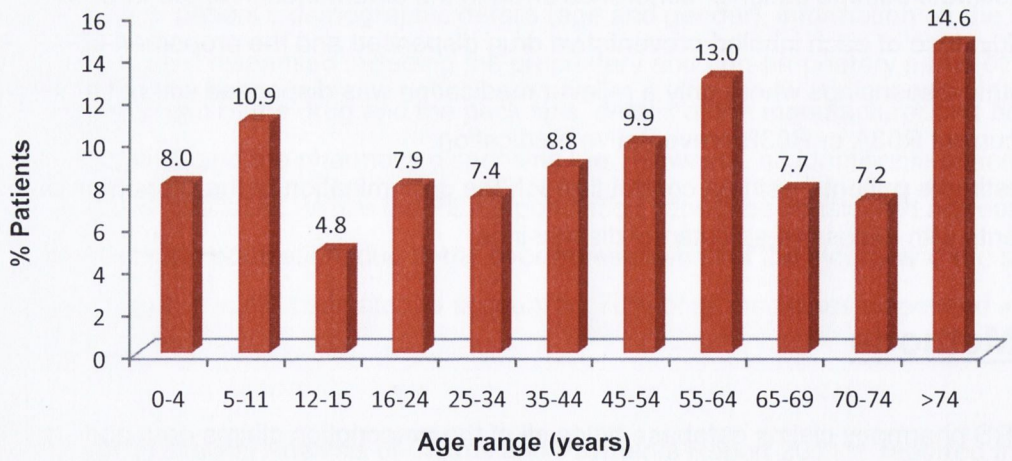


Figure 6.1 Age range of the patients dispensed an R03A or R03B medicine, licensed for asthma, in the identified 12 month period (N = 382,217)

6.3.2. Baseline product characteristics

In the 12 month period from April 1st 2012 - March 31st 2013, 203 individual GMS codes representing 202 different products were identified with ATC codes R03A or R03B. 29 of these products were identified as being licensed for COPD or allergic rhinitis only and

were excluded from further analysis. The excluded products included thirteen products with tiotropium bromide as the active ingredient, one product with glycopyrronium bromide as the active drug, two products with indacterol as the active drug, thirteen products with both ipratropium bromide and salbutamol as the active components and one nasal preparation containing fluticasone furoate. Furthermore, one product (Aerobec® Autohaler) was dispensed to one patient but as this product was withdrawn from the market in 2001, this product was also excluded. The remaining 171 products are outlined in Table 6.1 below.

Table 6.1 R03A and R03B products licensed for asthma

Drug	Strength + Dose	Pure generic products	Branded generic products	Proprietary products	Parallel import products	Total number of products
Beclometasone	50 mcg 200 dose		2	1	3	6
	100 mcg 200 dose		2	2	2	6
	200mcg 200 dose		2			2
	250 mcg 100 dose			1		1
	250 mcg 200 dose		2	1	4	7
Beclometasone (HFA)	50 mcg 200 dose			2		2
	100 mcg 200 dose			2		2
Budesonide	100 mcg 200 dose			1	4	5
	100 mcg 120 dose			1		1
	200 mcg 100 dose			3	5	8
	200 mcg 120 dose			1		1
	400 mcg 50 dose			2	2	4
Budesonide respules	0.5 mg/2 ml 20 dose	1	1	1		3
	1 mg/2 ml 20 dose		1	1		2
Budesonide + formoterol	100/6 mcg 120 dose			1	1	2
	200/6 mcg 120 dose			1	1	2
	400/12 mcg 60 dose			1	1	2
Ciclesonide	80 mcg 60 dose			1		1
	160 mcg 60 dose			1		1

Drug	Strength + Dose	Pure generic products	Branded generic products	Proprietary products	Parallel import products	Total number of products
Fluticasone	50 mcg 60 dose			1		1
	50 mcg 120 dose			1		1
	100 mcg 60 dose			1		1
	125 mcg 60 dose			1		1
	125 mcg 120 dose			2	3	5
	250 mcg 60 dose			3		3
	250 mcg 120 dose			2	2	4
	500 mcg 60 dose			1		1
Fluticasone respules	0.5 mg/2 ml 10 dose			1	1	2
	2 mg/2 ml 10 dose			1	1	2
Fluticasone + formoterol	50/5 mcg 120 dose			1		1
	125/5 mcg 120 dose			1		1
	250/10 mcg 120 dose			1		1
Fluticasone + salmeterol	50/25 mcg 120 dose			1		1
	125/25 mcg 120 dose			1		1
	250/25 mcg 120 dose			1	2	3
	100/50 mcg 60 dose			1	1	2
	250/50 mcg 60 dose			1	4	5
	500/50 mcg 60 dose			1	7	8
Formoterol	6 mcg 60 dose			1	1	2
	12 mcg 60 dose			2	2	4
Ipratropium bromide	20 mcg 200 dose			1		1

Drug	Strength + Dose	Pure generic products	Branded generic products	Proprietary products	Parallel import products	Total number of products
Ipratropium bromide respules	250 mcg/ml 20 dose		2	1		3
	250 mcg/ml 60 dose		1	1		2
	500 mcg/2 ml 20 dose		2	1		3
	500 mcg/2 ml 60 dose		1	1		2
Mometasone	200 mcg 30 dose			1		1
	200 mcg 60 dose			1		1
	400 mcg 30 dose			1		1
	400 mcg 60 dose			1		1
Nedocromil	2mg 112 dose			1		1
Salbutamol	100 mcg 200 dose	1	11	5	8	25
	200 mcg 60 dose			1		1
Salbutamol respules	2.5 mg/2.5 ml 20 dose		2	1	2	5
	5 mg/2.5 ml 20 dose		2	1		3
Salmeterol	25 mcg 120 dose		1	2	3	6
	50 mcg 60 dose			1		1
Sodium cromoglycate	20 mg 112 dose			1		1
Terbutaline	500 mcg 100 dose			1	6	7
	500 mcg 200 dose				1	1
Terbutaline respules	2.5 mg/ml 2ml 20 dose			1		1

HFA = Hydrofluoralkane

6.3.3. Median cost of the items dispensed in the 12 month period

The data set was analysed to investigate if the data had a normal distribution using the Kolmogrov-Smirnov test. This test revealed that the data were skewed to the right. Consequently, the median and interquartile range (IQR) was used in preference to the mean and standard deviation in the ensuing analysis. In the identified 12 month period, the median (IQR) cost of the items dispensed per patient was €61.27 (€326.00) (N = 385,297). Among patients < 45 years, the median cost per patient was €24.19 (€79.83) (N = 182,230). Among patients < 45 years, the median cost per patient was analysed according to age range and community drug scheme and the results are outlined in the subsections below.

6.3.3.1. Median cost of the items dispensed according to community drug scheme

The median cost of the R03A and R03B prescription items dispensed to a patient, in the identified 12 month period, was determined according to patients' community drug scheme. The results are displayed in the table below.

Table 6.2 Median cost of the R03A and R03B items dispensed in the 12 month period according to community drug scheme

Healthcare scheme	N	Median (IQR) cost
GMS	156948	€18.90 (61.67)
DPS	24197	€64.64 (194.43)
LTI	1085	€73.95 (191.19)

6.3.3.2. Median cost of the items dispensed according to age range

The median cost of the R03A and R03B prescription items dispensed to a patient, in the identified 12 month period, was determined according to patients' age range (< 45 years). The results are displayed in the table below.

Table 6.3 Median cost of the R03A and R03B items dispensed in the 12 month period according to patients' age range

Age range	N	Median (IQR) cost
0-4 years	30,465	€9.45 (22.48)
5-11 years	41,649	€18.42 (43.87)
12-15 years	18,386	€27.51 (79.14)
16-24 years	30,068	€33.70 (108.97)
25-34 years	28,141	€40.23 (141.16)
35-44 years	33,521	€50.11 (191.48)

6.3.4. Total quantities and costs of inhaled and nebulised asthma treatments dispensed in the 12 month period

Within the extracted data for the identified 12 month period, there were a number of entries corresponding to dispensed medication, which could not be matched with valid GMS or DPS numbers in the PCRS pharmacy claims database. This may have been due to an incorrectly entered GMS/DPS number when the item was dispensed or due to the expiration of the patient's GMS/DPS card. These medications were dispensed to patients by community pharmacists but the PCRS did not pay for the medications. Consequently, the cost of these items is not included in the ensuing analysis as the PCRS did not pay for the medications but the items are included when a sum total of items is presented, as patients were prescribed and did receive these items. 5,093 items were not paid for by PCRS. This number consists of 2,761 SABA inhalers, 63 LABA inhalers, 801 corticosteroid inhalers and 1,531 combined corticosteroid/LABA inhalers. The total cost of these items was €114,336.13.

6.3.4.1. Total quantities and costs of each product dispensed

Table 6.4 Total quantities and costs of inhaled and nebulised corticosteroids

Drug name + dose	Product type	Total items (All patients)	Total cost (All patients)	Total items (< 45 yrs.)	Total cost (< 45 yrs.)
Beclometasone 50 mcg 200 dose	Proprietary	34,371	€214,839.50	31,165	€194,799.37
	Generic	37,049	€200,136.70	31,293	€168,842.97
	Parallel import	2,356	€10,944.22	2,198	€10,271.51
Beclometasone 100 mcg 200 dose	Proprietary	58,879	€717,497.60	39,250	€478,256.58
	Generic	92,908	€983,635.20	52,831	€558,183.79
	Parallel import	1,298	€6,813.10	844	€4427.93
Beclometasone 200 mcg 200 dose	Generic	20,116	€424,253.20	7,503	€158,239.05
Beclometasone 250 mcg 100 dose	Proprietary	152	€2763.30	46	€832.60
Beclometasone 250 mcg 200 dose	Proprietary	41,407	€1,077,982.00	12,240	€318,614.04
	Generic	74,771	€1,697,857.00	19,523	€442,776.73
	Parallel import	2,735	€67,838.84	887	€22,140.21
Beclometasone HFA 50 mcg 200 dose	Proprietary	712	€7,732.32	233	€2,530.38
Beclometasone HFA 100 mcg 200 dose	Proprietary	3,159	€73,415.16	575	€13,363.00
Budesonide 100 mcg 120 dose	Proprietary	367	€3,611.28	216	€2125.44
Budesonide 100 mcg 200 dose	Proprietary	4,389	€89,725.11	2,014	€41,190.33
	Parallel import	659	€13,181.01	365	€7,323.99
Budesonide 200 mcg 100 dose	Proprietary	17,688	€342,071.65	4,212	€81,292.14
	Parallel import	2,272	€44,390.85	638	€12,484.29
Budesonide 200 mcg 120 dose	Proprietary	234	€4,037.93	87	€1,501.86
Budesonide 400 mcg 50 dose	Proprietary	9,818	€188,342.20	1,207	€23,096.12
	Parallel import	516	€9,851.94	71	€1,360.15
Budesonide resp. 0.5 mg/2 ml 20 dose	Proprietary	62,286	€1,456,188.00	9,105	€210,734.13
	Generic	7,401	€147,737.06	891	€17,275.13
Budesonide resp. 1 mg/2 ml 20 dose	Proprietary	63,198	€2,130,210.00	5,475	€184,208.05
	Generic	644	€20,240.97	24	€675.26
Ciclesonide 80 mcg 60 dose	Proprietary	464	€8,827.96	109	€2,062.79

Drug name + dose	Product type	Total items (All patients)	Total cost (All patients)	Total items (< 45 yrs.)	Total cost (< 45 yrs.)
Ciclesonide 160 mcg 60 dose	Proprietary	3,396	€77,769.24	775	€17,747.50
Fluticasone 50 mcg 60 dose	Proprietary	804	€4904.40	689	€4,202.90
Fluticasone 50 mcg 120 dose	Proprietary	14,591	€129,560.90	13,836	€122,719.55
Fluticasone 100 mcg 60 dose	Proprietary	2,769	€27,189.72	1,865	€18,313.24
Fluticasone 125 mcg 60 dose	Proprietary	919	€9,695.45	747	€7880.85
Fluticasone 125 mcg 120 dose	Proprietary	15,977	€337,098.50	12,785	€269,903.33
	Parallel import	594	€11,976.36	491	€9896.67
Fluticasone 250 mcg 60 dose	Proprietary	5,570	€110,136.22	1,525	€30,104.01
Fluticasone 250 mcg 120 dose	Proprietary	17,429	€644,099.00	4,049	€149,616.11
	Parallel import	438	€15,489.48	110	€3,890.10
Fluticasone 500 mcg 60 dose	Proprietary	4,115	€143,001.22	661	€22,962.84
Fluticasone resp. 0.5 mg/2 ml 10 dose	Proprietary	23,424	€247,125.79	2,991	€31,550.85
	Parallel import	1,301	€13,309.24	90	€925.82
Fluticasone resp. 2 mg/2 ml 10 dose	Proprietary	21,853	€624,648.49	2,573	€73,533.48
	Parallel import	971	€26,902.26	51	€1,413.72
Mometasone 200 mcg 30 dose	Proprietary	284	€6,225.08	85	€1,901.00
Mometasone 200 mcg 60 dose	Proprietary	333	€11,480.53	133	€4,582.73
Mometasone 400 mcg 30 dose	Proprietary	223	€6,883.73	57	€1,754.76
Mometasone 400 mcg 60 dose	Proprietary	236	€12,273.92	97	€5,020.12
TOTALS		**655,076**	**€12,403,893.63**	**266,612**	**€3,736,527.42**

A parallel import product is one that is therapeutically equivalent to a product already licensed in Ireland and which is imported from an EU member state or a country within the European Economic Area. It may be distributed in Ireland provided the importer obtains an authorisation to market the product[640].

Table 6.5 Total quantities and costs of inhaled combined corticosteroids and long-acting β_2-agonists

Drug name + dose	Product type	Total items (All patients)	Total cost (All patients)	Total items (< 45 yrs.)	Total cost (< 45 yrs.)
Budesonide+ Formoterol 100/6 mcg 120 dose	Proprietary	17,991	€838,722.40	8,396	€390,942.25
	Parallel import	670	€30,271.54	333	€15,104.33
Budesonide+ Formoterol 200/6 mcg 120 dose	Proprietary	197,081	€9,875,807.00	52,763	€2,643,972.19
	Parallel import	3,454	€167,898.94	1,067	€51,866.87
Budesonide+ Formoterol 400/12 mcg 60 dose	Proprietary	158,729	€7,889,803.00	21,019	€1,044,729.08
	Parallel import	1,664	€80,257.19	187	€9,017.87
Fluticasone+ Formoterol 50/5 mcg 120 dose	Proprietary	7	€189.00	4	€108.00
Fluticasone+ Formoterol 125/5 mcg 120 dose	Proprietary	28	€1118.88	8	€319.68
Fluticasone+ Formoterol 250/10 mcg 120 dose	Proprietary	38	€2093.04	13	€716.04
Fluticasone+ Salmeterol 50/25 mcg 120 dose	Proprietary	12,391	€360,830.70	9,099	€264,963.96
Fluticasone+ Salmeterol 125/25 mcg 120 dose	Proprietary	30,822	€1,396,319.00	14,426	€653,386.49
Fluticasone+ Salmeterol 250/25 mcg 120 dose	Proprietary	201,612	€12,545,484.00	31,429	€1,955,822.94
	Parallel import	4,202	€252,289.05	596	€35,804.79
Fluticasone+ Salmeterol 100/50 mcg 60 dose	Proprietary	25,578	€852,733.40	10,697	€356,742.89
	Parallel import	122	€3,776.96	40	€1,245.48
Fluticasone+ Salmeterol 250/50 mcg 60 dose	Proprietary	163,720	€7,257,700.00	30,163	€1,337,523.77
	Parallel import	22,266	€968,714.30	4,292	€186,767.58
Fluticasone+ Salmeterol 500/50 mcg 60 dose	Proprietary	194,343	€11,527,000.00	22,454	€1,331,187.36
	Parallel import	32,626	€1,901,430.00	3,780	€220,275.63
TOTALS		**1,067,344**	**€55,952,438.40**	**210,766**	**€10,500,497.20**

Table 6.6 Total quantities and costs of inhaled and nebulised short-acting β_2-agonists

Drug name + dose	Product type	Total items (All patients)	Total cost (All patients)	Total items (< 45 yrs.)	Total cost (< 45 yrs.)
Salbutamol 100 mcg 200 dose	Proprietary	771,202	€2,474,387.00	331,409	€1,062,683.00
	Generic	433,364	€2,164,334.00	158,018	€718,229.50
	Parallel import	107,317	€331,418.50	47,468	€14,611.95
Salbutamol 200 mcg 60 dose	Proprietary	28,560	€154,500.70	8,973	€48,609.00
Salbutamol resp. 2.5 mg/2.5 ml 20 dose	Proprietary	75,029	€105,096.40	18,670	€26,158.38
	Generic	60,963	€107,982.50	10,783	€19,091.84
	Parallel import	3,809	€5,352.21	798	€1,110.01
Salbutamol resp. 5 mg/2.5 ml 20 dose	Proprietary	29,022	€77,549.18	5,838	€15,599.68
	Generic	11,096	€69,408.48	1,498	€9,391.54
Terbutaline 500 mcg 100 dose	Proprietary	35,718	€333,189.50	11,055	€103,160.09
	Parallel import	9,318	€88,407.70	2,865	€27,305.27
Terbutaline 500 mcg 200 dose	Parallel import	401	€7,574.18	118	€2,207.24
Terbutaline resp. 2.5 mg/2 ml 20 dose	Proprietary	310	€1,416.34	149	€701.80
TOTALS		**1,566,109**	**€5,920,617.00**	**597,642**	**€2,048,859.00**

Table 6.7 Total quantities and costs of inhaled cromones

Drug name + dose	Product type	Total items (All patients)	Total cost (All patients)	Total items (< 45 yrs.)	Total cost (< 45 yrs.)
Nedocromil 2mg 112 dose	Proprietary	68	€1,954.90	2	€57.40
Sodium cromoglycate 20 mg 112 dose	Proprietary	610	€8,851.26	89	€1,285.28
TOTALS		**678**	**€10,806.16**	**91**	**€1,342.68**

Table 6.8 Total quantities and costs of inhaled long-acting β_2-agonists licensed for asthma

Drug name + dose	Product type	Total items (All patients)	Total cost (All patients)	Total items (< 45 yrs.)	Total cost (< 45 yrs.)
Formoterol 6 mcg 60 dose	Proprietary	652	€13,752.72	170	€3,591.00
	Parallel import	2	€42.12	1	€21.06
Formoterol 12 mcg 60 dose	Proprietary	4,163	€108,060.57	647	€16,537.38
	Parallel import	126	€3,169.42	6	€152.92
Salmeterol 25 mcg 120 dose	Proprietary	11,824	€347,379.10	1,536	€45,140.69
	Generic	17	€448.29	1	€26.37
	Parallel import	372	€10,688.45	77	€2,214.46
Salmeterol 50 mcg 60 dose	Proprietary	2,454	€71,310.54	438	€12,733.38
TOTALS		**19,610**	**€554,851.21**	**2,876**	**€80,417.00**

Table 6.9 Total quantities and costs of inhaled and nebulised ipratropium bromide (anti-cholinergic)

Drug name + dose	Product type	Total items (All patients)	Total cost (All patients)	Total items (< 45 yrs.)	Total cost (< 45 yrs.)
Ipratropium bromide 20 mcg 200 dose	Proprietary	53,312	€142,442.10	10,360	€27,685.29
Ipratropium bromide 250 mcg/ml 20 dose	Proprietary	14,459	€26,895.27	2,368	€4,405.46
	Generic	6,943	€12,981.89	859	€1,597.87
Ipratropium bromide 250 mcg/ml 60 dose	Proprietary	12,643	€72,842.43	1,204	€7,031.29
	Generic	19	€111.26	0	0
Ipratropium bromide 500 mcg/2 ml 20 dose	Proprietary	14,355	€26,424.05	513	€944.74
	Generic	6.018	€11,291.61	218	€401.76
Ipratropium bromide 500 mcg/2 ml 60 dose	Proprietary	19,442	€131,888.69	920	€6235.25
	Generic	22	€152.32	0	0
TOTALS		**127,203**	**€425,029.62**	**16,442**	**€48.301.66**

The total cost of the products outlined in Tables 6.4 - 6.9, dispensed in the identified 12 month period, was €75,267,636 for *all patients* and €16,367,643 for *patients < 45 years.* A total of 3,436,020 items were dispensed for *all patients* in this period and 1,094,429 items were dispensed for patients *< 45 years.*

6.3.4.2. Total quantities and costs according to age range and device type

The total quantities and costs of all inhaled asthma treatments were analysed according to age range (< 45 years) and device type and the results are outlined in the tables below. The age range for some patients was not identified in the PCRS database and these patients were excluded from this analysis.

Table 6.10 Total quantities and costs of inhaled corticosteroids according to age and device

Drug name + dose	Age range (years)	Device type	Total items	Total cost
Beclometasone 50 mcg 200 dose	0 - 4	pMDI	24,599	€142,869
		Easi-breathe	737	€4,112
	5 -11	pMDI	25,840	€149,994
		Easi-breathe	2,330	€13,002
	12 - 15	pMDI	3,651	€21,055
		Easi-breathe	855	€4,771
	16 - 24	pMDI	2,197	€12,639
		Easi-breathe	599	€3,342
	25 -34	pMDI	1,403	€8,028
		Easi-breathe	252	€1,406
	35 -44	pMDI	1,530	€8,881
		Easi-breathe	246	€1,373

Drug name + dose	Age range (years)	Device type	Total items	Total cost
Beclometasone 100 mcg 200 dose	0 - 4	pMDI	8,564	€97,002
		Easi-breathe	294	€3,193
	5 -11	pMDI	27,335	€308,808
		Clickhaler	19	€274
		Easi-breathe	3,084	€33,492
	12 - 15	pMDI	10,829	€122,094
		Clickhaler	9	€129
		Easi-breathe	2,909	€31,592
	16 - 24	pMDI	11,565	€129,350
		Clickhaler	24	€351
		Easi-breathe	3,739	€40,606
	25 -34	pMDI	8,819	€98,921
		Clickhaler	7	€105
		Easi-breathe	2,286	€24,826
	35 - 44	pMDI	10,429	€117,168
		Clickhaler	14	€204
		Easi-breathe	2,454	€26,650
Beclometasone 200 mcg 200 dose	0 - 4	pMDI	113	€2,383
		Easi-breathe	11	€232
	5 -11	pMDI	566	€11,937
		Easi-breathe	179	€3,775
	12 - 15	pMDI	402	€8,478
		Easi-breathe	344	€7,255
	16 - 24	pMDI	921	€19,424
		Easi-breathe	1,002	€21,132
	25 -34	pMDI	878	€18,517
		Easi-breathe	778	€16,408
	35 -44	pMDI	1,116	€23,536
		Easi-breathe	1,137	€23,979
Beclometasone 250 mcg 100 dose	0 - 4	Clickhaler	0	€0
	5 -11		2	€33
	12 - 15		7	€127
	16 - 24		2	€35
	25 -34		1	€17
	35 -44		33	€602

Drug name + dose	Age range (years)	Device type	Total items	Total cost
Beclometasone 250 mcg 200 dose	0 - 4	pMDI	85	€2,024
		Easi-breathe	8	€186
	5 -11	pMDI	734	€17,992
		Easi-breathe	120	€2,789
	12 - 15	pMDI	1,436	€35,186
		Easi-breathe	403	€9,366
	16 - 24	pMDI	5,309	€128,952
		Easi-breathe	1,608	€37,370
	25 -34	pMDI	7,380	€178,160
		Easi-breathe	1,940	€45,086
	35 - 44	pMDI	10,230	€247,289
		Easi-breathe	3,073	€71,419
Beclometasone HFA 50 mcg 200 dose	0 - 4	pMDI	7	€76
		Autohaler	1	€11
	5 -11	pMDI	54	€586
		Autohaler	13	€141
	12 - 15	pMDI	19	€206
		Autohaler	4	€43
	16 - 24	pMDI	28	€304
		Autohaler	33	€358
	25 -34	pMDI	29	€315
		Autohaler	3	€33
	35 - 44	pMDI	19	€206
		Autohaler	20	€217
Beclometasone HFA 100 mcg 200 dose	0 - 4	pMDI	0	€0
		Autohaler	0	€0
	5 -11	pMDI	2	€46
		Autohaler	13	€302
	12 - 15	pMDI	24	€558
		Autohaler	19	€442
	16 - 24	pMDI	90	€2,092
		Autohaler	107	€2,487
	25 -34	pMDI	119	€2,766
		Autohaler	41	€953
	35 - 44	pMDI	58	€1,348
		Autohaler	101	€2,347
Budesonide 100 mcg 120 dose	0 - 4	pMDI	43	€423
	5 -11		91	€895
	12 - 15		34	€335
	16 - 24		32	€315
	25 -34		8	€79
	35 - 44		8	€79

Drug name + dose	Age range (years)	Device type	Total items	Total cost
Budesonide 100 mcg 200 dose	0 - 4	Turbohaler	71	€1,465
	5 -11		830	€16,828
	12 - 15		414	€8,444
	16 - 24		483	€9,899
	25 -34		303	€6,160
	35 - 44		256	€5,268
Budesonide 200 mcg 100 dose	0 - 4	Turbohaler	14	€240
		Novolizer	1	€20
	5 -11	Turbohaler	310	€6,018
		Novolizer	21	€387
	12 - 15	Turbohaler	461	€8,931
		Novolizer	1	€20
	16 - 24	Turbohaler	1,399	€27,111
		Novolizer	10	€193
	25 -34	Turbohaler	1,249	€24,129
		Novolizer	13	€260
	35 - 44	Turbohaler	1,314	€25,354
		Novolizer	30	€600
Budesonide 200 mcg 120 dose	0 - 4	pMDI	2	€35
	5 -11		11	€190
	12 - 15		13	€224
	16 - 24		18	€311
	25 -34		21	€363
	35 - 44		22	€380
Budesonide 400 mcg 50 dose	0 - 4	Turbohaler	3	€59
	5 -11	Turbohaler	12	€215
	12 - 15	Turbohaler	54	€1,028
	16 - 24	Turbohaler	252	€4,786
	25 -34	Turbohaler	346	€6,528
		Novolizer	3	€60
	35 - 44	Turbohaler	588	€11,386
		Novolizer	2	€40
Ciclesonide 80 mcg 60 dose	0 - 4	pMDI	2	€39
	5 -11		1	€19
	12 - 15		7	€132
	16 - 24		56	€1,061
	25 -34		21	€399
	35 - 44		22	€412
Ciclesonide 160 mcg 60 dose	0 - 4	pMDI	0	€0
	5 -11		11	€252
	12 - 15		10	€229
	16 - 24		116	€2,656
	25 -34		206	€4,717
	35 - 44		429	€9,824

Drug name + dose	Age range (years)	Device type	Total items	Total cost
Fluticasone 50 mcg 60 dose (Diskus) or 120 dose (pMDI)	0 - 4	Diskus	45	€275
		pMDI	4,885	€43,232
	5 -11	Diskus	353	€2,153
		pMDI	7,026	€62,378
	12 - 15	Diskus	148	€903
		pMDI	1,035	€9,179
	16 - 24	Diskus	43	€262
		pMDI	419	€3,744
	25 -34	Diskus	35	€214
		pMDI	171	€1,513
	35 - 44	Diskus	62	€378
		pMDI	215	€1,921
Fluticasone 100 mcg 60 dose	0 - 4	Diskus	21	€206
	5 -11		554	€5,439
	12 - 15		555	€5,449
	16 - 24		481	€4,726
	25 -34		97	€953
	35 - 44		141	€1,385
Fluticasone 125 mcg 60 dose (pMDI60) or 120 dose (pMDI120)	0 - 4	pMDI 60	121	€1,277
		pMDI 120	1,655	€34,871
	5 -11	pMDI 60	377	€3,977
		pMDI 120	6,533	€137,690
	12 - 15	pMDI 60	112	€1,182
		pMDI 120	2,408	€50,761
	16 - 24	pMDI 60	72	€760
		pMDI 120	1,564	€32,960
	25 -34	pMDI 60	30	€317
		pMDI 120	475	€10,003
	35 - 44	pMDI 60	33	€348
		pMDI 120	592	€12,484
Fluticasone 250 mcg 60 dose	0 - 4	Diskus	1	€20
		pMDI	3	€54
	5 -11	Diskus	48	€966
		pMDI	21	€378
	12 - 15	Diskus	143	€2,881
		pMDI	16	€288
	16 - 24	Diskus	348	€7,012
		pMDI	117	€2,105
	25 -34	Diskus	214	€4,311
		pMDI	71	€1,278
	35 - 44	Diskus	481	€9,688
		pMDI	58	€1,043

Drug name + dose	Age range (years)	Device type	Total items	Total cost
Fluticasone 250 mcg 120 dose	0 - 4	pMDI	59	€2,178
	5 -11		349	€12,885
	12 - 15		491	€18,092
	16 - 24		1,131	€41,735
	25 -34		983	€36,323
	35 - 44		1,124	€41,485
Fluticasone 500 mcg 60 dose	0 - 4	Diskus	2	€69
	5 -11		8	€276
	12 - 15		11	€384
	16 - 24		84	€2,914
	25 -34		172	€5,976
	35 - 44		384	€13,344
Mometasone 200 mcg 30 dose	0 - 4	Twisthaler	0	€0
	5 -11		8	€177
	12 - 15		15	€348
	16 - 24		8	€182
	25 -34		25	€552
	35 - 44		29	€643
Mometasone 200 mcg 60 dose	0 - 4	Twisthaler	0	€0
	5 -11		5	€175
	12 - 15		2	€68
	16 - 24		37	€1,276
	25 -34		33	€1,140
	35 - 44		56	€1,923
Mometasone 400 mcg 30 dose	0 - 4	Twisthaler	0	€0
	5 -11		0	€0
	12 - 15		0	€0
	16 - 24		2	€56
	25 -34		22	€695
	35 - 44		33	€1,004
Mometasone 400 mcg 60 dose	0 - 4	Twisthaler	0	€0
	5 -11		0	€0
	12 - 15		8	€411
	16 - 24		16	€847
	25 -34		50	€2,570
	35 - 44		23	€1,192

Table 6.11 Total quantities and costs of combined inhaled corticosteroids and long-acting β_2-agonists according to age and device

Drug name + dose	Age range (years)	Device type	Total items	Total cost
Budesonide + Formoterol 100/6 mcg 120 dose	0 - 4	Turbohaler	75	€3,483
	5 -11		2,449	€113,570
	12 - 15		2,181	€101,901
	16 - 24		1,595	€74,197
	25 -34		1,105	€51,349
	35 - 44		1,275	€59,245
Budesonide + Formoterol 200/6 mcg 120 dose	0 - 4	Turbohaler	46	€2,305
	5 -11		1,089	€54,529
	12 - 15		3,962	€198,476
	16 - 24		13,806	€691,454
	25 -34		13,724	€687,254
	35 - 44		20,756	€1,039,436
Budesonide + Formoterol 400/12 mcg 60 dose	0 - 4	Turbohaler	26	€1,287
	5 -11		128	€6,352
	12 - 15		362	€17,982
	16 - 24		3,464	€172,181
	25 -34		5,974	€296,856
	35 - 44		11,049	€548,991
Fluticasone + Formoterol 50/5 mcg 120 dose	0 - 4	pMDI	0	€0
	5 -11		2	€54
	12 - 15		0	€0
	16 - 24		1	€27
	25 -34		1	€27
	35 - 44		0	€0
Fluticasone + Formoterol 125/5 mcg 120 dose	0 - 4	pMDI	0	€0
	5 -11		0	€0
	12 - 15		1	€40
	16 - 24		2	€80
	25 -34		1	€40
	35 - 44		4	€160
Fluticasone + Formoterol 250/10 mcg 120 dose	0 - 4	pMDI	0	€0
	5 -11		0	40
	12 - 15		1	€55
	16 - 24		1	€55
	25 -34		5	€275
	35 - 44		6	€330
Fluticasone + Salmeterol 50/25 mcg 120 dose	0 - 4	pMDI	1,194	€34,769
	5 -11		5,316	€154,802
	12 - 15		1,151	€33,518
	16 - 24		589	€17,152
	25 -34		334	€9,726
	35 - 44		480	€13,978

Drug name + dose	Age range (years)	Device type	Total items	Total cost
Fluticasone + Salmeterol 100/50 mcg 60 dose	0 - 4	Diskus	57	€1,897
	5 -11		2,116	€70,490
	12 - 15		2,588	€86,422
	16 - 24		3,022	€100,840
	25 -34		1,276	€42,500
	35 - 44		1,608	€53,470
Fluticasone + Salmeterol 125/25 mcg 120 dose	0 - 4	pMDI	540	€24,322
	5 -11		4,764	€215,525
	12 - 15		2,921	€132,544
	16 - 24		2,371	€107,294
	25 -34		1,725	€78,200
	35 - 44		2,035	€92,305
Fluticasone + Salmeterol *250/25* mcg 120 dose (pMDI) or *250/50* mcg 60 dose (Diskus)	0 - 4	Diskus	43	€1,918
		pMDI	54	€3,356
	5 -11	Diskus	582	€25,742
		pMDI	830	€51,609
	12 - 15	Diskus	2,547	€112,802
		pMDI	1,529	€95,076
	16 - 24	Diskus	8,267	€365,744
		pMDI	5,825	€362,252
	25 -34	Diskus	9,153	€405,179
		pMDI	9,116	€567,080
	35 - 44	Diskus	13,571	€599,975
		pMDI	14,272	€887,392
Fluticasone + Salmeterol 500/50 mcg 60 dose	0 - 4	Diskus	29	€1,719
	5 -11		187	€10,985
	12 - 15		436	€25,948
	16 - 24		3,207	€189,696
	25 -34		7,541	€445,752
	35 - 44		14,571	€861,683

Table 6.12 Total quantities and costs of inhaled short-acting β_2-agonists according to age and device

Drug name + dose	Age range (years)	Device type	Total items	Total cost
Salbutamol 100 mcg 200 dose	0 - 4	pMDI	56,419	€176,773
		Clickhaler	0	€0
		Easi-breathe	431	€3,426
		Novolizer	2	€18
	5 -11	pMDI	99,473	€311,698
		Clickhaler	33	€263
		Easi-breathe	6,264	€49,794
		Novolizer	32	€285
	12 - 15	pMDI	43,133	€135,100
		Clickhaler	37	€297
		Easi-breathe	7,482	€59,477
		Novolizer	30	€250
	16 - 24	pMDI	76,819	€240,559
		Clickhaler	91	€731
		Easi-breathe	13,583	€107,976
		Novolizer	26	€219
	25 -34	pMDI	88,037	€276,175
		Clickhaler	32	€257
		Easi-breathe	9,458	€75,185
		Novolizer	38	€338
	35 - 44	pMDI	119,314	€374,613
		Clickhaler	34	€276
		Easi-breathe	12,371	€101,203
		Novolizer	62	€552
Salbutamol 200 mcg 60 dose	0 - 4	Diskus	13	€63
	5 -11		904	€4,846
	12 - 15		1,952	€10,620
	16 - 24		2,458	€13,300
	25 -34		1,426	€7,775
	35 - 44		2,178	€11,771
Terbutaline 500 mcg 100 dose	0 - 4	Turbohaler	47	€445
	5 -11		1,141	€10,611
	12 - 15		1,873	€17,580
	16 - 24		3,923	€37,167
	25 -34		3,217	€30,102
	35 - 44		3,649	€33,867
Terbutaline 500 mcg 200 dose	0 - 4	Turbohaler	0	€0
	5 -11		1	€22
	12 - 15		7	€105
	16 - 24		30	€565
	25 -34		58	€1,086
	35 - 44		22	€428

Table 6.13 Total quantities and costs of inhaled long-acting β_2-agonists according to age and device

Drug name + dose	Age range (years)	Device type	Total items	Total cost
Formoterol 6mcg 60 dose	0 - 4	Turbohaler	0	€0
	5 -11		25	€532
	12 - 15		14	€299
	16 - 24		39	€820
	25 -34		43	€903
	35 - 44		49	€1,036
Formoterol 12 mcg 60 dose	0 - 4	Turbohaler	0	€0
		Aerolizer	0	€0
	5 -11	Turbohaler	3	€82
		Aerolizer	16	€397
	12 - 15	Turbohaler	25	€660
		Aerolizer	11	€273
	16 - 24	Turbohaler	52	€1,368
		Aerolizer	20	€494
	25 -34	Turbohaler	79	€2,088
		Aerolizer	89	€2,211
	35 - 44	Turbohaler	132	€3,502
		Aerolizer	223	€5,540
Salmeterol 25 mcg 120 dose	0 - 4	pMDI	27	€801
	5 -11		122	€3,577
	12 - 15		69	€2,040
	16 - 24		173	€5,066
	25 -34		432	€12,681
	35 - 44		782	€22,952
Salmeterol 50 mcg 60 dose	0 - 4	Diskus	0	€0
	5 -11		7	€202
	12 - 15		13	€379
	16 - 24		78	€2,270
	25 -34		158	€4,594
	35 - 44		177	€51,443

Table 6.14 Total quantities and costs of inhaled ipratropium bromide according to age and device

Drug name + dose	Age range (years)	Device type	Total items	Total cost
Ipratropium bromide 20 mcg 200 dose	0 - 4	pMDI	4,688	€12,523
	5 -11		884	€2,363
	12 - 15		215	€574
	16 - 24		474	€1,268
	25 -34		1,262	€3,450
	35 - 44		2,626	€7,015

6.3.4.3. Total costs according to community drug scheme

The total cost price of these items dispensed under the GMS, DP and LTI schemes was investigated for all patients and for those < 45 years. Once again, patients whose age range was not identified in the PCRS database were excluded from the second part of the analysis (patients < 45 years).

Table 6.15 Total quantities and costs of inhaled and nebulised asthma treatments dispensed according to community drug scheme

Therapeutic class	Patient group	GMS	DPS	LTI
		Total Cost	Total Cost	Total Cost
SABA	All patients	€5,035,759	€848,759	€38,275
	< 45 years	€1,801,012	€306,121	€12,876
LABA	All patients	€426,134	€124,922	€4146
	< 45 years	€62,161	€15,681	€253
ICS	All patients	€10,667,570	€1,679,570	€66668
	< 45 years	€3,059,947	€592,359	€23,167
ICS + LABA*	All patients	€44,445,525	€11,011,637	€513221
	< 45 years	€742,0820	€2,586,448	€109260
Totals	**All patients**	**€60,574,988**	**€13,664,888**	**€622,310**
	<45 years	**€12,343,940**	**€3,500,609**	**€145,556**

*SABA = short-acting β_2-agonist, LABA = long-acting β_2-agonist, ICS = inhaled corticosteroid, * = combination product.*

6.3.4.4. Total costs according to month claimed

The total cost of inhaled and nebulised asthma treatments claimed from the PCRS in each of the12 months was investigated for all patients and for those < 45 years. Once again, patients whose age range was not identified in the PCRS database were excluded from the second part of the analysis (patients < 45 years). In order to determine the presence of any trends in dispensing over the 12 month period the number of items dispensed in each of the ICS, ICS with LABA and SABA categories was plotted against the month dispensed for all patients and for those < 45 years. The results are displayed below.

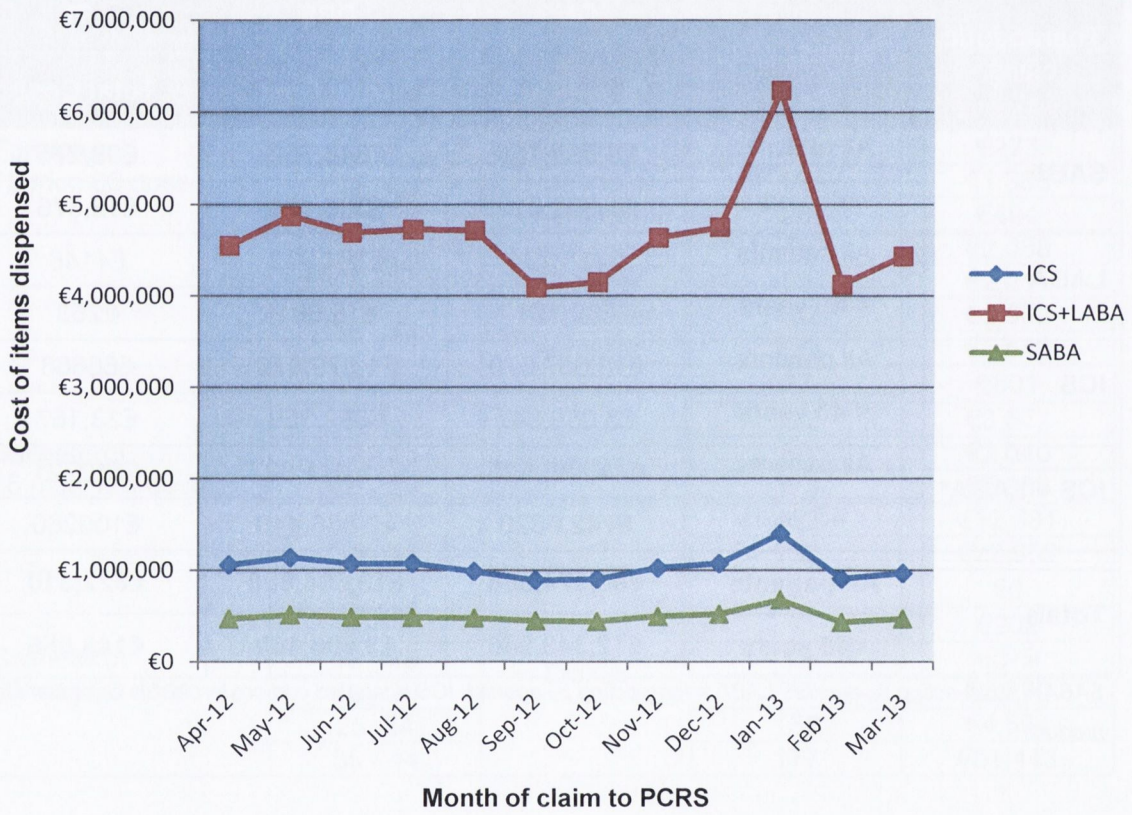


Figure 6.2: The total cost of the items dispensed in each therapeutic category for all patients classified according to the month that payment was claimed for the items from the PCRS.

The cost of the items claimed from the PCRS peaked in January and was at the lowest level in both February and September for all three therapeutic groups.

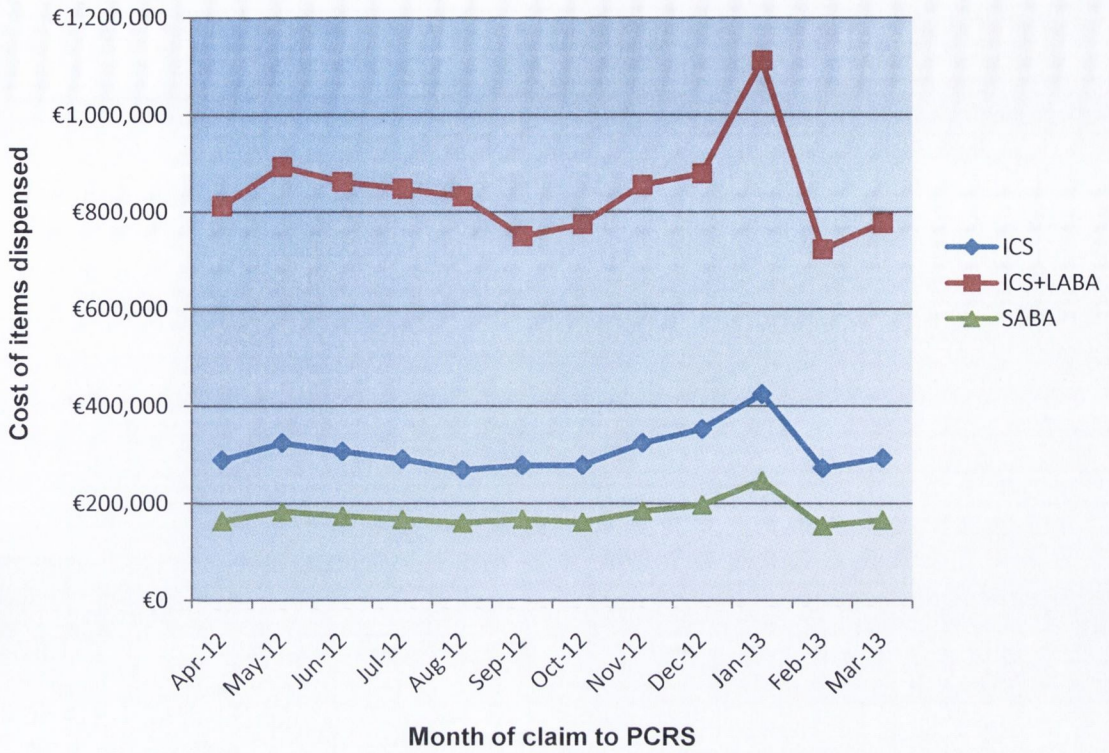


Figure 6.3: The total cost of the items dispensed in each therapeutic category for patients < 45 years, classified according to the month that payment was claimed for the items from the PCRS.

The cost of the items claimed from the PCRS peaked in January for all three therapeutic groups. Smaller rises in cost were also observed in May, November and December.

6.3.5. Proportions of preparations, therapeutic class and device type dispensed in 12 month period

A detailed analysis of the extracted data was conducted to determine the proportions of each type of preparation dispensed, the proportions of each therapeutic class dispensed and the proportions of each inhaler device type dispensed in the identified 12 month period. The results are outlined in the ensuing subsections.

6.3.5.1. Proportion of each type of preparation dispensed in 12 month period

Table 6.16 Proportion of each preparation type dispensed in 12 month period

Drug	Strength + Dose	% Generics	% Proprietary	% Parallel imports	% Total (N) All ages	% Total (N) < 45 yrs.
Beclometasone	50 mcg 200 dose	1.08%	1.0%	0.07%	2.15% (73,776)	5.91% (64,656)
	100 mcg 200 dose	2.70%	1.71%	0.04%	4.46% (153,085)	8.49% (92,925)
	200mcg 200 dose	0.59%	0%	0%	0.59% (20,116)	0.69% (7,503)
	250 mcg 100 dose	0%	0.004%	0%	0.004% (152)	2.98% (32,651)
	250 mcg 200 dose	2.18%	1.21%	0.08%	3.46% (118,913)	0.004% (46)
Beclometasone (HFA)	50 mcg 200 dose	0%	0.02%	0%	0.02% (712)	0.02% (233)
	100 mcg 200 dose	0%	0.09%	0%	0.09% (3,159)	0.05% (575)
Budesonide	100 mcg 200 dose	0%	0.13%	0.02%	0.15% (5,048)	0.22% (2,379)
	100 mcg 120 dose	0%	0%	0%	0.01% (367)	0.02% (216)
	200 mcg 100 dose	0%	0.51%	0.07%	0.58% (19,960)	0.44% (4,850)
	200 mcg 120 dose	0%	0.007%	0%	0.007% (234)	0.008% (87)
	400 mcg 50 dose	0%	0.29%	0.02%	0.31% (10,334)	0.12% (1,278)
Budesonide respules	0.5 mg/2 ml 20 dose	0.22%	1.81%	0%	2.03% (69,687)	0.91% (9,996)
	1 mg/2 ml 20 dose	0.02%	1.84%	0%	1.86% (63,842)	0.50% (5,499)

Drug	Strength + Dose	% Generics	% Proprietary	% Parallel imports	% Total (N) All ages	% Total (N) < 45 yrs.
Budesonide + formoterol	100/6 mcg 120 dose	0%	0.52%	0.02%	0.54% (18,661)	0.8% (8,729)
	200/6 mcg 120 dose	0%	5.74%	0.1%	5.75% (200,535)	4.92% (53,830)
	400/12 mcg 60 dose	0%	4.62%	0.05%	4.67% (160,393)	1.94% (21,206)
Ciclesonide	80 mcg 60 dose	0%	0.01%	0%	0.01% (464)	0.01% (109)
	160 mcg 60 dose	0%	0.1%	0%	0.1% (3,396)	0.07% (775)
Fluticasone	50 mcg 60 dose	0%	0.02%	0%	0.02% (804)	0.06% (689)
	50 mcg 120 dose	0%	0.42%	0%	0.42% (14,591)	1.26% (13,836)
	100 mcg 60 dose	0%	0.8%	0%	0.8% (2,769)	0.17% (1,865)
	125 mcg 60 dose	0%	0.03%	0%	0.03% (919)	0.07% (747)
	125 mcg 120 dose	0%	0.46%	0.02%	0.48% (16,571)	1.21% (13,276)
	250 mcg 60 dose	0%	0.16%	0%	0.16% (5,570)	0.14% (1,525)
	250 mcg 120 dose	0%	0.51%	0.01%	0.52% (17,867)	0.38% (4,159)
	500 mcg 60 dose	0%	0.12%	0%	0.12% (4,115)	0.06% (661)
Fluticasone respules	0.5 mg/2 ml 10 dose	0%	0.68%	0.04%	0.72% (24,725)	0.28% (3,081)
	2 mg/2 ml 10 dose	0%	0.64%	0.03%	0.67% (22,824)	0.24% (2,624)
Fluticasone + formoterol	50/5 mcg 120 dose	0%	0.0002%	0%	0.0002% (7)	0.0004% (4)
	125/5 mcg 120 dose	0%	0.001%	0%	0.001% (28)	0.0007% (8)
	250/10 mcg 120 dose	0%	0.001%	0%	0.001% (38)	0.001% (13)

Drug	Strength + Dose	% Generics	% Proprietary	% Parallel imports	% Total (N) All ages	% Total (N) < 45 yrs.
Fluticasone + salmeterol	50/25 mcg 120 dose	0%	0.36%	0%	0.36% (12,391)	0.83% (9,099)
	125/25 mcg 120 dose	0%	0.9%	0%	0.9% (30,822)	1.32% (14,426)
	250/25 mcg 120 dose	0%	5.87%	0.12%	5.99% (205,814)	2.93% (32,025)
	100/50 mcg 60 dose	0%	0.74%	0.004%	0.74% (25,700)	0.98% (10,737)
	250/50 mcg 60 dose	0%	4.76%	0.65%	5.41% (185,986)	3.15% (34,455)
	500/50 mcg 60 dose	0%	5.67%	0.95%	6.62% (226,969)	2.40% (26,234)
Formoterol	6 mcg 60 dose	0%	0.02%	0% (2)	0.02% (654)	0.02% (171)
	12 mcg 60 dose	0%	0.12%	0.004%	0.12% (4,289)	0.06% (653)
Ipratropium bromide	20 mcg 200 dose	0%	1.55%	0%	1.55% (53,312)	0.95% (10,360)
Ipratropium bromide respules	250 mcg/ml 20 dose	0.2%	0.42%	0%	0.62% (21,402)	0.29% (3,228)
	250 mcg/ml 60 dose	0.001%	0.37%	0%	0.37% (12,662)	0.11% (1,204)
	500 mcg/2 ml 20 dose	0%	0.42%	0.18%	0.6% (20,373)	0.07% (732)
	500 mcg/2 ml 60 dose	0%	0.57%	0.001%	0.57% (19,454)	0.08% (920)
Mometasone	200 mcg 30 dose	0%	0.008%	0%	0.008% (284)	0.008% (85)
	200 mcg 60 dose	0%	0.008%	0%	0.01% (333)	0.01% (133)
	400 mcg 30 dose	0%	0.006%	0%	0.006% (223)	0.005% (57)
	400 mcg 60 dose	0%	0.007%	0%	0.007% (236)	0.009% (97)
Nedocromil	2mg 112 dose	0%	0.002%	0%	0.002% (68)	(2)
Salbutamol	**100 mcg 200 dose**	**12.61%**	**22.44%**	**3.12%**	**38.18% (1,311,883)**	**49.06% (536,895)**
	200 mcg 60 dose	0%	0.83%	0%	0.83% (28,560)	0.82% (8,973)

Drug	Strength + Dose	% Generics	% Proprietary	% Parallel imports	% Total (N) All ages	% Total (N) < 45 yrs.
Salbutamol respules	2.5 mg/2.5 ml 20 dose	1.77%	2.18%	0.11%	4.06% (139,801)	2.76% (30,251)
	5 mg/2.5 ml 20 dose	0.32%	0.84%	0%	1.16% (40,118)	0.67% (7,336)
Salmeterol	25 mcg 120 dose	0.0005%	0.34%	0.01%	0.35% (12,213)	0.15% (1,614)
	50 mcg 60 dose	0%	0.07%	0%	0.07% (2,454)	0.04% (438)
Sodium cromoglycate	20 mg 112 dose	0%	0.02%	0%	0.02% (610)	0.008% (89)
Terbutaline	500 mcg 100 dose	0%	1.04%	0.27%	1.31% (45,036)	1.27% (13,920)
	500 mcg 200 dose	0%	0%	0.01%	0.01% (401)	0.01% (118)
Terbutaline respules	2.5 mg/ml 2 ml 20 dose	0%	0.01%.	0%	0.01% (310)	0.01% (149)

6.3.5.2. Proportion of each class of inhaled/nebulised asthma treatment dispensed in 12 month period

The proportion of each class of inhaled or nebulised asthma treatment was determined for the overall data set and for those < 45 years. The results are outlined in the table below.

Table 6.17 Proportion of each asthma treatment dispensed in 12 month period

Inhaled asthma treatment	% Dispensed (All ages) N = 3,436,020	% Dispensed (< 45 years) N =1,094,429
Inhaled SABA (Salbutamol, terbutaline)	40.33%	51.16%
Nebulised SABA (Salbutamol, terbutaline)	5.23%	3.44%
Inhaled anti-cholinergics (Ipratropium bromide only)	1.55%	0.95%
Nebulised anti-cholinergics (Ipratropium bromide only)	2.16%	0.55%
Inhaled LABA (Formoterol, salmeterol)	0.56%	0.27%
Inhaled corticosteroid (Beclometasone, budesonide, ciclesonide, fluticasone, mometasone)	17.89%	22.41%
Nebulised corticosteroid (Budesonide, fluticasone)	5.28%	1.93%
Inhaled corticosteroid + LABA (Formoterol + budesonide/fluticasone, salmeterol + fluticasone)	30.98%	19.27%
Inhaled cromones (Nedocromil, sodium cromoglycate)	0.02%	0.008%

SABA = short-acting selective β_2-agonist, LABA = long-acting selective β_2-agonist

Percentages do not add up to 100% due to rounding

6.3.5.3. Inhaler device type distribution according to asthma treatment

Ten distinct inhaler device types were identified within the 171 products. The proportion of each device type dispensed in each ATC class was determined and the results are displayed in Table 6.18 below.

Table 6.18 Inhaler device type distribution

ATC07	Device type	% per device type
R03AC02 (Salbutamol)	pMDI	85.13%
	Clickhaler	0.06%
	Easi-breathe	13.39%
	Diskus	1.37%
	Novolizer	0.04%
R03AC03 (Terbutaline)	Turbohaler	100%
R03AC12 (Salmeterol)	pMDI	83.56%
	Diskus	16.44%
R03AC13 (Formoterol)	Turbohaler	66.71%
	Aerolizer	33.29%
R03BA01 (Beclometasone)	pMDI	81.76%
	Autohaler	0.36%
	Clickhaler	0.08%
	Easi-breathe	17.81%
R03BA02 (Budesonide)	pMDI	3.75%
	Turbohaler	95.36%
	Novolizer	0.88%
R03BA05 (Fluticasone)	pMDI	84.97%
	Diskus	15.03%
R03BA07 (Mometasone)	Twisthaler	100%
R03BA08 (Ciclesonide)	pMDI	100%
R03AK06 (Salmeterol + fluticasone)	pMDI	36.19%
	Diskus	63.81%
R03AK07 (Formoterol + budesonide/fluticasone)	pMDI	0.10%
	Turbohaler	99.90%
R03BB01 (Ipratropium bromide)	pMDI	100%
R03BC01 (Cromoglycate)	Spinhaler	100%
R03BC03 (Nedocromil)	pMDI	100%

6.3.5.4. Inhaler device type distribution according to age range

Table 6.19 Inhaler device distribution according to age

Age (yrs.)	% per device type								
	AZ	AH	CH	DS	EB	NZ	pMDI	TW	TH
0-4	0	1.2	0	11.9	7.1	2.4	63.1	0	14.3
5-11	0.8	1.62.	2.4	14.5	5.6	2.4	50.0	1.6	21.0
12-15	0.8	1.6	2.4	14.3	7.1	2.4	49.2	2.4	19.8
16-24	0.7	1.4	2.1	14.8	6.3	2.8	47.9	2.8	21.1
25-34	0.7	1.5	2.2	15.4	6.6	2.2	27.1	2.9	21.3
35-44	0.7	1.5	2.2	15.3	6.6	2.2	48.2	2.9	20.4
Overall < 45	**0.04**	**0.03**	**0.03**	**8.29**	**7.86**	**0.02**	**73.32**	**0.04**	**10.37**

AZ = Aerolizer, AH = Autohaler, CH = Clickhaler, DS = Diskus, EB = Easi-breathe, NZ = Novolizer, pMDI = pressurised metered-dose inhaler, TW = Twisthaler, TH = Turbohaler.

6.3.6. Median weekly dose per drug

As discussed in **Error! Reference source not found.**, the data are not normally distributed, so the median (IQR) was used when determining the weekly dose per drug. The results are outlined in Tables 6.20 - 6.24 below.

Table 6.20: Median weekly dose of inhaled corticosteroids (R03BA)

Drug	Strength	Median (IQR) weekly dose (all ages)	Median (IQR) weekly dose (< 45 years)	Min. RR (puffs/wk)	Adherent
Beclometasone	50 mcg	3.8 (7.7)	2.3 (4.6)	14	✗
	100 mcg	7.7 (11.5)	3.8 (7.7)	14	✗
	200 mcg	7.7 (15.4)	3.8 (7.7)	14	✗
	250 mcg 100 dose	7.7 (13.5)	3.8 (11.5)	14	✗
	250 mcg 200 dose	11.5 (19.3)	7.7 (11.5)	14	✗
Beclometasone (HFA)	50 mcg	11.5 (19.2)	7.7 (15.4)	14	✗
	100 mcg	15.4 (28.9)	7.7 (15.4)	14	✗
Budesonide	100 mcg 200 dose	7.7 (11.5)	3.8 (7.7)	14	✗
	100 mcg 120 dose	2.3 (2.3)	2.3 (2.3)	14	✗
	200 mcg 100 dose	5.8 (11.6)	3.8 (5.8)	7	✗
	200 mcg 120 dose	2.3 (4.6)	2.3 (2.3)	7	✗
	400 mcg	3.8 (9.6)	1.9 (3.8)	7	✗
Ciclesonide	80 mcg	3.5 (8.1)	2.3 (3.5)	7	✗
	160 mcg	4.6 (9.2)	2.3 (5.8)	7	✗
Fluticasone	50 mcg 60 dose	2.3 (3.5)	2.3 (2.3)	14	✗
	50 mcg 120 dose	4.6 (6.9)	4.6 (6.9)	14	✗
	100 mcg	2.3 (5.8)	2.3 (4.6)	14	✗
	125 mcg 60 dose	2.3 (2.3)	1.2 (2.3)	14	✗
	125 mcg 120 dose	4.6 (9.2)	4.6 (6.9)	14	✗
	250 mcg 60 dose	3.5 (8.1)	3.5 (4.6)	14	✗
	250 mcg 120 dose	9.2 (16.2)	4.6 (6.9)	14	✗
	500 mcg	5.8 (10.4)	3.5 (8.1)	14	✗
Mometasone	200 mcg 30 dose	1.2 (2.6)	1.2 (1.3)	7	✗
	200 mcg 60 dose	3.5 (6.9)	3.5 (6.9)	7	✗
	400 mcg 30 dose	1.2 (2.9)	0.9 (1.6)	7	✗
	400 mcg 60 dose	2.3 (6.4)	1.7 (4.6)	7	✗

Min. RR = Minimum recommended dosage regimen for asthma according to the summary of product characteristics for each product. Adherence refers to the median weekly dose for patients < 45 years.

Table 6.21 Median weekly dose of combined inhaled corticosteroids and long-acting β-agonists (R03AK)

Drug	Strength	Median (IQR) weekly dose (all ages)	Median (IQR) weekly dose (< 45 years)	Min. RR (puffs/wk)	Adherent
Budesonide + formoterol	100/6 mcg	4.6 (11.5)	4.6 (6.9)	14	✗
	200/6 mcg	6.9 (16.2)	4.6 (11.5)	14	✗
	400/12 mcg	8.1 (11.5)	3.5 (8.1)	14	✗
Fluticasone + formoterol	50/5 mcg	2.3 (2.3)	2.3 (2.3)	14	✗
	125/5 mcg	2.3 (0)	2.3 (0)	14	✗
	250/10 mcg	2.3 (0)	2.3 (0)	14	✗
Fluticasone + salmeterol	50/25 mcg	6.9 (11.5)	6.9 (9.2)	14	✗
	125/25 mcg	6.9 (13.9)	6.9 (11.5)	14	✗
	250/25 mcg	11.5 (20.8)	6.9 (13.3)	14	✗
	100/50 mcg	3.5 (8.1)	3.5 (5.8)	14	✗
	250/50 mcg	4.6 (9.2)	3.5 (5.8)	14	✗
	500/50 mcg	5.8 (9.2)	3.5 (6.9)	14	✗

Adherence refers to the median weekly dose for patients < 45 years

Table 6.22: Median weekly dose of long-acting selective β_2-agonists (R03AC)

Drug	Strength	Median (IQR) weekly dose (all ages)	Median (IQR) weekly dose (< 45 years)	Min. RR (puffs/wk)	Adherent
Formoterol	6 mcg 60 dose	3.5 (8.1)	2.3 (3.5)	7	✗
	12 mcg 60 dose (Oxis)	8.1 (11.5)	2.3 (4.6)	7	✗
	12 mcg 60 dose (Foradil)	4.6 (10.4)	2.3 (5.8)	14	✗
Salmeterol	25 mcg 120 dose	11.5 (18.5)	4.6 (9.2)	28	✗
	50 mcg 60 dose	4.6 (10.4)	3.5 (5.8)	14	✗

Adherence refers to the median weekly dose for patients < 45 years

Table 6.23 Median weekly dose of short-acting selective β_2-agonists (R03AC)

Drug	Strength	Median (IQR) weekly dose (all ages)	Median (IQR) weekly dose (< 45 years)	Max. RR (puffs/wk)	Adherent
Salbutamol	100 mcg	7.7 (15.4)	3.8 (7.7)	4	✓
	200 mcg	4.6 (10.4)	3.5 (5.8)	2	✗
Terbutaline	500 mcg 100 dose	5.8 (11.5)	4.6 (6.9)	2	✗
	500 mcg 200 dose	7.7 (14.4)	3.8 (7.7)	2	Possibly*

Max. RR: Maximum recommended dosage regimen indicative of well controlled asthma according to GINA guidelines[1].

**: One 200 dose Terbutaline inhaler is equivalent to 3.8 puffs per week for 52 weeks. This exceeds the maximum recommended usage indicative of well controlled asthma. However, as one cannot obtain <1 inhaler, it is possible that the median usage is indicative of adherence and well controlled asthma.*

Adherence refers to the median weekly dose for patients < 45 years

Table 6.24 Median weekly dose of anti-cholinergics (ipratropium bromide)

Drug	Strength	Median (IQR) weekly dose (all ages)	Median (IQR) weekly dose (< 45 years)	Max. RR (puffs/wk)	Adherent
Ipratropium bromide	20 mcg	7.7 (23.0)	3.8 (3.8)	4	✓

Adherence refers to the median weekly dose for patients < 45 years

6.3.6.1. Salbutamol usage among patients in the 12 month period

According to the GINA guidelines[1], one of the criteria used to define well controlled asthma is that the patient does not need reliever treatment more frequently than twice per week. For salbutamol 100 mcg, the most commonly dispensed reliever medication, patients may need 2 puffs to obtain relief from acute bronchospasm, excluding any severe exacerbations where considerably more medication is needed for relief. As a result, the maximum weekly dose of salbutamol 100 mcg should be 4 puffs for patients with well controlled asthma. However, salbutamol 100 mcg is a 200 dose preparation, which if used weekly would result in 3.85 puffs used per week, but obtaining 2 salbutamol canisters in the year would allow a patient to use a maximum of 7.7 puffs per week. Consequently, the proportion of patients who obtained both 1 and 2 salbutamol canisters during the 12 month period was investigated.

Table 6.25 Salbutamol usage among patients over 12 month period

Number of canisters dispensed in 12 months	All salbutamol users (N = 324513)	Salbutamol users < 45 years (N = 181075)
1 canister = < 4 puffs/week	43.5%	51.6%
2 canisters = < 8 puffs/week	14.9%	16.9%
> 2 canisters = > 8 puffs/week	41.6%	31.5%

Further analysis was conducted on patients < 45 years to investigate if patients' age range influenced their salbutamol usage. The results are displayed graphically below.

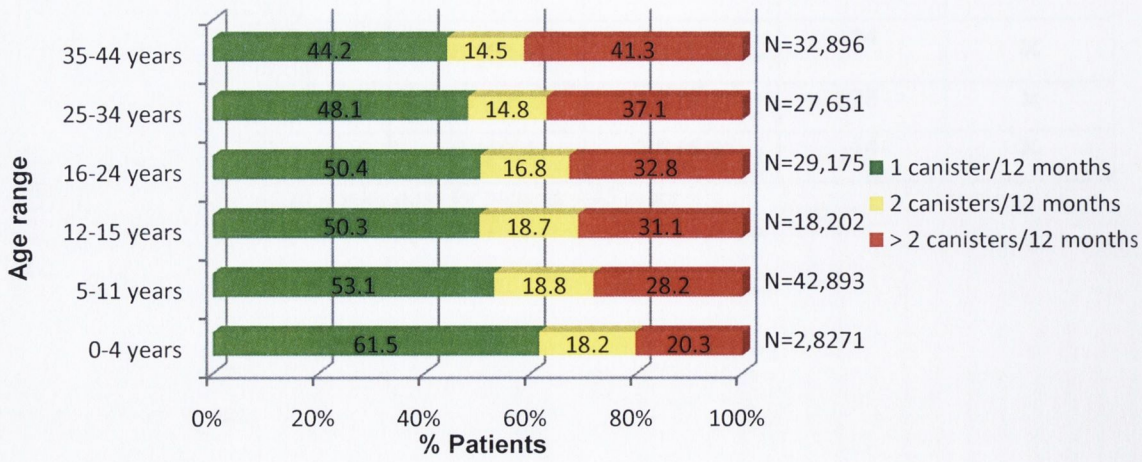


Figure 6.4: Number of salbutamol canisters dispensed to each patient < 45 years classified according to age range ($p < 0.001$, χ^2 test).

A significantly smaller proportion of the paediatric patients, particularly those < 12 years, were dispensed >2 canisters of salbutamol in the 12 month period compared to adult patients (> 15 years).

6.3.7. Concurrent users of inhaled corticosteroids and short-acting β-agonists

The proportion of concurrent monthly dispensings of ICS/ICS - LABA (preventative medication) in conjunction with a SABA was analysed for all patients and those < 45 years. In addition, the proportion of monthly dispensings for inhaled SABA products without a concurrent preventative product and the proportion of dispensings for preventative medication without a concurrent inhaled SABA were investigated. The results are outlined in Table 6.26 below. A more in-depth analysis was conducted on the dispensings of patients < 45 years and these are outlined in the following subsections.

Table 6.26 Proportion of concurrent dispensings

Dispensing	All patients	Patients < 45 years
SABA + steroid	42.1%	52.2%
SABA only*[1]	20.3%	29%
Steroid only*[2]	30.6%	17.2%
Neither steroid/SABA*[3]	7.0%	1.6%

*[1]: *SABA only refers to a dispensing where a SABA was dispensed but ICS/ICS with LABA product was not dispensed in the same month.*

*[2]: *Steroid only refers to a dispensing where an ICS/ICS with LABA product was dispensed but a SABA was not dispensed in the same month.*

*[3]: *Not steroid/SABA refers to a dispensing where an R03A/R03B product, which was not a SABA or an ICS/ICS-LABA, was dispensed e.g. an anticholinergic product.*

6.3.7.1. Level of concurrent dispensings according to community drug scheme

The proportion of concurrent dispensings, in patients under 45 years, across each of the healthcare schemes and any significant differences between them was determined. The results are outlined in the table below.

Table 6.27 Proportion of concurrent dispensings according to healthcare scheme

Dispensing	GMS (N =473128) % dispensings	DPS (N = 72217) % dispensings	LTI (N = 3192) % dispensings	Significance (χ^2 test).
SABA + steroid	51.2%	58.6%	58.2%	<0.001
SABA only*[1]	31.2%	15.0%	13.5%	<0.001
Steroid only*[2]	15.8%	25.6%	27.9%	<0.001
Not steroid/SABA*[3]	1.8%	0.8%	0.4%	NS

*[1]: *SABA only refers to a dispensing where a SABA was dispensed but an ICS/ICS with LABA product was not dispensed in the same month.*

*[2]: *Steroid only refers to a dispensing where an ICS/ICS with LABA product was dispensed but a SABA was not dispensed in the same month.*

*[3]: *Not steroid/SABA refers to a dispensing where an R03A/R03B product, which was not a SABA or an ICS/ICS-LABA, was dispensed e.g. an anticholinergic product.*

A significantly greater proportion of monthly DPS and LTI dispensings consisted of a preventative product with or without a bronchodilator product compared to monthly GMS dispensings. Unsurprisingly, a significantly greater proportion of monthly GMS dispensings consisted of a bronchodilator product without a concurrent preventative product compared to monthly DPS/LTI dispensings.

6.3.7.2. Level of concurrent dispensings according to age range

The proportion of concurrent dispensings, in patients under 45 years, across the age ranges and any significant differences between them was determined. The results are outlined in the graph below.

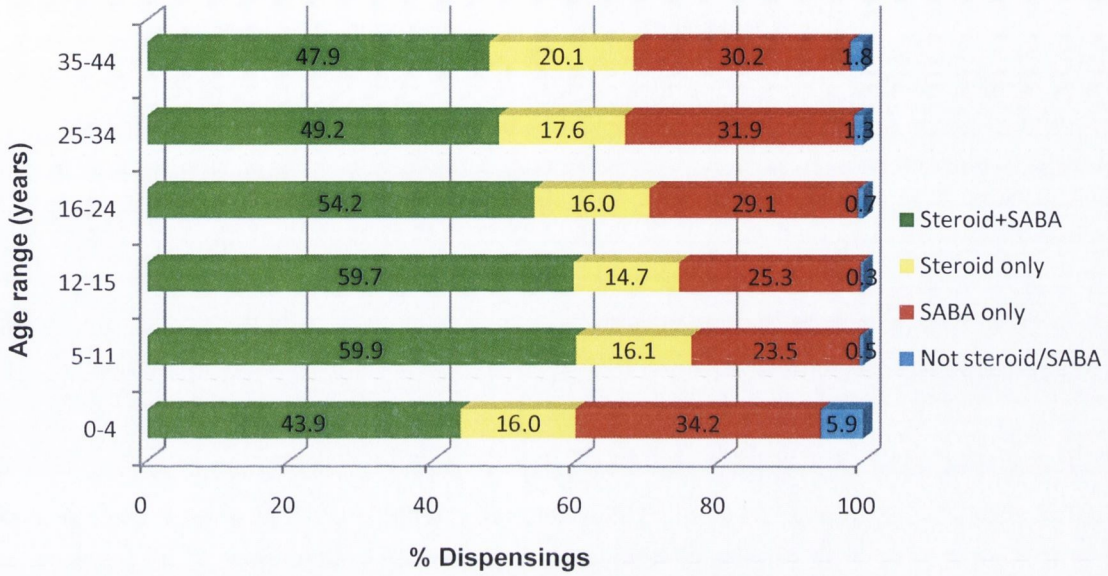


Figure 6.5: Proportion of dispensings of either a SABA only, a steroid only, or a SABA and a steroid, classified according to age range ($p< 0.001$, χ^2 test).

'SABA only' refers to a dispensing where a SABA was dispensed but an ICS/ICS with LABA product was not dispensed in the same month.

'Steroid only' refers to a dispensing where an ICS/ICS with LABA product was dispensed but a SABA was not dispensed in the same month

'Not steroid/SABA' refers to a dispensing where an R03A/R03B product, which was not a SABA or an ICS/ICS-LABA, was dispensed e.g. an anticholinergics product.

A significantly smaller proportion of the dispensings for patients aged 0-4 years, 25-34 years and 35-44 years were for concurrent SABA and preventative products compared to the dispensings for patients aged 5-24 years. Unsurprisingly a significantly smaller proportion of the dispensings for patients aged 5-15 years were for SABA products without a concurrent preventative product compared to those for patients aged 0-4 years and 25-44 years.

6.4. Discussion

6.4.1. Demographic data

According to the 'Statistical Yearbook of Ireland 2012' published by the CSO, the population of Ireland on Census night April 10th 2011 was 4,588,252 persons and 3,009,900 persons were < 45 years[637]. Consequently, 8.40% of the population of Ireland were dispensed an R03A or R03B medication under the GMS, DP or LTI schemes between April 1st 2012 and March 31st 2013. In addition, 6.1% of the population < 45 years were dispensed at least one R03A or R03B medication under one of these three community drug schemes over the same time period. As the medications included in the R03A and R03B ATC classes only include inhaled medications and the PCRS pharmacy claims database does not have any information on the prescription medicines dispensed to most patients who do not qualify for a medical card and whose medication does not exceed €144 per month, 6.1% is not representative of the percentage of people in Ireland with asthma. The precise prevalence of asthma in Ireland is unclear. The WHS reported a prevalence of 'doctor diagnosed asthma' of 9.4% among adults aged 18-45 years in Ireland[639]. However, according to the CSO Quarterly National Household Survey of Q3 2010, 7% of the adult population reported having asthma (self-report)[116]. Asthma prevalence among children is likely to be higher as phase 3 of the International Study of Asthma and Allergies in Children reported that 21.5% of children aged 13-14 years in Ireland had 'asthma ever'[641].

6.4.2. Total quantities and costs of inhaled and nebulised asthma treatments dispensed in the 12 month period.

6.4.2.1. Total quantities and costs of each product dispensed

a) Inhaled corticosteroids

The total cost of all R03A and R03B items, licensed for asthma was > €75,000,000 for all patients and > €16,000,000 for patients < 45 years. However, an analysis of the data reveals that cost savings can be made. For inhaled beclometasone products there are a number of areas where savings can be made. Firstly, the Clickhaler devices, delivering beclometasone 100 mcg and 250 mcg strengths are considerably more expensive than the proprietary pMDI equivalents (Asmabec Clickhaler 250 mcg, Focus Pharmaceuticals Ltd., cost per dose (CPD) €0.17/250 mcg; Becotide 250 mcg Glaxo Wellcome Ltd; CPD = €0.13/250 mcg). Furthermore, there are generic alternatives available for beclometasone products of all strengths that offer considerable savings compared to the proprietary

brands (Becotide 250 mcg Glaxo Wellcome Ltd, CPD = €0.13/250 mcg; Beclazone 250 mcg CFC-free, Iva Pharmaceuticals Ireland Ltd., CPD = €0.11/250 mcg). While a saving of €0.02/250 mcg might not seem like much, if the 41,407 proprietary beclometasone 250 mcg 200 dose preparations, dispensed in the identified 12 months, were replaced with the generic alternative, this would result in a total saving of almost €150,000. Replacing the 34,371 proprietary beclometasone 50 mcg 200 dose preparations and the 58,879 proprietary beclometasone 100 mcg 200 dose preparations dispensed with the generic alternatives would lead to savings of > €140,000. Consequently, the generic substitution of three proprietary products would lead to savings of ~€300,000 in 12 months. (The cost prices quoted here and in subsequent sections were obtained from the PCRS drug price file, July 2013). This information is particularly relevant in Ireland at the present time due to the recent enactment of the Health (Pricing and Supply of Medical Goods) Act 2013[642]. This Act provides for the introduction of a system of generic substitution by pharmacists and reference pricing of authorised medicines. Under this Act, pharmacists can dispense a lower cost version of a medicine, from a list of approved interchangeable medicines, even when a more expensive version has been prescribed. The reference price is a common reimbursement price that is established for a group of interchangeable medicines. If a patient requests a particular branded medicine that is more expensive than the reference priced products, he/she will have to pay the difference. This applies to all patients, irrespective of their community drug scheme. No respiratory medicines have been included in the list of interchangeable medicines to date.

To date, there are no generic alternative preparations available for inhaled budesonide, ciclesonide, fluticasone and mometasone preparations. There are parallel import preparations available for a number of the budesonide and fluticasone preparations but not for the ciclesonide and mometasone preparations. However, a guaranteed supply of parallel import preparations is not always possible from the wholesalers. The GINA guidelines provide estimated equipotent doses of inhaled corticosteroids[1]. When the CPD of beclometasone 500 mcg daily (low dose inhaled corticosteroid) is compared with the equivalent doses of budesonide, ciclesonide, fluticasone and mometasone is it evident that beclometasone is considerably cheaper per dose than the other alternatives. The CPD of 500 mcg beclometasone is €0.26/500 mcg (proprietary) or €0.22/500 mcg (generic). However, the CPD of the estimated equipotent doses of budesonide, ciclesonide, fluticasone and mometasone (all proprietary) are, €0.30/400 mcg budesonide, €0.35/250 mcg fluticasone, €0.38/160 mcg ciclesonide and €0.54/200 mcg mometasone (60 dose preparation). Inhaled corticosteroids vary in both potency and bioavailability, but there are few studies that have confirmed the relevance of these differences due to the relatively flat dose-response relationships in asthma[643]. Reviews comparing the clinical

effectiveness and short-term safety of the available inhaled corticosteroids at equipotent doses in both adults and children were unable to demonstrate consistent significant differences in clinical outcomes and adverse effects between the compared inhaled asthma drugs[644-647]. Consequently, due to the absence of any significant differences in clinical effectiveness or adverse effect profiles, beclometasone should be recommended as the first line low dose inhaled corticosteroid for the treatment of asthma leading to considerable savings. However, it is essential to ensure that the asthma patient is both willing and physically able to use a beclometasone pMDI inhaler, prior to its prescription and he/she must be educated using a combination of verbal instructions and a physical demonstration prior to its use.

AstraZeneca has discontinued production of Pulmicort 100 mcg and Pulmicort 200 mcg CFC-free preparations, therefore the availability of this preparation is limited. These pMDI preparations offered cheaper alternatives to the equivalent Turbohaler preparation (Pulmicort CFC-free 100 mcg CPD = €0.08/100 mcg, Pulmicort Turbohaler 200 mcg CPD = €0.09/100mcg).

b) Inhaled combined corticosteroids and long-acting β_2-agonists

The total cost of the combined ICS - LABA products for all patients and for those < 45 years represented the largest expense among the R03A and R03B medications, licensed for asthma. However, the number of these products dispensed was considerably less than the number of inhaled corticosteroid products dispensed. There are currently no generic alternatives available for these products, but there are a number of parallel import alternatives for the combinations budesonide with formoterol and fluticasone with salmeterol. The parallel import alternatives do offer considerable savings of €0.01 - 0.03/CPD compared to the proprietary preparations, but, once again, their availability is not always guaranteed from the wholesalers. However, in the absence of generic alternatives, the use of parallel import products, where available would lead to considerable savings. For example, if the 158,729 budesonide/formoterol 400/12 mcg proprietary products were replaced with the P.C.O. Manufacturing Ltd. alternatives a saving of > €230,000 could be generated.

Prescription of a low dose inhaled corticosteroid in conjunction with a LABA is step 3 in the GINA guidelines for asthma management, and a medium/high dose corticosteroid in conjunction with a LABA is step 4 in those guidelines. However, these guidelines recommend that a patient should only be commenced on step 3 of the guidelines if their symptoms are indicative of severely uncontrolled asthma. Prescription of a low dose inhaled corticosteroid is the initial treatment recommended for most treatment-naive

patients[1]. Friedman and colleagues[648] and Blanchette and colleagues[649] investigated whether the use/initiation of combination therapy was consistent with best-practice asthma guidelines in a large cohort of American patients. Both research groups concluded that a large proportion of study participants (> 60% in both studies) did not meet the criteria for the use/commencement of an inhaled corticosteroid in conjunction with a LABA. While this research was not conducted among Irish patients, it is possible that a proportion of patients in Ireland do not meet the requirements necessary for the initiation of combination therapy. As a result, it is imperative that all physicians caring for asthma patients are made aware of the GINA guidelines on asthma management[1] advising that the initial therapy for the majority of treatment naive patients is a low dose inhaled corticosteroid.

c) Inhaled asthma reliever treatments

Short-acting β_2-agonists (salbutamol and terbutaline) are the reliever medications of choice in asthma[1]. The choice of the delivery device has a considerable impact on the cost of an inhaled reliever preparation. The most expensive proprietary salbutamol pMDI costs €3.20 for 200 doses (Ventolin Evohaler 100 mcg. 200 dose aerosol, Glaxo Wellcome Ltd.), and the cheapest generic costs €2.49 (Gerivent 100 mcg 200 dose aerosol, Gerard Laboratories Ltd.). However, the other salbutamol delivery devices are considerably more expensive. For 200 doses of salbutamol 100 mcg, the Clickhaler device costs €7.57, the Easi-breathe devices cost €7.92-€7.95, the Novolizer costs €6.44 for cartridge refills only and €8.90 when the inhaler device is included, and the Diskus device costs €4.48 for 60 doses of salbutamol 200 mcg. Furthermore, terbutaline is only available as a Turbohaler device. The proprietary device costs €6.38 (Bricanyl Turbohaler 100 dose inhaler, AstraZeneca Pharmaceuticals Ireland Ltd.), there are no generic alternatives available and the cheapest parallel import costs €5.85 (Bricanyl (IPS Healthcare) Turbohaler 100 dose inhaler). Following a review of interventional studies on inhaler technique in Chapter 1, it was concluded that, in the absence of any physical or mental disabilities, the majority of adult patients can learn the correct pMDI technique if they are educated using a combination of verbal instructions and a physical demonstration, and the correct technique is continuously reinforced over time. Consequently, if a salbutamol pMDI was the delivery device of choice, and the generic preparation was the product of choice, considerable savings could be made. For example, if the 50,006 Clickhaler/Easi-breathe/Novolizer devices used by patients < 45 years were switched to a proprietary pMDI device €235,678 could be saved and if the switch was made to a generic device, an additional €35,504 could be saved. In addition, if the 11,050 proprietary terbutaline 100 dose Turbohaler devices used by patients < 45 years were replaced with pMDI devices a saving of €34,271 could be made in the case of a switch to proprietary devices and an additional saving of €7,849 could be made if

generic pMDIs were used in the replacement. (In all instances the least expensive devices were used in the calculations, *e.g.* the cost of the Novolizer refill cartridges was used not the cost of the cartridges and the inhaler.)

6.4.2.2. Total quantities and costs according to age range and device type

The key finding in this section is in relation to patients < 5 years. Firstly, the GINA guidelines on the management of asthma in children aged 5 years and younger[650] state that LABA preparations are not recommended for patients < 5 years. Consequently, combined ICS with LABA preparations should not be prescribed for these patients. However, despite this recommendation 2,064 ICS with LABA inhalers and 27 LABA inhalers were prescribed for patients < 5 years in the identified 12 month period. Furthermore, the GINA guidelines[1] advise that while ipratropium bromide can be used as an alternative bronchodilator in patients who experience adverse effects from short-acting β_2-agonists it is not recommended as a bronchodilator for children < 5 years due to a lack of evidence supporting its use[650,651]. However, despite this recommendation, 4,688 ipratropium bromide inhalers were dispensed to patients < 5 years in the identified 12 month period. This data provide evidence that a proportion of physicians caring for asthma patients < 5 years are not aware of the best-practice asthma guidelines for this group of patients, or choose not to adhere to these guidelines and urgently need to be informed and educated on them.

6.4.2.3. Total costs according to community drug scheme

In patients < 45 years, the total cost of SABA, LABA, ICS and ICS with LABA items dispensed under the GMS scheme was considerably greater than the total cost of these item dispensed under both the DP and LTI schemes. This result is unsurprising as 84% of the patients who were dispensed at least one R03A or R03B preparation had a full medical card, only 15% had a DPS card and 1% had an LTI card. Unfortunately, data on the R03A and R03B prescription items dispensed to patients who did not exceed the €144 DPS threshold are not available as it would be very interesting to investigate whether or not cost was exerting a negative influence on patients' adherence with their preventative medications. A number of studies have investigated the impact of copayments (fixed fee per prescription) and coinsurance (percentage of the total prescription charge) on medication utilisation. Campbell and colleagues[652] investigated the impact of increasing prescription copayments on asthma medication use in a cohort of 40,784 patients aged 12-64 years across the United States. They discovered that patients whose average monthly copayment increased by ≥ $5 per month of medication supplied, had greater than one month's preventative asthma medication supply less in the 12 month period

compared to those without such an increase in their monthly copayments. Dormuth and colleagues[653] investigated the impact of two sequential changes in the public drug insurance plan in British Columbia for people ≥ 65 years on inhaled medications. Before January 2002, people ≥ 65 years had full coverage for their prescription costs, excluding fees. This was replaced with the implementation of fixed copayments in January 2002, and by a 25% coinsurance plus income-based deductible policy in May 2003. They discovered that the implementation of these changes to the public drug insurance policy were associated with significant reductions in the utilisation of inhaled medications, mostly due to increased cessation rates and decreased initiation rates. Ungar and colleagues[654] investigated the influence of prescription cost-sharing on asthma medication use in children. Once again, they discovered that the mean annual number of asthma medications was significantly lower among children in the high-cost sharing group compared to those in the low- and zero-cost sharing groups. These studies provide evidence that copayments and coinsurance impact negatively on asthma medication usage among adults and children. Consequently, it is probable that a proportion of patients in Ireland, who have to pay the full cost of their asthma medications, may opt not to have their more expensive preventative medication(s) dispensed every month, but instead may chose to rely on the cheaper reliever medications. However, patients with suboptimal medication regimens, consisting of overuse of reliever medications and underuse of preventative medications have a significantly greater risk of ED visits, unscheduled GP visits and hospitalisations due to asthma than those with optimal medication regimens[655] and the use of these health care services is financially burdensome.

6.4.2.4. Total costs according to month dispensed

Figures 6.2 and 6.3 revealed a number of interesting trends in the number of items dispensed across the 12 month period. In all three therapeutic groups (ICS, ICS with LABA and SABA), for all patients and those < 45 years, January was the month in which the greatest expenditure occurred. However, as each community pharmacy submits its electronic claims at the end of each calendar month, it is likely that the data recorded for the month claimed are referring to the items dispensed the preceding month. Thus, the largest number of items was dispensed in December for each of the three drug classes. This is unsurprising as, anecdotally, December is the busiest month for dispensings in community pharmacy due to the seasonal closure of the vast majority of pharmacies on December 25th, 26th and January 1st. For asthma patients, < 45 years, the cost of the items claimed in November and December, corresponding to items dispensed in October and November were higher than the cost of the items dispensed in other months. October marks the beginning of the 'flu season', which can extend to April, so this is also

unsurprising. Upper respiratory viral infections are strongly associated with deterioration of asthma control and asthma exacerbations in both adults and children[587-591], indicating the need for an increase in preventative and reliever asthma medications[1]. Consequently, an increase in the number of items dispensed in October, November and December may be due to patients contracting respiratory viral infections. Another peak in dispensing costs for patients < 45 years was observed in the PCRS claims in May and June, corresponding to dispensings in April and May. It is likely that this increase in dispensings may have been due to comorbid seasonal allergic rhinitis as grass pollination occurs at the end of spring and the beginning of summer[656]. The presence of comorbid allergic rhinitis has been shown to be a significant predictor for higher annual asthma medication costs in adults and children[657,658]. In October 2012, the Irish Pharmaceutical Healthcare Association (IPHA) reached a three year agreement with the Department of Health and Children on the supply of medicines in Ireland, which came in to effect on November 1st 2012. This resulted in substantial reductions in the price of medicines, particularly patent expired medicines[659]. However, these price reductions did not appear to have a substantial influence on the monthly costs of the R03A and R03B medicines licensed for asthma dispensed in the identified 12 month period.

6.4.3. Proportions of preparations, therapeutic class and device type dispensed in the 12 month period

6.4.3.1. Proportion of each type of preparation/therapeutic class dispensed in the 12 month period

For patients < 45 years the greatest proportion of R03A and R03B preparations dispensed in the identified 12 month period were inhaled SABA preparations. Indeed, there were almost 10% more inhaled SABA preparations dispensed than both inhaled ICS and ICS with LABA preparations combined. The total number of inhaled ICS and ICS with LABA preparations dispensed to patients < 45 years in the identified 12 month period was 456,178. However, there were 182,230 patients < 45 years who received at least one R03A or R03B preparations, licensed for asthma, in the 12 months. It is possible that a proportion of these patients are at step 1 of the GINA guidelines' treatment steps, whereby as-required reliever medication is sufficient to control their asthma or they only suffer from exercise induced bronchoconstriction relieved by reliever medication. However, inhaled corticosteroids are currently the most effective medications for the treatment of persistent asthma, indeed they are recommended at every treatment step after step 1. Low dose inhaled corticosteroids are the recommended initial preventative medication for both adults and children who do not present with symptoms of severely

uncontrolled asthma. The recommended option for adults and children > 5 years who are not controlled with a low dose inhaled corticosteroid is to step up treatment to the combination of a low dose inhaled corticosteroid with a LABA[1]. The two main alternative preventative medication options in persistent asthma are a leukotriene receptor antagonist or sustained release theophylline. Neither of these medications was included in this data analysis as they are oral medications; therefore, it is possible that a proportion of patients were dispensed one of these medications as their asthma preventative medication. However, both options are less effective alone than inhaled corticosteroids[660-662], in adults and children, and are recommended as alternative add-on therapies, so the proportion of patients, particularly adult patients, prescribed one of these medications alone is likely to be small.

Consequently, it appears that a considerable proportion of patients < 45 years, believed to have asthma, either did not receive any preventative asthma medication or did not receive preventative asthma medication on a regular basis in the 12 month period. There may be a number of possible reasons for this. Firstly, the patients may not have been prescribed an inhaled corticosteroid or combined inhaled corticosteroid with LABA medication by their GP or consultant, they may have been advised to stop taking the medication or take it less regularly when asymptomatic[226] or they may have been advised to step down their medication following at least three months of well controlled asthma. Secondly, patients may have been prescribed one of these preventative medications initially, but did not return to their physician to get the prescription renewed once it was finished/expired. Thirdly, patients may have been prescribed one of these preventative medications but chose not to adhere to the prescribed regimen by taking less than the prescribed dose, failing to use the preventative medication regularly or choosing not to take the medication at all. Poor adherence to preventative asthma medications has been well documented in the literature[162,163,391,663] and has been described in detail in Chapter 2. In addition, there is evidence in the literature of barriers GPs encounter when prescribing regular inhaled corticosteroids. These include lack of familiarity with the guidelines, lack of outcome expectancy, lack of agreement and lack of expected patient adherence[200,231,249]. All of these possible explanations may have contributed to the considerably lower proportion of ICS and ICS with LABA preparations dispensed compared to the proportion of inhaled SABA preparations dispensed in the 12 month period.

6.4.3.2. Inhaler device type distribution according to asthma treatment

Analysis of the distribution of the inhaler device types according to asthma treatment revealed a number of points. Firstly, when the pMDI is an available option it appears to be the inhaler device of choice for the delivery of inhaled salbutamol, salmeterol,

beclometasone and fluticasone. However, for the delivery of budesonide the Turbohaler is the inhaler device of choice. However, this may be because there is only limited availability of the pMDI preparation as it has been discontinued by AstraZeneca. Interestingly, the Diskus is the device of choice in preference to the pMDI for the delivery of the combined preparation salmeterol and fluticasone. This analysis was conducted on the dispensings of all patients (*i.e.* COPD and asthma patients). The dose of salmeterol and fluticasone recommended for COPD patients with a FEV_1 < 60% predicted is 50 mcg salmeterol and 500 mcg fluticasone, according to the summary of product characteristics (SPC) for Seretide®. However, this combination product is only available as a Diskus, as is the next closest Seretide® product of 50 mcg salmeterol and 250 mcg fluticasone. This might explain the preference for Diskus preparations over pMDI preparations in this instance.

6.4.3.3. Inhaler device type distribution according to age range

The GINA guidelines on the management of asthma in children aged 5 years and younger[650] recommend that children under 4 years use a pMDI with a spacer and face mask and those aged 4 -5 years use a pMDI with a spacer and mouthpiece. No alternative inhaler device is recommended for patients under 5 years, but a nebuliser is recommended for children who cannot effectively master the use of a spacer device. However, in the identified 12 months only 63% of the R03A and R03B inhaler devices dispensed to children under 4 years were pMDIs. The remaining 37% consisted of Turbohalers, Autohalers, Easi-breathe devices, Diskus devices or Novolizer devices, indeed, 29% were dry-powder inhalers. This finding is very concerning as dry-powder inhalers are not recommended for use in children under 5 years due their inability to reliably and consistently generate an inspiratory flow rate sufficient to disaggregate the drug agglomerates into drug particles within the respirable range[664,665]. This finding provides additional evidence (see 6.4.2.2) that a proportion of physicians are unaware of the best-practice guidelines for treating asthma patients < 5 years, or they are choosing not to follow these guidelines.

6.4.4. Median weekly dose per drug

6.4.4.1. Median weekly dose of inhaled corticosteroids/inhaled corticosteroids and long-acting β-agonists

For the treatment of asthma, irrespective of severity, a twice daily dosing regimen is recommended for inhaled beclometasone, beclometasone HFA and fluticasone. Consequently, the minimum median weekly dose, indicative of regular adherence, for

each of these inhaled preparations should be 14 puffs. However, for beclometasone, the highest median weekly dose was 7.7 puffs and for fluticasone, the highest median weekly dose was 4.6 puffs. Neither of these median weekly doses indicate regular inhaled corticosteroid adherence. For beclometasone HFA, the median weekly dose of both the 50 mcg strength preparation and the 100 mcg strength preparation was 7.7 puffs, which also indicates irregular adherence.

According to the SPC, the minimum recommended dosage regimen for inhaled ciclesonide is once daily dosing for ciclesonide 160 mcg and this can be reduced to 80 mcg once daily for some adult patients. Therefore, for regular adherence to ciclesonide the median weekly dose should be 7 puffs. However, the median weekly dose calculated for both ciclesonide 80 mcg and 160 mcg was 2.3 puffs.

The SPC for inhaled mometasone, recommends a starting dose of 400 mcg once daily for most adult patients with mild to moderate asthma, therefore the minimum weekly dose should be 7 puffs. However, the median weekly dose for the 30 dose preparation was 0.9 puffs and 1.7 puffs for the 60 dose preparation. According to the SPC, some adult patients achieve better asthma control on a twice daily dosing regimen of mometasone 200 mcg, and some patients can be adequately maintained on 200 mcg once daily. The minimum median weekly dose for regular adherence, assuming a once daily dosing regimen, would be 7 puffs but the median weekly doses of the 30 dose and 60 dose mometasone 200 mcg preparations were 1.2 and 3.5 puffs respectively.

The recommended dosing schedule for budesonide is more complicated. For adults and children > 5 years the recommended dose for mild to moderate asthma is 200-800 mcg in single or divided doses. Consequently, determining whether or not the median weekly doses represent regular budesonide adherence is more difficult. However, the median weekly dose of budesonide 400 mcg was 1.9 puffs, and the median weekly dose of the 200 mcg strength was 3.8 puffs, therefore even if once daily dosing was prescribed these median doses do not represent regular adherence. The median weekly dose of budesonide 100 mcg 200 dose was 3.8 puffs. However, according to both the GINA guidelines[1] and the SPC for budesonide, 200 mcg is the lowest recommended daily dose for adults and children > 5 years. Therefore, a minimum median weekly dose of 14 puffs would be representative of regular budesonide adherence.

According to the SPC for combined fluticasone and salmeterol preparations, a twice daily dosage regimen is recommended irrespective of the dose prescribed, so the minimum median weekly dose representative of regular adherence is 14 puffs. However, the

median weekly doses for the fluticasone and salmeterol preparations ranged from 3.5 - 6.9, indicative of irregular adherence. Combined fluticasone and formoterol preparations were only licensed in Ireland for the first time in October 2012 so they will be excluded from the discussion.

Determining the level of adherence with combined budesonide and formoterol preparations is complicated by the presence of SMART (Symbicort® Maintenance and Reliever Therapy), whereby the budesonide/formoterol combination inhaler is used as both the preventative and reliever inhaler[666]. However, irrespective of SMART, the usual recommended dosage regimen is twice daily dosing. Consequently, for the majority of patients, the median weekly dose representative of regular adherence is 14 puffs, but the median weekly doses of the budesonide/formoterol preparations ranged from 3.5 puffs to 4.6 puffs.

These results reveal that the median weekly dose per patient of corticosteroid and combined corticosteroid with LABA preparations was not representative of regular adherence. However, it is possible that the level of adherence is even lower than these results suggest as having a medication dispensed does not necessarily translate into using the medication as prescribed or even at all. This may be particularly true of medical card patients who only pay €1.50 per item dispensed and these patients comprise 84% of the patients included in this analysis. Poor medication adherence among asthma patients has been discussed in depth in Chapter 2. However, it is also possible that a proportion of these patients may have had their preventative medication stepped down following at least three months of well controlled asthma or their asthma medication may have been changed over the 12 month period to an alternative medication.

6.4.4.2. Median weekly dose of inhaled short-acting β-agonists/ipratropium bromide

One of the characteristics of well controlled asthma, according to the GINA guidelines[1] is the need for reliever treatment no more frequently than twice per week. Patients may need 2 puffs of salbutamol 100 mcg or ipratropium bromide 20 mcg to obtain relief from bronchospasm, excluding any severe exacerbations where considerably more medication is needed for relief. As a result, the maximum median weekly dose of salbutamol/ipratropium bromide indicative of controlled asthma would be 4 puffs per week. The median weekly dose per patient was 3.8 puffs for salbutamol and 3.8 puffs for ipratropium bromide, both indicative of controlled asthma. For terbutaline 500 mcg and salbutamol 200 mcg, only 1 puff is recommended to obtain relief from bronchospasm so

the maximum median weekly dose should be 2 puffs. However, the median weekly dose per patient for salbutamol 200 mcg was 3.5 puffs and for terbutaline 500 mcg 100 dose, it was 4.6 puffs, indicting uncontrolled asthma. The median weekly dose of salbutamol 100 mcg was surprising due to widespread reports of excessive reliever usage in the literature[151,155,172,173,241]. Consequently, further analysis was conducted to investigate the breakdown of salbutamol usage among patients < 45 years. The results are discussed in the subsection below.

6.4.4.3. Salbutamol usage among patients over the 12 month period

Amongst patients < 45 years who obtained a 100 mcg salbutamol 200 dose inhaler in the identified 12 month period, > 30% obtained more than 2 such inhalers. Further analysis was conducted to investigate if this result was influenced by age and it was observed that as patients' age range increased the percentage of patients obtaining > 2 salbutamol inhalers in the 12 month period also increased. A significantly smaller proportion of paediatric patients, particularly those < 12 years, had > 2 salbutamol inhalers dispensed in the 12 month period compared to adult patients. These findings suggest that the paediatric asthma patients included in this analysis required less rescue reliever treatment, in the identified 12 month period, implying better asthma control, compared to the adult asthma patients. The results on the level of concurrent SABA and ICS/ICS - LABA dispensings according to age range (see 6.3.7.2) help to provide a valid explanation for this finding. The proportion of preventative medication dispensings to paediatric patients (5 - 15 years) was significantly higher than the proportion of such monthly dispensings to adult patients. This result implies a higher level of medication adherence among paediatric patients than adult patients, provided the dispensed medications were used as prescribed. There is evidence in the literature that preventative medication adherence rates of > 75% are needed to prevent asthma exacerbations[597] and poor medication adherence is a major cause of poor clinical outcomes[599]. Consequently, it is likely that higher preventative medication adherence among paediatric patients is a major reason why they received significantly fewer salbutamol dispensings than adult patients in the 12 month period.

6.4.5. Concurrent users of inhaled corticosteroids and short-acting β-agonists

Of the patients < 45 years, 29% of their monthly dispensings were for a bronchodilator without a concurrent preventative medication. As discussed in 6.4.3.1, inhaled corticosteroids are the most effective treatment for persistent asthma and are

recommended at every asthma treatment step after step 1[1] so it is unlikely that the majority of adult and paediatric patients with persistent asthma would be prescribed an alternative oral preventative asthma treatment as their primary preventative medication. It is possible that a proportion of these patients have mild asthma that is managed with as needed reliever medication, but overall it is likely that a considerable proportion of these patients did not get a preventative medication dispensed due to poor adherence. In addition, it is possible that the percentage of patients included in this analysis with poor adherence to their preventative medications is considerably larger, because as discussed previously, having a medication dispensed does not mean that it is used as prescribed. This may be less likely in the case of patients who have to pay for their medications, but these patients only comprise ~15% of the patients included in this data set.

6.4.5.1. Level of concurrent dispensings according to community drug scheme

A significantly greater proportion of monthly DPS dispensings consisted of a preventative product with or without a bronchodilator product compared to monthly GMS dispensings. There are two possible interpretations of this result. One interpretation is that, in most instances, the medication dispensed to a DPS family unit must exceed €144 for the claims to be submitted electronically to the PCRS for payment. As most SABA inhalers are considerably less expensive than the vast majority of ICS/ICS - LABA preparations, DPS patients who did not also obtain their preventative medications may not have exceeded the €144 and so the details of their dispensed medications are unlikely to have been submitted to the PCRS, as no additional payment was required. Consequently, a proportion of DPS family units whose medication exceeded €144 may have obtained their preventative medication because it was now effectively free, from their perspective, even though they might not have used it regularly. Another possible interpretation is than even though GMS patients only pay €1.50 per medication dispensed, not all of these patients are getting their preventative medications dispensed (provided they are prescribed for them) if they are not required or being used, possibly due to irregular adherence. This adds credence to the results of this analysis as it implies that, at least a proportion of GMS patients are only obtaining the medications that they are using or they require and not those that they do not use/require. Prior to 2010, GMS patients did not pay any levy for their prescription medicines, they were obtained free at the point of dispensing. In 2010 a 50 cent levy per item was introduced and this was subsequently increased to €1.50[667]. This 'symbolic' levy per item was introduced to disincentivise patients partaking in prescription medicines that were not needed while remaining sufficiently affordable to ensure essential medicines were still obtained[668]. This premise relies on patients' ability

to distinguish between essential and non-essential medicines. However, the results outlined in Chapter 5 on patients' knowledge of asthma and their medication adherence revealed that a considerable proportion were unaware of the need for regular use of preventative medications, suggesting that a proportion of patients may not consider their preventative medication to be an essential medicine.

6.4.5.2. Level of concurrent dispensings according to age range

A significantly greater proportion of the monthly dispensings to patients < 5 years and to those aged 25 - 44 years were for SABA inhalers in the absence of a concurrent preventative medication. However, a significantly smaller proportion of the monthly dispensings to patients aged 5-15 years were for SABA inhalers without a concurrent preventative medication. There may be a number of explanations for this. The recommended daily inhaled corticosteroid doses for children under 5 years are understandably lower than those for older children and adults. Consequently, if a child < 5 years is prescribed 100 mcg beclometasone or 100 mcg fluticasone daily in divided doses, even with regular adherence a 200 dose beclometasone 50 mcg inhaler will last him/her ~ 3 months and a 120 dose fluticasone 50 mcg inhaler will last ~ 2 months, so he/she will need fewer monthly dispensings of his/her preventative medication.

Children are dependent on their parents or guardians for most of their healthcare decisions. As a result, the decision to obtain the child's preventative asthma medication and adhere to the prescribed regimen is the responsibility of the parent or caregiver. Conn and colleagues[669] investigated parents' perceived necessity for, and concerns about, their children's asthma medication and the impact of these beliefs on their children's medication adherence. They discovered that for almost 80% of parents, beliefs about the need for their children's preventative asthma medication outweighed their concerns and children's mean adherence scores increased with parents' increasing beliefs about necessity relative to concern. Similarly, Koster and colleagues[670] and van Dellen and colleagues[671] reported that parents' beliefs about the need for inhaled corticosteroids or a positive attitude towards these medications was associated with higher medication adherence rates. Consequently, it is likely that the parents of the children aged 5 - 15 years (and probably those < 5 years also) believe in the need for their children's preventative medication to control their asthma and so a significantly smaller proportion of the monthly dispensings to these patients are for only SABA inhalers compared to adult patients. However, the assumption cannot be made that all of the preventative medication dispensed to these children was actually taken as prescribed.

6.4.6. Limitations of the study

There are a number of limitations to this study. Firstly, as mentioned throughout the discussion, having a medication dispensed does not automatically translate into medication usage. Patients may have opted not to use the dispensed medication at all or they may have chosen to use the medication differently to the manner prescribed, *i.e.* dose or frequency alteration. This may be particularly true of GMS patients who only pay €1.50 per item dispensed. However, the fact that the proportion of GMS dispensings for preventative medication was significantly lower than the DPS dispensings for these medications suggests that at least a proportion of GMS patients may only be obtaining the medications that they require or are using. In addition, the majority of medical cards are provided to low-income family units. Socioeconomic class, educational level and the degree of health literacy have all been shown to impact on medication adherence[672-674], but investigating the potential impact of these factors was beyond the scope of this study. Another limitation of the study is that, the PCRS pharmacy database only contains minimal information on the medication dispensed to private patients, which does not exceed €144 per month. Thus, the results may not be representative of the Irish asthma population as a whole, as the elderly, the young and the socially disadvantaged are overrepresented. However, at present, there is no alternative means of obtaining information on the inhaled respiratory medication dispensed nationally over a 12 month period. Calculating the median weekly dosage per drug, and determining concurrent usage relied on the premise that a patients' asthma prescription regimen did not change over the identified 12 month period. It did not account for changes in the prescription regimen, *e.g.* change of drug, stepping up or down prescribed dose. Finally, as the data extracted from the PCRS database were not linked to diagnosis an age cut-off point of 45 years was used to distinguish asthma patients from COPD patients. This method of discrimination is not fool-proof and so a proportion of asthma patients who were ≥ 45 years may have been excluded. However, using an age cut-off point is an established method of identifying asthma patients in preference to COPD patients, and was used in both the WHS[639] and the ECRHS[638].

6.5. Conclusion

A detailed analysis of the data extracted from the PCRS pharmacy claims database revealed a number of salient points. Firstly, it is evident that there a number of ways in which considerable savings can be made to annual expenditure on R03A and R03B medicines. Firstly, if the recommended inhaled corticosteroid for first line treatment were beclometasone delivered by a pMDI considerable savings could be made over using

alternative inhaled corticosteroids delivered by alternative devices, especially as there do not appear to be any significant differences in clinical effectiveness or adverse effect profiles between the available inhaled corticosteroids[644-647]. In addition, salbutamol delivered by a pMDI should be the recommended asthma reliever of choice as it substantially less expensive than terbutaline preparations and salbutamol preparations delivered by alternative devices. Furthermore, using inhaler devices that require different techniques can reduce patients' abilities to use both devices correctly[31], so a patient's reliever and preventer should both be delivered by the same device. In addition, choosing generic beclometasone and salbutamol pMDI preparations in preference to proprietary preparations would result in further savings. However, to encourage adherence all patients should be provided with comprehensive training on pMDI technique initially and this training should be reinforced over time. In addition, it is essential to ensure that patients are willing to use a pMDI device and any compliance issues should be investigated and addressed during training.

Almost €56 million of the ~€75 million spent on R03A and R03B medicines, licensed for asthma, was spent on combined ICS - LABA products. It is essential, therefore, that physicians caring for asthma patients, are made aware that best-practice asthma guidelines only recommend prescribing these medications when a medium dose of inhaled corticosteroids alone is not sufficient to achieve asthma control. The recommended initial preventative asthma medication for all patients is a low dose inhaled corticosteroid[1]. In addition, if asthma control has been maintained for 3 months, GINA guidelines[1] recommend that treatment is stepped down, according to established recommendations, with the aim of determining the lowest dose and treatment step necessary to maintain control. Adhering to these best-practice recommendations should also result in considerable savings.

The treatment of a proportion of asthma patients < 5 years is not in accordance with two of the recommendations outlined in the GINA guidelines for this age group[650]. Firstly, 37% of the inhalers dispensed to this patient group were not pMDIs, despite the fact that the pMDI with a spacer/facemask is the only recommended delivery device, other than a nebuliser, for these patients. Secondly, ipratropium bromide is not recommended as a reliever medication for asthma patients < 5 years, yet ~4,700 of these inhalers were dispensed to this patient group in the 12 month period. Consequently, it is evident that a proportion of physicians caring for asthma patients < 5 years need to be made aware of the best-practice guidelines for treating this patient group.

The total number of inhaled preventative medication preparations dispensed to patients < 45 years, and the median weekly doses calculated for these products, imply that a

considerable proportion of these patients are poorly adherent with their preventative medication. In addition, the proportion of patients with > 2 dispensings of salbutamol, indicates that a proportion of these patients are using excessive quantities of reliever medication, indicative of poorly controlled asthma. Excessive reliever use is unsurprising given the indications of poor preventative medication adherence amongst a considerable proportion of patients. However, excessive reliever use and adherence with preventative medications varied significantly with age. Paediatric patients appeared to be more adherent with their preventative medications and obtained fewer salbutamol inhalers annually than adult patients. As discussed, the health of paediatric patients is the responsibility of their parents/guardians so it is possible that their beliefs about their children's need for preventative asthma medication is a major contributor to this observed difference in adherence and salbutamol usage.

In conclusion, there is considerable scope for savings in the annual expenditure on R03A and R03B medications licensed for asthma. Awareness needs to be raised, amongst a proportion of physicians, about the best-practice guidelines for treating asthma patients < 5years. Adherence to preventative asthma medications and excessive reliever use is a considerable problem in Ireland, particularly among adult patients. Consequently, it is imperative that a concerted effort is made by all healthcare professionals caring for asthma patients to educate patients on the importance of adherence to their preventative medications.

7. A model inhaler technique service for the future

7.1. Research objectives

At the outset, a number of research objectives were outlined. The first objective was to determine the current state of asthma care in the primary care setting according to community pharmacists, GPs and practice nurses. This was successfully accomplished using nationwide anonymous postal surveys. The Demonstration Project was the focus of the second objective. However, while the role of the community pharmacist in asthma management both prior to and following the initiation of the Demonstration Project was successfully elucidated, it was not possible to interface with the project, gather appropriate baseline data and monitor the parameters longitudinally as the project progressed. Structured interviews with the community pharmacists enrolled in the project revealed that this was primarily due to a lack of communication and collaboration between the participating GPs and community pharmacists, and the absence of a clearly defined role for the community pharmacist. The lessons learned from the Demonstration Project helped in the design and implementation of the Brief Intervention, a community pharmacist-led educational intervention on inhaler technique. A review of asthma-specific quality of life instruments, prior to the implementation of the intervention ensured that a validated and appropriate instrument was included to evaluate the effect of the intervention the quality of life of participating patients. The final objective was to conduct a pharmacoeconomic evaluation of R03A and R03B medicines licensed for asthma and to determine the level of adherence to these medications. This was successfully completed using data extracted from the PCRS pharmacy claims database for an identified twelve month period.

The primary objective of this research project was to investigate the role of the community pharmacist in optimising patients' inhaler use. Each of the individual studies within the research project revealed important and relevant information to assist in the design of the model community pharmacy-based inhaler technique intervention for future implementation. The design of the necessary study tools and protocols in conjunction with the subsequent implementation and evaluation of this model would be a very valuable body of work for researchers in the future. The model inhaler technique intervention is outlined in detail below.

7.1.1. Model community pharmacy-based inhaler technique service

According to the Health Status and Health Service Utilisation National Household Survey quarterly report 2010[116], published by the Central Statistics Office, 7% of the adult population of Ireland suffer from asthma. Indeed, asthma is the most prevalent condition (10%) among young adults (18-24 years). However, the AIRI survey[151] revealed that only 8% of the asthma patients included in the study had completely controlled asthma, as classified by the GINA guidelines[1]. In addition, the results of the QAM-CP, QAM-GP and QAM-PN (Chapter 2) revealed that the majority of health-care professionals in primary care believe that a large proportion of their patients have uncontrolled asthma. It is likely that one of the factors contributing to sub-optimal asthma care in the primary care setting is lack of physician time to provide guideline concordant care to every patient with a chronic disease. Furthermore, the population of Ireland is increasing, and like other developed countries, the life expectancy is increasing[675]. The prevalence of chronic diseases is expected to increase in the future. In Europe, chronic pulmonary disease is increasing in prevalence and prevalence greatly increases with age[114]. COPD is the major contributor to the increasing age-related prevalence, but inhaler technique training is equally relevant for people with COPD. Community pharmacists are optimally placed to expand their role in the management and care of patients with chronic diseases, such asthma, as they have at least monthly contact with these patients due to their need for prescription refills. In addition, the evidence base for the clinical benefits of pharmacists' involvement in asthma care is compelling[6,41,157,171,218,344]. The implementation of a nationwide community pharmacy based inhaler technique service is one example of how pharmacists could expand their professional responsibilities in asthma care.

Five key elements are essential to the design and implementation of a model nationwide community pharmacy-based inhaler technique training service: national governance, education and training of both undergraduate pharmacy students and qualified community pharmacists, communication and collaboration between health-care professionals, a national campaign on asthma awareness, and the actual inhaler technique service. The relationships between these five elements are outlined in Figure 7.1.

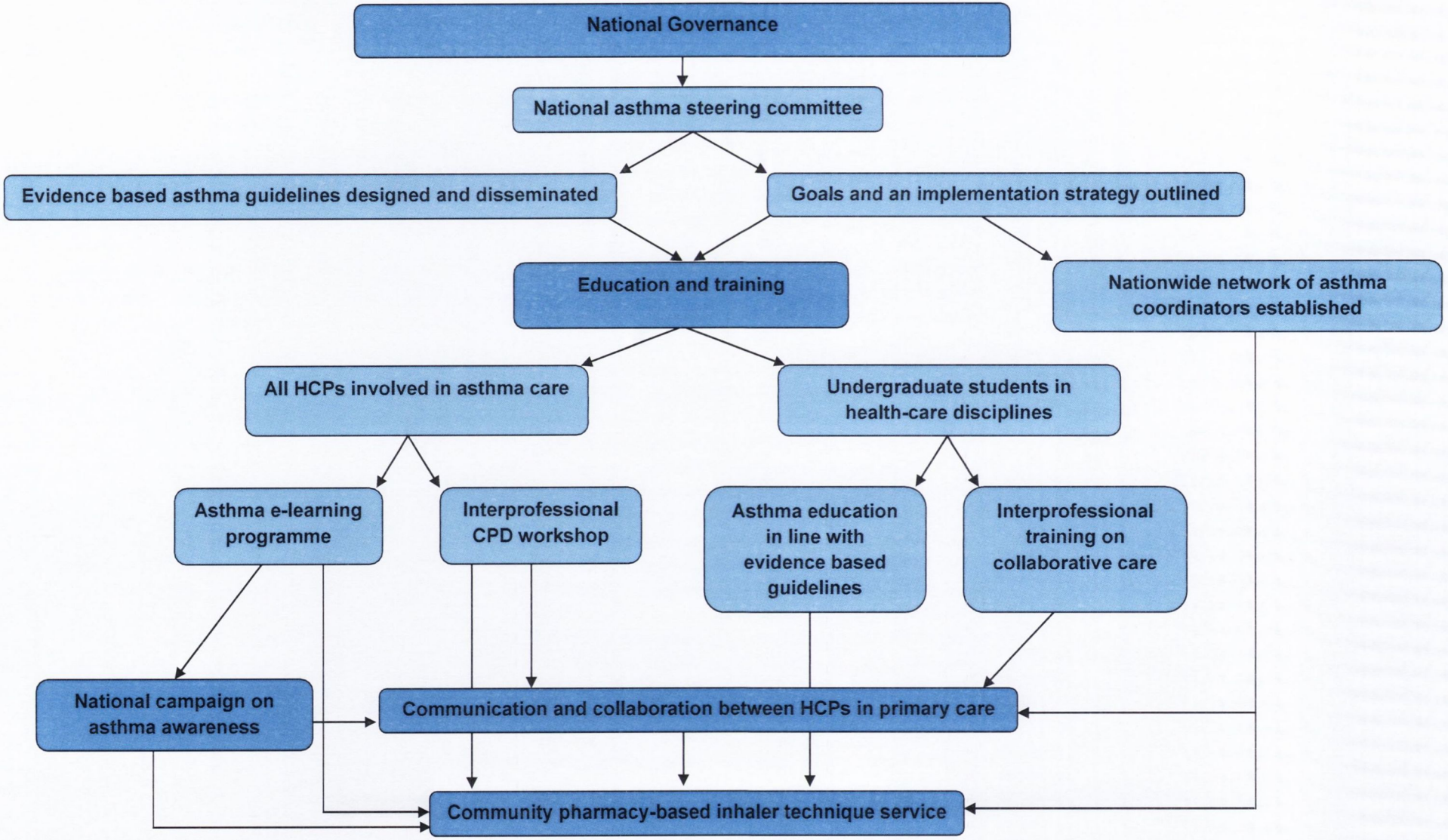


Figure 7.1: Model community pharmacy-based inhaler technique service. (HCP = health-care professional)

7.1.1.1. National Governance

The results of the QAM-CP, QAM-GP and QAM-PN revealed that asthma care in the primary care setting is sub-optimal. Overall, the respondent health-care professionals believe that a large proportion of their asthma patients have inadequate inhaler technique, rarely use a peak flow meter and do not possess a written asthma management plan. In addition, they believe that the majority of them have asthma that is partly controlled or uncontrolled and they have low expectations of disease management. The results of the Exit Questionnaire (Chapter 5) revealed that one of the changes needed to incorporate a more intensive level of patient counselling into routine community pharmacy practice was the implementation of a structured chronic disease programme. Consequently, it is evident that the current system of asthma care is inadequate and needs to be completely overhauled to facilitate the provision of asthma care that is in accordance with evidence-based asthma guidelines.

The GINA guidelines[1] recommend that evidence-based asthma guidelines must be disseminated and implemented at local and national level, in order to instigate changes in patient care and subsequent improvements in asthma outcomes. The ten-year asthma programme in Finland is an excellent example of how a nationwide asthma programme can successfully reduce asthma morbidity and its impact on society[115]. A number of factors underpinned the success of this programme. Firstly, the Ministry of Social Affairs and Health in Finland acknowledged that asthma was an issue of public importance and appointed a steering committee to design and implement a national asthma programme. The committee outlined goals and an implementation strategy. Two vital components of the implementation strategy were the provision of education and training to all health-care professionals involved in asthma care and the establishment of a network of asthma coordinators in every healthcare centre and community pharmacy nationwide[115,341].

In Ireland, the Minister for Health recognised the need to improve asthma care. As a result, the Health Service Executive established the Clinical Strategy and Programmes, one of which is the National Asthma Programme (NAP). A multidisciplinary steering committee (National Asthma Programme working group) was established to design and implement the NAP. The vision of the NAP is that 'every person with asthma should reach their maximum health and quality of life potential through the prevention, early detection and effective treatment of asthma'. In order to achieve this goal the committee developed a number of quality, access and value objectives. In accordance with the GINA guideline implementation strategies[1], the committee collaborated with the ICGP in the adoption and adaptation of the GINA guidelines to produce three sets of national asthma guidelines: (1) 'Asthma Control in General Practice 2012' (not publicly available to

date), (2) 'Emergency Asthma Guideline Management of the Acute Adult Asthma Patient'[676] and (3) Emergency Asthma Guideline Management of the Acute Paediatric Asthma Patient (not publicly available to date). These guidelines will act as the 'gold standard' in both the education of health-care professionals and the nationwide implementation of best-practice asthma care.

7.1.1.2. Education and training

a) Continuing professional development

In order to ensure the successful implementation of a nationwide community pharmacy-based inhaler technique service, it is imperative that all community pharmacists involved are familiar with the evidence-based asthma guidelines and are proficient in the required inhaler technique skills for all of the inhalation devices that are available commercially. Therefore, community pharmacists should be required to complete an education programme to ensure their competency prior to the initiation of an inhaler technique service.

In Finland, an intensive education programme was organised for all health-care professionals involved in asthma care using a step-wise approach beginning with the pulmonary and paediatric hospital units, followed by the local primary care coordinators and then the remaining health-care professionals[115]. The main educational activities included training sessions, seminars and national asthma forums. In Australia, education was provided using a combination of seminars, distance learning modules, workshops and in-service programmes for health-care professionals[107]. In Ireland, the NAP in conjunction with the ASI developed an online asthma education programme for all health-care professionals consisting of six e-learning modules. Funding for the education programme was achieved in the HSE National Service Plan 2011[677] and under the Deliverable Outputs for the National Asthma Programme in the National Service Plan 2012[678] the education programme needed to be operational by the 2nd quarter of 2012 and this was achieved. The education programme is currently available online at *www.elearning.asthmasociety.ie* and on HSELanD, the online Learning and Development resource for all health-care professionals employed by the HSE. In order to encourage maximum participation from health-care professionals the education programme is accredited for Category 1 approval from An Bórd Altranais, 6 CPD credits from ICGP and 6 hours of continuing education from the Irish Centre for Continuing Pharmaceutical Education (ICCPE) (This will need to be amended when the Institute of Pharmacy is operational).

The engagement with an online learning programme on evidence-base asthma guidelines is not sufficient as successful learning should be self-directed, collegial and reflective and

all three aspects are necessary[679]. As a result, interactive workshops are also needed and should reinforce the knowledge obtained from the online learning programme, include a practical session on inhaler technique, provide training on communication skills, and education on the different perspectives of health-care professionals and patients about chronic diseases[176,680,681]. The practical session on inhaler technique should be based on the 'train the trainer' approach where experts in the area train the attending pharmacists on the correct inhaler techniques and then educate them on the optimum methods for training their asthma patients. This method is proven to result in the successful dissemination of the education to a large population[682]. Basheti and colleagues[176] demonstrated that a single workshop encompassing educational presentations, physical technique demonstrations and practice sessions, peer assessment and feedback, and the subsequent provision of repeated education on inhaler technique by pharmacists to their patients, resulted in the maintenance of pharmacists' own inhaler technique skills over a two year period. Consequently, this approach should inform the design of the inhaler technique workshops.

Pharmacists who participated in the Brief Intervention experienced difficulties recruiting patients and these difficulties have also been documented in the literature[557,631-633]. Indeed, pharmacists who participated in a specialised asthma service specifically requested training on patient recruitment[633]. Furthermore, one of the barriers to participating in practice based research that was highlighted in another study of community pharmacists was a perceived lack of the skills needed to recruit patients[683]. Kaae and Norgard[558] used semi-structured interviews to investigate the strategies used by community pharmacists to optimise patient participation in the Inhaler Technique Assessment Service in Denmark. They discovered that successful recruitment strategies followed a common sequence whereby the pharmacist/staff member would put forward a question that would pique the interest of the customer or make him/her consider that his/her asthma treatment was lacking in some way. The pharmacist/staff member followed this opening question with a persuasive argument highlighting that the inhaler service was filling an unmet need in asthma care. However, this recruitment strategy was not always successful and this may be due to a lack of understanding among health-care professionals about how the patients themselves view their asthma[558]. Research has suggested that health-care professionals and patients have divergent views on chronic diseases and their management. Health-care professionals, overall, hold a technical view of chronic illness whereby their focus is on the physiological processes involved. In contrast, patients, in general, hold a life-world view, focusing on how the illness and its treatments influence their daily lives[684,685]. Consequently, it is essential that the interactive workshop includes an educational component on the different perspectives of health-care

professionals and patients about chronic diseases, thus allowing pharmacists to develop recruitment strategies that focus on the life-world view of the patients in preference to their own clinical-world view.

Communication and collaboration will be discussed in 7.1.1.3 below. However, in the context of continuing professional development (CPD) a number of issues are relevant. Firstly, in Ireland CPD is usually undertaken by each health-care profession separately. However, collaboration among health-care professionals, particularly the issue of shared decision making in patient care, necessitates a deviation from isolated profession-based CPD[686]. As a result, the aforementioned interactive workshop should be provided as an interdisciplinary workshop for community pharmacists, GPs and practice nurses involved in asthma care. However, interprofessional education involves 'practitioners or students from two or more professions engaging in learning *with*, *from* and *about each other* to enable effective collaboration and improve health outcomes'[687]. Therefore, it is not sufficient for health-care professionals to learn *with* each other. The Building a Better Tomorrow Initiative (BBTI) was a CPD program established in Atlantic Canada to enhance the collaborative skills of the health-care professionals in primary care and encourage the development of interprofessional collaboration[688]. Six CPD modules were developed and delivered in a workshop format using the 'train the trainer' approach. Those that were perceived to be most beneficial were the modules on team building, conflict resolution and understanding primary care. Qualitative studies of the participants revealed that the initiative improved interprofessional relationships and resulted in an increased understanding of and attitude towards interprofessional collaboration[688]. Consequently, a similar interprofessional workshop incorporating modules on team building, conflict resolution and understanding primary care is likely to be beneficial in encouraging interprofessional collaboration in the primary care setting in Ireland.

The results of the Exit Questionnaire (Chapter 5) revealed that one of the proposed changes to community pharmacy that would facilitate the incorporation of more extensive patient counselling was the provision of training for pharmacy staff members. Similarly, Saini and colleagues[680] reported that following the implementation of an educational intervention for community pharmacists on specialised asthma care, the participating pharmacists requested that their staff members were also provided with similar training as they would be directly involved in patient recruitment. Kaae and Christensen[681] investigated the barriers to the long term implementation of a pharmacy-based inhaler technique service. They discovered that one of the major barriers was the involvement of all the pharmacy staff members due to a perceived/actual lack of self-efficacy and lack of experience with the increased level of counselling required. Consequently, an interactive

workshop should also be provided to all pharmacy staff members. It should include a brief overview of the evidence-based asthma guidelines but its primary focus should be on inhaler technique and the communication skills and strategies needed to encourage patient participation in a pharmacy-based cognitive service[176,558].

b) Undergraduate education

It is imperative that all student pharmacists are provided with education on asthma that is in accordance with evidence-based asthma guidelines[1]. In addition, they should be trained on the inhaler techniques of all the commercially available devices and on how to train their asthma patients. The asthma education module should be reviewed annually and updated to reflect changes in best practice guidelines and the availability of novel inhalation devices.

Undergraduate education is an excellent opportunity to promote, encourage and educate health-care students about collaborative patient care. The WHO recognises that the provision of interprofessional education is essential to the preparation of a health-care workforce that is competent in interprofessional collaboration and so better equipped to respond to patients' health needs[689]. In March 2001, the Institute of Medicine, a branch of the National Academy of Sciences, released a report on the quality of health-care in America entitled 'Crossing the Quality Chasm: A New Health System for the 21st Century'[690]. This report recommends providing more opportunities for interdisciplinary training to students in health-care disciplines so that they are equipped with the skills necessary to provide collaborative care in their professional lives[690]. In 2005-2006, the American Association of Colleges of Pharmacy convened a Council of Faculty Interprofessional Education Task Force responsible for interprofessional education. In 2006-2007, the Task Force developed a series of six student competencies that should be achievable through a curriculum for interprofessional education. These competencies were: (1) understanding team organisation/function, (2) assessing and enhancing team performance, (3) communicating with team members, (4) demonstrating leadership, (5) resolving conflict and building consensus, and (6) setting common patient care goals[691]. Interprofessional education should commence in the first year of the undergraduate programme when students appear most enthusiastic about interprofessional learning and continue throughout the undergraduate programme to maintain the enthusiasm[687,692]. A number of barriers to the successful implementation of interprofessional education have been identified among academic administers; these include scheduling difficulties, rigid curricula, 'turf battles' and a lack of perceived value[693,694]. It is imperative that academic administrators understand, appreciate the advantages and facilitate the need for interprofessional education. Motivating academic administrators and faculty members to

embrace interprofessional education is the responsibility of leaders in the each of the professional fields of medicine, pharmacy and nursing[695].

7.1.1.3. Communication and collaboration

The NAP is being designed and implemented by a multidisciplinary group with a focus on collaborative care and this should provide the initial impetus for the promotion of collaborative working relationships between the health-care professionals involved, but this alone is unlikely to be sufficient. In Chapter 2, results of the QAM-CP, QAM-GP and QAM-PN revealed that limited communication exists between the three health professions. In addition, one of the main reasons proposed for the modest improvement in patient counselling by pharmacists following the initiation of the Demonstration Project was the infrequent communication between pharmacists and both GPs and practice nurses (discussed in Chapter 3). The provision of interprofessional education and interdisciplinary CPD is likely to support interprofessional collaboration. In addition, the successful implementation of a new pharmacy-based inhaler technique service requires support from local GPs and practice nurses and bidirectional communication between all three groups. The initiation and subsequent maintenance of collaboration in primary care may be facilitated by the appointment of one GP and one practice nurse in each general practice and one pharmacist in each community pharmacy as the local asthma coordinators, as this strategy proved very successful in Finland[115]. These contact persons should then be responsible for organising meetings within their local areas to ensure quality of shared asthma care for their patients. Alternatively, if the appointment of one contact pharmacist per pharmacy is not a feasible option, it may be more practical to appoint a liaison pharmacist for the region. Indeed, to facilitate the methadone protocol scheme in the Eastern Regional Health Authority three liaison pharmacists were employed. Their primary role is to interface between pharmacists dispensing methadone in primary and tertiary care, responding to queries on patient- and pharmacy-related issues and providing support to local pharmacists[696]. A study by O'Connor and colleagues demonstrated the success of this support service in addition to the ongoing need for the service even after the methadone protocol scheme had been well established[696]. In the context of the NAP and the inhaler technique service, the liaison pharmacists could fulfil two important roles: the provision of support to their pharmacist colleagues and the facilitation of communication between pharmacists and their local GPs and practice nurses.

Research in America has demonstrated that the pharmacist is usually the relationship initiator in the establishment of successful collaborative working relationships[213], this was also the case in Finland[342]. Thus to encourage optimal conditions for success, the

contact/liaison pharmacist should take responsibility for organising the meetings initially. In addition, research has shown that regular team meetings are important as they facilitate interprofessional communication and they have been associated with effective teamwork and increased innovation[697,698]. Numerous barriers to the establishment of successful CWRs have been discussed in Chapter 2, but research has shown that many of these barriers are perceived barriers that do not materialise or prove significant when collaboration occurs[271,272,699]. In addition team meetings have been identified as a way of addressing professional barriers[697].

7.1.1.4. National campaign on asthma awareness

Results from the QAM-CP, QAM-GP and QAM-PN revealed that health-care professionals believe that their asthma patients have low expectations of disease management. In addition, community pharmacists who participated in the Brief Intervention believed that one of the major barriers to participation in the study was a lack of understanding among patients about the level of asthma control that is achievable. Consequently, it is evident that a national campaign aimed at raising awareness about the level of asthma control that is achievable with appropriate therapeutic management is urgently needed. This campaign should also highlight the message that community pharmacists can play an instrumental role in helping patients achieve asthma control, as this might aid patient recruitment to the inhaler technique service.

In 1988, private and public sector agencies in Australia collaborated to conduct a health promotion campaign, called 'Could it be asthma?', aimed at raising awareness about asthma nationwide[700]. A mass media campaign was launched and directed at primary care physicians and the general public. 20,000 physicians received an asthma information mailshot about asthma management and the campaign, and the public were involved through a multimedia campaign. The campaign resulted in an increased knowledge of asthma symptoms and was moderately successful in raising asthma awareness[700].

In 2008, European Antibiotic Awareness Day was the first Europe-wide health promotion campaign focused on reducing the inappropriate use of antibiotics, particularly for upper respiratory tract infections[701]. Thirty-two countries were involved in 2008 and the campaign expanded annually with forty countries participating in 2012[702]. The National Prescribing Service in Australia launched a similar nationwide health promotion campaign from 2000 to 2004[703]. Both of these campaigns were widely implemented and highlight a number of factors needed for the design and implementation of a successful national awareness campaign. Firstly, strong political and stakeholder support is a critical factor.

In addition, support from patient organisations such as the ASI would be very valuable[701]. Secondly, a social marketing approach should be applied to the design of the campaign[701]. Social marketing is a commercial marketing strategy whereby the target population is involved in the planning process to identify optimum methods for reaching that population and achieving the desired outcomes[704]. Adopting a social marketing approach can increase the chances of achieving a sustainable behavioural change in the target population[704,705]. The campaign materials should contain a key message that is grounded in scientific evidence. They should be disseminated in a multi-media campaign encompassing television, radio and regional and national publications for maximum exposure. The campaign should be directed at both health-care professionals and the general population concurrently. Finally, in order to achieve sustainable behaviour changes the campaign should be repeated annually[701,703].

7.1.1.5. Inhaler technique service

The design and production of the materials required for this service, in addition to its coordination and implementation and the subsequent evaluation of the service would constitute a very comprehensive and valuable future research project.

a) Provision of standardised materials to all community pharmacies

After the completion of the interactive asthma workshop outlined in 7.1.1.2(a) every community pharmacist should receive a standard tool kit containing the following items:

- Standard patient registration forms
- 'Show and Tell' inhaler technique training protocol[41] (Chapter 5)
- Inhaler technique checklists for all commercially available devices
- Starter supply of placebo inhalers and contact information to obtain additional supplies
- Inhaler technique reminder labels to attach to patients' inhalers
- Age specific data collection questionnaires consisting of basic demographic information, the ACT[555] and the mini-AQLQ[384,385].
- GP form for completion at the end of the inhaler technique service.
- Posters and patient leaflets advertising and explaining the inhaler technique service

b) Description of the protocol

The NHS in the UK has introduced a number of additional pharmaceutical services including the Minor Aliment Service, the Chronic Medication Service and the Acute

Medication Service[552]. The protocols used to implement these additional services in Scotland informed the design of the inhaler technique service protocol outlined below:

1. All patients with diagnosed asthma, who are registered with a GP, are eligible to register for the inhaler technique service.
2. An eligible patient can only register with one community pharmacy.
3. Registration only occurs once unless a patient has withdrawn from the service or is transferring pharmacies.
4. At registration, the pharmacist completes a standard registration form that details the patient's name, address, date of birth, personal public service (PPS) number, medical card/DPS card number where relevant, name and address of patient's GP and name and address of the community pharmacy. The patient and the pharmacist both sign the completed form and this is indicative of the provision of informed consent by the patient.
5. The patient completes an age-specific data collection questionnaire prior to the counselling service.
6. In the private consultation room/area the patient demonstrates his/her inhaler technique using the appropriate placebo and the pharmacist completes the relevant inhaler technique checklist.
7. The pharmacist counsels the patient on inhaler technique using the 'Show and Tell' inhaler technique training protocol and attaches an inhaler technique reminder label to the patient's inhaler, as outlined in Chapter 5.
8. At the end of the counselling session, the pharmacist completes the GP form that details the patient's name and address, the name and address of the pharmacy, the date, the pre-training inhaler technique score, and whether the patient successfully mastered the correct technique after counselling.
9. If the pharmacist believes that the patient is not capable of mastering the correct inhaler technique (*e.g.* due to poor dexterity), the patient is referred to the GP with the completed GP form advising that the patient's inhaler device should be changed.

c) Paperwork

The original completed patient registration form, data collection questionnaire, inhaler technique checklist(s) and GP form are retained in the community pharmacy. A copy of the patient registration form is mailed with the monthly reimbursement claims to the PCRS. A copy of the GP form is mailed/faxed to the GP.

d) Patient Medication Record

A note should be added to the patient's PMR that he/she registered for the inhaler technique service and it should include the date for his/her next counselling session. The second counselling session should be provided after a 1-month interval and then repeated every 6 months thereafter, as patients need repeated reinforcement to maintain the correct technique[41,43,48].

e) Online database and evaluation

The evaluation of the impact of this nationwide service would be an essential aspect, as demonstrating the benefit of the service would hopefully facilitate the expansion of the role of community pharmacists in the future[561]. The evaluation could be achieved by constructing an online database. Pharmacists would input the results of their patients' pre-inhaler technique checklist scores, their ACT scores and their Mini-AQLQ scores, after each consultation. These results could be harvested and analysed on a quarterly basis by the researcher to determine the impact of providing this community pharmacy-based inhaler technique service on patients' technique and their asthma control status. These results could be circulated to community pharmacies nationwide in a trade publication, *e.g.* the Pharmaceutical Society of Ireland's monthly newsletter. Communicating the results of this service to the participating pharmacists in a trade publication would be important as one of the barriers to participation in practice-based research is that the results of the research are poorly communicated to the participants[683]. In addition, repeated updates might encourage reluctant pharmacists and their staff to engage with the service[681].

f) Remuneration

The need for remuneration to facilitate the provision of an intensive counselling service was identified as one of the changes needed in community pharmacy in the Exit Questionnaire (Chapter 5). Indeed, the lack of remuneration has been identified as a barrier to the provision of enhanced services in a number of pharmacy-based studies[207,405,622,706]. In order to qualify for remuneration, every community pharmacist must complete the online education programme and attend the interactive workshop. He/she can then register the community pharmacy in which he/she works with the PCRS as one that provides the inhaler technique service. Payments to the community pharmacy should be provided monthly according to tiered payments relating to the number of patients registered for the service. The number of patients would be calculated based on the number of completed patient registration forms mailed to PCRS. However, it is likely that this service would be cost-effective. Incorrect inhaler technique is associated with poor

asthma control[6,9,10] and poor asthma control is the largest contributor to the economic burden of asthma[573].

7.2. Conclusion

Addressing each of the original research objectives revealed a number of significant points about asthma management in the primary care setting in Ireland. The nationwide surveys of community pharmacists, GPs and practice nurses on asthma care in the primary care setting uncovered a number of issues. Firstly, community pharmacists and practice nurses believe that asthma management among the majority of their patients is sub-optimal, but GPs have a more optimistic and possibly unrealistic view of their patients, possibly due to infrequent consultations, poor communication or inadequate assessment methods, and this view is not in accordance with the published literature[148,151,155,156,280,391]. Both pharmacists and practice nurses have a narrow perception of their roles in asthma management and the majority of asthma care appears to be considered the remit of the GP. However, the majority of GPs do not appear to be providing their patients with guideline-concordant care. In addition, there appears to limited communication and collaboration between these health-care professionals.

Evaluating the role of the pharmacist in asthma management in the Demonstration Project highlighted two main points. Firstly, it confirmed some of the perceptions and findings of the QAM-CP. The baseline results revealed that pharmacists seem to infrequently assess and reinforce their patients' inhaler technique and rarely counsel their patients on the importance of the peak flow meter, two issues that were also highlighted by the QAM-CP. In addition, pharmacists appear to discuss infrequently the prescribed asthma medications with their patients. Secondly, pharmacists appeared to have minimal involvement in the Demonstration Project. Interviews with the pharmacists enrolled in the project revealed that this was most likely due to the limited communication with the participating GPs/practice nurses and due to the lack of a clearly defined role for pharmacists in the project.

The review of asthma-specific quality of life instruments was an essential pre-requisite when designing the Brief Intervention. This review ensured that the most relevant and valid instrument was used to detect any changes in quality of life in the study.

The Brief Intervention revealed three issues. Firstly, time is a significant barrier to the provision of a specialised asthma service in community pharmacy, particularly in the absence of reimbursement. In addition, patient recruitment to and persistence with a free cognitive service is difficult, most likely due to a lack of awareness of the level of asthma control that is achievable. Secondly, a large proportion of asthma patients enrolled in the study had sub-optimal asthma control, poor quality of life, poor medication adherence, a

lack of knowledge about many aspects of asthma and its treatments and poor inhaler technique. These results were in accordance with the views of community pharmacists and practice nurses recorded by the QAM-CP and QAM-PN. Finally, despite the time limitations and difficulties with patient recruitment, the provision of training on inhaler technique by the participating pharmacists resulted in a significant improvement in patients' inhaler technique scores at the follow-up consultations. This translated into significant improvements in asthma control and asthma-specific quality of life.

The pharmacoeconomic evaluation of R03A and R03B medicines licensed for asthma, dispensed over an identified 12 month period, revealed a number of issues. Firstly, considerable savings in annual expenditure on these medicines is possible if the recommended first line preventative and reliever asthma medications are beclometasone and salbutamol respectively, delivered by pMDIs. Secondly, the results revealed that average adherence with preventative asthma medications was poor and a substantial proportion of participants had excessive reliever medication usage, indicative of uncontrolled asthma. However, paediatric patients appeared to have significantly better adherence and significantly less reliever usage than adult patients did.

In conclusion, it is evident that the current system of asthma care, where each profession is operating in isolation and the burden of care is the responsibility of the GP, is not viable. In order to improve asthma care, each health-care professional should be familiar with the evidence-based asthma guidelines and collaborate with each other to provide the patient with team-based guideline-concordant asthma care. This project has demonstrated that community pharmacists can play a vital role in asthma care by successfully educating patients on inhaler technique. The model community pharmacy-based inhaler technique service uses the lessons learnt in each of the chapters of this research project to inform the five elements that would facilitate the implementation of this service on a national level, thus allowing pharmacists to expand their role in asthma disease management. The design, implementation and evaluation of the model inhaler technique service would constitute a very valuable future research project.

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8. Appendices

1. Cover letter for community pharmacists regarding QAM-CP

UNIVERSITY OF DUBLIN
SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES,
TRINITY COLLEGE,
DUBLIN 2, IRELAND.

February 2010

Dear Colleague,

As part of my M.Sc. (Research) that I am undertaking in TCD School of Pharmacy, I am investigating the management of asthma in primary care. At present a number of health-care professionals are participating in an initial pilot study developed by the Asthma Society of Ireland to improve asthma management in Ireland, which it is hoped will lead on to a nationwide project.

This pilot study and the proposed nationwide project involve the participating health-care professionals (GPs, pharmacists and practice nurses) collaborating in the management of their asthma patients in a more structured way. In this programme, community pharmacists focus on their clause 9 responsibilities (prescription review, patient counselling *etc.*), but there is greater awareness of the community pharmacist's role and activities among other members of the primary healthcare team, and agreement on liaison between team members. Online and practical training is provided.

Participating patients are encouraged to become actively involved in managing their asthma through education on using a personal asthma management plan, using a peak flow meter to monitor asthma control, and correct use of inhalers.

I have enclosed a questionnaire which is being sent to all pharmacies nationwide, aimed at determining the **opinions of community pharmacists about asthma management in the primary care setting** at the present time, and your opinions about the proposed nationwide project. As most of the questions simply require a box to be ticked, the questionnaire is quick to fill in, and should take **no more than 10 minutes**.

The questionnaire is anonymous and confidential. There is no way of tracing answers to a particular pharmacist or pharmacy. All answers will be aggregated in order to obtain an overall view of community pharmacists' opinions nationwide. I should be very grateful if you would complete this questionnaire and return it to me in the enclosed FREEPOST envelope, or any envelope addressed to:
FREEPOST, Pharmaceutical Care, School of Pharmacy, Trinity College, Dublin 2 (no stamp required)
as soon as you can, and **by March 12th if possible**.

I realise you have many demands on your time, but your participation will ensure that the survey accurately reflects the views of community pharmacists in Ireland.

For further information about my research or information about how to get involved in the proposed nationwide project to improve asthma management in Ireland, please do not hesitate to contact me at 01-896-2943 or by email at *bucklekn@tcd.ie* .

Many thanks for your help. It is greatly appreciated.

Niamh Buckley M.P.S.I.

2. Reminder letter for community pharmacists regarding QAM-CP

UNIVERSITY OF DUBLIN
SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES,
TRINITY COLLEGE,
DUBLIN 2, IRELAND.

March 2010

Dear Colleague,

Questionnaire for Community Pharmacists on Asthma Management

A short while ago, you should have received a letter from me enclosing a questionnaire about your opinions on asthma management in the community setting at the present time and your opinions about a nationwide project being proposed by the Asthma Society of Ireland.

If you have already completed and returned this questionnaire, I'd like to thank you very much. Because of its anonymous format, it is not possible to identify and thank individual respondents. However, I'm very grateful for all the replies I've received to date.

The purpose of the questionnaire is to gather information from community pharmacists about the interventions they currently carry out with their asthma patients, the factors that influence their ability to counsel asthma patients, communication between pharmacists and other health-care professionals such as GPs and practice nurses, their views about asthma management among their patients at present, and their opinions about the proposed nationwide project on asthma management. This information will be analysed and used as a guideline in the development of the proposed nationwide asthma management project.

If you have not completed it yet, may I encourage you to do so? (Another copy has been enclosed.) The accuracy of the data depends on getting responses from as many pharmacists as possible. I realise you have many demands on your time, so the questionnaire has been kept as brief as possible. **Most people report it took them just 7 minutes.**

If you have any queries or if you require any additional information please do not hesitate to contact me at 01-896-2943 or by email at *bucklekn@tcd.ie* .

Many thanks for your help. It is greatly appreciated.

3. Questionnaire on asthma management for community pharmacists

QUESTIONNAIRE FOR **COMMUNITY PHARMACISTS** ON ASTHMA MANAGEMENT

A Baseline Characteristics

1. **Please indicate your gender.** ❑ Male ❑ Female

2. **Please indicate the year you began practising as a community pharmacist.** _____

3. **Please indicate your age bracket.** ❑ 21-35 ❑ 36-45 ❑ 46-55 ❑ > 55

4. **In which county is the pharmacy located?** Co. _____

5. **Which best describes the pharmacy location?** ❑ City ❑ Suburban ❑ Town ❑ Rural

6. **Is the pharmacy independently owned or one of a chain of pharmacies?**
   ❑ Independently owned ❑ Small chain (2-3) ❑ Medium chain (4-10) ❑ Large chain (>10)

7. **Please indicate your professional status.** ❑ Pharmacy owner ❑ Employee pharmacist

8. **What dispensing software do you use?** _____

9. **On average, how many staff members are working together in the pharmacy premises at any given time?** *Please indicate the number for each staff category (pharmacists = 2 etc.)*

   Pharmacists _____ Registered pharmaceutical assistants _____

   Pharmaceutical technicians _____ Counter assistants _____

   Pre-registration students _____ Other (please specify) _____

10. **On average how many items are dispensed daily?** _____

B Opinions on current asthma treatment/management

11. **How satisfactory is the current level of asthma care in community pharmacies nationwide?**
    ❑ Very satisfactory ❑ Satisfactory ❑ No opinion ❑ Unsatisfactory ❑ Very unsatisfactory

12. **On average, how good is your asthma patients' understanding of asthma as a disease?**
    ❑ Good understanding ❑ Some understanding ❑ Little understanding ❑ No understanding

13. **On average, do you think that your asthma patients understand the indications for their different asthma medications (*e.g.* reliever versus preventer inhaler)?**
    ❑ Good understanding ❑ Some understanding ❑ Little understanding ❑ No understanding

14. **In your view, what percentage of your asthma patients use their inhalers properly?** _____%

15. **In your view, what percentage of your asthma patients have peak flow meters which they use regularly?** _____%

16. **In your opinion, what percentage of your asthma patients have well controlled asthma (*i.e.* need reliever inhaler < 2 times/week)?** _____%

17. **On average, do your asthma patients have a good level of medication compliance?**
    ❑ Highly compliant ❑ Fairly compliant ❑ Poorly compliant

18. **In your opinion are asthma exacerbations (with hospitalisation) common among your asthma patients?**
    ❑ Very common ❑ Common ❑ Uncommon ❑ Very uncommon ❑ Don't know

19. What percentage of <u>your</u> asthma patients do you *estimate* have a personal asthma management plan and are actively involved in their treatment? _____% ❑ No idea

20. Do you believe your asthma patients typically have low expectations of disease management (e.g. think daily use of a reliever inhaler is normal)? ❑ Yes ❑ No ❑ Don't know

C Interventions with asthma patients

21. In your current practice how often do you carry out the following interventions with your asthma patients? (For each statement please indicate the number from 1-4 which best describes your answer)
1=ALWAYS 2=OFTEN 3=SOMETIMES 4=NEVER

(a) Demonstrate the use of a newly prescribed inhalation device? ___

(b) Provide verbal information to the patient about newly prescribed asthma medication (other than dosage regimen)? ___

(c) Demonstrate the use of a peak flow meter? ___

(d) Advise patients on the importance of a peak flow meter in monitoring asthma control? ___

(e) Check for over-use of short-acting β-agonist inhalers at prescription renewals? ___

(f) Counsel the patient in the event of overuse of short-acting β-agonist inhalers? ___

(g) Check for under-use of corticosteroid inhalers at prescription renewals? ___

(h) Counsel the patient in the event of under-use of corticosteroid inhalers? ___

(i) Check a patient's inhalation technique every 6-12 months? ___

(j) Advise patients on contraindicated over-the-counter products? ___

(k) Provide advice on non-pharmacological measures to improve quality of life? ___

(l) Ask the patient questions to assess his/her level of asthma control at prescription renewals? ___

(m) Check for any drug-related adverse effects at prescription renewals? ___

(n) Refer the patient to his/her GP in the case of drug-related problems? ___

(o) Advise patients on the correct action to take in the event of signs of worsening asthma? ___

(p) Advise patients to ask their GP for a personalised asthma action plan to allow increased self-management of asthma? ___

From the interventions identified above, please identify <u>the 5 interventions that you consider the most important</u>, starting with the most important.
Please write the letters corresponding to these interventions in the numbered spaces (1-5) below.

Most important → *decreasing importance*

1. _____ 2. _____ 3. _____ 4. _____ 5. _____

D Factors influencing pharmacists' interventions with asthma patients

22. Do you think that establishing a pharmacist-patient relationship is necessary to promote good asthma management? ❑ Yes ❑No
Please elaborate on your answer: _____
_____
_____

23. What, if any, are the major barriers to developing the pharmacist-patient relationship?
_____
_____
_____

24. For each statement please indicate the number from 1-5 which best describes your answer:
1 = Strongly agree, 2 = Agree, 3 = Neutral, 4 = Disagree, 5 = Strongly disagree

(a) Time is a major factor which influences my ability to counsel my asthma patients ___

(b) I do not feel competent to assess and educate my asthma patients on correct inhalation technique. ___

(c) I do not feel competent to assess and educate my asthma patients on the correct use of the peak flow meter ___

(d) A sufficient number of skilled pharmacists in the pharmacy allow me to counsel my asthma patients appropriately ___

(e) A sufficient number of skilled pharmaceutical technicians in the pharmacy allow me to counsel my asthma patients appropriately ___

(f) It is not my role to counsel an asthma patient to improve his/her level of asthma control. ___

(g) When I counsel my asthma patients they are receptive to the advice provided ___

(h) I have sufficient knowledge about asthma and its treatment to enable me to counsel my patients effectively ___

(i) It is difficult to counsel my asthma patients; they think I am interfering when I offer them advice ___

(j) I do not counsel my asthma patients because I feel I am underpaid to do so ___

(k) I only counsel my asthma patients when they ask for my advice ___

Please indicate any other factors that influence your ability to counsel your asthma patients (*whether positively or negatively*)._____

_____

E Communication with other health-care professionals

25. How many times in a typical week do you communicate with a GP about an asthma patient? ____/wk

26. What form does this communication <u>usually</u> take? *Please tick one only.*
❑ Telephone ❑ Fax ❑ Letter ❑ Message carried by patient ❑ Other: _____

27. Typically, what is the nature of the communication?
(Please number 1-7 with 1 being most prevalent and 7 being least prevalent. Only use each number once.)

__Suggested inhaler device change
__Suggested dosage change
__Drug interactions
__ Other (please specify) _____
__Non-compliance (underuse of medication)
__Side effects
__Non-compliance (overuse of medication)

28. Does the communication usually lead to a resolution of the issue? ❑ Yes ❑ No

If NO, why not? _____

29. In your opinion, are the current *frequency* and *method* of communication satisfactory?
Frequency: ❑ Satisfactory ❑ Unsatisfactory *Method:* ❑ Satisfactory ❑ Unsatisfactory

If **UNSATISFACTORY**, what changes are needed to improve pharmacist-GP communication?

30. How many times in a typical week do you communicate with a practice nurse about an asthma patient? ____/wk

31. What form does this communication <u>usually</u> take? *Please tick one only.*
❑ Telephone ❑ Fax ❑ Letter ❑ Message carried by patient ❑ Other: _____

32. Typically, what is the nature of the communication with practice nurses?
(Please number 1-7 with 1 being most prevalent and 7 being least prevalent. Only use each number once.)

__Suggested inhaler device change
__Suggested dosage change
__Drug interactions
__Non-compliance (underuse of medication)
__Side-effects
__Non-compliance (overuse of medication)
__ Other (please specify) _____

33. Does the communication usually lead to a resolution of the issue? ❑ Yes ❑ No

If NO, why not? _____

34. In your opinion, are the current *frequency* and *method* of communication satisfactory?
Frequency: ❑ Satisfactory ❑ Unsatisfactory *Method:* ❑ Satisfactory ❑ Unsatisfactory

If **UNSATISFACTORY**, what changes are needed to improve pharmacist- nurse communication?

35. To optimise asthma care in the primary care setting, do you think there is a need for increased inter-professional communication between pharmacists and GPs/practice nurses?
Pharmacists and GPs: ❑ Yes ❑ No *Pharmacists and nurses:* ❑ Yes ❑ No

Please elaborate on your answer:

F Proposed national asthma project

The Asthma Society of Ireland (ASI) has developed a project to improve asthma management in the community setting, which is being implemented in conjunction with the Department of Health and Children, the Health Service Executive and the Irish Pharmacy Union. Please refer to the cover letter for details.

36. In relation to the proposed asthma project, what are your views on the feasibility of the project on a national scale in terms of:
Time constraints:

Patient co-operation:

Inter-professional communication:

37. In your opinion, what, if any, are the major barriers to the success of this project?

38. What factors, if any, about the proposed project do you find desirable and why?

39. What factors, if any, about the proposed project do you find undesirable and why?

****** Thank you for completing this questionnaire. Your help is greatly appreciated.*******
Please return the questionnaire in the FREEPOST envelope provided, or any envelope addressed to:
FREEPOST, Pharmaceutical Care, School of Pharmacy, Trinity College, Dublin 2. (No stamp required.)

4. Cover letter for GPs and practice nurses regarding QAM-GP and QAM-PN

UNIVERSITY OF DUBLIN
SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES,
TRINITY COLLEGE,
DUBLIN 2, IRELAND.

January 2011

Dear Doctor,

As part of my Ph.D. that I am undertaking in TCD School of Pharmacy, I am investigating the management of asthma in primary care.

I have enclosed two questionnaires, one for General Practitioners (pink) and one for practice nurses (yellow), which are being sent to all general practices nationwide. The aim of the questionnaires is to determine the **opinions of both GPs and practice nurses about asthma management in the primary care setting** at the present time. As most of the questions simply require a box to be ticked, the questionnaire is quick to fill in, and should take **no more than 5 minutes**.

The questionnaire is anonymous and confidential. There is no way of tracing answers to a particular respondent or practice. All answers will be aggregated in order to obtain an overall view of GPs' and practice nurses' opinions nationwide. I should be very grateful if you and your colleague would complete the relevant questionnaires and return them to me in the enclosed FREEPOST envelope, or any envelope addressed to:

FREEPOST, Pharmaceutical Care, School of Pharmacy, Trinity College, Dublin 2 (no stamp required) as soon as you can, and **by January 31st if possible**.

I realise you have many demands on your time, but your participation will ensure that the survey accurately reflects the views of GPs and practice nurses in Ireland.

For further information about my research please do not hesitate to contact me on 01-896-2943 or by email at *bucklekn@tcd.ie* .

Many thanks for your help. It is greatly appreciated.

Niamh Buckley M.P.S.I.

5. Reminder letter for GPs and practice nurses regarding QAM-GP and QAM-PN

UNIVERSITY OF DUBLIN
SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES,
TRINITY COLLEGE,
DUBLIN 2, IRELAND.

February 2011

Dear Doctor,

Questionnaire for General Practitioners and Practice Nurses on Asthma Management

A short while ago, you should have received a letter from me enclosing two questionnaires about your opinions and those of the practice nurse on asthma management in the community setting at the present time.

If you and the practice nurse have already completed and returned these questionnaires, I would like to thank you both very much. Because of its anonymous format, it is not possible to identify and thank individual respondents. However, I'm very grateful for all the replies I've received to date.

The purpose of the questionnaire is to gather information from GPs and practice nurses about the interventions they currently carry out with their asthma patients, communication between GPs and practice nurses, and community pharmacists, and their views about asthma management among their patients at present.

If you both have not completed the questionnaires yet, may I encourage you to do so? (Another copy of both has been enclosed.) The accuracy of the data depends on getting responses from as many GPs and practice nurses as possible. I realise you both have many demands on your time, so the questionnaires have been kept as brief as possible. **Most people report it took them less than 5 minutes.**

If you have any queries or if you require any additional information please do not hesitate to contact me at 01-896-2943 or by email at *bucklekn@tcd.ie* .

Many thanks for your help. It is greatly appreciated.

Niamh Buckley M.P.S.I.

6. Questionnaire on asthma management for GPs

QUESTIONNAIRE FOR **GENERAL PRACTITIONERS** ON ASTHMA MANAGEMENT

A. Baseline Characteristics

1. **Please indicate your gender.** ❑ Male ❑ Female
2. **Please indicate the year you began practising as a General Practitioner.** _____
3. **Please indicate your age bracket.** ❑ 21-35 ❑ 36-45 ❑ 46-55 ❑ > 55
4. **In which county is the practice located?** Co. _____
5. **Which best describes the practice location?** ❑ City ❑ Suburban ❑ Town ❑ Rural
6. **Please indicate your professional status.** ❑ Practice owner/stakeholder ❑ Employee GP
7. **On average, how many patients do you see daily?** _____

B. Opinions on current asthma treatment/management

8. **How satisfactory is the current level of asthma care in the primary care setting nationwide?**
   ❑ Very satisfactory ❑ Satisfactory ❑ No opinion ❑ Unsatisfactory ❑ Very unsatisfactory
9. **On average, how good is your asthma patients' understanding of asthma as a disease?**
   ❑ Good understanding ❑ Some understanding ❑ Little understanding ❑ No understanding
10. **On average, do you think that your asthma patients understand the indications for their different asthma medications (*e.g.* reliever versus preventer inhaler)?**
    ❑ Good understanding ❑ Some understanding ❑ Little understanding ❑ No understanding
11. **In your view, what percentage of your asthma patients use their inhalers properly?** _____%
12. **In your view, what percentage of your asthma patients have peak flow meters which they use regularly?** _____%
13. **In your opinion, what percentage of your asthma patients have well controlled asthma (*i.e.* need reliever inhaler < 2 times/week)?** _____%
14. **On average, do your asthma patients have a good level of medication compliance?**
    ❑ Highly compliant ❑ Compliant ❑ Somewhat compliant ❑ Poorly compliant
15. **In your opinion are asthma exacerbations (with hospitalisation) common among your asthma patients?**
    ❑ Very common ❑ Common ❑ Uncommon ❑ Very uncommon ❑ Don't know
16. **What percentage of your asthma patients do you *estimate* have a personal asthma management plan and are actively involved in their treatment?** _____% ❑ No idea
17. **Do you believe your asthma patients typically have low expectations of disease management (e.g. think daily use of a reliever inhaler is normal)?** ❑ Yes ❑ No ❑ Don't know

C. Communication with community pharmacists

18. **How many times in a typical week do you communicate with a community pharmacist about an asthma patient?** ____/wk ❑ Less than once/week
19. **What form does this communication usually take?** *Please tick one only.*
    ❑ Telephone ❑ Fax ❑ Letter ❑ Message carried by patient ❑ Other: _____

P.T.O. →

20. Typically, what is the nature of the communication?

(Please number 1-7 with 1 being most prevalent and 7 being least prevalent. Only use each number once.)

__Inhaler device change
__Dosage change
__Drug interactions
__Non-compliance (underuse of medication)
__Side effects
__Non-compliance (overuse of medication)
__ Other (please specify) _____

21. Does the communication usually lead to a resolution of the issue? ❑ Yes ❑ No

If NO, why not? _____

22. In your opinion, are the current *frequency* and *method* of communication satisfactory?

Frequency: ❑ Satisfactory ❑ Unsatisfactory *Method:* ❑ Satisfactory ❑ Unsatisfactory

If **UNSATISFACTORY**, what changes are needed to improve GP-pharmacist communication?

D. Interventions with asthma patients

23. In your current practice how often do <u>YOU</u> carry out the following interventions with your asthma patients? (For each statement please indicate the number from 1-4 which best describes your answer, **or N if it is the job of the practice nurse**)

1=ALWAYS 2=OFTEN 3=SOMETIMES 4=NEVER N=Job of Practice Nurse

(a) Demonstrate the use of a newly prescribed inhalation device? ___
(b) Provide verbal information to the patient about newly prescribed asthma medication (other than dosage regimen)? ___
(c) Demonstrate the use of a peak flow meter? ___
(d) Advise patients on the importance of a peak flow meter in monitoring asthma control? ___
(e) Check for over-use of short-acting β-agonist inhalers at prescription renewals? ___
(f) Counsel the patient in the event of overuse of short-acting β-agonist inhalers? ___
(g) Check for under-use of corticosteroid inhalers at prescription renewals? ___
(h) Counsel the patient in the event of under-use of corticosteroid inhalers? ___
(i) Check a patient's inhalation technique every 6-12 months? ___
(j) Advise patients on contraindicated over-the-counter products? ___
(k) Provide advice on non-pharmacological measures to improve quality of life? ___
(l) Ask the patient questions to assess his/her level of asthma control at prescription renewals? ___
(m) Check for any drug-related adverse effects at prescription renewals? ___
(n) Advise patients on the correct action to take in the event of signs of worsening asthma? ___
(o) Provide patients with a personalised asthma action plan to allow self-management of asthma? ___

24. On average, how much time do you spend in consultation with an asthma patient?

❑ <5 min ❑ 5-10 min ❑ 11-20 min ❑ 21-30 min ❑ >30 min

25. In your opinion, is this sufficient time to adequately counsel the asthma patient?

❑ Yes ❑ No

******** Thank you for completing this questionnaire. Your help is greatly appreciated.*********

Please return the questionnaire in the FREEPOST envelope provided, or any envelope addressed to:
FREEPOST, Pharmaceutical Care, School of Pharmacy, Trinity College, Dublin 2. (No stamp required.)

7. Questionnaire on asthma management for practice nurses

QUESTIONNAIRE FOR **PRACTICE NURSES** ON ASTHMA MANAGEMENT

A. Baseline Characteristics

1. **Please indicate your gender.** ❑ Male ❑ Female
2. **Please indicate the year you began practising as a nurse.** _____
3. **Please indicate your age bracket.** ❑ 21-35 ❑ 36-45 ❑ 46-55 ❑ > 55
4. **In which county is the practice located?** Co. _____
5. **Which best describes the practice location?** ❑ City ❑ Suburban ❑ Town ❑ Rural
6. **On average, how many patients do you see daily?** _____

B. Opinions on current asthma treatment/management

7. **How satisfactory is the current level of asthma care in the primary care setting nationwide?**
   ❑ Very satisfactory ❑ Satisfactory ❑ No opinion ❑ Unsatisfactory ❑ Very unsatisfactory
8. **On average, how good is your asthma patients' understanding of asthma as a disease?**
   ❑ Good understanding ❑ Some understanding ❑ Little understanding ❑ No understanding
9. **On average, do you think that your asthma patients understand the indications for their different asthma medications (*e.g.* reliever versus preventer inhaler)?**
   ❑ Good understanding ❑ Some understanding ❑ Little understanding ❑ No understanding
10. **In your view, what percentage of your asthma patients use their inhalers properly?** _____%
11. **In your view, what percentage of your asthma patients have peak flow meters which they use regularly?** _____%
12. **In your opinion, what percentage of your asthma patients have well controlled asthma (*i.e.* need reliever inhaler < 2 times/week)?** _____%
13. **On average, do your asthma patients have a good level of medication compliance?**
    ❑ Highly compliant ❑ Compliant ❑ Somewhat compliant ❑ Poorly compliant
14. **In your opinion are asthma exacerbations (with hospitalisation) common among your asthma patients?**
    ❑ Very common ❑ Common ❑ Uncommon ❑ Very uncommon ❑ Don't know
15. **What percentage of your asthma patients do you *estimate* have a personal asthma management plan and are actively involved in their treatment?** _____% ❑ No idea
16. **Do you believe your asthma patients typically have low expectations of disease management (e.g. think daily use of a reliever inhaler is normal)?** ❑ Yes ❑ No ❑ Don't know

C. Communication with community pharmacists

17. **How many times in a typical week do you communicate with a community pharmacist about an asthma patient?** ____/wk ❑ Less than once/week
18. **What form does this communication usually take?** *Please tick one only.*
    ❑ Telephone ❑ Fax ❑ Letter ❑ Message carried by patient ❑ Other: _____

P.T.O. ⟶

19. Typically, what is the nature of the communication?

(Please number 1-7 with 1 being most prevalent and 7 being least prevalent. Only use each number once.)

__Inhaler device change
__Dosage change
__Drug interactions
__Non-compliance (underuse of medication)
__Side effects
__Non-compliance (overuse of medication)
__ Other (please specify) _____

20. Does the communication usually lead to a resolution of the issue? ❑ Yes ❑ No

If NO, why not? _____

21. In your opinion, are the current *frequency* and *method* of communication satisfactory?

Frequency: ❑ Satisfactory ❑ Unsatisfactory
Method: ❑ Satisfactory ❑ Unsatisfactory

If **UNSATISFACTORY**, what changes are needed to improve Practice Nurse-pharmacist communication?

D. Interventions with asthma patients

22. In your current practice how often do <u>YOU</u> carry out the following interventions with your asthma patients? (For each statement please indicate the number from 1-4 which best describes your answer) **1=ALWAYS 2=OFTEN 3=SOMETIMES 4=NEVER**

(a) Demonstrate the use of a newly prescribed inhalation device? ___
(b) Provide verbal information to the patient about newly prescribed asthma medication (other than dosage regimen)? ___
(c) Demonstrate the use of a peak flow meter? ___
(d) Advise patients on the importance of a peak flow meter in monitoring asthma control? ___
(e) Check for over-use of short-acting β-agonist inhalers at prescription renewals? ___
(f) Counsel the patient in the event of overuse of short-acting β-agonist inhalers? ___
(g) Check for under-use of corticosteroid inhalers at prescription renewals? ___
(h) Counsel the patient in the event of under-use of corticosteroid inhalers? ___
(i) Check a patient's inhalation technique every 6-12 months? ___
(j) Advise patients on contraindicated over-the-counter products? ___
(k) Provide advice on non-pharmacological measures to improve quality of life? ___
(l) Ask the patient questions to assess his/her level of asthma control at prescription renewals? ___
(m) Check for any drug-related adverse effects at prescription renewals? ___
(n) Advise patients on the correct action to take in the event of signs of worsening asthma? ___
(o) Provide patients with a personalised asthma action plan to allow self-management of asthma? ___

23. On average, how much time do you spend in consultation with an asthma patient?

❑ <5 min ❑ 5-10 min ❑ 11-20 min ❑ 21-30 min ❑ >30 min

24. In your opinion, is this sufficient time to adequately counsel the asthma patient?

❑ Yes ❑ No

******** Thank you for completing this questionnaire. Your help is greatly appreciated.*********

Please return the questionnaire in the FREEPOST envelope provided, or any envelope addressed to:
FREEPOST, Pharmaceutical Care, School of Pharmacy, Trinity College, Dublin 2. (No stamp required.)

8. Ethical approval letter for the Demonstration Project

THE UNIVERSITY OF DUBLIN
TRINITY COLLEGE

SCHOOL OF MEDICINE
FACULTY OF HEALTH SCIENCES

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Ms Fedelma McNamara
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Ms Niamh Buckley,
School of Pharmacy and Pharmaceutical Sciences,
Trinity College,
D 2

Thursday, 22 April 2010

Study: Integrated approach to asthma management in the primary care setting

Dear Applicant (s),

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in November 2009, we are pleased to inform you that the above project has been approved without further audit.

Yours sincerely

Prof. Orla Sheils
Chairperson
Faculty of Health Sciences Ethics Committee

Cc
Sheila Ryder
School of Pharmacy and Pharmaceutical Sciences,
Trinity College,
D 2

9. Patient questionnaire used in the Demonstration Project

Patient ID Number:

Date:

A Demonstration Project to Optimise Asthma Care in General Practice

PATIENT QUESTIONNAIRE

Age: _____ years			**☐ Male ☐ Female**				
How many years have you had Asthma?						_____ years	
In last 12 months how many times did you visit your GP due to asthma?						_____ times	
In last 12 months how many times did you attend A&E due to asthma?						_____ times	
In last 12 months were you admitted to hospital because of Asthma?						☐ Yes	☐ No
If Yes – how many times?						_____ times	
In last 12 months did you have to use a nebuliser for your asthma?						☐ Yes	☐ No
If Yes – how many times?						_____ times	
In last 12 months have you taken oral steroids for your asthma?						☐ Yes	☐ No
In the last 12 months have you missed school or work due to asthma?						☐ Yes	☐ No
If Yes - How many days in total?	_____ days		School or Work (Please circle one)				
How often do you use your Reliever (Blue) Inhaler/week?						_____ times	
Have you ever been given a personal, written asthma action plan?						☐ Yes	☐ No
Did you have the 'flu vaccine' last year?						☐ Yes	☐ No
Have you ever had Spirometry to measure how well your lungs are working?						☐ Yes	☐ No
Do you have an Asthma Attack Card?						☐ Yes	☐ No
Have you ever been given written information/education about asthma?						☐ Yes	☐ No
Has your GP/Practice Nurse ever shown you how to use:							
Your inhaler	☐ Yes	☐ No		Peak flow meter	☐ Yes	☐ No	
Do you collect your own asthma medications from your pharmacist?							
☐ Always	☐ Usually		☐ Sometimes		☐ Never		
How often do you visit your pharmacist (whether for prescription or for other purchase) – please tick appropriate box:							
☐ Every Month	☐ Every 2 – 3 months		☐ Every 3 – 6 months		☐ Every 6 – 12 months		
Has your pharmacist ever given you advice or information on:							
Inhaler Technique	☐ Yes	☐ No		Peak Flow Meter	☐ Yes	☐ No	
Has your pharmacist ever discussed your asthma medications with you?						☐ Yes	☐ No
Has your pharmacist ever queried your use of Reliever (Blue) inhaler with you?						☐ Yes	☐ No
Please complete the Asthma Control Test overleaf and enter your score here							

(If you have any difficulty completing this questionnaire your practice nurse will be pleased to help you when you visit the surgery

10. Exit interview with community pharmacists who were enrolled in the Demonstration Project

Hello, my name is Niamh Buckley, I am a Ph.D. student in the School of Pharmacy in TCD. I was wondering would you have 5 minutes to answer a few questions on the Asthma Demonstration pilot project which was run by the ASI? I just want to determine any positive/negative effects of the project but I am not affiliated with the ASI so all the answers will be confidential and recorded anonymously.

I sent out an anonymous questionnaire to everyone who was involved. Unfortunately the response rate wasn't great so I'm hoping to fill in some of the gaps now.

Okay now I am going to ask you a few questions related to time commitment and counselling asthma patients. Some of the questions are multiple choice so just choose the most applicable response for you.

A. Time Commitment and Communication

1. Did you counsel any official ASI patients? **Yes** **No**
   If No: Answer the next few questions in relation to your asthma patients in general
2. On average, how much time was needed to counsel each patient on his condition and appropriate medication use per consultation? ____ min
3. Was this amount of time **Acceptable** **Moderately acceptable** **Unacceptable** for you?
4. Do you think this level of patient counselling can routinely be incorporated into daily practice? **Yes** **No**
5. What percentage of your asthma patients did you seek to counsel in detail on asthma following the launch of the pilot study? ___ %
6. How receptive were your asthma patients to counselling?
   Very receptive **Receptive** **Somewhat receptive** **Unreceptive**
   Very unreceptive
7. In general, how much understanding of their medication did your patients have before counselling?
   Good understanding **Some understanding** **Little understanding**
   No understanding
8. On average, how good was your patients' inhaler technique before counselling?
   Very good **Good** **Average** **Poor** **Very poor**

9. On a scale of 1 to 5 where 1 = not essential and 5 = absolutely essential how essential is it to have demonstration devices of the following items in the pharmacy when counselling asthma patients?
   (1) Peak flow meters ____ (2) Placebo inhalers _____ (3) Spacers _____

Right, we're nearly there. Just a few questions on your communication with GPs and nurses.

B. Inter-professional Communication

10. Typically, how often did you communicate with the participating GP in relation to the study as it progressed?
    Was it: Daily Once/twice a week Once a month Less than once a month Not at all
11. Was the frequency of communication...
    Satisfactory Fairly satisfactory Unsatisfactory
12. Was the method of communication...
    Satisfactory Fairly satisfactory Unsatisfactory
    Repeat items 10 - 12 in relation to ***practice nurse***
13. Finally, did you perceive this programme to be successful?
    Yes No
14. Do you think it's feasible to rollout this programme on a national scale?
    Yes No

Right that's great I'd just like to finish by getting some demographic data from you to help me analyse the results. If there's any question you would rather not answer, please just say so.

C. Demographic Data

Male/female, County:

15. What year did you begin practising as a community pharmacist?____
16. Which of the following age brackets do you fall into?
    21-35, 36-45, 46-55, >55
17. What best describes the pharmacy location?
    City Suburban Town Rural
18. Is the pharmacy independently owned or one of a chain of pharmacies?
    If chain: **Small (2-3) Medium (4-10) Large (>10)**
19. Are you a pharmacy owner or an employee pharmacist?

20. On average how many hours per week do you work?___

21. On average, how many items are dispensed daily?___

22. How many pharmacists work together on a daily basis?___

Thank you very much for you taking the time to answer all my questions! Is there anything you would like to add?

11. Ethical approval letter for the Brief Intervention

THE UNIVERSITY OF DUBLIN
TRINITY COLLEGE

SCHOOL OF MEDICINE
FACULTY OF HEALTH SCIENCES

Trinity College, Dublin 2, Ireland
Tel: +353 1 896 1476
Fax: +353 1 671 3956
email: medicine@tcd.ie

Professor Dermot Kelleher, MD, FRCPI, FRCP, F Med Sci
Head of School of Medicine
Vice Provost for Medical Affairs

Ms Fedelma McNamara
School Administrator
email: medschadmin@tcd.ie

Ms Niamh Buckley,
School of Pharmacy and Pharmaceutical Sciences,
Trinity College,
Dublin 2

Thursday, 9th September, 2010

Study: Specialised approach to asthma management in the community pharmacy setting

Dear Applicant (s),

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in April 2010, we are pleased to inform you that the above project has been approved without further audit.

Yours sincerely

Prof. Orla Sheils
Chairperson
Faculty of Health Sciences Ethics Committee

Cc
Sheila Ryder,
School of Pharmacy and Pharmaceutical Sciences,
Trinity College,
Dublin 2

12. Cover letter for TEST community pharmacists regarding the Brief Intervention

UNIVERSITY OF DUBLIN
SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES,
TRINITY COLLEGE,
DUBLIN 2, IRELAND.

May 2011

Dear Colleague

As discussed by phone, as part of my Ph.D. that I am undertaking in Trinity College Dublin, I am carrying out a research project entitled 'The impact of a community pharmacist-led intervention on asthma management in the primary care setting'.

In essence, this study involves educating patients on correct inhaler technique with the use of specific pre-printed reminder labels. Patients will also be provided with peak flow meters and educated on measuring their peak expiratory flow rates to monitor their asthma control. The aim of this study is to improve patients' knowledge about their inhalation devices with the subsequent goal of improving their level of asthma control.

I would be delighted if you agreed to participate in this study. I have enclosed a detailed description of what my research entails and a consent form. If you require any additional information, please do not hesitate to contact me on 01-896-2943/087-7605114 or by e-mail at bucklekn@tcd.ie

Yours sincerely,

Niamh Buckley

13. Information leaflet for TEST pharmacists on the Brief Intervention



Information Leaflet for Pharmacists on an Asthma Management Intervention in Primary Care

Introduction
In essence, this study is a community pharmacist led intervention, whereby the pharmacist will educate asthma patients on correct inhaler technique using specific pre-printed reminder labels. He/she will also provide the patient with a peak flow meter (which I will supply) and teach him/her how to measure peak expiratory flow rate (PEFR). The aim of this study is to improve patients' knowledge about their inhalation devices with the subsequent goal of improving their level of asthma control.

Procedures:
I would be greatly obliged if you would agree to participate in this study. Participation in the study would involve recruiting two groups of ten patients (20 patients in total) diagnosed with asthma who are regular customers at the pharmacy, seven years or older, and who are not pregnant or intending to become pregnant in the next six months. One of these groups will be a **control group** and the other a **test group**. You will be provided with information leaflets for your patients that clearly outline what the research project involves, and the information that will be required from them. They will also be asked to sign and return a consent form to indicate their agreement to participate in the study.

Once recruited I would ask that you have two consultations with each patient in both the test group and the control group, initially (baseline interview) and one month after baseline. The format of the consultations in brief is as follows:

A. Test Patients

1. Administration of 2 questionnaires for self-completion by the patient.
2. Education, assessment and measurement of peak expiratory flow rate (PEFR).
3. Education and assessment of inhaler technique.
4. Provision of an Asthma Diary for patient completion over the following 2 weeks.

B. Control patients

1. Administration of 2 questionnaires for self-completion by the patient.
2. Education, assessment and measurement of PEFR.
3. Provision of an Asthma Diary for patient completion over the following 2 weeks.

I will provide you with all of the necessary forms for assessing and recording PEFR and inhaler technique. Postage paid envelopes will be supplied for the return of all completed questionnaires and assessment forms. Patient names will not be returned to me; they will be replaced by an anonymous numbering system to ensure confidentiality.

Confidentiality:
Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study group.



Information Leaflet for Pharmacists on an Asthma Management Intervention in Primary Care

Compensation:
There is no remuneration for participation in this study. This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation:
Participation in this study is voluntary. You may withdraw at any time. If you decide not to participate, or if you withdraw, you will not be penalised.

Stopping the study:
You should understand that the investigators may withdraw your participation in the study at any time without your consent.

Permission:
This study has the approval of the Faculty of Health Sciences Research Ethics Committee in Trinity College Dublin.

Further Information:
You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Niamh Buckley who can be telephoned at 01-896-2943 or by e-mail at bucklekn@tcd.ie. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

How to join the study:
You have been provided with a consent letter to sign if you agree to participate in this study. **A period of at least one week will be provided for you to reflect on this request and decide if you would like to be involved in the study**. The data obtained from the study will be retained securely for a period of 5 years and will not be used in any future unrelated study without your permission being sought.

14. Informed consent form for TEST pharmacists on the Brief Intervention



Informed Consent Form for Pharmacists on an Asthma Management Intervention in Primary Care

PRINCIPAL INVESTIGATORS
Niamh Buckley (Lead investigator, Trinity College Dublin).
Sheila Ryder (Research supervisor, Trinity College Dublin).

I, the participant, am willing to recruit two groups of patients with asthma, a test group and a control group, seven years or older, who are not pregnant or intending to become pregnant in the next six months and who get their medication dispensed regularly at the pharmacy, and conduct a series of two consultations with them as outlined in the Information Leaflet.

I will provide the researcher with an anonymised copy of all completed forms and questionnaires.

Participants' identities will remain confidential. Their names will not be published and will not be disclosed to anyone outside the study group. The data provided will not be used in any further study without the permission of the participants. The results of this study may be published in a journal; however all participant's identities will remain confidential and will not be published.

YOU HAVE A PERIOD OF AT LEAST 7 DAYS TO REFLECT ON THIS REQUEST AND DECIDE IF YOU WOULD LIKE TO BE INVOLVED IN THIS STUDY.

DECLARATION:
I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this agreement.

I understand I may withdraw from the study at any time.

Participant's name: .....

Contact details: .....

Participant's signature: .....

Date:.....

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

INVESTIGATOR'S SIGNATURE:..... **Date:**.....

15. Cover letter for CONTROL pharmacists on the Brief Intervention

UNIVERSITY OF DUBLIN
SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES,
TRINITY COLLEGE,
DUBLIN 2, IRELAND.

May 2011

Dear Colleague

As discussed by phone, as part of my Ph.D. that I am undertaking in Trinity College Dublin, I am carrying out a research project entitled 'The impact of a community pharmacist-led intervention on asthma management in the primary care setting'.

In essence, this study involves educating patients on measuring peak expiratory flow (using peak flow meters that I will supply) and using these measurements as a means of monitoring their asthma control. The aim of this study is to investigate the effect of this education and training on patients' asthma control.

I would be delighted if you agreed to participate in this study. I have enclosed a detailed description of what my research entails and a consent form. If you require any additional information, please do not hesitate to contact me on 01-896-2943 or by e-mail at bucklekn@tcd.ie

Yours sincerely,

Niamh Buckley

16. Information leaflet for CONTROL pharmacists on the Brief Intervention



Information Leaflet for Pharmacists on an Asthma Management Intervention in Primary Care

Introduction
In essence, this study is a community pharmacist led intervention, whereby the pharmacist will provide the patient with a peak flow meter (which I will supply) and teach him/her how to measure peak expiratory flow rate (PEFR). The aim of this study is to improve patients' knowledge about the importance of peak flow measurements in monitoring asthma control with the subsequent goal of improving their asthma management.

Procedures:
I would be greatly obliged if you would agree to participate in this study. Participation in the study would involve recruiting twenty patients diagnosed with asthma who are regular customers at the pharmacy, seven years or older, and who are not pregnant or intending to become pregnant in the next six months. You will be provided with information leaflets for your patients that clearly outline what the research project involves, and the information that will be required from them. They will also be asked to sign and return a consent form to indicate their agreement to participate in the study.

Once recruited I would ask that you have two consultations with each patient, initially (baseline interview) and one month after baseline. The format of the consultations in brief is as follows:

Consultation with patients

1. Administration of 2 questionnaires for self-completion by the patient.
2. Education, assessment and measurement of PEFR.
3. Provision of an Asthma Diary for patient completion over the following 2 weeks.

I will provide you with the necessary forms for assessing and recording PEFR. Postage paid envelopes will be supplied for the return of all completed questionnaires and assessment forms. Patient names will not be returned to me; they will be replaced by an anonymous numbering system to ensure confidentiality.

Confidentiality:
Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study group.

Compensation:
There is no remuneration for participation in this study. This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation:
Participation in this study is voluntary. You may withdraw at any time. If you decide not to participate, or if you withdraw, you will not be penalised.

Stopping the study:
You should understand that the investigators may withdraw your participation in the study at any time without your consent.



Information Leaflet for Pharmacists on an Asthma Management Intervention in Primary Care

Permission:
This study has the approval of the Faculty of Health Sciences Research Ethics Committee in Trinity College Dublin.

Further Information:
You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Niamh Buckley who can be telephoned at 01-896-2943 or by e-mail at bucklekn@tcd.ie. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

How to join the study:
You have been provided with a consent letter to sign if you agree to participate in this study. **A period of at least one week will be provided for you to reflect on this request and decide if you would like to be involved in the study**. The data obtained from the study will be retained securely for a period of 5 years and will not be used in any future unrelated study without your permission being sought.

17. Informed consent form for CONTROL pharmacists on the Brief Intervention



Informed Consent Form for Pharmacists on an Asthma Management Intervention in Primary Care

PRINCIPAL INVESTIGATORS
Niamh Buckley (Lead investigator, Trinity College Dublin).
Sheila Ryder (Research supervisor, Trinity College Dublin).

I, the participant, am willing to recruit twenty patients with asthma, seven years or older, who are not pregnant or intending to become pregnant in the next six months and who get their medication dispensed regularly at the pharmacy, and conduct a series of two consultations with them as outlined in the Information Leaflet.

I will provide the researcher with an anonymised copy of all completed forms and questionnaires.

Participants' identities will remain confidential. Their names will not be published and will not be disclosed to anyone outside the study group. The data provided will not be used in any further study without the permission of the participants. The results of this study may be published in a journal; however all participant's identities will remain confidential and will not be published.

YOU HAVE A PERIOD OF AT LEAST 7 DAYS TO REFLECT ON THIS REQUEST AND DECIDE IF YOU WOULD LIKE TO BE INVOLVED IN THIS STUDY.

DECLARATION:
I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this agreement.

I understand I may withdraw from the study at any time.

Participant's name: .....

Contact details: .....

Participant's signature: .....

Date:.....

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

INVESTIGATOR'S SIGNATURE:..... **Date:**.....

18. Information leaflet for adult TEST patients participating in the Brief Intervention

Information Leaflet for Asthma Patients (≥ 18 years) on an Asthma Management Intervention in Primary Care

Aim of study:
This aim of this study is to investigate the effects of a specialised intervention by your community pharmacist on your asthma control, quality of life, medication usage and knowledge of asthma.

Procedures:
This study involves a series of 2 consultations between you and your community pharmacist. The format of each consultation will be as follows:

1. Complete 2 questionnaires on your asthma control, medication use, asthma knowledge and quality of life.
2. Pharmacist trains you to use a peak flow meter and records your score and peak flow rate.
3. Pharmacist ensures you are using your inhalers properly using specialised reminder labels and records your score.
4. Pharmacist gives you an Asthma Diary to record your peak flow rate, symptoms, reliever inhaler use and asthma-related absences over the coming two weeks. The Asthma Diary should be posted when completed using the postage paid envelope provided.

You may participate in the study as long as you are over the age of 7 years with a clinical diagnosis of asthma and you are not pregnant or likely to become pregnant, evidently suffering from dementia or have severe learning disabilities or communication problems (as these would make the consultation process very difficult).

This study has the potential to improve asthma management leading to improved asthma control. There are no risks associated with participation. Your identity will remain confidential. Participation in this study is voluntary.

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Niamh Buckley at 01 896-2943 or by e-mail at bucklekn@tcd.ie

How to join the study:
You have been provided with a consent letter to sign if you agree to participate in this study. **A period of at least one week will be provided for you to reflect on this request and decide if you would like to be involved in the study**. The data obtained from the study will be retained securely for a period of 5 years and will not be used in any future unrelated study without your permission being sought.

19. Informed consent form for adult TEST patients participating in the Brief Intervention



Informed Consent Form for Asthma Patients (≥ 18 years) on an Asthma Management Intervention in Primary Care

PRINCIPAL INVESTIGATORS:
Niamh Buckley (Lead investigator, Trinity College Dublin).
Sheila Ryder (Research supervisor, Trinity College Dublin).

I, the participant will have two consultations with my pharmacist and during each I will complete 2 questionnaires and be trained and assessed on using a peak flow meter and using my inhalers. I will complete an Asthma Diary of my peak flow readings, asthma symptoms, reliever inhaler use and asthma-related absences over 2 weeks and return it in the postage paid envelope provided.

My identity will remain confidential. My name will not be published and will not be disclosed to anyone outside the study group. All data provided will not be used in any further study without my permission. The results of this study may be published in a journal; however my identity will remain confidential and will not be published.

YOU HAVE A PERIOD OF AT LEAST 7 DAYS TO REFLECT ON THIS REQUEST AND DECIDE IF YOU WOULD LIKE TO BE INVOLVED IN THIS STUDY

DECLARATION:
I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this agreement. I understand I may withdraw from the study at any time.

Participant's name: .....

Contact details: .....

GP's details: .....

Participant's signature: .....

Date:.....

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

Investigator's signature:..... **Date:**.....

20. Information leaflet for paediatric TEST patients participating in the Brief Intervention



Information Leaflet for Asthma Patients (7-17 years) on an Asthma Management Intervention in Primary Care

Aim of study:
This aim of this study is to investigate the effects of a specialised intervention by the community pharmacist on your child's asthma control, quality of life, medication usage and knowledge of asthma.

Procedures:
This study involves a series of 2 consultations between your child and the community pharmacist, in your presence. The format of each consultation will be as follows:

1. Complete 2 questionnaires on your child's asthma control, medication use, asthma knowledge and quality of life.
2. Pharmacist trains your child to use a peak flow meter and records his/her score and peak flow rate.
3. Pharmacist ensures your child is using his/her inhalers properly using specialised reminder labels and records his/her score.
4. Pharmacist gives your child an Asthma Diary to record his/her peak flow rate, symptoms, reliever inhaler use and asthma-related absences over the coming two weeks. The Asthma Diary should be posted when completed using the postage paid envelope provided.

Your child may participate in the study as long as he/she is over the age of 7 years with a clinical diagnosis of asthma and does not have severe learning disabilities or communication problems (as these would make the consultation process very difficult).

This study has the potential to improve asthma management leading to improved asthma control. There are no risks associated with participation. Your child's identity will remain confidential. Participation in this study is voluntary.

You can get more information or answers to your questions about the study, your child's participation in the study, and your rights, from Niamh Buckley at 01 896-2943 or by e-mail at bucklekn@tcd.ie

How to join the study:
You have been provided with a consent letter to sign if you agree to your child's participation in this study. **A period of at least one week will be provided for you to reflect on this request and decide if you would like your child to be involved in the study**. The data obtained from the study will be retained securely for a period of 5 years and will not be used in any future unrelated study without your permission being sought.

21. Informed consent form for paediatric TEST patients participating in the Brief Intervention



Informed Consent Form for Asthma Patients (7-17 years) on an Asthma Management Intervention in Primary Care

PRINCIPAL INVESTIGATORS:
Niamh Buckley (Lead investigator, Trinity College Dublin).
Sheila Ryder (Research supervisor, Trinity College Dublin).

My child, the participant, will have two consultations with the pharmacist and during each he/she will complete 2 questionnaires and be trained and assessed on using a peak flow meter and using his/her inhalers. He/she will complete an Asthma Diary of his/her peak flow readings, asthma symptoms, reliever inhaler use and asthma-related absences over 2 weeks and return it in the postage paid envelope provided.

My child's' identity will remain confidential. His/her name will not be published and will not be disclosed to anyone outside the study group. All data provided will not be used in any further study without my permission and that of my child. The results of this study may be published in a journal, however my child's identity will remain confidential and will not be published.

YOU HAVE A PERIOD OF AT LEAST 7 DAYS TO REFLECT ON THIS REQUEST AND DECIDE IF YOU WOULD LIKE YOUR CHILD TO BE INVOLVED IN THIS STUDY

DECLARATION:
I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this agreement. I understand I may withdraw from the study at any time.

Participant's (child's) name: .....

Contact details: .....

GP's details: .....

Participant's (child's) signature: .....

Date: .....

Name of consenter, parent or guardian: .....

Signature of consenter, parent or guardian: .....

Relation to participant (child): .....

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

Investigator's signature:..... **Date:**.....

22. Information leaflet for adult CONTROL patients participating in the Brief Intervention



Information Leaflet for Asthma Patients (≥ 18 years) on an Asthma Management Intervention in Primary Care

Aim of study:
This aim of this study is to investigate the effects of a specialised intervention by your community pharmacist on your asthma control, quality of life, medication usage and knowledge of asthma.

Procedures:
This study involves a series of 2 consultations between you and your community pharmacist. The format of each consultation will be as follows:

1. Complete 2 questionnaires on your asthma control, medication use, asthma knowledge and quality of life.
2. Pharmacist trains you to use a peak flow meter and records your score and peak flow rate.
3. Pharmacist gives you an Asthma Diary to record your peak flow rate, symptoms, reliever inhaler use and asthma-related absences over the coming two weeks. The Asthma Diary should be posted when completed using the postage paid envelope provided.

You may participate in the study as long as you are over the age of 7 years with a clinical diagnosis of asthma and you are not pregnant or likely to become pregnant, evidently suffering from dementia or have severe learning disabilities or communication problems (as these would make the consultation process very difficult).

This study has the potential to improve asthma management leading to improved asthma control. There are no risks associated with participation. Your identity will remain confidential. Participation in this study is voluntary.

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Niamh Buckley at 01 896-2943 or by e-mail at bucklekn@tcd.ie

How to join the study:
You have been provided with a consent letter to sign if you agree to participate in this study. **A period of at least one week will be provided for you to reflect on this request and decide if you would like to be involved in the study**. The data obtained from the study will be retained securely for a period of 5 years and will not be used in any future unrelated study without your permission being sought.

23. Informed consent form for adult CONTROL patients participating in the Brief Intervention



Informed Consent Form for Asthma Patients (≥ 18 years) on an Asthma Management Intervention in Primary Care

PRINCIPAL INVESTIGATORS:
Niamh Buckley (Lead investigator, Trinity College Dublin).
Sheila Ryder (Research supervisor, Trinity College Dublin).

I, the participant will have two consultations with my pharmacist and during each I will complete 2 questionnaires and be trained and assessed on using a peak flow meter. I will complete an Asthma Diary of my peak flow readings, asthma symptoms, reliever inhaler use and asthma-related absences over 2 weeks and return it in the postage paid envelope provided.

My identity will remain confidential. My name will not be published and will not be disclosed to anyone outside the study group. All data provided will not be used in any further study without my permission. The results of this study may be published in a journal; however my identity will remain confidential and will not be published.

YOU HAVE A PERIOD OF AT LEAST 7 DAYS TO REFLECT ON THIS REQUEST AND DECIDE IF YOU WOULD LIKE TO BE INVOLVED IN THIS STUDY

DECLARATION:
I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this agreement. I understand I may withdraw from the study at any time.

Participant's name: .....

Contact details: .....

GP's details: .....

Participant's signature: .....

Date:.....

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

Investigator's signature:..... **Date:**.....

24. Information leaflet for paediatric CONTROL patients participating in the Brief Intervention



Information Leaflet for Asthma Patients (7-17 years) on an Asthma Management Intervention in Primary Care

Aim of study:
This aim of this study is to investigate the effects of a specialised intervention by the community pharmacist on your child's asthma control, quality of life, medication usage and knowledge of asthma.

Procedures:
This study involves a series of 2 consultations between your child and the community pharmacist, in your presence. The format of each consultation will be as follows:

1. Complete 2 questionnaires on your child's asthma control, medication use, asthma knowledge and quality of life.
2. Pharmacist trains your child to use a peak flow meter and records his/her score and peak flow rate.
3. Pharmacist gives your child an Asthma Diary to record his/her peak flow rate, symptoms, reliever inhaler use and asthma-related absences over the coming two weeks. The Asthma Diary should be posted when completed using the postage paid envelope provided.

Your child may participate in the study as long as he/she is over the age of 7 years with a clinical diagnosis of asthma and does not have severe learning disabilities or communication problems (as these would make the consultation process very difficult).

This study has the potential to improve asthma management leading to improved asthma control. There are no risks associated with participation. Your child's identity will remain confidential. Participation in this study is voluntary.

You can get more information or answers to your questions about the study, your child's participation in the study, and your rights, from Niamh Buckley at 01 896-2943 or by e-mail at bucklekn@tcd.ie

How to join the study:
You have been provided with a consent letter to sign if you agree to your child's participation in this study. **A period of at least one week will be provided for you to reflect on this request and decide if you would like your child to be involved in the study**. The data obtained from the study will be retained securely for a period of 5 years and will not be used in any future unrelated study without your permission being sought.

25. Informed consent form for paediatric CONTROL patients participating in the Brief Intervention



Informed Consent Form for Asthma Patients (7-17 years) on an Asthma Management Intervention in Primary Care

PRINCIPAL INVESTIGATORS:
Niamh Buckley (Lead investigator, Trinity College Dublin).
Sheila Ryder (Research supervisor, Trinity College Dublin).

My child, the participant will have two consultations with the pharmacist and during each he/she will complete 2 questionnaires and be trained and assessed on using a peak flow meter. He/she will complete an Asthma Diary of his/her peak flow readings, asthma symptoms, reliever inhaler use and asthma-related absences over 2 weeks and return it in the postage paid envelope given.

My child's identity will remain confidential. His/her name will not be published and will not be disclosed to anyone outside the study group. All data provided will not be used in any further study without my permission and that of my child. The results of this study may be published in a journal, however my child's identity will remain confidential and will not be published.

YOU HAVE A PERIOD OF AT LEAST 7 DAYS TO REFLECT ON THIS REQUEST AND DECIDE IF YOU WOULD LIKE YOUR CHILD TO BE INVOLVED IN THIS STUDY

DECLARATION:
I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this agreement. I understand I may withdraw from the study at any time.

Participant's (child's) name: .....

Contact details: .....

GP's details: .....

Participant's (child's) signature: .....

Date: .....

Name of consenter, parent or guardian: .....

Signature of consenter, parent or guardian: .....

Relation to participant (child): .....

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

Investigator's signature:..... **Date:**.....

26. Protocol for TEST patient consultations

1. **Administration of questionnaires**

   - Give the patient two *(age appropriate)* questionnaires, the **Patient Questionnaire** and the **Quality of Life Questionnaire**, for self-completion in the pharmacy.

2. **Peak Expiratory Flow Rate (PEFR)**

   - Assess and score the patient's ability to accurately measure PEFR and record the technique score on the **Peak Flow Assessment Form.**
   - If the patient can accurately measure PEFR and does not require further training this initial PEFR value can be used as one of the three values needed to determine the Peak Flow Reading.
   - If the patient is not competent in use of the Peak Flow Meter, disregard this initial value and train the patient on the correct technique.
   - Demonstrate the correct technique to the patient and ask him/her to repeat the demonstration until his/her technique is perfected. This may take several attempts.
   - Now ask the patient to measure his/her PEFR again. Record the values obtained for all 3 attempts. The best value of 3 is the Peak Flow Reading for the patient. Each value is recorded on the **Peak Flow Assessment Form.**

3. **Inhaler technique**

   - Assess and score the patient's ability to use his/her inhaler(s) correctly using the appropriate placebo and inhaler checklist, and record the technique score on the checklist form.
   - If necessary, educate the patient on correct technique by going through each step on the checklist and demonstrating it correctly.
   - Repeat this cycle of assessment and demonstration up to 3 times if needed.
   - Now highlight the steps in technique that the patient had difficulty with on the relevant pre-printed '**Inhaler technique label'** supplied.
   - Attach this label to the patient's inhaler, without obscuring any essential information on the device. This highlighted label acts as a daily reminder of the correct inhalation technique and the step(s) with which the patient had difficulty.
   - If the patient's inhalation technique is correct on the initial assessment, still attach the label to the device but do not highlight any of the steps.
   - At each subsequent visit repeat the education and assessment and attach a new label to the patient's inhaler with the relevant step(s) highlighted.

4. **Asthma Diary**

   - Provide the patient with an Asthma Diary, explain how to complete it and ask the patient to do so over the following 2 week period.
   - Ask the patient to return the diary to me, the researcher, when it is complete, using the postage paid envelope provided.
   - Obtain the patient's phone number if possible and with his/her permission ring him/her after one week as a reminder to complete the diary.

5. **Arrange next consultation**

   - Arrange a suitable time for the subsequent consultation (2nd consultation 1 month after initial consultation)
   - With the patient's permission, arrange to ring him/her 3 days before the next consultation as a reminder.

27. Protocol for CONTROL patient consultations

1. **Administration of questionnaires**

- Give the patient two (*age appropriate*) questionnaires, the **Patient Questionnaire** and the **Quality of Life Questionnaire** for self-completion in the pharmacy.

2. **Peak Expiratory Flow Rate (PEFR)**

- Assess and score the patient's ability to accurately measure PEFR and record the technique score on the **Peak Flow Assessment Form.**
- If the patient can accurately measure PEFR and does not require further training this initial PEFR value can be used as one of the three values needed to determine PEFR.
- If the patient is not competent in use of the Peak Flow Meter, disregard this initial value and train the patient on the correct technique.
- Demonstrate the correct technique to the patient and ask him/her to repeat the demonstration until his/her technique is perfected. This may take several attempts.
- Now ask the patient to measure his/her PEFR again. Record the values obtained for all 3 attempts. The best value of 3 is the Peak Flow Reading for the patient. Each value is recorded on the **Peak Flow Assessment Form.**

3. **Asthma Diary**

- Provide the patient with an Asthma Diary, explain how to complete it and ask the patient to do so over the following 2 week period.
- Ask the patient to return the diary to me, the researcher, when it is complete, using the postage paid envelope provided.
- Obtain the patient's phone number if possible and with his/her permission ring him/her after 1 week as a reminder to complete the diary.

4. **Arrange next consultation**

- Arrange a suitable time for the subsequent consultation (2nd consultation 1 month after initial consultation).
- With the patient's permission, arrange to ring him/her 3 days before the next consultation as a reminder.

28. Control, Knowledge and Adherence questionnaire for adults

DATE:	PATIENT ID:	PHARMACY:

PATIENT QUESTIONNAIRE (>12 years)

A Baseline Characteristics

1. **Gender of patient:** ❑ Male ❑ Female

2. **Age of patient:** ❑ 13-16 ❑ 17-30 ❑ 31-50 ❑ 51-65 ❑ >65

3. **Smoking status**: ❑ Non-smoker ❑ Ex-smoker ❑ Smoker,
   If Smoker, on average how many cigarettes do you smoke daily? _____/day

4. **Do you have a medical card?** ❑ Yes ❑ No

5. **Do you have a Drugs Payment Scheme (DPS) card?** ❑ Yes ❑ No

6. **Approximately how many times in the last 12 months did you visit your GP about asthma?__/yr**

7. **Do you have a written asthma management plan?** ❑ Yes ❑ No

8. **When you were prescribed your inhaler(s) initially, who, if anyone, demonstrated how to use the inhaler(s)?** (You may tick more than one if appropriate to you)
   ❑ GP ❑ Nurse ❑ Pharmacist ❑ Nobody ❑ Other (please indicate)_____

B Asthma Control Test

9. **Please complete the following by circling the number that applies to you.**

a) **In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or at home.**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

b) **During the past 4 weeks, how often have you had shortness of breath?**

More than once a day	Once a day	3 to 6 times a week	Once or twice a week	Not at all
1	2	3	4	5

c) **During the past 4 weeks how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?**

4 or more nights a week	2 to 3 nights a week	Once a week	Once or twice	Not at all
1	2	3	4	5

d) **During the past 4 weeks how often have you used your reliever inhaler (e.g. Ventolin, Salamol, Bricanyl, Gerivent or other salbutamol inhaler) or nebulizer medication?**

3 or more times per day	1 or 2 times per day	2 or 3 times per week	Once a week or less	Not at all
1	2	3	4	5

e) **How would you rate your asthma control during the past 4 weeks?**

Not controlled at all	Poorly controlled	Somewhat controlled	Well controlled	Completely controlled
1	2	3	4	5

PTO ⟶

C Asthma Knowledge Questionnaire

10. Please complete the following by circling True or False, If you don't know the answer to a question LEAVE IT BLANK.

		True	False
(a)	You can become addicted to asthma medications if you use them all the time.	T	F
(b)	An asthma action plan can prevent hospitalizations due to asthma.	T	F
(c)	When you know that you are going to be exposed to something that triggers your asthma, you should take the recommended medication just before exposure.	T	F
(d)	Going from a cold to hot environment can trigger asthma, but going from a hot to cold environment does not trigger asthma.	T	F
(e)	Side effects are less likely with inhaled medications than with tablets.	T	F
(f)	With preventer medications, it does not matter if some doses are missed or if you go on and off them.	T	F
(g)	If you get a cold or flu, you should increase your asthma medications.	T	F
(h)	You should use "preventer medication" when you have an asthma attack.	T	F
(i)	Some medications can trigger asthma attacks	T	F
(j)	When you know that you are going to be exposed to something that triggers your asthma, you should wait until you develop symptoms before taking medication.	T	F
(k)	You should take "reliever medication" as soon as you recognize the first sign of asthma.	T	F
(l)	Blue puffer (Ventolin/Salamol/Bricanyl/Gerivent) is called "a preventer medication,' so it should be used every day although you are well.	T	F

D Medication Adherence Questionnaire

11. Please complete the following by ticking the box that applies to you:

a) Do you sometimes forget to take your preventative asthma medication?
❑ Yes ❑ No ❑ Not prescribed for me

b) Over the past 2 weeks, were there any days when you used more than 8 puffs of your reliever inhaler in one day?
❑ Yes ❑ No

c) Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?
❑ Yes ❑ No

d) When you travel or leave home, do you sometimes forget to bring along your medications?
❑ Yes ❑ No

e) Did you take your preventative asthma medication yesterday?
❑ Yes ❑ No ❑ Not prescribed for me

f) When you feel like your asthma is under control, do you sometimes reduce or stop taking your preventative asthma medicine?
❑ Yes ❑ No ❑ Not prescribed for me

g) Do you ever feel hassled about sticking to your asthma treatment plan?
❑ Yes ❑ No ❑ Not relevant to me

h) How often do you have difficulty remembering to take all your preventative asthma medication?
❑Never ❑Rarely ❑Sometimes ❑ Often ❑Always ❑ Not prescribed for me

29. Control, Knowledge and Adherence questionnaire for children

DATE:	PATIENT ID:	PHARMACY:

PATIENT QUESTIONNAIRE (7-12 years)

A Baseline Characteristics

1. **Gender of patient:** ❑ Male ❑ Female
2. **Age of patient:** ❑ 7-9 ❑ 10-12
3. **Does your child have a medical card?** ❑ Yes ❑ No
4. **Does your child have a Drugs Payment Scheme (DPS) card?** ❑ Yes ❑ No
5. **Approximately how many times in the last 12 months did your child visit the GP about his/her asthma?** _____ /year.
6. **Does your child have a written asthma management plan?** ❑ Yes ❑No
7. **When your child was prescribed inhaler(s) initially, who, if anyone, demonstrated how to use the inhaler(s)?** (You may tick more than one if appropriate)
   ❑ GP ❑ Nurse ❑ Pharmacist ❑ Nobody ❑ Other (please indicate)_____

B Asthma Control Test

8. **Please complete the following by circling the number that applies to your child.**

a) **In the past 4 weeks, how much of the time did your child's asthma keep him/her from getting as much done at work, school or at home.**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

b) **During the past 4 weeks, how often has your child had shortness of breath?**

More than once a day	Once a day	3 to 6 times a week	Once or twice a week	Not at all
1	2	3	4	5

c) **During the past 4 weeks how often did your child's asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake him/her up at night or earlier than usual in the morning?**

4 or more nights a week	2 to 3 nights a week	Once a week	Once or twice	Not at all
1	2	3	4	5

d) **During the past 4 weeks how often has your child used his/her reliever inhaler (e.g. Ventolin, Salamol, Bricanyl, Gerivent or other salbutamol inhaler) or nebulizer medication?**

3 or more times per day	1 or 2 times per day	2 or 3 times per week	Once a week or less	Not at all
1	2	3	4	5

e) **How would you rate your child's asthma control during the past 4 weeks?**

Not controlled at all	Poorly controlled	Somewhat controlled	Well controlled	Completely controlled
1	2	3	4	5

PTO→

C Asthma Knowledge Questionnaire

9. Please complete the following by circling True or False, <u>if you don't know the answer to a question LEAVE IT BLANK.</u>

		True	False
(a)	Your child can become addicted to asthma medications if he/she uses them all the time.	T	F
(b)	An asthma action plan can prevent hospitalizations due to asthma.	T	F
(c)	When your child knows that he/she is going to be exposed to something that triggers his/her asthma, he/she should take the recommended medication just before exposure.	T	F
(d)	Going from a cold to hot environment can trigger asthma, but going from a hot to cold environment does not trigger asthma.	T	F
(e)	Side effects are less likely with inhaled medications than with tablets.	T	F
(f)	With preventer medications, it does not matter if some doses are missed or if your child goes on and off them.	T	F
(g)	If your child gets a cold/flu, he/she should increase his/her asthma medications.	T	F
(h)	Some medications can trigger asthma attacks.	T	F
(i)	Your child should use "preventer medication" when he/she has an asthma attack.	T	F
(j)	When your child knows that he/she is going to be exposed to something that triggers his/her asthma, he/she should wait until he/she develops symptoms before taking medication.	T	F
(k)	Parents should give "reliever medication" to a child as soon as they recognize the first sign of asthma.	T	F
(l)	Blue puffer (Ventolin/Salamol/Bricanyl/Gerivent) is called "a preventer medication,' so it should be used every day although your child is well.	T	F

D Medication Adherence Questionnaire

10. Please complete the following by ticking the box that applies to your child:

a) Does your child sometimes forget to take his/her preventative asthma medication?
❑ Yes ❑ No ❑ Not prescribed for my child

b) Over the past 2 weeks, were there any days when your child used more than 8 puffs of the reliever inhaler in one day?
❑ Yes ❑ No

c) Has your child you ever cut back or stopped taking his/her medication without telling the doctor because he/she felt worse when he/she took it?
❑ Yes ❑ No

d) When your child travels or leaves home, does he/she sometimes forget to bring along his/her medications?
❑ Yes ❑ No

e) Did your child take his/her preventative asthma medication yesterday?
❑ Yes ❑ No ❑ Not prescribed for my child

f) When your child feels like his/her asthma is under control, does he/she sometimes reduce/stop taking the preventative asthma medicine?
❑ Yes ❑ No ❑ Not prescribed for my child

g) Does your child ever feel hassled about sticking to his/her asthma treatment plan?
❑ Yes ❑ No ❑ Not relevant to my child

h) How often does your child have difficulty remembering to take all his/her preventative asthma medication?
❑ Never ❑ Rarely ❑ Sometimes ❑ Often ❑ Always ❑ Not prescribed for my child

30. Mini asthma-specific quality of life questionnaire for adults

DATE:	PATIENT ID:	PHARMACY:

QUALITY OF LIFE QUESTIONNAIRE (> 12 years)

In general, how much time during the last 2 weeks did you? (Please circle the number that applies to you)

		All of the time	Most of the time	A Good Bit of the time	Some of the time	Little bit of the time	Hardly any of the time	None of the time
1	Feel SHORT OF BREATH as a result of your asthma?	1	2	3	4	5	6	7
2	Feel bothered by or have to avoid DUST in the environment?	1	2	3	4	5	6	7
3	Feel FRUSTRATED as a result of your asthma?	1	2	3	4	5	6	7
4	Feel bothered by COUGHING?	1	2	3	4	5	6	7
5	Feel AFRAID OF NOT HAVING YOUR ASTHMA MEDICATION AVAILABLE?	1	2	3	4	5	6	7
6	Experience a feeling of CHEST TIGHTNESS or CHEST HEAVINESS?	1	2	3	4	5	6	7
7	Feel bothered by or have to avoid CIGARETTE SMOKE in the environment	1	2	3	4	5	6	7
8	Have DIFFICULTY GETTING A GOOD NIGHT'S SLEEP as a result of your asthma?	1	2	3	4	5	6	7
9	Feel CONCERNED ABOUT HAVING ASTHMA?	1	2	3	4	5	6	7
10	Experience a WHEEZE in your chest?	1	2	3	4	5	6	7
11	Feel bothered by or have to avoid going outside because of WEATHER OR AIR POLLUTION?	1	2	3	4	5	6	7

How limited have you been during the last 2 weeks doing these activities as a result of your asthma?
(Please circle the number that applies to you)

		Totally limited	Extremely limited	Very limited	Moderate limitation	Some limitation	A little limitation	No limitation
12	STRENUOUS ACTIVITIES (such as hurrying, exercising, running up stairs, sports)	1	2	3	4	5	6	7
13	MODERATE ACTIVITIES (such as walking, housework, gardening, shopping, climbing stairs)	1	2	3	4	5	6	7
14	SOCIAL ACTIVITIES (such as talking, playing with pets/children, visiting friends/relatives)	1	2	3	4	5	6	7
15	WORK-RELATED ACTIVITIES (tasks you have to do at work/at home if not employed)	1	2	3	4	5	6	7

31. Mini paediatric asthma-specific quality of life questionnaire

DATE:	PATIENT ID:	PHARMACY:

QUALITY OF LIFE QUESTIONNAIRE (7 - 12 years)

Please complete **all** questions by circling the number that best describes how you have been during the **last week as a result of your asthma**.

How **bothered** have you been **during the last week** by:

		Extremely bothered	Very bothered	Quite bothered	Somewhat bothered	Bothered a bit	Hardly bothered at all	Not bothered
1.	Coughing	1	2	3	4	5	6	7
2.	Wheezing	1	2	3	4	5	6	7
3.	Tightness in your chest	1	2	3	4	5	6	7

In general, **how often during the last week** did you:

		All of the time	Most of the time	Quite often	Some of the time	Once in a while	Hardly any of the time	None of the time
4.	Feel OUT OF BREATH because of your asthma?	1	2	3	4	5	6	7
5.	Feel TIRED because of your asthma?	1	2	3	4	5	6	7
6.	Have trouble SLEEPING AT NIGHT because of your asthma?	1	2	3	4	5	6	7
7.	Feel FRUSTRATED because of your asthma?	1	2	3	4	5	6	7
8.	Feel FRIGHTENED OR WORIED because of your asthma?	1	2	3	4	5	6	7
9.	Feel IRRITABLE (grumpy) because of your asthma?	1	2	3	4	5	6	7
10.	Feel DIFFERENT OR LEFT OUT because of your asthma?	1	2	3	4	5	6	7

How **bothered** have you been **during the last week** doing:

		Extremely bothered	Very bothered	Quite bothered	Somewhat bothered	Bothered a bit	Hardly bothered at all	Not bothered
11.	PHYSICAL ACTIVITIES (such as running, swimming, sports, walking uphill/upstairs and bicycling)?	1	2	3	4	5	6	7
12.	BEING WITH ANIMALS (such as playing with pets and looking after animals)?	1	2	3	4	5	6	7
13.	ACTIVITIES WITH FRIENDS AND FAMILY (such as playing during school break and doing things with your friends and family)?	1	2	3	4	5	6	7

32. Inhaler technique checklists

Date:	Patient ID Number:	Pharmacy:

1. PRESSURISED METERED DOSE INHALER

	CHECKLIST	Yes	No	N/A
1.	Remove cap.			
2.	Shake well.			
3.	Breathe out gently away from mouthpiece.			
4.	Hold inhaler upright.			
5.	Put mouthpiece between teeth without biting and close lips to form a good seal.			
6.	Start to breathe in slowly through mouth and press down firmly on canister.			
7.	Continue to breathe in slowly and deeply while removing mouthpiece from mouth.			
8.	Hold breath for about 10 seconds or as close to 10 seconds as possible.			
9.	Breathe out gently away from mouthpiece.			
10.	If an extra dose is needed, wait a minimum of 30 seconds and then repeat steps 2 to 9. **If a second dose is not required at this point, reviewer marks N/A and awards 1 point for this line.**			
	Patient replaces cap on inhaler.	No score		
	RESULTANT SCORE: ____ out of 10 points			

Reminder label attached in pharmacy?	**Yes**	**No**

N.B. If 'No' please provide patient with a reminder label to attach at home.

Date:	Patient ID Number:	Pharmacy:

2. EASI-BREATHE INHALER

	CHECKLIST	Yes	No	N/A
1.	Shake inhaler.			
2.	Remove cap (Removing cap primes inhaler; this is necessary for every dose)			
3.	Breathe out gently away from mouthpiece.			
4.	Hold inhaler upright.			
5.	Put mouthpiece between teeth without biting to form good seal.			
6.	Do not block air-holes on top.			
7.	Breathe in steadily through mouthpiece. Do not stop breathing when inhaler 'puffs', but continue taking a deep breath.			
8.	Remove inhaler from mouth.			
9.	Hold breath for about 10 seconds or as close to 10 seconds as possible.			
10.	Breathe out gently away from mouthpiece and immediately replace cap (Replacing cap is necessary even if a second dose is needed, since subsequent removal primes the inhaler)			
11.	If a second dose is needed, wait a minimum of 30 seconds before repeating steps 1 to 10. **If a second dose is not required at this point, reviewer marks N/A and awards 1 point for this line.**			
	Patient holds inhaler upright and immediately closes cap	No score		
	RESULTANT SCORE: ____ out of 11 points			

Reminder label attached in pharmacy?	Yes	No

N.B. If 'No' please provide patient with a reminder label to attach at home.

Date:	Patient ID Number:	Pharmacy:

3. TURBOHALER

	CHECKLIST	Yes	No	N/A
1.	Unscrew and remove cover.			
2.	Keep inhaler upright.			
3.	Twist grip around and then back until click is heard.			
4.	Breathe out gently away from mouthpiece.			
5.	Place mouthpiece between teeth without biting and close lips to form a good seal.			
6.	Breathe in strongly and deeply.			
7.	Remove inhaler from mouth.			
8.	Hold breath for about 10 seconds or as close to 10 seconds as possible.			
9.	Breathe out gently away from mouthpiece.			
10.	If an extra dose is needed, wait a minimum of 30 seconds and then repeat steps 2 to 9 **If a second dose is not required at this point, reviewer marks N/A and awards 1 point for this line.**			
	Patient replaces cover on inhaler.	No score		
RESULTANT SCORE: ____ out of 10 points				

Reminder label attached in pharmacy?	**Yes**	**No**

N.B. If 'No' please provide patient with a reminder label to attach at home.

Date:	Patient ID Number:	Pharmacy:

4. DISKUS

	CHECKLIST	Yes	No	N/A
1.	To open, hold outer casing of Diskus in one hand whilst pushing thumb grip away until click is heard.			
2.	Hold Diskus with mouthpiece towards you.			
3.	Slide lever away until it clicks (this makes the dose available for inhalation and moves the dose counter on).			
4.	Hold the Diskus level.			
5.	Breathe out gently away from mouthpiece.			
6.	Place mouthpiece between teeth without biting and close lips to form a good seal.			
7.	Breathe in steadily and deeply.			
8.	Remove inhaler from mouth.			
9.	Hold breath for about 10 seconds or as close to 10 seconds as possible.			
10.	Breathe out gently away from mouthpiece.			
11.	To close, slide thumb grip back towards you as far as it will go until it clicks.			
12.	If a second dose is required, wait a minimum of 30 seconds, then repeat steps 1 to 11. **If a second dose is not required at this point, reviewer marks N/A and awards 1 point for this line**			
	RESULTANT SCORE: ____ out of 12 points			

Reminder label attached in pharmacy?	**Yes**	**No**

N.B. If 'No' please provide patient with a reminder label to attach at home.

Date:	Patient ID Number:	Pharmacy:

5. QVAR AUTOHALER

	CHECKLIST	Yes	No	N/A
1.	Remove cap.			
2.	Hold inhaler upright.			
3.	Push lever up.			
4.	Breathe out gently away from mouthpiece.			
5.	Put mouthpiece between teeth without biting and close lips to form good seal.			
6.	Breathe in slowly and deeply.			
7.	Keep breathing in after click is heard.			
8.	Remove inhaler from mouth.			
9.	Hold breath for 10 seconds or as close to 10 seconds as possible.			
10.	Breathe out gently away from mouthpiece.			
11.	Push lever down.			
12.	If a second dose is needed, wait a minimum of 30 seconds then repeat steps 2 to 11. **If a second dose is not required at this point, reviewer marks N/A and awards 1 point for this line.**			
	Patient replaces cover on inhaler	No score		
	RESULTANT SCORE: ____ out of 12 points			

Reminder label attached in pharmacy?	**Yes**	**No**

N.B. If 'No' please provide patient with a reminder label to attach at home.

Date:	Patient ID Number:	Pharmacy:

6. CLICKHALER

	CHECKLIST	Yes	No	N/A
1.	Hold inhaler upright and remove cover.			
2.	Shake inhaler.			
3.	Continue to hold inhaler upright with thumb on base and finger on coloured push button.			
4.	Press button down firmly once and release.			
5.	Breathe out gently away from mouthpiece.			
6.	Put mouthpiece between teeth without biting and close lips to form a good seal.			
7.	Breathe in steadily and deeply.			
8.	Remove inhaler from mouth and hold breath for 10 seconds or as close to 10 seconds as possible.			
9.	Breathe out gently away from mouthpiece.			
10.	If a second dose is needed at this point, wait a minimum of 30 seconds before repeating steps 2 to 9. **If a second dose is not required at this point, reviewer marks N/A and awards 1 point for this line.**			
	Patient replaces cover on inhaler.	No score		
	RESULTANT SCORE: ___ out of 10 points			

Reminder label attached in pharmacy?	**Yes**	**No**

N.B. If 'No' please provide patient with a reminder label to attach at home.

Date:	Patient ID Number:	Pharmacy:

7. NOVOLIZER

	CHECKLIST	Yes	No	N/A
1.	Hold inhaler horizontal.			
2.	Remove the cap by lightly pressing together at the sides and sliding forwards in the direction of the arrow to remove.			
3.	Push down hard on the coloured button until it reaches the stop. You will hear a loud click and the colour of the control window will change from red to green.			
4.	Release the coloured button.			
5.	Breathe out gently away from mouthpiece.			
6.	Put mouthpiece between teeth without biting and close lips to form a good seal.			
7.	Inhale steadily and deeply (you should hear a click indicating you have achieved adequate force for correct inhalation).			
8.	Keep inhaling after click is heard.			
9.	Remove inhaler from mouth and hold breath for 10 seconds or as close to 10 seconds as is comfortable.			
10.	Breathe out slowly through the nose away from mouthpiece.			
11.	If a second dose is required at this point, wait a minimum of 30 seconds before repeating steps 3 to 10. **If a second dose is not required at this point, reviewer marks N/A and awards 1 point for this line.**			
	Patient replaces cover on inhaler.	No score		
	RESULTANT SCORE: ___ out of 11 points			

Reminder label attached in pharmacy?	**Yes**	**No**

N.B. If 'No' please provide patient with a reminder label to attach at home.

Date:	Patient ID Number:	Pharmacy:

8. SPINHALER

	CHECKLIST	Yes	No	N/A
1.	Hold spinhaler upright with mouthpiece pointing downwards.			
2.	Unscrew body.			
3.	Put coloured end of spincap into cup of propeller, ensuring it spins freely.			
4.	Screw the two parts together and hold horizontal.			
5.	Move grey sleeve up and down once or twice to pierce capsule.			
6.	Breathe out gently away from mouthpiece.			
7.	Put inhaler into mouth so lips touch flange.			
8.	Breathe in quickly and deeply.			
9.	Remove the inhaler from mouth and hold breath for about 10 seconds or as close to 10 seconds as possible.			
10.	Breathe out gently away from mouthpiece.			
11.	If any powder is left in spincap repeat steps 6 to 10 until it is empty. **If the spincap has been emptied by one inhalation, and it is not necessary to repeat steps 6 to 10 reviewer marks N/A and awards 1 point for this line.**			
	Open the body of the inhaler again and dispose of used capsule.	No score		
	RESULTANT SCORE: ___ out of 11 points			

Reminder label attached in pharmacy?	**Yes**	**No**

N.B. If 'No' please provide patient with a reminder label to attach at home.

Date:	Patient ID Number:	Pharmacy:

9. AEROLIZER

	CHECKLIST	Yes	No	N/A
1.	Remove the cap.			
2.	Hold the base of the inhaler firmly and turn mouthpiece in the direction of the arrow.			
3.	Remove one capsule from the foil pack just before use and place it flat on the base of the capsule chamber.			
4.	Close capsule chamber by turning the mouthpiece back until a click is heard.			
5.	Hold inhaler upright.			
6.	Squeeze the two blue buttons inwards at the same time to pierce the capsule, then release.			
7.	Breathe out fully away from mouthpiece.			
8.	Put mouthpiece between teeth without biting and close lips to form a good seal.			
9.	Breathe in rapidly but steadily and as deeply as you can.			
10.	Remove the inhaler from mouth and hold breath for about 10 seconds or as close to 10 seconds as possible.			
11.	Breathe out gently away from mouthpiece.			
12.	If any powder is left in the capsule repeat steps 7 to 11 until it is empty. **If the capsule has been emptied by one inhalation, and it is not necessary to repeat steps 7 to 11 reviewer marks N/A and awards 1 point for this line.**			
	Discard capsule from compartment in base of inhaler and replace cap.	No score		
	RESULTANT SCORE:___ out of 12 points			

Reminder label attached in pharmacy?	Yes	No

N.B. If 'No' please provide patient with a reminder label to attach at home.

33. Inhaler technique reminder labels

1. pMDI

1. Remove cap.
2. Shake well.
3. Breathe out gently away from mouthpiece
4. Hold inhaler upright
5. Place mouthpiece between teeth and lips.
6. Breathe in slowly & press down on canister.
7. Continue to breathe in slowly while removing mouthpiece from mouth.
8. Hold breath for ~10 seconds.
9. Breathe out gently away from mouthpiece.

2. Easi-breathe

1. Shake inhaler.
2. Remove cap.
3. Breathe out gently away from mouthpiece.
4. Hold inhaler upright.
5. Place mouthpiece between teeth and lips.
6. Do not block air holes.
7. Breathe in steadily through mouthpiece. Do **NOT** stop breathing in when inhaler 'puffs'.
8. Remove inhaler & hold breath for 10 seconds.
9. Breathe out slowly and replace cap

3. Turbohaler

1. Unscrew and remove cover.
2. Keep inhaler upright.
3. Twist grip around & back until click is heard.
4. Breathe out gently away from mouthpiece.
5. Place mouthpiece between teeth and lips.
6. Breathe in strongly and deeply.
7. Remove inhaler from mouth & hold breath for 10 seconds.
8. Breathe out gently away from mouthpiece.

4. Diskus

1. Push thumb grip away until click is heard.
2. Hold Diskus with mouthpiece towards you.
3. Slide lever away until it clicks.
4. Hold Diskus level.
5. Breathe out gently away from device.
6. Place mouthpiece between teeth and lips.
7. Breathe in steadily and deeply.
8. Remove inhaler & hold breath for ~10 sec.
9. Breathe out gently away from mouthpiece.
10. To close, slide thumb grip back until it clicks.

5. Qvar

1. Remove cap.
2. Hold inhaler upright.
3. Push lever up.
4. Breathe out gently away from mouthpiece.
5. Place mouthpiece between teeth and lips.
6. Breathe in slowly & deeply.
7. Keep breathing in after click is heard.
8. Remove inhaler & hold breath for ~10 sec.
9. Breathe out gently.
10. Push lever down.

6. Clickhaler

1. Hold inhaler upright & remove cover.
2. Shake inhaler.
3. Continue to hold inhaler upright with thumb on base & finger on coloured push button.
4. Press button down once & release.
5. Breathe out gently away from mouthpiece.
6. Place mouthpiece between teeth and lips.
7. Breathe in steadily and deeply.
8. Remove inhaler & hold breath for 10 sec.
9. Breathe out gently away from mouthpiece.

7. Novolizer

1. Hold inhaler horizontal & remove cap.
2. Push down coloured button. You will hear a click & window will change from red to green.
3. Release coloured button.
4. Breath out gently away from mouthpiece.
5. Place mouthpiece between teeth and lips.
6. Inhale deeply. You should hear a click.
7. Do **NOT** stop inhaling after click is heard.
8. Remove inhaler & hold breath for ~10 sec.
9. Breathe out gently.

8. Aerolizer

1. Remove cap.
2. Hold base, turn mouthpiece in direction of arrow.
3. Remove 1 capsule & put flat in base of chamber.
4. Close by turning mouthpiece back until 'click' heard.
5. Hold inhaler upright.
6. Squeeze 2 blue buttons inwards then release.
7. Breathe out fully away from mouthpiece.
8. Put mouthpiece between teeth and lips.
9. Breathe in rapidly and deeply.
10. Remove inhaler & hold breath for ~10 sec.
11. Breathe out gently.

9. Spinhaler

1. Hold inhaler upright and unscrew body.
2. Put coloured end of spincap into propeller ensuring it spins freely.
3. Screw two parts together & hold horizontal.
4. Move grey sleeve up & down once or twice.
5. Breathe out gently away from mouthpiece.
6. Put inhaler in mouth so lips touch flange.
7. Breathe in quickly & deeply.
8. Remove inhaler & hold breath for ~10 sec.
9. Breathe out slowly

34. Peak flow meter technique checklist

Date:	Patient ID Number:	Pharmacy:

PEAK FLOW ASSESSMENT FORM

	CHECKLIST	Yes	No
1.	Ensure that the cursor is back to zero and the fingers do not block movement of the cursor.		
2.	Stand up straight.		
3.	Hold Peak Flow Meter level/straight.		
4.	Take a steady, deep breath in.		
5.	Place mouthpiece between teeth and seal lips around it.		
6.	Blow a hard fast breath out.		
7.	Measure where the cursor stops.		
	Repeat steps 1 to 7 twice (to get two further peak flow readings) Record all three readings; the highest of the three readings is the patient's **Peak Flow Reading.**	No score	
	RESULTANT SCORE: _____ out of 7 points		

PEFR	Value (L/min)
Attempt 1	
Attempt 2	
Attempt 3	
Best value (Peak Flow Reading)	

35. Peak expiratory flow reference charts

As peak expiratory flow (PEF) is highly variable between patients, the patient's personal best value (*i.e.* the best value obtained when they are clinically well) and diurnal variation in PEF are used in asthma guidelines, rather than age- and sex-dependent reference values. However, if a patient has never used a peak flow meter before and does not know his/her personal best value the following charts may be used to as an approximate reference tool. However, please be mindful that these are only rough estimations and you should use your own professional judgement in all instances where you suspect that a patient's asthma is not well controlled regardless of what the reference chart indicates.

The reference charts available below were obtained from the 'Updated Emergency Asthma Care Pack' published by Asthma UK and modified in June 2010, for more details see *http://www.asthma.org.uk/document.rm?id=400*

Normal EU scale values for Peak Expiratory Flow in young people.

FEMALE LITRES PER MINUTE (BTPS)	HEIGHT (CM)	MALE LITRES PER MINUTE (BTPS)
65	100	66
119	110	121
173	120	176
226	130	231
280	140	286
333	150	341
387	160	395
441	170	450
494	180	505
548	190	560

Normal values for 'EU-scale' peak flows in litres per minute BTPS derived from modified Godfrey equations (*Godfrey S, Kamburoff PL, Naim JL. Spirometry, lung volumes and airway resistance in normal children ages 5 to 18. Br J Dis Chest 1970; 64: 15-24.*) From Sept 2004 the EU scale must be used on peak flow meters.

Normal values for peak expiratory flow on the EU scale

	AGE (yrs)	HEIGHT (CM) 135 (4ft 5in)	140 (4ft 7in)	145 (4ft 9in)	150 (4ft 11in)	155 (5ft 1in)	160 (5ft 3in)	165 (5ft 5in)	170 (5ft 7in)	175 (5ft 9in)	180 (5ft 11in)	185 (6ft 1in)	190 (6ft 3in)	195 (6ft 5in)
Male	15	454	467	479	491	502	512	523	532	542	551	559	568	576
	20	508	522	536	549	561	573	585	596	606	616	626	635	644
	25	541	557	571	585	598	611	623	635	646	656	667	677	686
	30	559	575	590	604	618	631	644	656	667	678	689	699	709
	35	566	582	597	611	625	638	651	663	675	686	697	707	717
	40	563	579	594	609	622	636	648	660	672	683	694	707	714
	45	554	570	585	599	612	625	638	650	661	672	683	693	703
	50	540	556	570	584	597	610	622	633	645	655	666	676	685
	55	523	538	551	565	578	590	602	613	624	634	644	654	663
	60	503	517	530	543	555	567	578	589	600	610	619	628	637
	65	481	494	507	519	531	542	553	564	574	583	592	601	610
	70	458	471	483	495	506	516	527	537	546	555	564	572	580
	75	434	446	458	469	480	490	500	509	518	527	535	543	551
	80	410	422	433	443	453	463	472	481	490	498	506	513	520
Female	15	379	387	394	401	408	414	420	426	431	437	442	447	451
	20	402	410	418	426	433	440	446	452	458	464	469	474	479
	25	414	422	430	438	445	452	459	465	471	477	483	488	493
	30	417	426	434	442	449	456	463	469	475	481	487	492	497
	35	415	424	432	440	447	454	461	467	473	479	484	490	495
	40	409	417	425	433	440	447	454	460	566	472	477	482	487
	45	400	408	416	423	430	437	443	450	455	461	466	471	476
	50	389	396	404	411	418	425	431	437	442	448	453	458	463
	55	376	383	391	398	404	411	417	422	428	433	438	443	448
	60	362	369	376	383	389	395	401	407	412	417	422	427	431
	65	347	354	361	368	374	379	385	390	395	400	405	409	414
	70	332	339	346	352	358	363	368	374	378	383	387	392	396
	75	317	324	330	336	341	347	352	357	361	366	370	374	378
	80	302	308	314	320	325	330	335	340	344	348	352	358	360

Normal values for 'EU-scale' peak flows in Litres per Minute BTPS derived from modified Nunn and Gregg values (MR Miller – Airways J 2004; 2(2):80-2.).
From Sept 2004 the EU scale must be used on peak flow meters.

36. Asthma diary

DATE:	PATIENT ID:	PHARMACY:

ASTHMA DIARY

PEAK FLOW RATE

In the box below record your **Peak Flow Rate morning and evening for 2 weeks** before taking your morning/evening asthma medication as applicable.
When recording Peak Flow Rate please record the **best of three blows**.

WEEK 1 date beginning: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Peak Flow Rate MORNING SCORE							

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Peak Flow Rate BEDTIME SCORE							

	Mon.	Tues.	Wed.	Thur.	Fri.	Sat.	Sun.
How many puffs of RELIEVER inhaler (blue inhaler) did you use in the past 24 hours?							

WEEK 2 date beginning: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Peak Flow Rate MORNING SCORE							

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Peak Flow Rate BEDTIME SCORE							

	Mon.	Tues.	Wed.	Thur.	Fri.	Sat.	Sun.
How many puffs of RELIEVER inhaler (blue inhaler) did you use in the past 24 hours?							

In the past 2 weeks, were you absent from work/school (if applicable) because of your asthma?
Yes ❑ No ❑
If Yes, how many days in the past 2 weeks were you absent?_____ days

******* Thank you for completing this Asthma Diary. Your help is greatly appreciated.*******
Please return the Asthma Diary in the FREEPOST envelope provided, or any envelope addressed to: FREEPOST, Pharmaceutical Care, School of Pharmacy, Trinity College, Dublin 2. (No stamp required.)

37. Cover letter for TEST pharmacists regarding the Exit Questionnaire

UNIVERSITY OF DUBLIN
SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES,
TRINITY COLLEGE,
DUBLIN 2, IRELAND.

March 2013

Dear Colleague,

Pharmacist-led asthma intervention project

I would like to take this opportunity to express my sincere thanks for your participation in this asthma project. The project was completely reliant on your goodwill and enthusiasm and I really appreciate all of the time and hard work that you contributed. I would also like to apologise for my lack of communication over the past eight months; unfortunately, I had to take a leave of absence from my studies for medical reasons. The project is currently drawing to a close and I have enclosed a questionnaire aimed at determining your opinions about the project. I understand that many participating pharmacists had difficulty recruiting patients, but your views on the barriers to patient recruitment are very important as they will be extremely useful in the design of future projects.

The questionnaire should only take 5 minutes. As most of the questions simply require a box to be ticked, the questionnaire is quick to fill in.

The questionnaire is anonymous and confidential. There is no way of tracing answers to a particular pharmacist or pharmacy. All answers will be aggregated in order to obtain an overall view of community pharmacists who participated in the project. I should be very grateful if you would complete this questionnaire and return it to me in the enclosed FREEPOST envelope, or any envelope addressed to: *FREEPOST, Pharmaceutical Care, School of Pharmacy, Trinity College, Dublin 2,* as soon as you can, and **by April 5th if possible**.

I realise you have many demands on your time, but your participation will ensure that the questionnaire accurately reflects the opinions of community pharmacists involved in the project and will subsequently aid the design of future asthma interventions.

In addition, I would ask you to **return any remaining completed patient questionnaires** to the afore-mentioned address.

For further information about my research, please do not hesitate to contact me at bucklekn@tcd.ie

Many thanks for your help. It is greatly appreciated.

Niamh Buckley M.P.S.I.

36. Exit questionnaire for TEST pharmacists

Exit Questionnaire for Community Pharmacists on Pharmacist-Led Asthma Project

A Baseline Characteristics

1. **Please indicate your gender**: ❑ Male ❑ Female
2. **Please indicate the year you began practising as a community pharmacist** _____
3. **Please indicate your professional status:** ❑ Pharmacy owner ❑ Employee pharmacist

B Initial consultation

4. **At recruitment, overall how receptive were patients towards participating in the project?**
   ❑ Very receptive ❑ Receptive ❑ Somewhat receptive ❑ Poorly receptive ❑ Unreceptive
5. **If/when patients did not wish to participate in the project please indicate the impact that each of the following barriers had on their participation on a scale of 1-5:**

   1 = Great impact, 2= Impact, 3 = Some impact, 4 = Little impact, 5 = No impact

a) Insufficient time. _____
b) Lack of patient interest. _____
c) Lack of need as patient believes he/she is already sufficiently knowledgeable about asthma. _____
d) Lack of need as patient believes his/her asthma is currently well controlled. _____
e) Patient believes that the pharmacist is interfering. _____
f) Patient prefers to consult with the GP about his/her asthma. _____
g) Patient is unaware of the level of asthma control that is achievable. _____
h) Other (please specify) _____ _____

6. **On average, how much time was needed to complete the initial consultation? _____ minutes**
7. **In your opinion, was this an acceptable amount of time for you?**
   ❑ Very acceptable ❑ Acceptable ❑ Somewhat acceptable ❑Unacceptable
8. **If the paperwork required for the study was eliminated would it be feasible to incorporate this level of patient counselling into daily practice?** ❑ Yes ❑ No
9. **In your opinion, do you think pharmacists should charge for counselling patients on inhaler technique and peak flow meter use?** ❑ Yes ❑ No

   If so, how much should be charged for this service? €_____ per consult. ❑ No charge
10. **On average, do you think patients would be willing to pay for this service?**
    ❑ Very willing ❑ Willing ❑ Somewhat willing ❑ Unwilling

C Patient receptiveness: Second consultation

11. **How receptive were the participating patients to engaging in the second consultation?**
    ❑ Very receptive ❑ Receptive ❑ Somewhat receptive ❑ Poorly receptive ❑ Unreceptive
12. **If/when patients did not wish to participate in the second consultation please indicate the impact that each of the following barriers had on their participation on a scale of 1-5:**

    1 = Great impact, 2= Impact, 3 = Some impact, 4 = Little impact, 5 = No impact

a) Insufficient time. _____
b) Lack of patient interest. _____
c) The initial consultation was too time-consuming. _____
d) Patient believes that he/she does not need a second consultation. _____
e) Other (please specify) _____ _____

13. **On average, how much time was needed to complete the second consultation? _____ minutes**

PTO →

D Your perceptions of the project

14. In your opinion, how beneficial was this project for your participating asthma patients?

❑ Very beneficial ❑ Beneficial ❑ Somewhat beneficial ❑ Not beneficial

15. On average, were your participating patients appreciative of the counselling they received?

❑ Very appreciative ❑ Appreciative ❑ Somewhat appreciative ❑ Unappreciative

16. Did you find the inhaler technique checklists useful?

❑ Very useful ❑ Useful ❑ Somewhat useful ❑ Not useful

17. Were the inhaler technique reminder labels useful for the patients?

❑ Very useful ❑ Useful ❑ Somewhat useful ❑ Not useful

18. Did you find the peak flow meter technique checklist useful?

❑ Very useful ❑ Useful ❑ Somewhat useful ❑ Not useful

19. Did the project have any impact of your relationships with the participating patients?

❑ Improved my relationships ❑ No impact on relationships ❑ Negative impact on my relationships

20. Did the project have any impact on your knowledge of inhaler technique and peak flow meter technique?

(i) *Inhaler technique* ❑ Improved my knowledge ❑ No impact on my knowledge

(ii) *Peak flow meter technique* ❑ Improved my knowledge ❑ No impact on my knowledge

21. What factors, if any, did you find desirable about the project?

_____

_____

22. What factors, if any, did you find undesirable about the project?

_____

_____

23. What changes, if any, could be made to facilitate the incorporation of this level of intensive counselling into routine pharmacy practice?

_____

_____

********* Thank you for completing this questionnaire. Your help is greatly appreciated.*********

Please return the questionnaire in the FREEPOST envelope provided, or any envelope addressed to: FREEPOST, Pharmaceutical Care, School of Pharmacy, Trinity College, Dublin 2. (No stamp required.)